

**Comments received on the second set of discussion papers informing the report of the
UN Interagency Coordination Group on AMR to the UN Secretary-General**

- **Member States**
 - Brazil
 - Canada
 - Costa Rica
 - Finland
 - France
 - Germany
 - Iraq
 - Japan
 - Netherlands
 - Norway
 - Sweden
 - United Kingdom
 - United States
- **CSOs & NGOs**
 - Antibiotic Resistance Coalition
 - Infectious Diseases Society of America
 - LSHTM Antimicrobial Resistance Centre
 - MSF Access Campaign
 - World Medical Association & International Federation for Medical Students Association
 - World Veterinary Association
- **Private**
 - AMR Industry Alliance
 - Animal Health Institute
 - Animal Medicines Australia
 - Health for Animals
 - International Dairy Federation
- **Individuals**
 - Jennifer Cole
 - Muhammad-Bashir Bolajoko
 - Marco Haenssger
 - Walter Okelo
 - Céline Pulcini
 - Michael Ryan
 - Ellen Silbergeld
 - Rick Watkins
 - Martin Wierup
- **Other**
 - Medicines for Malaria Venture
 - Medicines Patent Pool
 - South Centre
 - United Nations Development Programme

Member States

Brazil

From: [IBAMA/Email que não permite resposta pelo destinatário.](#)
To: [IACG-secretariat;](#)
Subject: Processo 02000.010734/2018-60. Resistência Antimicrobiana.
Date: 31 August 2018 22:44:28
Attachments:

Prezados,

em atendimento ao Ofício nº 5558/2018-MMA, informo que, conforme resposta anexa da Coordenadora Geral Substituta da CGASQ, o IBAMA nada tem a acrescentar aos documentos em questão.

Att.,
Stéfanie Sarmento Mitre Leite
Chefe Substituta da Divisão de Assuntos Internacionais do IBAMA

Unofficial English translation:

Answering to the letter # 5558/2018-MMA, I inform that, according to the answer attached from the Deputy General Coordinator of CGASQ (Coordenação-Geral de Avaliação e Controle de Substâncias Químicas/General-Coordination of Control and Evaluation of Chemical Substances), the IBAMA (Instituto Brasileiro do Meio Ambiente/Brazilian Institute of Environment) has nothing to add to the documents in question.

Best regards,
Stéfanie Sarmento Mitre Leite
Deputy Head of International Affairs Division of IBAMA (Instituto Brasileiro do Meio Ambiente/Brazilian Institute of Environment)

Comments from the Government of Canada on IACG Discussion Papers

Future Global Governance for Antimicrobial Resistance

General Comments:

- Canada supports collaborative and cooperative global action to address the threat of AMR, but remains uncertain about the need to create additional bodies/structures that may duplicate ongoing efforts in this area.
- This document seems to be going in the right direction with respect to the environment and focusing on effluent standards and monitoring efforts to understand the environment as a reservoir; however, there still remain a few ambiguities.
- Aiming for a Global Multi-Stakeholder Agreement in 10 years is ambitious but more realistic than other proposals that have been made in the past. Related to this proposed deliverable, there are several things that should be considered:
 - For an entity like the Global Steering Board to have the influence and resources to deliver on the proposed mandate, including laying the groundwork for a potential treaty, it will have to have widespread support at political levels from around the world. Any impression that its work is not truly global, or held to be a true priority of governments, will make it more difficult for the Board to gain traction.
 - The organizational structure of the Global Steering Board and of the High Level Commission will need to be elaborated, with due consideration given to the pros and cons of standalone organizations vs. hosting arrangements.
 - The four specialized UN Agencies that will make up the Standing Secretariat are not currently resourced to undertake this level of activity. Without appropriate support, the Board will be challenged in delivering credible scientific and policy synthesis, stakeholder outreach, and/or political momentum.
 - While the G20 is in a unique position to engage in the international conversation on AMR, it is not globally representative and is not an organization and thus does not have the support of a secretariat to undertake this work. Priorities are determined by the President and while a specific working group could be struck to look into this issue, the priority it is given would depend upon the Presidency.
 - Overall, it would be preferable for a UN body to carry out this work, as they would be equipped to convene the four specialized UN agencies, as well as see through the long term vision of this initiative.
 - The main issue will remain the financing of such a structure and it will be essential to develop a concrete plan in this regard.

**ADDITIONAL COMMENTS FROM CANADA ON THE IACG DISCUSSION PAPER: “FUTURE GLOBAL GOVERNANCE FOR ANTIMICROBIAL RESISTANCE”
(August 2018)**

Page/Paragraph	Addition/Deletion/Quoted text	Comment
Page 5, 15 th bullet point in “Shared One Health needs”	To fully engage with the private sector	Suggest deleting this bullet point, as private sector is mentioned already in the third bullet point.
Page 5, 2 nd bullet point in “Specific Sector needs: Environment”		What is the context of this bullet? Precautionary principle in terms of disposal of antimicrobials in the environment? Given that the last bullet in this section captures wastewater standards/ effluent it’s not clear what the 2 nd bullet means in the context of the environment. It is also unclear how the precautionary principle would be applied in the case of the environment or why this is a specific need, considering that the same principle is not being applied in the human or food sectors.
Page 5, 2 nd bullet point in “Specific Sector needs: Environment”	Application of precautionary principle in short-term whilst evidence base is established	Fix wording from “principal” to “principle”.
Page 7, Paragraph 8	This must be done through the engagement of expert advisors from areas/fields broader than the AMR system, employing a system for expert input such as the Intergovernmental Panel on Climate Change (IPCC) Working Group model.	Include missing word (either areas or fields).
Page 11, 1 st paragraph after bullet points	... (human, environment, veterinary, agriculture, and food), Industry/ Private Sector, Academia and Regulators. These groups take on a variety of roles, from engaging and educating on optimal use of quality assured products to encouraging innovation for better disease prevention, diagnostics and treatment across the One Health spectrum.	Environment doesn’t typically have responsibility for any of these roles listed.
Page 17, 2 nd paragraph	“Driving this resistance is a complex collection of human activity through antimicrobial	We don’t yet have enough information to state that the environment broadly is driving the creation of resistance. Suggest further clarifying what

**ADDITIONAL COMMENTS FROM CANADA ON THE IACG DISCUSSION PAPER: “FUTURE GLOBAL GOVERNANCE FOR ANTIMICROBIAL RESISTANCE”
(August 2018)**

Page/Paragraph	Addition/Deletion/Quoted text	Comment
	exposure in healthcare, agriculture (including aquaculture and crops), and the environment thereby threatening global health, livelihoods, and food security.”	is meant by environment.
Page 17, 4 th paragraph	“To date, agriculture has attracted less attention in debates about AMR. Yet the trend towards increasing use of antibiotics in livestock rearing, crop production, and aquaculture highlight that action needs taking in agriculture as well as in respect of human health and the environment.”	A review of this sentence may be beneficial...also, agriculture and aquaculture happen in the environment (responsibilities lie with a variety of departments).
Page 26, 1 st paragraph	Human health has garnered the most attention, but still lacks strong political action; agriculture and animal antimicrobial use requires both more attention and political action; and AMR in the environment lags far behind in both respects and in its evidence-base.	AMR lags behind in both respects – does this mean both human health and agriculture/animal use, or both attention and action? Suggest revising the sentence to avoid confusion.
Page 42		Further emphasis should be on avoiding the duplication of any existing efforts/mechanisms in place. There are various initiatives on AMR at the global level and so efforts should be directed at how efforts could be aligned to strengthen the work underway as opposed to duplicating it.
Page 43, 3 rd paragraph	Similarly, the Ministers of Agriculture and Ministers of Environment have no mandate over human health.	Suggest adding “and Ministers of Environment”.

Combined input from the Government of Canada on IACG Discussion Papers

Optimize Use of Antimicrobials

General Comments:

- This document seems to be going in the right direction with respect to the environment and focusing on effluent standards and monitoring efforts to understand the environment as a reservoir.
- On the whole, it is fairly well written. There are some common statements that seem to get misused a little. The word 'optimize' always should have the context of 'for the purpose of mitigating AMR'; otherwise it can be used to justify intentional misuse.
- On the human side of things and on the agriculture side of things, committed funding is required to study the effective duration of antimicrobial use.

1) What kind of support (other than financial) is needed to translate the existing guidance into implementable actions?

- Building knowledge and awareness about antimicrobial stewardship through enhanced and coordinated education for prescribers, dispensers and end users of antimicrobials.
- Having access to IPC expertise to adapt/adopt guidance.
- Developing mechanisms/tools to collect antimicrobial usage data and surveillance of multi-drug resistant organisms.
- Consistent/comparable analysis of pooled data.
- Sharing best practices among comparable facilities to help with adapting/adopting guidance.
- Consistent/standardized periodic IPC education and training for healthcare providers and allied staff.
- Buy-in at an international level.
- Buy-in at a national/federal, provincial, territorial level, including political commitment to combat AMR with regulatory enforcement and ongoing leadership on the AMR issue, with effective coordination across sectors and including representation from Indigenous groups.
- Buy-in by all stakeholders, including industry, healthcare professionals, veterinarians, farmers, environmentalists, relevant associations, the public in general.
- Education in schools from a young age but also in universities and medical/veterinary schools.
- Involvement of research funding organizations and health technology assessors.
- Involvement of national advisory groups and associations (such as those related to immunization, which could be involved to provide an emphasis on vaccination to prevent infections).
- Need for clinical practice antimicrobial use guidelines by animal species. Need for the technical capacity to develop these.

2) How can policy makers be assisted to further develop and implement infection prevention and control in human and animal health and plants and be convinced to invest now to mitigate the escalating and future costs and obtain benefits far beyond preventing AMR?

- Support/encourage more research on IPC which also looks at patient outcomes and costs.

- There is need for effective and ongoing two-way communication between governments (as policy makers) and stakeholders, such as: physicians and their governing bodies; veterinarians and their governing bodies; agriculture and their associations; pharmaceutical industry; the public/patients.
- There is need for ongoing surveillance/monitoring of AMR at the international, national, regional, and local (municipalities/hospitals) level. It is difficult to manage what has not been measured. Such initiatives require good governance and funding.
- Cost-benefit analysis of interventions against AMR could show the benefits of early implementation of these measures.

3) What incentives or initiatives are needed for behaviour change towards responsible use in the health sector (hospitals, community health centres) and in the food and animal production sectors (animal and plant health professionals, food producers and manufacturers, consumers)?

- Promoting an institutional culture that sustains adherence and linking IPC adherence to patient outcomes.
- There should be systematic education and ongoing training for healthcare professionals and the public.
- Strong and clear packaging and labelling requirements for antimicrobials should be implemented.
- Monitoring of prescribing behaviours and applying feedback systems/auditing.
- Effective regulation and monitoring of antibiotic purchases and usage.
- The availability of local antibiograms would assist prescribers of antibiotics for appropriate prescribing.
- Encourage prescription of narrow spectrum targeted antibiotics (when AMU is warranted).
- Discourage online access without a prescription to unregulated antimicrobials.
- Clear labelling of all food products – e.g. ongoing promotion of labelling for antibiotic-free meat, poultry, eggs, etc.
- In the food and animal production sectors (animal and plant health professionals, food producers and manufacturers), increased costs of production could be passed on to the consumer if products meet a certain standard, as it is the case with existing labelling practices (e.g. organic products). For all involved, awareness campaigns would be helpful, although it is not clear if their impact is sustained over time.

4) What is needed to generate evidence-based data that link the misuse of antimicrobials and the development and spread of AMR via the environment? How can we use the available data to develop effective policy solutions to influence policy makers?

- Systematic reviews of the literature, meta-analyses of the data, GRADE (Grades of Recommendation, Assessment, Development and Evaluation) approach using PICO (population, intervention, comparison, outcomes) questions with recommendations.
- Perhaps whole genome sequencing of genetic markers of resistance that are found in the environment, to be compared with those in the human, animal and plant populations.
- Expert groups could be convened to discuss what a minimum data set could look like for environmental surveillance of AMR. Also, harmonizing what is meant when ‘the environment’ is being discussed, what the scope of the environment means. When does looking at AMR in the environment need to move from targeted studies into true core surveillance activities for a country (i.e. development of criteria for this).

5) What approaches are needed to ensure the industry and investors manufacture and market antimicrobials responsibly, and not stimulate overuse or contribute to environmental pollution?

- Industry should be consulted and involved in the development and implementation of conservation approaches to ensure buy-in. This includes recognition that new economic incentive models may be required to encourage industry to promote responsible marketing and use of antimicrobials. Alternatively, restrictions on the marketing and manufacturing processes of antimicrobials could be legislated by governments to force compliance.
- A combination of regulatory and enforcement measures would be effective, as long as an adequate resources were available.

6) Changing practices needs the support of the industry – how can we balance the availability of a public good such as effective antimicrobials, with a private industry perspective?

- Strategies/mechanisms/approaches to encourage the development of antimicrobials, without compromising access to high-quality, affordable antimicrobials when use is appropriate.
- Encourage development of point-of-care diagnostics to promote more effective/targeted use of antimicrobials.
- Encourage development of vaccines and alternatives to prevent infections/stimulate populations' immunity.

7) What are the mechanisms to enhance the availability and utility of global resources for the end user (communities to individuals) to optimize or reduce the need for the use of antimicrobials and mitigate the unintentional exposure to the environment?

- Disseminate resources through National IPC organizations and/or professional organizations.
- Leadership is needed at the international, national and provincial level.
- International, national and provincial buy-in to harmonized approaches. We cannot work in silos in an environment of international travel, immigration, drug development, agriculture, food chain, etc.
- Social determinants of health in populations are important to address, so as to reduce infectious diseases and need for antimicrobials.
- WASH (water, sanitation and hygiene) should be reinforced in all populations/socioeconomic groups/work environments, public transport, restaurants.
- Encourage/support vaccination programs to prevent infectious diseases where possible.
- Develop and use point-of-care diagnostics to guide prescribing of antimicrobials.

**ADDITIONAL COMMENTS FROM CANADA ON THE IACG DISCUSSION PAPER: “OPTIMIZE USE OF ANTIMICROBIALS”
(August 2018)**

Page/Paragraph	Addition/Deletion/Quoted text	Comment
Page 1, 3 rd bullet point		Implementation should follow the first bullet as they are closely linked.
Page 2, 2 nd last paragraph	The Challenge: Effective infection prevention and control (IPC) averts infections associated with health care, and protects both patients and health workers. IPC has a crucial role in the response to AMR, as it reduces the transmission of microbes, including antimicrobial-resistant organisms, thereby reducing the future need for antimicrobials.	This is not the challenge. Suggest putting the second paragraph as the challenge.
Page 2, last paragraph	Several recent alerts, most notably during the epidemic of Ebola virus disease in West Africa, have raised awareness of this issue; yet adequate IPC is still a challenge in many countries.	The implementation or application or uptake of adequate IPC is still a challenge.
Page 3, first paragraph	Resistance to behaviour change among health workers may also be an issue.	Standardized education and training of healthcare providers is a big factor.
Page 3, first paragraph	...the lack of recognition of the role of IPC in reducing the AMR-spread of resistant and susceptible bacterial infections, in comparison to compared-with the importance given to appropriate antibiotic use...	As IPC has an impact on the spread of bacterial infections, both resistant or susceptible, suggest revising the sentence to: “... the lack of recognition of the role of IPC in reducing the spread of resistant and susceptible bacterial infections, in comparison to the importance given to appropriate antibiotic use...”.
Page 4, 2 nd last paragraph	Unfortunately, animal producers do not always adhere to optimal practices relying on the availability of cheap antimicrobials to prevent and treat infections...	Need to specify here ‘do not always adhere to optimal practices for AMR’ because they likely do believe they are adhering to optimal cost effective practices for rearing their animals.
Page 5, 3 rd paragraph		I think this section is missing that countries should include as part of their national action plans the development of species-specific clinical practice guidelines. This statement may be added to the revised Codex Code of Practice, but as that document is several years away from completion, it

**ADDITIONAL COMMENTS FROM CANADA ON THE IACG DISCUSSION PAPER: “OPTIMIZE USE OF ANTIMICROBIALS”
(August 2018)**

Page/Paragraph	Addition/Deletion/Quoted text	Comment
		bears mentioning specifically here.
Page 5, 4 th paragraph	Animal production is expected to increase in the coming years as a result of economic and population expansion, and it is expected that the use of antimicrobials will increase concomitantly.	Is it the rate of use that will increase, or rather the overall quantities of antimicrobials that will increase? It should be articulated as to which is meant here, because it could be unnecessarily inflammatory otherwise.
Page 6, 3 rd paragraph	The challenge: Effective measures to reduce the burden of foodborne bacterial diseases could also reduce the need for antimicrobial therapy and prevent the spread of AMR.	“Effective measures to reduce the burden of foodborne bacterial diseases” can be confusing. It would be better here to use more precise language, such as “effective measures to reduce the incidence of foodborne bacterial disease” (if that is indeed what is meant). ‘Burden’ has many meanings – burden to the individual patient, burden to the healthcare system, and burden to the economy. But not everyone has that same interpretation of ‘burden’; hence it would be helpful to specify.
Page 6, 3 rd paragraph	Diarrhoeal diseases are the most common infections resulting from consumption of contaminated food and water .	Include “and water” to this sentence.
Page 6, 4 th paragraph	When these bacteria become resistant, the resulting disease becomes more difficult to treat.	Remove the word “these”.
Page 6, 4 th paragraph	Soil, water, manure used as fertilizer and human handling are probable sources of contamination in food production.	Human handling of what? Suggest a revision is needed for clarity.
Page 6, 4 th paragraph	Soil, water, manure used as fertilizer and human handling are probable sources of contamination in food production.	It is not clear if this refers solely to plants or also to animals. If it includes animals, the list of sources should include animal to animal transmission.
Page 6, last paragraph	These challenges can be addressed mitigated largely by ensuring good hygiene and biosecurity and by finding and adopting effective, practical alternatives for preventing and treating microbial infections in plants and animals.	Replace the word “addressed” with “mitigated”. The solutions identified are good, but it may be a little simplistic to say that the challenges can be addressed. Work on food safety has been going on for decades and still foodborne illnesses are a significant problem, so we can’t expect that they are going to be easily eliminated.
Page 6, last paragraph	These challenges can be addressed largely by ensuring good hygiene and biosecurity and by	What type of good hygiene is meant here? Farm workers washing their hands? Or does this mean good farming practices or good hygiene at

**ADDITIONAL COMMENTS FROM CANADA ON THE IACG DISCUSSION PAPER: “OPTIMIZE USE OF ANTIMICROBIALS”
(August 2018)**

Page/Paragraph	Addition/Deletion/Quoted text	Comment
	finding and adopting effective, practical alternatives for preventing and treating microbial infections in plants and animals.	slaughter plants? Or does this mean good food prep hygiene of consumers in their kitchen?
Page 7, 1 st paragraph	To complement these, OIE has made a list of antimicrobial agents of veterinary importance, and recently updated recommendations on their use.	‘Their’ is ambiguous here. The OIE has not updated how their list should be used, but has updated some recommendations on certain classes of antimicrobials (in particular colistin).
Page 8, 1 st paragraph	The environment must also be considered in determining how antimicrobials, antibiotic resistance genes (ARGs), mobile genetic elements (MGEs) and resistant microbes spread from humans, animals, plants and waste (industrial or from households).	Would suggest specifying ‘the natural environment’ to be clear about the intended scope.
Page 8, 2 nd paragraph	Other challenges include the lack of routine, standardized monitoring to determine the trends in AMR from environmental sources, and difficulty in defining the intersecting environment...	What is the ‘intersecting environment’?
Page 8, 2 nd paragraph	Other challenges include the lack of routine, standardized monitoring to determine the trends in AMR from environmental sources, and difficulty in defining the intersecting environment, and therefore in designating leadership and responsibility. There are high risks of duplication and of neglect of important areas.	Neglect is likely a bigger issue than duplication.
Page 8, last paragraph	The Joint Programming Initiative on Antimicrobial Resistance (JPI AMR) promotes research and shared knowledge about the causes and consequences of AMR in the environment include .	The word include should be removed.
Page 9, Figure 1		Suggest the figure is missing a couple of things: 1. Antimicrobials (urine and feces) from animals and 2. Human preventive uses

**ADDITIONAL COMMENTS FROM CANADA ON THE IACG DISCUSSION PAPER: “OPTIMIZE USE OF ANTIMICROBIALS”
(August 2018)**

Page/Paragraph	Addition/Deletion/Quoted text	Comment
Page 9, Figure 1	Accidental and intentional release of antimicrobials from production plants.	Typo in figure (the word “intentional”).
Page 10, last paragraph	While overuse of antimicrobials is the main concern with regard to AMR, access to and the affordability of medicines, including antimicrobials, remain a challenge in LMICs. Paradoxically, underuse of antimicrobials (for example the relatively widespread practice of purchasing and consuming a single tablet) can also potentially cause the development and spread of AMR.	Given the recent debate around the traditional advice about the importance of finishing a full course of ABX, recommend adding the word “potentially”.
Page 10/12		Further emphasis should be placed on the role of emerging health IT, big data and artificial intelligence solutions to better manage AMR conditions and contribute to R&D innovation and stewardship.

Combined input from the Government of Canada on IACG Discussion Papers

Meeting the Challenge of Antimicrobial Resistance: From Communication to Collective Action

General Comments:

- From an IPC standpoint, the primary message would be to prevent and control infection to reduce the use of antibiotics and the development of resistance by: developing and implementing user-friendly evidence-based IPC guidance; strategies to ensure their implementation in practice to modify behaviour; educate and train healthcare providers and allied staff in healthcare settings.

1) How can we best measure and prioritize efforts that communicate AMR effectively, so that limited resources are used optimally?

- Develop global communication strategies and materials especially in countries where there are already some Action Plans in place and then adapt for local needs.
- Identify key objectives for communication strategies, appropriate outcome measurements and performance indicators.
- Share best communication practices across the various countries involved in the fight against AMR.
- Set appropriate benchmarking with short, mid-term and long-term priorities e.g. raising awareness as a short-term objective, whereas communication for behavioural changes is longer term.

2) What are the major barriers to changes in antimicrobial use and management among priority stakeholder groups and communications recommendations to tackle these?

- Knowledge gaps exist for both healthcare professionals and patients on how to use antimicrobials more effectively. In an effort to help address this knowledge gap, Health Canada now requires prudent use statements in both the Prescribing Information and the Patient Medication Information of all antimicrobials marketed in Canada. IT tools could also be used to remind prescribers and distributors of the authorized indications or recommended use for specific antimicrobials and the possibility for the development of resistance due to inappropriate use.
- In addition to education efforts on the appropriate use of antimicrobials, healthcare professionals often lack effective and timely diagnostic tools that can enable appropriate prescribing. In the absence of such tools, prescribing guidelines may aid healthcare professionals in choosing effective treatments.

3) What are appropriate and practical incentives for changes in practice? What lessons might be learned from other areas, from vaccinations to WASH (water, sanitation and hygiene) campaigns, that could inform what the IACG might recommend?

- To encourage changes in practice, new governance tools (e.g. regulations and organizational accreditation) and standards for prescribing, dispensing and distributing antimicrobials could be developed.

4) What research agenda is needed to support efforts to communicate AMR? How might this communications research best be funded and coordinated?

- Research is needed to identify the communication gaps that exist at all levels, from raising awareness to behavioural changes. This includes identification of the societal, demographic and socioeconomic determinants, knowledge translation for AMR and tools for improvement of health literacy.
- Private/public partnerships could be leveraged to provide research funding and coordination.
- There is also a need for more coordinated international research on when and how to appropriately use antimicrobials. Research could also be used to examine the current standards of care and establish effective, alternative treatment options that do not involve antibiotics.

5) What model approaches best mobilize key actors in tackling AMR while raising awareness? How might one best structure a multi-stakeholder platform for AMR communications and a community of practice linking these key communications focal points?

- Local grassroots campaigns with both a public champion (opinion leader) and technical expert (scientific leader) from each sector should be encouraged.
- Need to acknowledge that even though multi-stakeholder platforms (MSPs) represent the current trend globally, there remain challenges with successful implementation in contexts such as AMR (primarily due to global socioeconomic inequities).
- The MSP could be used as an opportunity for capacity building, but the composition is critical – no party affected by what is being discussed should be excluded e.g. need to determine which stakeholders are implicated (or ask them to self-determine) and what are the legitimate organizations to represent them.
- MSPs are costly; hence global funds would need to be available to address lack of financial means and lack of technical knowledge for appropriate country and regional representation.
- The MSP could at the same time act as a forum for exchange of experience and best practice (community of practice) on the implementation of the AMR National Action Plans across sectors and at local, regional, national and country level, where stakeholders can engage in discussions about sustainable measures against AMR.

6) Where and what would be the most strategic opportunities for investing in efforts that communicate AMR? How can the Tripartite agencies and other intergovernmental agencies be supported to carry out this work?

- Industry could be encouraged to provide a set percentage of sales revenues from drug products to be spent on good AMR stewardship, such as public education campaigns.
- Sharing of best practices and lessons learned should be enhanced across all involved agencies.

7) How can we best scale promising strategies for changing individual behaviour into collective action to effect AMR change? What groups might be enlisted in these efforts? What role does civil society, professional societies and industry trade associations among others constructively play in these efforts, and how might this be supported?

- There may be an increased need for action-oriented knowledge rather than technical knowledge to craft coherent strategies and visions that will be translated into collective action to effect AMR change.
- By taking this next step, a tailored/targeted education strategy may change an individual's concept of power (underlying rationale is that individuals are influenced by their viewpoint on their own power to resolve an issue) and transform individual behaviours/actions into collective actions.
- As with other significant public health issues all groups must be enlisted, from the general public to healthcare professionals –AMR is a shared responsibility.

8) What opportunities are there for enabling effective monitoring for accountability towards effecting AMR change? What enabling conditions are critically important for such efforts, and how can we best ensure that these conditions are met?

- Appropriate regulatory frameworks should be supported by effective compliance strategies and enabled when possible by necessary resources.
- Adequate information technology (IT) monitoring systems and associated funding could be employed.

IACG Discussion Paper

July 2018

Reduce unintentional exposure and the need for antimicrobials, and optimize their use

Strengthen the training programs established on hygiene, prevention and control of infections for the personnel of food processing plants of animal and plant health, reinforce the use of personal protective equipment, since in the field workers is not done because it is considered only for hospital use and you have the concept that being the majority of sex male should not be used, workers who use it are ridiculed.

Improve the management of wastewater, through the reinforcement of monitoring and control programs, standardize methodologies for the final disposal of antimicrobial waste, define the competencies and responsibilities among the authorities responsible for the improvement of environmental health and all its components.

It is necessary to put pressure on the Presidents of the Republic, so that they become aware of the importance of antimicrobial resistance and at the same time allocate financial resources to work. Some poor countries are eager to work, we make a great effort but we do not have resources, to answer each of these questions we need resources to develop and implement strategies in the human, animal, plant and environment.

Meeting the Challenge of Antimicrobial Resistance: From Communication to Collective Action

In the case of agriculture and livestock, strategies must be found to reduce the use of antimicrobials, but at the same time provide other alternatives to eliminate pests in plants. In animal use, it is necessary to look for nature-friendly alternatives that replace antimicrobials as a growth factor.

The antimicrobials that are used in plants (agriculture) are prescribed by agronomists, this is without attention in many countries, it is an important point that must be addressed.

Pilot plans such as plant production (agriculture) with antimicrobial reduction and applying methods to combat pests, which are more friendly to the environment.

It is important to bear in mind that in some countries such as Costa Rica, agronomists are in charge of prescribing antimicrobials for plants (non-animal plant agriculture) and in many cases they are prescribed by non-professionals.

It is important to highlight here the education that the doctor must provide to the patient about the use of the antimicrobials that are prescribed, how to take, at the right times, the correct doses and for which microorganisms the prescribed antimicrobial is effective, importance of complete the scheme and not sharing antimicrobials with other people.

It is important to include antimicrobial resistance in the syllabus of the university, this for veterinary medicine students and for graduate veterinarians you can work through the professional school, it can be compulsory or as a re-certification, the issue of resistance to antimicrobials.

It is important to create alternatives for the substitution of antimicrobials as a growth factor, because if we do not give options to farmers and producers of animal farms, there is a lot of resistance and rejection, since they indicate that they need replacement alternatives to replace antimicrobials and have positive results in crops and production animals.

Each country must make national regulations for pharmaceutical companies to prepare and present a plan for the management and final disposal of medicines, raw materials and their waste.

Finland

Comments of the IACG discussion papers, set 2, 31.8.2018; Finland

Jari Jalava, PhD, Senior Expert

National Institute for Health and Welfare

Chairman of the MTKA*

and

Nina Kaario

Senior Veterinary Officer

DVM, Specialist in Veterinary Medicine, Environmental Health and Food Control

Food Safety Unit

Ministry of Agriculture and Forestry

***Finnish National Expert Group on Antimicrobial Resistance Control and Prevention (MTKA)**

<https://thl.fi/fi/web/infektiaudit/yhteystiedot/asiantuntijatyoryhmat/mikrobilaake-resistenssin-torjunnan-kansallinen-asiantuntijaryhma>

IACG discussion papers:

IACG_Future_global_governance_for_AMR_120718.pdf

nation IACG_Optimize_use_of_antimicrobials_120718.pdf

IACG_Meeting_challenge_AMR_communication_to_collective_action_270718.pdf

Comments:

- The discussion papers 4.-5. handle the AMR problem widely and thoroughly and cover most areas related to the problem. They provide a good base for the future work.
- Concrete practical guidelines would be needed.

- Calculations and estimations on what would be the minimum level of practical timely/human resources needed in order to be able to accomplish the proposed concrete actions.
- One area that could be covered more thoroughly is the evaluation and comparison of the level of human and economic resources that is used in different countries in addressing the AMR problem and, in addition, what the impact of the level of the used resources has been on reducing AMR.
- One area that could also be covered is the concrete actions already made in different countries, such as IT-systems, good practices and solutions, on which the knowledge could be spread among countries.
- IACG:s mandate is to provide also practical guidance for approaches needed to ensure sustained effective global action. Practical guidance would help the countries with limited resources to carry out the proposed measures.
- Some other areas that could be addressed more thoroughly in practical guidelines would be behavior change, animal welfare, supporting the development of good immune defense in animals, the role of the environment, the mechanisms of antimicrobial resistance: how it develops and spreads

Specific comments

Discussion paper IACG_Optimize_use_of_antimicrobials_120718.pdf

A priority list of actions would be useful. Are topic areas, in the box 1, listed in significance order?

Questions

- What kind of support (other than financial) is needed to translate the existing guidance into implementable actions? **timely resources, human resources**
- How can policy makers be assisted to further develop and implement infection prevention and control in human and animal health and plants and be convinced to invest now to mitigate the escalating and future costs and obtain benefits far beyond preventing AMR? **the effects on the system in place in a country, and the effects of the new actions should be evaluated**
- What incentives or initiatives are needed for behaviour change towards responsible use in the health sector (hospitals, community health centres) and in the food and animal production sectors (animal and plant health professionals, food producers and manufacturers, consumers). **system change, professional incentives, economic incentives**
- What is needed to generate evidence-based data that link the misuse of antimicrobials and the development and spread of AMR via the environment? How can we use the available data to develop effective policy solutions influence policy makers? **build IT-systems, evaluate the correlation between AMU and AMR**

- What approaches are needed to ensure the industry and investors manufacture and market antimicrobials responsibly, and not stimulate overuse or contribute to environmental pollution? **market other, safe and innovative alternatives**
- Changing practices needs the support of the industry - how can we balance the availability of a public good such as effective antimicrobials, with a private industry perspective? **market other, safe and innovative alternatives**
- What are the mechanisms to enhance the availability and utility of global resources for the end user (communities and individuals) to optimize or reduce the need for the use of antimicrobials and mitigate the unintentional exposure to the environment? **spread the knowledge on new innovations and scientific development: for example success stories on how to handle situations without antimicrobials either by preventing or by treating differently e.g. how to change behavior**

Discussion paper

Meeting the Challenge of Antimicrobial Resistance:

From Communication to Collective Action

Key Questions for Stakeholders

1. How can we best measure and prioritize efforts that communicate AMR effectively, so that limited resources are used optimally? **The measures, including their effort/profit ratio, should be prioritized, in the global scale, and put in a rough order of priority. Which measures are of profound importance and on which to – after that – build the next/rest of the measures. Start from the most important measures and use the limited resources to the concrete work to get the first measures done. Every country can start from the point where they already are. In some countries, many things are already in place due to longstanding efforts.**
2. What are the major barriers to changes in antimicrobial use and management among priority stakeholder groups and communications recommendations to tackle these? **Lack of resources to train and spread the knowledge and change behaviour. Costs. Economic competition. The economic hardship when investing in animal welfare, preventing infections, using alternatives and bringing new alternatives to the market. There is no guidelines on how to treat instead of antimicrobials, how to avoid antimicrobials, how to train general public, how to change behaviour. The pharmaceutical industry has to take their share of the responsibility.**
3. What are appropriate and practical incentives for changes in practice? **Economic benefits, professional benefits (expertise, scientific), timely and effort benefits.** What lessons might be learned from other areas, from vaccination to WASH (water, sanitation and hygiene) campaigns, that could inform what the IACG might recommend? **Before campaigning, it would be good to find out among the target group, what they already know and what would need to be changed.**

4. What research agenda is needed to support efforts to communicate AMR? How might this communications research best be funded and coordinated? **The different mechanisms how AMR develops, spreads, persists, changes, transforms etc. With that knowledge it is easier to communicate AMR.**
5. What model approaches best mobilize key actors in tackling AMR while raising awareness? How might one best structure a multi-stakeholder platform for AMR communications and a community of practice linking these key communications focal points?
6. Where and what would be the most strategic opportunities for investing in efforts that communicate AMR? How can the Tripartite agencies and other intergovernmental agencies be supported to carry out this work?
7. How can we best scale promising strategies for changing individual behavior into collective action to effect AMR change? What groups might be enlisted in these efforts? What role does civil society, professional societies and industry trade associations among others constructively play in these efforts, and how might this be supported? **Justify the measures by the need to change behavior and by science that shows that unnecessary use of antimicrobials can harm the development and function of human and animal body.**
8. What opportunities are there for enabling effective monitoring for accountability towards effecting AMR change? What enabling conditions are critically important for such efforts, and how can we best ensure that these conditions are met? **Benchmarking of pharmaceutical industry, global agreement on AMU and AMR data from different countries.**

France

CONSULTATION IACG – Position France

Sur les "key messages" (en tête du document communication) :

Le PNUE, qui a travaillé sur le sujet AMR & environnement, n'apparaît pas explicitement. Il semble nécessaire de le mentionner et de l'associer sans doute plus en amont à la démarche tripartite (OMS, FAO, OIE).

Dans les messages narratifs

Il semble nécessaire de compléter la « *war metaphor* » par la « *comparison with climate change* », qui peut être utile pour faire le message sous-jacent. De même plus loin, l'évocation des campagnes de contrôle du tabac évoquées pourrait être complétées par une référence à la sécurité routière. Il semble en effet très important de faire rentrer dans la sphère publique les similitudes, voire les liens, au sein des couples « production de gaz à effet de serres/utilisation inappropriée des antibiotiques » d'une part et « réchauffement climatique/AMR » d'autre part. Les méthodes utilisées pour populariser les liens entre Santé et Biodiversité pourrait ainsi inspirer ces développements.

Sur le document sur la R&D

Celui-ci apparaît comme quelque peu décevant, en ce qu'il n'analyse pas en profondeur les problématiques soulevées et n'apporte que peu de propositions concrètes.

Il serait souhaitable d'ajouter également dans cette partie une référence aux travaux du HUB R&D AMR, et sur l'articulation possible avec celui-ci.

Unofficial English translation:

On the "key messages" (at the beginning of the communication document):

UNEP, which has worked on AMR & environment, does not appear explicitly. It seems necessary to mention it and to associate it probably further upstream with the tripartite approach (WHO, FAO, OIE).

In narrative messages

It seems necessary to supplement the "war metaphor" by the "comparison with climate change", which can be useful for making the underlying message. As well, the evocation of the tobacco control campaigns mentioned above could be supplemented by a reference to road safety. It seems indeed very important to bring into the public sphere the similarities, even the links, within couples "greenhouse gas production / inappropriate use of antibiotics" on the one hand and "global warming / AMR" d 'somewhere else. The methods used to popularize the links between Health and Biodiversity could thus inspire these developments.

On the document on R & D

This appears to be somewhat disappointing, in that it does not analyze in depth the issues raised and provides few concrete proposals.

It would be desirable to add also in this part a reference to the work of the HUB R & D AMR, and on the possible articulation with it.

Germany

From: [Müller Dr., Susanna -Z23 BMG](#)
To: [IACG-secretariat](#)
Cc: [Reitenbach, Dagmar -Z23 BMG](#); [Z23 BMG](#); [Clarici Dr., Alexandra -322 BMG](#); [Klaus, Ina -PG PhD BMG](#);
Subject: German comments on the discussion papers prepared by the IACG
Date: 14 September 2018 18:42:28

Dear Tim,

First of all I would like to apologize for the delayed answer. Many thanks to the secretariat for all the work.

Generally, the three papers outline an excellent effort to minimize antimicrobial resistances on a global scale using a holistic, “One Health” approach, i.e. by addressing human and animal medicine, agriculture and food production as well as the environment. It foresees a coordinated and concerted effort by member states politicians, health care, agriculture and food sector actors, environmental and water agencies as well as pharmaceutical business, in order to achieve the goal of reducing the occurrence and spread of antimicrobial-resistant microorganisms.

Please find attached our comments on the documents:

1. „Future Global Governance for Antimicrobial Resistance”

- Many thanks to the IACG for the extensive compilation of options for a governance mechanism on AMR. However, we don't see the need for a new governance mechanism, especially not in the format shown on page 9.
- AMR is an important topic that needs to be addressed globally and that requires coordination on all levels in line with the “One Health approach” It is therefore important to build on current structures/initiatives/organizations in order to offer simplicity and sustainability while addressing AMR challenges. Creating a new governance structure takes time before it can work efficiently. Addressing and coordinating AMR issues should be dealt with in the context of established governance structures. We do agree with the IACG that continued and increased support of the tripartite (WHO, FAO, OIE (and as suggested by the IACG UNEP) is needed. Aligning existing AMR strategies and guidelines would be a first step in providing a coordinated response to AMR, that is highly needed.
- With regard to R&D, we strongly disagree with several of the aims stated in the document “Future Global Governance for AMR”. In particular, the development of a global, multi-stakeholder agreement, a pooled fund, or a binding global commitment with accountability clearly assigned at every level is not a promising approach. It seems unrealistic, given the complexity of the matter and sovereignty of states (and science as such) with regard to R&D policies. We also query that an overly complex governance structure (with a mandate covering everything from surveillance to R&D to access, use and regulation) will be able to secure and more effectively organize sufficient funding and resources. Instead, there is need for a diverse range of smaller and customized initiatives working in a coordinated way and meeting different R&D needs, that can easily be adjusted to the evolving situation of AMR.
- More stakeholders than in the past need to be involved in the process of reducing antibiotic resistance (not only WHO, FAO and OIE). AMR is not just a human, veterinary and agricultural issue, it requires also the involvement of the research, environment and

finance sectors. In this respect, AMR probably differs from other health challenges.

-

- In recent years, a large number of initiatives have been established and commitments made.

The document does not sufficiently take into account these already existing structures / initiatives / programs (e.g. G7 or G20 activities - Global AMR R & D Hub, EU initiatives). It remains unclear how these initiatives - partly with their own monitoring mechanisms - could be incorporated into a broader governance mechanism.

- Monitoring of commitments from these initiatives need to be strengthened. In addition better coordination is needed to avoid duplication, but this does not necessarily requires a new governance mechanism.
 - As an alternative to the proposal, a further strengthening of the tripartite (WHO/FAO/OIE) should be considered, enabling the organizations to carry out more extensive monitoring tasks for the implementation of measures.
 - We agree that the tripartite should be expanded with the United Nations Environment Programme.
 - It has to be taken into account that the current situation in the Member States is very different, both in terms of existing structures and the resistance situation. Globally consistent goals may not be the best way.
-
- The relation of the proposed "Global Multistakeholder Agreement" and the Global Action Plan and its monitoring and evaluation process remains unclear. Are there already considerations how the proposed mechanism should be funded?
 - Whether new structures have to be set up or whether existing structures should be strengthened and/or expanded needs to be discussed broadly with all stakeholders. The current document can only be a first step. The member states should be involved very closely in its further development.
 - The Global AMR R&D Hub is not mentioned in the Discussion Paper on Future Global Governance for AMR. It should however be referenced as an instrument already implementing part of the requirements listed in the paper for the area of R&D: The Hub aims to support leading funders in coordinating research funding on AMR and is thus an important governance mechanism on AMR research and development. More specifically, the Global AMR R&D Hub, while fully respecting the members' sovereignty, aims at giving evidence-based guidance for funding decisions. Guided by the global priorities set by WHO, FAO, OIE and other relevant intergovernmental organizations and following the One Health approach, the Hub advocates for investment in R&D for AMR and will help paving the ground for multi-donor support for prioritized activities.
 - Generally, we question the need for an extensive, new governance structure, covering all aspects from R&D in human and animal health to access and stewardship. The discussion paper does not provide a convincing rationale for this. Experience with GAVI and the Global Fund (which have a much more focused mandate than the proposed AMR-body would have) shows that it takes considerable time to build such complex (and costly) entities and to reach sufficient trust in their functioning and efficacy. We are thus very much in favour of addressing and coordinating AMR issues in the context of established governance structures (cf. requirement 6 in the paper). We advocate for a continued and increased support of the tripartite and the AMR Secretariat, perhaps with the help of lean support structures such as the Global AMR R&D Hub.

2.. „Reduce unintentional exposure and the need for antimicrobials, and optimize their use“

Please find the answers on the guiding questions below:

1. What kind of support (other than financial) is needed to translate the existing guidance into implementable actions?

- The existing guidance must be adapted to the situation at national or regional level (health care structure, resistance rates, antibiotic consumption) in order to be implemented.
- From our point of view, the exchange between countries regarding best practice models can be very helpful in the implementation of measures.

2. How can policy makers be assisted to further develop and implement infection prevention and control in human and animal health and plants and be convinced to invest now to mitigate the escalating and future costs and obtain benefits far beyond preventing AMR?

- Data on the effectiveness of appropriate measures (reduction of the number of cases with infectious diseases and resulting positive financial effects)
- Helpful are measures e.g. by WHO for the human health sector to assist Member States in the development of such programs.

3. What incentives or initiatives are needed for behavior change towards responsible use in the health sector (hospitals, community health centres) and in the food and animal production sectors (animal and plant health professionals, food producers and manufacturers, consumers)?

- A prescription obligation means that antibiotics will only be available after appropriate diagnosis by medical personnel. Training and education must be strengthened so that the necessary knowledge about the appropriate use of antibiotics is available.

In addition to that we see, that found only few minor aspects we would like to express our opinion on:

More emphasis should be put on scientific research which addresses detection methods and investigations into antibiotic resistances in foods and the environment, tracking contamination routes, antibiotic resistance monitoring, developing standardized antibiotic resistance testing methodology for different microorganisms, genetic basis and extent of transferable resistances, evolutionary studies on antibiotic resistances at the genome level and developing alternatives to antibiotic treatments need to be given more priority. Furthermore, there will be a need for a global database for whole genome sequences which includes tools for data annotation and analysis. This will be

necessary to track microorganisms and resistances for global epidemiological monitoring and for detecting transmission routes (e.g. travel, transport, environment, food, animals (birds)).

- This point takes reference to page 5 (shared one health needs), page 18 (executive summary, section a global forum is seen as essential to enable stakeholders to:....). Furthermore, page 24 (d) determining priority factors for addressing AMR, and page 28 (d) barriers to applying existing solutions and best practices.

2.) The heavy use of biocides (antiseptics, disinfectants) in the food and farming environments industry (also heavy metals used in the fish industry as sanitizers) may favor the development and increase

The heavy use of biocides (antiseptics, disinfectants) in the food and farming environments industry (also heavy metals used in the fish industry as sanitizers) may favor the development and increase of antibiotic resistances in food bacteria, as biocide resistances often result in cross-resistances towards antibiotics. This results from the fact that the same resistance mechanisms are induced. Thus, the inappropriate or overly excessive use of biocides in the food industry and farming environment should be given more attention.

- This point takes reference to page 4, point 3 (Optimizing use in animals and plants) and page 6 point 5 (Food safety and food production).
- This point also takes reference to page 21: The drivers of antimicrobial resistance are human health, agriculture and animals, and environmental contamination, on page 23 where biocides are actually mentioned under point c (antimicrobials and use in the environment) and on page 51 (scenario 2: a multi-stakeholder-negotiated AMR protocol - here one of the points could be reducing inappropriate use of biocides or heavy metals in primary and secondary food production).

3.) Studies on transfer of antibiotic-resistant bacteria from animal husbandry to fresh vegetables (plant produce, often eaten raw!) via manure or farm water /rivers via the food chain onwards to the consumers should be better investigated. The possibility of intervention by heating manure to inactivate microorganisms, or better waste water treatment (e.g. fourth purification stage (activated carbon) for waste water treatment) to inactivate residues, should be given higher priority. What also about removal of residues from water used for aquaculture?

- This point takes reference to page 4, point 3 (Optimizing use in animals and plants), page 6 point 5 (Food safety and food production) and point 6 (Environmental Contamination).
- This point also takes reference to the paper „Future global governance for

antimicrobial resistance“ on page 50 (scenario 2: A multi-stakeholder-negotiated AMR protocol): one of the points here could be to treat manure to inactivate bacteria and to remove antimicrobials from waste water.

4.) More emphasis should possibly be placed in finding alternative therapeutics, alternative (less intensive) farming practices and/or alternative treatments (e.g. protective cultures bacteriophages, endolysins, vaccines) to decrease antibiotic use.

This point takes reference to page 5, point 4 (Prevention and control of infection in animals)

This point also takes reference to the paper: ‘Future global governance for antimicrobial resistance’ on page 5 in the table ‘specific sector needs’, on page 25 section (d) determining the priority factors for addressing AMR (what can be done...), page 27 (a) major reports on AMR and what they tell us: Research and Development....., page 50: Scenario 2: A multi-stakeholder-negotiated AMR proposal bullet points: One could be: evaluation of use of alternatives to antibiotics, Page 63 (c) Alternative agricultural practices could be substituted for antibiotics) the point about less intensive farming and alternative farming methods may be appropriate here. We noticed and find it important that here in this section alternatives for antibiotics such as bacteriophages or vaccines are mentioned.

BR

Susanna

Yours sincerely

Dr. Susanna Müller

Z 23 – Global Health
Federal Ministry of Health

Friedrichstraße 108, 10117 Berlin

1.How can we best measure and prioritize efforts that communicate AMR effectively, so that limited resources are used optimally.

Priorities for targeting communications across a society are very important and can possibly be assessed by using assessment tool (to include private and public sectors) which could be developed by Tripartite agencies and their partners and should be tailored to a country's needs (No one-size-fits-all strategy) and easily tracked, this is done through

1. Study financial and human resources
2. Identification of gaps in the health and veterinary sector through studies carried out by government institutions in different regions
3. Focus on awareness, instructions and laws in force to spread AMR culture to various levels

2>What are the major barriers to changes in antimicrobial use and management among priority stakeholder groups and communications recommendations to tackle these?

The concept of drug resistance is one of the modern scientific phenomena that threaten public health globally and nationally in particular, which requires a change in public policy to address the phenomenon of pharmacological resistance to antimicrobials through the legislation of laws and regulations.

The major barriers to change in antimicrobial use is how to change behavior among the managers of health institutions & prescriber that need to develop a good plan to change behavior. In Iraq, decision-makers adopt the control of antimicrobial resistance through the development of the general policy from Ministers Council to eliminate the problem and to develop the best solution for cooperation of all sectors in order to limit the spread of the problem.

3.What are appropriate and practical incentives for changes in practice? What lessons might be learned from other areas, from vaccination to WASH (water, sanitation and hygiene) campaigns, that could inform what the IACG might recommend?

The lack of integration of the work between WASH & AMR program, which leads to the failure to complete the requirements of infection prevention, especially in countries that lack access to safe drinking water and sanitation, and therefore we need international decisions to promote the water program in cooperation with the program of resistance

4.What research agenda is needed to support efforts to communicate AMR? How might this communications research best be funded and coordinated?

There is no research agenda to identify and support AMR communication efforts.

We suggest having an international collaborative platform that coordinates national research funding and supports co-operative action for filling knowledge gaps on antimicrobial resistance with a One Health perspective.

The governments should support implementation of a strategy to eliminate/ control AMR and work to strengthen national capacity through epidemiological assessment, monitoring, surveillance, project evaluation and resource mobilization. However, the tripartite agencies have to fund and coordinate these researches in resource-limited countries.

5.What model approaches best mobilize key actors in tackling AMR while raising awareness? How might one best structure a multi-stakeholder platform for AMR communications and a community of practice linking these key communications focal points?

The **tailoring AMR programmes (TAP)**. model would be most appropriate in promoting awareness especially in countries like Iraq as it makes good use of fewer resources to empower health professionals and promote the rational use of antibiotics. Additionally, the rational use of medicines doesn't always get translated into the practice, therefore the **tailoring AMR programmes (TAP)**. model can be useful in bridging this gap.

6.Where and what would be the most strategic opportunities for investing in efforts that communicate AMR? How can the Tripartite agencies and other intergovernmental agencies be supported to carry out this work?

The best opportunity to promote AMR is to communicate it to undergraduate students before they qualify to practice. This can be done by making antimicrobial resistance a core component of professional education, training, certification and credentialing, continuing education in the health and veterinary sectors and all related courses and workshops. There is a need for global support to guide the Food and Agriculture Organization of the United Nations (FAO) to cooperate with the Ministry of Health and Agriculture, noting that there is currently only cooperation with the World Health Organization (WHO), noting that there are governmental efforts in communication between the relevant sectors (Ministry of Agriculture and Health).

7. How can we best scale promising strategies for changing individual behavior into collective action to effect AMR change? What groups might be enlisted in these efforts? What role does civil society, professional societies and industry trade associations among others constructively play in these efforts, and how might this be supported?

Iraq is one of the countries that has adopted a new behavioral change strategy

8. What opportunities are there for enabling effective monitoring for accountability towards effecting AMR change? What enabling conditions are critically important for such efforts, and how can we best ensure that these conditions are met?

Monitoring of NAP must include indicators that are transparent, actionable, and focused on measuring changes in behavior, not just attitudes or knowledge. Effective monitoring can give important impetus for motivating behavioral change. Such monitoring requires effective surveillance systems to produce data that when placed into the hands of civil society or the public will yield policy triggers.

REDUCE UNINTENTIONAL EXPOSURE AND THE NEED FOR ANTIMICROBIALS, AND OPTIMIZE THEIR USE

1.What kind of support (other than financial) is needed to translate the existing guidance into implementable actions?

Whole society support: professional association bodies, health organizations and collectives of hospitals and healthcare providers should play an important part in all initiatives for reducing antibiotic use in human, animal and environmental sectors. Therefore, education is important for all prescribers of antimicrobials for human and animal health so that they prescribe appropriately and consider alternatives to antibiotics for managing diseases. This should cover strategies to reduce total antimicrobial prescribing. It should be part of all stages of formal training and career through compulsory continuing education and professional development programmes. Run an IPC programme that aims to improve patient outcomes through the prevention and control of healthcare associated infections in all settings.

2.How can policy makers be assisted to further develop and implement infection prevention and control in human and animal health and plants and be convinced to invest now to mitigate the escalating and future costs and obtain benefits far beyond preventing AMR?

Develop or strengthen IPC program and AMR action plans, through a feasible, effective and acceptable framework that can be adapted from manger of any health care facility in addition to taking account of available resources and public health needs will improve IPC. Increasing acknowledgement of the threats posed by national guide of IPC is consider as important part of the solution to protect

people from these threats and focus on the International Health Regulations (IHR) which position IPC as a key strategy for dealing with public health threats of international concern .in addition to Focus on multimodal behaviour change approaches and bundles to supporting implementation of infection prevention & control.

3.What incentives or initiatives are needed for behaviour change towards responsible use in the health sector (hospitals, community health centres) and in the food and animal production sectors (animal and plant health professionals, food producers and manufacturers, consumers).

The antimicrobial stewardship is an important part of AMR national action plan that will be adapted in all health sectors (hospitals and community health centers) is guide the for rational use antibiotics by prescriber .

Manufacturers and those selling antibiotics to providers, farmers, consumers and others in both the healthcare delivery and food production systems should be prohibited from marketing for inappropriate uses or incentivizing medical and veterinary personnel to overuse or inappropriately prescribed antibiotics

4.What is needed to generate evidence-based data that link the misuse of antimicrobials and the development and spread of AMR via the environment? How can we use the available data to develop effective policy solutions influence policy makers?

Further data is necessary to determine whether the spread of antimicrobials in the environment significantly increases the risk of osteoarthritis. Studies have shown that the spread of antibiotic resistance in bacteria is of public health importance and can be increased by antibiotic contamination. Subsequentlywe need a joint monitoring program, for the purpose of exchanging information between different sectors

5.What approaches are needed to ensure the industry and investors manufacture and market antimicrobials responsibly, and not stimulate overuse or contribute to environmental pollution?

A greater emphasis in enforcing the pharmaceutical industry who manufacture antibiotics to take greater responsibility in the safe disposal of unused or expired antibiotics across the supply chain with Strengthen the laws and regulatory systems to ensure the safety, efficacy and quality of antimicrobials

6.Changing practices needs the support of the industry - how can we balance the availability of a public good such as effective antimicrobials, with a private industry perspective?

nill

7.What are the mechanisms to enhance the availability and utility of global resources for the end user (communities and individuals) to optimize or reduce the need for the use of antimicrobials and mitigate the unintentional exposure to the environment?

To improve the correct description of antimicrobial agents by legislating laws, attention to hygiene, strengthening the infection control program in health institutions, and reducing the use of antimicrobials in animal husbandry, fish farming and agriculture for the purpose of reducing environmental exposure in general.

August 31, 2018

We appreciate that the IACG has provided us with the opportunity to review and submit comments on the discussion paper.

We fully understand the importance of engaging various stakeholders other than Member States in the future governance framework. However, we believe that the core of such framework comprises Member State governments, which have been developing and implementing policies to control AMR, and the tripartite organizations, namely the OIE, WHO and FAO, which have been supporting such actions by Member States. Due consideration should be given to this point when details of the Global Steering Board are established, including membership and decision making procedures. Needless to say, securing transparency is critical for maintaining credibility of the Global Steering Board.

Based on the Global Action Plan, many Member States have developed and been implementing National Action Plans. The tripartite organizations are supporting this, and monitoring and encouraging global progress. If a governance system with binding commitment is contemplated, the need for this should be identified through examination of the existing working mechanism.

Finally, any new mechanism should be flexible enough to accommodate various stages of development.

Netherlands

From: [Grand, M.J.F. le \(Maria\)](#)
To: [IACG-secretariat](#); [Jong, D.A.J.J de \(Desiree\)](#)
Subject: RE: Discussion papers
Date: 11 September 2018 15:45:06

Dear IACG secretariat,

Thank you for the three new IACG discussion papers and the opportunity to provide feedback via this consultation procedure. I am sorry we could not make it before your deadline because of our overlapping holidays, but I still hope you can make use of our comments. I am writing you on behalf of the Netherlands Ministry of Health, Ministry of Agriculture and National Public Health Institute. Our main comments apply to the paper on 'Future Global governance of AMR'. The paper on 'Optimize use of antimicrobials' is in our view a duplication of effort that should be avoided since this important work is already being done at the global level by WHO. Finally, we had a quick scan through the paper on 'Meeting the Challenge of Antimicrobial Resistance: From Communication to Collective Action'. We do not have any substantial comments on this piece of work – we think in general it is a good paper and an important issue to address.

Input on the discussion paper on Future Global governance of AMR:

- Good piece of work, the proposal can trigger discussion on how to organise global ambition on tackling AMR. We can support the proposal to strive for a Treaty for this topic. We are wondering about suggestions to make sure the proposed Global Steering Board will have enough status – would it possibly need to be a body with a dedicated budget which can hold other actors accountable?
- An analysis of current cooperation mechanisms (UNGA), agreements (WHO GAP resolution) and global agenda-setting (G20, GHSA) would be useful in setting the scene why current efforts are apparently not enough? For now, we do not fully comprehend/follow why continuing along existing platforms (e.g. agreeing on goals to be met and actions to be taken in UNGA 2019 and report back every two years) would not be a suitable option to choose from. Would it not be possible for IACG to propose such clear One Health norms/goals?
- Link with tripartite combined with UNEP is mentioned. Agree that they are important actor that could function as a secretariat. However, be careful about what role they can and have to play. They are at the same time international research bodies, an advisory party towards governments and execute programs at local level. Moreover, not everybody is fully convinced about the true success of their collaboration and questions are raised about tangible results they have produced. So, is this the right timing to extend the partnership with UNEP and to add a new roles and tasks to their portfolio? (or will we end up in a bureaucratic mess..)
- UNEP is mentioned prominently, and other bodies like UNDP and possibly UNIDO, WB, etc are mentioned halfway annex 2. In our opinion, these bodies and involvement of these actors should be equally treated as UNEP, because the goal of IACG was to advise on the global level interagency coordination needed to tackle AMR. This goes beyond human, animal and environmental health domains; tackling AMR globally is mostly and development issue.
- G20 is mentioned as possible platform to link up with or make use of. However, level of ambition in tackling AMR in current draft resolution is very low. How do you envisage this group to take the topic forward as proposed?
- We relate to the proposal which states that if there is real urgency to act on a health priority, the creation of a new initiative can serve as a focal point for global efforts in terms of advocacy and fundraising at the global, regional and national level. At the same time the proposal mentions building on current structures wherever possible so as not to 're-invent the wheel' and offer simplicity and sustainability while still respecting the complexity of the AMR challenge. This feels like a balancing act for which we miss a draft of another scenario in which the current political pressure and opportunity of having AMR on the UNGA agenda is used more.

Kind regards,

Maria le Grand
Ministry of Health, Welfare and Sport
Public Health department | Infectious diseases

From: [das Neves, Carlos Goncalo](#)
To: [IACG-secretariat](#)
Subject: Public consultation- Inter-Agency Coordination Group on Antimicrobial Resistance Discussion Papers
Date: 31 August 2018 00:10:33

The Norwegian Veterinary Institute (NVI) avails itself of the opportunity to convey to WHO-FAO our thanks for the invitation to participate in the ongoing public consultation on AMR.

Concerning the documents provided for analysis NVI would like first of all to express its satisfaction to see such comprehensive documents that cover important aspects of the fight against AMR.

We would like to provide a short input only on the following topics:

PAPER: Communicating for change

o On pages 4-5-6 the documents refers to narratives shaping the response to AMR

Here we believe that the document does not stress enough the narrative of inter-generational importance of AMR. This is a major focus on sustainable development. Which is to say that correct AMR policies is not just about protecting ourselves, but is about saving future generations from a much worse scenario. So the generational narrative is important in communication as “If you don’t do it for yourself... do it for you kids” type of message. We believe this could be further explored in the document.

NVI also believes that new digital technologies and their importance and challenges in communicating AMR (talking of twitters, instagrams FB, digital education, distance learning, etc etc..) could be even more addressed in this document, as an important tool to achieve the many goals set forth in different inter-agencies' strategies for awareness, education and capacity building.

PAPER: Future global governance

o Page 5 table on Shares ONE HEALTH needs

NVI believes we may be missing something on Support (funding) for truly implementing the ONE HEALTH concept at a trans-sectorial/disciplinary front. There is some money for ONE HEALTH veterinary topics, lots for ONE HEALTH humans but very little for ONE HEALTH environment. One needs stronger investment on truly trans-disciplinary issues. This was mentioned further ahead on the SPECIFIC SECTOR NEEDS but needs to be on the main shared needs also.

Better coordination between major international players (WHO, WTO, WORLD BANK, OIE, IUCN, EU, UN, FAO, UNEP etc..) could also be further highlighted.

o Specific sector needs

NVI believes there could be a bigger focus on harmonized data collection, registry and

sharing (this works good on human side perhaps but far from good enough on animal side)

o Environment

On the ENGAGE regulators, NVI believes one could add also users/society – very few people understanding the importance of the environment for AMR so this should be a highly prioritized area.

Apart from these few remarks and as started earlier NVI strongly supports these extremely comprehensive papers and renews to you its availability to further cooperate as considered needed.

With our best regards,

Carlos Gonçalo das Neves

DVM PhD Dipl. ECZM (Wildlife Pop. Health)

European Veterinary Specialist

Head of Food Safety, AMR and Emerging Health Threats

Associate PProfessor

Veterinærinstituttet



31 August 2018
S2018/04315/FS

Public consultation on Interagency Coordination Group (IACG) discussion papers, in particular “Future Global Governance for Antimicrobial Resistance”

This is to provide feedback prepared within the Government Offices of Sweden in response to the public consultation regarding the discussion papers of the Interagency Coordination Group (IACG) on Antimicrobial Resistance (AMR).¹ Different relevant sectors have been involved in the preparation of the present feedback.

As expressed previously², we regard it to be of great importance that the follow-up of the high-level meeting on AMR in the UN General Assembly boosts coordination and commitment in the response to AMR, across the UN-system and beyond, and as per the One Health principle. In addition, we welcome the clear focus on aligning and mobilizing AMR action to the Sustainable Development Goals (SDGs).

General comments

The discussion paper on “Future Global Governance for Antimicrobial Resistance” is useful and addresses the core of the IACG mandate. Hence the present feedback focuses on this paper, although some of the feedback is also relevant for IACG’s work overall. Sweden’s view is that IACG should provide a political platform and advise on high level strategic policy issues. There is concern that some of the work of the IACG tends to become too technical, although the topics are highly relevant in general.

¹ www.who.int/antimicrobial-resistance/interagency-coordination-group/public-consultation-discussion-papers/en/

² Swedish feedback in the online consultation with regard to the draft work plan of the Interagency Coordination Group (IACG) on AMR (S2017/04470/FS)

Sweden concurs with the overall assessment that the status quo is not delivering sufficiently; the global governance for AMR must be strengthened. Notwithstanding that many relevant initiatives and structures are already in place, there is still need for more concrete, effective and long-term actions against AMR. There is need for an overarching mechanism to ensure sustained progress and coordination across sectors and activities. The scope of future work should for example consider access to antimicrobials, antimicrobial use (and prevention thereof) and R&D/innovation related to AMR.

Specific comments

In general, we agree with the needs and minimum requirements for an effective AMR governance mechanism that are outlined in the document (page 4-8). For example, we appreciate the attention given to surveillance and monitoring, integration with the wider global development agenda such as the existing SDG framework and building on current structures wherever possible. We welcome the focus on evidence-based and measurable targets as the basis for global governance. However, it should be further emphasized that the envisaged mechanism should support, and not take over, the normative and technical roles of the respective UN agencies.

Sweden welcomes discussion about a global multi-stakeholder agreement. In the discussion paper it is proposed that the ultimate goal should be to reach an agreement within the next 10 years (page 8). Self-regulation and non-binding commitments are valuable, but often prove to be insufficient. Now there is a window of opportunity to further explore the prospect and added value of a global multi-stakeholder agreement. Ten years appears to be quite a long timeline for reaching an agreement given the present high concern of the threat. A stepwise approach towards a comprehensive agreement may be helpful.

We agree with the notion that future global governance for AMR requires more than a strengthened tripartite collaboration. The roles and relations of the proposed high-level commission and the global steering board should be further clarified and reviewed (page 9-10). Caution is warranted to avoid duplication and ensure as lean and efficient administrative arrangements as possible. Establishing both a high-level commission and a global steering board may introduce too much complexity. The functions of the two

proposed bodies could possibly be carried out more efficiently by one body. Also, the relations to existing regular governance mechanisms within the UN-system should be made clear and explicit, in order to pre-empt any criticism that the regular governance would be circumvented.

Sweden supports the proposal to expand the tripartite collaboration between WHO, OIE and FAO to also include UNEP (page 8, 10-11). The collaboration and coordination between relevant UN agencies is key to an effective response to AMR according to the One Health concept. UNEP and the environment sector are important actors, in addition to other stakeholders such as the human and animal sectors. The environment and animal sectors must be engaged, especially considering that there has been less international attention for these aspects of the AMR-threat (page 26, 59). Nevertheless, it must not be forgotten that the main reason for the current global concern is the threat to effective treatment of human infections, at present as well as in the future. There is a need maintain a strong focus on inevitable shifts in practices within the human health sector, such shifts are a prerequisite for success in the fight against AMR. To benefit the efficiency of the work, we believe that it is apposite that there is a core group of concerned agencies, consisting of the four agencies mentioned above. Additional relevant UN agencies and international organisations should be involved, when/as appropriate. Importantly, the UN-system and relevant agencies should demonstrate leadership and initiative in the work against AMR. The tripartite collaboration should not be limited to a standing secretariat of a global governance mechanism. The realization of the expectations on this core group will naturally require sustainable financing.

The discussion paper highlights the importance of financial resources at national and international levels. We agree that the strong case for investing in AMR needs to be further developed and communicated, along with a narrative that encourages action. Sweden's position is that funding for global governance mechanisms should not necessitate additional obligatory financial contributions from MS. Linking AMR to the global development agenda should be coupled with efforts to mobilise funding from within existing budgetary frameworks. Established global frameworks, such as the Sustainable Development Goals of the 2030 Agenda and Universal Health Coverage, could provide additional coordination of funding efforts to prevent parallel tracks and suboptimal use of resources. Donors and

different funding mechanisms, e.g. through the World Bank, should be involved and utilised.

Moreover, with reference to page 64, we would like to underline that Sweden has positive experiences when it comes to combining EU's lowest use of antimicrobials in animals with a productive agriculture sector. On page 5 the importance of promoting production systems that imply good animal health and animal welfare and thus reducing the need for antibiotics is missing.

Regarding the work ahead

It is also relevant to start preparing for the handling of the UN Secretary-General's report to the UN General Assembly in 2019. The discussion paper does not focus on how the global governance mechanism should be established. A mandate from the UN Secretary-General and/or the UN General Assembly would be appropriate in the light of the urgency of the threat and the need to involve different sectors, and would provide a first step. The approach to developing and deciding such a mandate should be clarified in the near future in order to avoid delay and missed opportunities.

The importance of an enabling (political) landscape should be carefully considered. There is a need to reach out and communicate the overall strategic direction of the IACG and its concrete activities. As recognized in the discussion paper, outreach and advocacy are key to build momentum and support for the outcome of IACG's work. To this end, existing fora such as the EU, G20 and friend groups should be exploited, among other things. A transparent and inclusive approach for the full range of stakeholders should be ensured: low-, middle- and high-income countries, private sector, civil society, etc. Promoting the engagement of countries at different income levels, as well as representation of different sectors, will require a flexible approach.

The Government Offices of Sweden welcomes further dialogue regarding continued collaboration in the endeavour to ensure that high-level meeting on AMR in the UN General Assembly results in a strengthened and sustained response to AMR.



HM Government

UK Government response to the IACG Discussion Paper: Future Global Governance for Antimicrobial Resistance

Title: UK Government response to the Inter-Agency Coordination Group on AMR (IACG) Discussion Paper: Future Global Governance for Antimicrobial Resistance
Coordinating Author: Emergency Preparedness and Health Protection Policy Directorate, Global Health Security Programme, Department of Health and Social Care (GPH-EPHPP-GHS)
Document Purpose: Policy
Submission date: 31 August 2018
Contact details: Global Health Security Programme Department of Health and Social Care 6th Floor South 39 Victoria Street London SW1H 0EU United Kingdom

You may re-use the text of this document (not including logos) free of charge in any format or medium, under the terms of the Open Government Licence. To view this licence, visit www.nationalarchives.gov.uk/doc/open-government-licence/

© Crown copyright

www.gov.uk/dh

Guidance on the UK response

In the absence of set consultation questions included in the document, the UK has opted to respond to the Discussion Paper with overarching comments to the IACG's proposals, views on each of the sub-headings within the Discussion Paper and proposals regarding implementation.

Contributing authors

The UK Government response was coordinated by the Department of Health and Social Care with contributions from:

- Department of Health and Social Care (DHSC)
- Department for International Development (DFID)
- Foreign and Commonwealth Office (FCO)
- Medicines and Healthcare Products Regulatory Agency (MHRA)
- Veterinary Medicines Directorate (VMD)

Contents

1. UK Introductory comments.....	5
2. The needs for practical future global governance of AMR.....	6
Response methodology.....	6
Overarching comments.....	6
Specific queries, additions and suggested re-categorisations.....	7
Comments on the proposed 'Minimum Requirements'	9
3. Proposed global governance model for AMR.....	17
Response methodology.....	17
Comments on the proposed governance model.....	17
Comments on sub-sections.....	20
4. Annex 1: Wider considerations and opportunities identified	22
Response methodology.....	22
UK Comments on sub-sections	22

1. UK Introductory comments

- 1.1. The Government of the United Kingdom of Great Britain and Northern Ireland warmly welcomes the opportunity to comment on the Discussion Paper issued by the Inter-Agency Coordination Group on AMR (IACG) on Future Global Governance for Antimicrobial Resistance (AMR). It considers this a vital topic to be addressed with our global partners in our collective efforts to address AMR and would like to take this opportunity to thank the IACG for its diligence in developing their early thinking.
- 1.2. While the UK would tend to avoid the creation of new global governance structures, it agrees that the particular challenge of AMR requires international coordination, collaboration and consensus - and potentially a dedicated new and robust governance structure - to assure the future of antimicrobials as a global public good. This is because mitigating AMR is a huge 'One Health' challenge that requires multi-sectoral action across the domains of human health, animal health, agriculture, food safety, infrastructure (including access to clean water and sanitation) the environment and global trade. Robust, coordinated action from the traditional 'Tripartite' of WHO (for human health), FAO (for agriculture and food safety) and OIE (for animal health) is not sufficient. It also requires the active participation of and leadership from UNEP (for the environment) and many other UN and international organisations.
- 1.3. However, the establishment of a new standalone structure or body hosted within the UN system is likely to come at significant cost, and there is a risk that its objective of establishing a formal international agreement on AMR may not be met. It may also paradoxically lead to a slowing of progress in the meantime, whilst such an agreement is negotiated. The UK would also flag the current lack of appetite internationally for any new multilateral organisation and / or binding agreement which would need to be addressed before we even begin advocating for the content proposed in this paper.
- 1.4. Considering the challenges that the global community has faced thus far in terms of coming to mutual agreement on issues of regulation and funding for actions to address AMR, the proposal of a ten year plan to achieve a Global Multi-stakeholder Agreement is an ambitious timeframe. However, given the urgent need for accelerated action on AMR, ten years may also appear to be a long time over which to seek a new agreement.
- 1.5. The approach set out in the IACG Discussion Paper would benefit from a prior assessment of the likelihood of reaching such agreement to ensure that resources from the international community are being allocated in the most effective way. This would require more focused, specific consultation with UN member states. In parallel, a greater focus on securing country-level participation in establishing and implementing a series of quasi-legal instruments, such as voluntary guidelines and / or codes of conduct (for example developing or building on existing guidance on drug prescribing best practice, on water quality in effluent from active pharmaceutical ingredient manufacturing plants etc.) would help to build consensus and maintain momentum. This interim approach could be guided and supported by the Office of the UN Secretary General in New York along with the Tripartite + UNEP.
- 1.6. Should work on a new structure go ahead, there will need to be careful consideration around having the minimum organisation necessary (to control cost as well as to speed up implementation), a clear home, robust and transparent governance and reporting structure, and a sustainable, predictable multi-year funding model. These aspects will need to be addressed in detail before a decision to proceed (and whether it might be funded through core or project funding) can be made.

2. The needs for practical future global governance of AMR

Response methodology

- 2.1. The UK has provided specific queries, additions and re-categorisations against the suggested needs and overarching comments. For clarity, we have provided a 'tracked change' version of the table included in the Discussion Paper on page 5.

Overarching comments

- 2.2. Accountability mechanisms covering the secretariat level of the proposed structure (Figure 1) do not feature in the current model and should be included. Much as there is a need to hold countries and actors such as industry to account, so there is a need to hold the Tripartite itself and other actors – including key UN bodies - to account for positive, meaningful impact against objectives.
- 2.3. If one accepts that (for human health) functioning health systems are needed for sustainable progress to address AMR, then this brings in other targets and accountability mechanisms that are relevant to health systems strengthening, and to which the proposed governance arrangement should link, harness and support. This include but are not limited to examples such as the Abuja Declaration on Health System Financing in Africa (2001), the Paris Declaration on Aid Effectiveness (2005), and the Accra Agenda for Action (2008). Similarly for agriculture, the environment and the research and development agenda, investment needs to be stepped up and existing commitments already made through multi-party agreements should be met.
- 2.4. In the table on page 5, some of the needs that are under individual sectors in fact would appear to be generalised across them all – for example the need for regulatory frameworks is referenced under animal and environmental health but is equally relevant in human health.
- 2.5. Some of the needs seem to relate more to strategic approaches or desired behaviours than to governance arrangements *per se*, for example '*focus on patient / prescriber level interactions*', '*precautionary but pragmatic approach*.' Examples of items that do describe the needs are: '*political leadership*', '*global representation*' and '*empowered to negotiate...*'. It may be advisable to group these and clarify which are structural (i.e. pertaining to governance) pre-requisites and which are strategic.
- 2.6. It is important that the functions of the governance mechanism remain clear, high-level and complementary to those of the relevant technical UN agencies. At the same time, it is important to strengthen the Tripartite partnership on AMR, add UNEP to this and hold it collectively to account, ensuring that it is balanced in addressing the animal and human health and environmental agendas.

Specific queries, additions and suggested re-categorisations

Shared One Health needs

- Stability/certainty [\[Query: It is not clear what exactly this refers to – please expand\]](#)
- Harmonisation/alignment, adapted based on resource and context (phased approaches where required)
- Engagement outside UN system, e.g. private sector, professionals, regulators, civil society
- Clear mandate and formalised partnerships
- Empowered to negotiate global policies and regulations
- Political Leadership
- Global representation
- Transition support for LMICs
- Truly One Health approach
- Emphasis on the importance of prevention, diagnosis and alternatives
- Improved surveillance across many areas, e.g. antimicrobial use, resistance levels, infections, outcomes
- Appropriate access and stewardship, and a sustainable and resilient supply
- Mechanisms that brings together innovators, investors and implementers [and end users](#) productively
- Identify and communicate best practices/improve education
- To fully engage with the private sector
- Flexibility within global frameworks/policies for adaption to national systems
- Focus on patient/prescriber level interactions
- [Enforcement / accountability \[added\]](#)
- Global standards/regulations to provide a level playing field [\[moved from animal / agriculture / aquaculture / food\]](#)

Specific sector needs

Animal/Agriculture/Aquaculture/ Food

- Global standards/regulations to provide a level playing field [\[moved to shared One Health needs\]](#)
- Support (research, funding, technical and infrastructure) to adapt processes in low resource settings
- Focus on the development of affordable alternatives to antibiotics across all species and settings
- Consistent strategic approach that is supportive of trade and sector business models
- Precautionary but pragmatic approach

Environment

- Mechanism to set global consensus on standards
- Application of precautionary principle in short-term whilst evidence base is established
- Research to understand the relative contributions of different sources of contamination
- Better representation of sector in global conversation
- Engage regulators (drugs, water standards, etc.) as well as industries (drugs, high-use facilities, sewage, hospitals, run-off agriculture/food production)
- Supply chain transparency [added]

Human health

- Finding mechanisms to address the restrictions imposed by the WHO Framework of engagement [Query: we would welcome further explanation of these restrictions vis-à-vis work on AMR]
- Focus on the development of affordable alternatives to antibiotics across all species and settings [replicated from animal / agriculture / aquaculture / food]

Comments on the proposed 'Minimum Requirements'

Response methodology

2.7. The Discussion Paper proposes ten 'minimum requirements' for an effective AMR governance mechanism (pages 6-8). The UK has chosen to respond in the following format, setting out its view on what it considers missing from the proposed list before providing detailed feedback on each of the ten proposed 'requirements'. This detail includes whether each of the proposals is indeed a 'minimum requirement'; whether the UK considers there are any gaps in the description of the 'minimum requirement'; whether anything unnecessary has been included; and if there are any other global governance mechanisms which have successfully delivered similar 'requirements'.

Requirements that the UK considers fundamental that have not been listed

- 2.8. The proposed governance mechanism needs to align and synergise with those for wider initiatives and issues, including the 2030 Sustainable Development Agenda (SDGs) as an absolute minimum, as well as mechanisms such as the 2005 International Health Regulations.
- 2.9. The point around strengthening and formalising the Tripartite+UNEP relationship is essential and should not just be an 'additional consideration' in an Annex.
- 2.10. At present, involvement of national regulators and regulatory agencies is mentioned in several of the listed requirements separately. It would be more beneficial to combine these into one or two requirements to facilitate overview and focussed approach for the Tripartite+UNEP to take forward.

UK response to each of the proposed minimum requirements

1. Have a clear mandate to elevate global action on AMR across human and animal health, agriculture, food, and environment, supporting the translation of this action to the national level

- 2.11. This mandate should also explicitly mention aquaculture.
- 2.12. A 'One Health' response should be considered a minimum requirement and the UK firmly supports this ambition.
- 2.13. The publication of the latest data on the status of countries' national action plans, as collected by the Tripartite annual self-assessment questionnaire¹, has highlighted that countries with formalised multi-sectoral collaboration groups working across government agencies and beyond are associated with greater progress across the 'One Health' agenda. Formalisation means that these groups have clear terms of reference, funding sources and accountability mechanisms. However, most countries are operating at level B² (the second lowest level) in terms of using a multi-sectoral approach, meaning that a working group or collaboration group has been established but does not necessarily have clear terms of reference, funding source or accountability mechanisms.

¹ <http://www.who.int/antimicrobial-resistance/global-action-plan/database/en/>

² Level B is defined as having 'multi-sectoral working group(s) or coordination committee on AMR established with Government leadership.'

- 2.14. Since the majority of countries have not met the recommended requirements in this area, there is a need for increased technical assistance and support from countries with well-developed 'One Health' networks and from international organisations including the Tripartite+UNEP. This would include the scaling-up of existing programmes, training on the importance of the 'One Health' approach and embedding AMR into existing public sector roles that don't currently include AMR in their remit.
- 2.15. There may be a useful parallel with nutrition, which is similarly multi-sectoral and where progress has best been made by elevating the issue above the domain of individual sectors. 'Elevate' does not therefore just mean 'raising the profile' but raising it up to a level at which the multi-sectoral nature of AMR is best reflected and translated into coherent joint action (e.g. UN General Assembly rather than the World Health Assembly for human health, the UN Environment Assembly for the environment...).
- 2.16. It is also worth considering the experience of the Scaling Up Nutrition (SUN) movement: while this has been successful in mobilising action at the global level, a similar degree of success has not been seen at country level. Analysis of the reasons for this may provide useful insights for the design of a mechanism for AMR that is equally effective at both global and national level.

2. Engage stakeholders from across the AMR system to ensure both a global and true One Health approach, focused on delivery which recognises resource/context needs

- 2.17. Since AMR is a multi-sectoral issue, it is vital to engage all sectors and disciplines in the global response. The pharmaceutical and biotechnology industries has a key role to play in revitalising the development pipeline for new drugs, therapeutics, diagnostics and vaccines that will lessen the impact of AMR, promoting access to and good stewardship of existing and newly-developed health products and protecting the environment from contamination by antimicrobials, active pharmaceutical ingredients, resistant pathogenic microbes and resistance genes. The UK would like to see more pressure from global governance mechanisms for measurable action from industry, including holding signatories to account for agreements such as the 2016 Davos Declaration. We recognise the benefits that independent, civil society-led mechanisms, such as the Access to Medicines Foundation's AMR Benchmark³ can bring in this regard.
- 2.18. A key stakeholder to involve in any new governance mechanism is philanthropy (currently only mentioned implicitly in the reference to 'civil society'). Philanthropic organisations have major influence on action for global health issues: it is vital to engage them in the global governance on AMR.
- 2.19. The reference to a '*focus[ed] on delivery which recognises resource/context needs*' can be taken out as it is effectively covered by point three below.

3. Provide sufficient flexibility to be inclusive of different nations and sectors, recognising that while we all have the same goals we will start from different points, are driven by different incentives, and need different approaches to get there

- 2.20. Given that some countries have further to go than others on AMR, it is important that those with fewer resources are provided with the funding and technical assistance necessary to support cross-sectoral action on AMR at the highest political level. This

³ <https://amrbenchmark.org/>

support must be co-developed with them and be tailored and appropriate to their specific settings. To ensure high uptake of setting-specific policies, it is vital that they are both nationally and locally owned.

- 2.21. While flexibility of approach is crucial to encourage country-level engagement, there should be agreement on minimum goals to be achieved in defined time spans, such that over a defined period of time, a level playing field is established. Any governance mechanism or model should consider setting minimum standards that stakeholders and member states could achieve in specific timeframes across sectors. The trajectory to reach those minimum standards will of course vary according to the member state context.
- 2.22. We as a global community need a clear shared vision alongside a flexible approach. Too much emphasis on flexibility brings into question the purpose of a common accountability framework. It is important that whilst there is flexibility to allow for different starting points, contexts and approaches, there is also a common or shared vision of where all countries need to get to - with support if necessary - and a monitoring, evaluation and accountability framework around that.
- 2.23. Alternatively, a progressive framework using a modality similar to 'nationally determined contributions' agreed as part of the 2015 Paris Agreement on Climate Change – another major global public good issue - could also be considered but would still require member states to challenge themselves with robust and ambitious targets.
- 2.24. Finally, a model such as the 2016 Global Compact for Migration may be appropriate - either in the interim to a more complex treaty or as an alternative. This mechanism is considered in New York as being flexible, integrated and streamlined.

4. Secure binding global commitment for action, with accountability clearly assigned at every level

- 2.25. The UK supports setting the ambition for and working towards a binding global commitment to sustain and expand international action on AMR. To ensure that countries are complying with their commitments, we would recommend supra-national evaluation of compliance, in a similar vein to the voluntary joint external evaluations that are undertaken by countries wishing to assess themselves against the 2005 International Health Regulations.
- 2.26. As noted above, different countries clearly have different starting points, and will have varying capacity to meet the same requirements. We would therefore suggest that any global commitment includes a formalised system of voluntary support from high-income to low-income countries. The specific aims of this support would be to prepare countries to meet global commitments.
- 2.27. The Discussion Paper states that accountability for progress on AMR will be placed with individual countries. This brings into question the purpose and authority of a global accountability framework – where presumably there is a shared or mutual accountability between countries within that framework.
- 2.28. The UK would also argue for a stronger role to be placed on corporate social responsibility and industry and civil society-led transparent accountability frameworks to be integrated into an overarching global framework for action.

5. Integrate with the wider global development agenda to better align on and mobilise actions that create common good

- 2.29. The UK supports this point as a 'minimum requirement'.
- 2.30. The Discussion Paper states that '*there is an opportunity to garner greater support for activities [to achieve the 2030 Sustainable Development Goals] that have a positive impact on AMR*'. The UK agrees with this assertion, but it also needs to be recognised that progress on AMR may itself be dependent upon those activities, both directly and indirectly. For example, functioning health systems (in all their domains – supply chains, governance, financing etc.) are needed to gain traction on improved prescribing practice, and (as the text then goes on to imply in the example) progress on ensuring access to quality-assured antimicrobials is needed to create the space for engaging developing countries on AMR.
- 2.31. Within the human health sector, there is scope here to recognise the inter-dependencies between AMR and health systems strengthening, health security, nutrition and access to clean water and sanitation. Similarly, with regard to animal health, there needs to be a greater focus on strengthening access to veterinary services, especially in low- and middle-income countries.
- 2.32. The issue of phasing out antibiotics for growth promotion in agriculture also needs to be addressed, preferably with an international agreement, although this too will take time and highlights the challenge of agreeing an overarching Global Agreement within ten years as proposed in this consultation.
- 2.33. A key principle should be to stimulate and facilitate technology development and transfer to tackle AMR. This is likely to be of particular importance in the environmental field. For instance sewage treatment technologies are currently not capable of contributing to a reduction in AMR and in fact may very well be sites of active gene transfer.
- 2.34. As a development issue, it is essential that AMR is fully incorporated into the 2030 Sustainable Development Agenda. AMR is implicit, but not explicit, in many of the Sustainable Development Goals (SDGs) and this should be corrected as part of this process (as is being done for the integration of metrics around access to medicines currently). To keep AMR on the development agenda beyond the end of the SDG lifespan in 2030, AMR should be a specific aim of the SDG-successor.

6. Building on current structures wherever possible so as not to 're-invent the wheel' and offer simplicity and sustainability while still respecting the complexity of the AMR challenge

- 2.35. The UK considers this 'requirement' as vital. Whilst the UK very much sees the need for a clear and strong governance and accountability arrangement for AMR, it is of course necessary to keep the extent to which new structures are created to the minimum required to meet objectives, and to avoid duplication and overlap with the existing arrangements.
- 2.36. Hosting a lean and efficient secretariat within an existing UN agency presents less challenge than creating a new body, which would be much more problematic and likely take significantly longer to agree with other member states. If the latter is envisaged, then an extremely strong case would need to be made for it, with detailed costings and evidence for how the current standing functions in the existing structure (e.g. the AMR Secretariat of the WHO and the corresponding teams in FAO and OIE) would be amalgamated to avoid duplication. Either way, it will be important that the proposals

draw on lessons learnt from existing similar set ups, such as the creation of UNAIDS (a 'standalone' structure) or [UN Interagency Task Force on NCDs](#) (a 'hosted' structure).

- 2.37. Rather than creating a new structure (either standalone or hosted) on an open-ended basis, a time-bound mandate that needs to be formally renewed (rather than continued by default) should be considered. Further, there should be clarity on roles, responsibilities and accountabilities for each participating organisation.
- 2.38. Celebrating national good practice at a global level helps to support greater engagement on AMR from member states, injects a level of 'friendly competition' that encourages a race to the top and provides examples of how individual, country-level approaches can be tailored to varying environments more specifically. It would be preferable to have a single portal containing examples of best practice from different country settings that could be widely publicised and frequently updated. This work could be mapped by the Tripartite+UNEP and publicised widely.

7. Generate evidence-based targets and aligned tasks, supported by transparent multidimensional metrics and indicators, to identify a clearer way forward

- 2.39. The UK agrees with this 'requirement'. Metrics and indicators are needed to drive action and support accountability at both national and global levels. A built-in mechanism is also required to review such targets on a regular basis and ensure these are aligned with the latest evidence base.
- 2.40. It will be important to consider the data systems (and their limitations) that underpin the metrics and indicators, particularly in developing country contexts. The development of these should be framed within wider health systems strengthening, health security, livelihoods/agriculture and economic development initiatives. The challenge in will be to have sufficient data of sufficient quality to drive accountability, whilst designing collection and analysis to fit local capacity and capability, especially in resource-poor settings.
- 2.41. Part of the remit of any future governance mechanism should be to work up a set of standard processes for inter-operable open data standards across the whole 'One Health' agenda. The mechanism should then encourage (or even mandate) the use of minimum core data sets to allow comparability and measurability over time. It would also be useful to include targets for the use of these core data standards by countries, industry and others as part of the governance mechanism.
- 2.42. Under this goal, the UK would push strongly for a clear evaluation policy – possibly by peer review - of AMR interventions adopted across the world, and the transparent and open publication of details of the inputs, activities, outputs, outcomes and impact of all AMR interventions, regardless of level of perceived success. It is important for the diverse range of AMR stakeholders to be clear on what works well, what works less well and why. The UK believes that this should be part of a culture shift towards learning from each other rather than blaming.

8. Be a credible and respected voice, synthesising evidence and adding weight to global negotiations

- 2.43. The UK strongly agrees with this 'requirement' – although it will need to be framed and managed in a way that avoids duplicating or impinging upon the role of the sector-specific agencies within the Tripartite. There may well be circumstances where this AMR-specific governance mechanism takes on the responsibility and mandate for the

delivery of particular actions currently led by a single UN agency. This would require very careful management.

- 2.44. It should be made clear that any future governance mechanism would commission activities as part of its role in generating evidence, rather than generating that evidence itself. The latter should be independent of the governance mechanism itself and would require sufficient budget and associated budgetary scrutiny to deliver this objective.
- 2.45. The governance mechanism would have a role not just in synthesising evidence, but in giving strategic direction and commissioning research to underpin its choice of (regulatory) interventions and to make the objective case for these. To the extent that targets or binding commitments are put into place, these will need to be aligned to the current evidence base and remain flexible to respond in an agile manner when new evidence emerges. This is essential given the ever-evolving patterns of drug-resistance. Synthesising this evidence base will in turn identify key gaps to be filled (for example the extent to which people take antibiotics for diarrhoea which might be prevented by improved access to clean water and sanitation or to which farmers use antimicrobials inappropriately in animal husbandry and why).

9. Harness communication to present a more compelling case for action, recognising the needs of different audiences from public to policy

- 2.46. The UK agrees with this 'requirement' and would go further to suggest the integration of behavioural economics in the objective. There are good points made in the accompanying text about the need to make the economic and financial case (building on the existing work of the independent 2016 AMR Review⁴) and moving towards a positive framing of the potential for action on AMR, both highly relevant to developing countries.
- 2.47. It is important that countries with fewer resources are provided with the funding and technical assistance necessary to both build support for cross-sectoral action on AMR at the highest political level and tailor communications approaches to specific settings.
- 2.48. Multi-stakeholder global campaigns such as the UN Foundation's *Nothing But Nets*⁵ campaign or the UN-led *Every Woman, Every Child*⁶ campaign could serve as useful examples for harnessing the power of communication in a complicated eco-system of UN organisations, donors and member states.
- 2.49. Currently, the communications programmes globally tend to focus more on the human health sector. Efforts need to be expanded and sustained in communications programmes in agriculture and the environment. One example is that of food security, an increasingly pertinent global challenge, which will be severely impacted should multi-sectoral action on AMR not be taken.
- 2.50. Part of the future governance mechanism's remit here might be to find ways to change global norms and expectations about antibiotic use, both in livestock and in humans.

⁴ <https://amr-review.org/>

⁵ <https://nothingbutnets.net/>

⁶ <http://www.everywomaneverychild.org/>

10. Have the means to harness and create change, securing and more effectively organising sufficient funding and resourcing to implement and deliver AMR transition initiatives

- 2.51. Any new governance structure should be sustainably funded and resourced with the right expertise. Any future global governance mechanism should have a mandate to ensure that sufficient investment is made to tackle AMR, i.e. it should have a key role to advocate and support countries to put in place adequate financing strategies for AMR-related policies and action, including involving the private sector, civil society and philanthropy where appropriate.
- 2.52. It should be clear whether securing funding is a function solely of the governance mechanism, or whether it resides elsewhere as well – for example within member states themselves (supported in the case of developing countries by donors), Tripartite member organisations etc. It is probably most appropriate for the mechanism to maintain an overview of funding needs and resources, and to drive accountability for fulfilment of funding commitments by member states, donors and agencies as well as for the effective use of available resources. Models could include a multi-donor trust fund (such as the one used to support the Intergovernmental Panel on Climate Change⁷) or voluntary assessed contributions (such as the model used by the WHO Framework Convention on Tobacco Control⁸).
- 2.53. In the IACG's recommendations to the UN Secretary General, the UK would recommend including suggestions as to what it considers the most efficient and appropriate funding model for the case of AMR.
- 2.54. The work of '*generating evidence on potential interventions, evaluating trade-offs [and] adapting solutions to country needs*' is very important. The question is, however, whether this work best sits within the global governance structure, or would be better taken up at the more operational level, for example within the Tripartite+UNEP, or within any structure such as the Global AMR R&D Hub⁹, which could be brought in under the governance structure or closely aligned to it.
- 2.55. In terms of 'influencing regulation', a key principle should be to ensure that antimicrobial use for humans and animals is brought under a transparent regulatory system in all countries to tackle the significant sales of illegal or sub-standard products. However, regulatory changes that might result in constrained access to such products must be linked to effective measures to improve access to quality-assured products in developing countries. This would help achieve political buy-in and - even more importantly - ensure that the net result is greater rather than reduced equity of access to effective antimicrobials to be used appropriately.
- 2.56. The global regulatory framework might also extend to formal constraints on the use of antimicrobials in livestock, although again this would need to be linked to measures to ensure that any real or perceived adverse effects of such restrictions are borne equitably and are managed, including access to alternative solutions that improve overall animal husbandry practices without a net economic cost to farmers and smallholders.
- 2.57. Working with relevant authorities including member states, the Tripartite+UNEP should set standards for drug developers, manufacturers and suppliers globally with a view to defining robust standards of quality-assurance, appropriate waste disposal and

⁷ <http://www.ipcc.ch/>

⁸ <http://www.who.int/fctc/en/>

⁹ <https://www.gesundheitsforschung-bmbf.de/en/GlobalAMRHub.php>

environmental measures to prevent contamination. The expectation should be that manufacturers, particularly of active pharmaceutical ingredients, would follow these standards and minimum goals to maintain a level playing field internationally (linking with requirement 3 above). In order to make progress here, the UK would welcome more active involvement of investors to help drive better and more transparent industry behaviours and quality-assured supply chains, not just for consumers in high-income countries but for all.

- 2.58. Any future governance mechanism should incorporate efforts to minimise falsified or substandard medicines - both for humans and for animals - working with and through member states and their loco-regional requirements. A Tripartite lead in taking forward this effort would be most appropriate.

3. Proposed global governance model for AMR

Response methodology

3.1. The UK has provided overarching comments on the model (Figure 1) proposed in the Discussion Paper and comments against each of the sub-sections on pages 8-11.

3.2. In developing its response to the model, the UK considered the following questions:

- a) *What are the strengths and weaknesses of the model proposed in Figure 1?*
- b) *Where are the gaps?*
- c) *Of the stakeholders listed that feed into the Global Steering Group (industry, civil society, regulators, professionals, academia), are there any missing?*
- d) *Are the timelines feasible?*
- e) *If you strongly disagree with the proposed model, could you provide an alternative or suggest additions? Please include a diagram if necessary.*
- f) *Should a binding agreement be the ultimate aim? If not, please suggest an alternative.*

3.3. In developing its response to the sub-sections referring to the model, the UK considered whether there were any gaps in the proposals, and if anything unnecessary had been included.

Comments on the proposed governance model

a. What are the strengths and weaknesses of the model proposed in Figure 1?

3.4. The strong emphasis on the need to engage with the private sector is positive and helpful.

3.5. The emphasis on binding commitments and moving towards implementation (rather than discussion) indicates the appetite to be outcome- or results-focused, a desire that the UK shares wholeheartedly.

3.6. The key aspects of the model seem to be the multi-stakeholder agreement and the High-Level Commission, as it is these that are most distinct from – and additional to – the current arrangements.

3.7. It is not clear from the model what the relationship would be with the Tripartite, particularly at the level of the Standing Secretariat. Would the proposed Standing Secretariat in effect be the forum in which the relevant agencies come together on AMR? Or would it be in addition to existing corporate structures (e.g. the WHO's AMR Secretariat which works alongside its equivalent in the FAO and OIE).

b. Where are the gaps?

3.8. In due course, more detail will be needed on the linkages with the members of the (enhanced) Tripartite (i.e. WHO, OIE, FAO and UNEP), with wider stakeholders (for

example the private sector and academia), and with higher-level structures (for example the UN General Assembly or even the UN Security Council).

- 3.9. Given the importance of funding mechanisms to ensure sustainability of the global governance mechanism, it would be worth explicitly including funding options for each of the proposed levels within the diagram itself.

c. Of the stakeholders listed that feed into the Global Steering Group (industry, civil society, regulators, professionals, academia), are there any missing?

- 3.10. Consumers or service-users (who may not be represented by overarching civil society organisations) are missing.

d. Are the timelines feasible?

- 3.11. Delivering an overarching Global Multi-Stakeholder Agreement in 10 years is ambitious: some feedback suggests that this may be a project of up to 15-20 years. Conversely, a decade is also a long time to wait for the urgent action that needs to be taken on AMR. If this timeframe is maintained, the global community will have 10 years of lead-in time to realise this aim, so we should push for the most robust and accountable mechanism possible, and not settle for half measures.
- 3.12. If the timeframe was to be extended, or even if it as kept as is, a Voluntary Code of Conduct (expanded to include all stakeholders, not just industry) could be developed as an interim milestone, which would provide a useful basis (albeit in soft law) for effective implementation to begin. This could also help to ensure a more participatory process that includes a focus on country level action and lessons learnt, strengthening country ownership and buy-in.

e. If you strongly disagree with the proposed model, could you provide an alternative or suggest additions? Please include a diagram if necessary.

- 3.13. The UK agrees with the proposed model presented, and has outlined some reservations and suggestions, which are highlighted throughout this document and specifically in relation to the model's structure below, which we hope will be helpful for the IACG in developing their recommendations.
- 3.14. It would have been useful to include other models for consideration. Annex 2 includes other possible scenarios, but none of these has a country-level focus. The Code of Conduct option (proposed in Annex 2) revolves around industry but could actually be developed using a multi-stakeholder approach, for example.
- 3.15. The vertical way in which the governance model is depicted suggests the international agreement sits at the top of a governance structure. This would be a deliverable that would then require oversight and monitoring. Instead, maybe the Secretariat role needs to be emphasised more, together with the interaction with other groups and sectors (consumer bodies, food producers, pharmaceutical companies etc.). Perhaps a horizontal diagram, bringing in others and introducing a sense of the role to be played at country level, would be useful.

f. Should a binding agreement be the ultimate aim? If not, please suggest an alternative.

- 3.16. The UK agrees that a binding agreement on AMR should be the ultimate aim, not least because the stakes are so high. This aim will be ambitious - and challenging - to deliver but that does not mean the global community should not begin to try.
- 3.17. However, in its recommendations the IACG should also take into consideration the risks of not getting such an agreement into place, or of this taking a longer time than expected. The pursuit of an agreement in ten years' time could paradoxically slow down progress in the meantime, if countries and relevant parties put action on hold pending the negotiation of an agreement. There would need to be a strategy for managing these risks including a back-up plan if agreement is not reached. There must be useful lessons to be learnt from other global challenges, e.g. climate change. Developing a voluntary Code of Conduct - engaging all stakeholders - would be a useful milestone and help to build consensus (there are examples of this having been done, in the area of fisheries, for example, or on land tenure).
- 3.18. The mechanism will need to be set up in a way that avoids undue political interference and is mindful of industry agendas that may conflict with the successful management of antimicrobials as a global public good. Once established, it must be allowed to carry on with its work without countries being able to pull out at any time.
- 3.19. The idea of a treaty has many attractions in terms of binding countries to action and because it can offer answers on finance and governance issues. However, the UK would like to see a more detailed assessment of the likelihood of being able to draft a treaty that both has teeth and broad wide buy-in. Without a consultation among countries about appetite and likely political positions in relation to a treaty it is hard to assess whether this is a sensible goal within 10 years. The UK notes that this is quite short given the treaty would have to be drafted, consulted on, presented to the UN General Assembly or relevant Conference of Parties for endorsement, be open for ratification and accession before it can come into force.
- 3.20. One approach might be to have a series of subsidiary agreements, rather than aiming for a single all-encompassing one in the longer-term future. This would allow aspects for which it is easier to reach consensus to be put into place in the near-term, without them being held back by more controversial and potentially intractable aspects. An example of a similar approach would be the 1992 UN Framework Convention on Climate Change, under which sits the Kyoto Protocol (1997), the Marrakesh Accords (2001), the Bali Road Map (2007), the Copenhagen Accord (2009), the Cancun Agreements (2010), the Doha Amendment (2012), the Warsaw Outcomes (2013), and the Paris Agreement (2015). A less ambitious but perhaps more feasible option would be to develop voluntary guidelines, using a soft law approach.

Comments on sub-sections

Model structure

- 3.21. The simplicity of the model is important at this stage. However, the paper is not very specific on the details of the structure – where the component parts would be housed, how they would be staffed, what they would cost and so on. This is understandable at this stage but these details would need to be developed and costed before proceeding further.
- 3.22. The G20 could indeed provide a useful forum to secure funding for the Global Steering Board. However, in approaching the world's largest economies only on this issue we would need to be wary of framing AMR purely as a high or upper-middle income country problem. Furthermore, any request for funding and support to G20 countries only would need to be managed very carefully as other countries will also need to be taken on this journey and contribute both resources and ideas.
- 3.23. Furthermore, for all elements of this model to function harmoniously together, it is important that each level gets the funding necessary, and that the management of such funds is undertaken transparently.

Model function

- 3.24. The point about every level of the structure engaging with national and regional policy-makers – particularly ensuring engagement with low- and middle-income countries – is vital to ensure broad political and technical engagement worldwide. However, technical assistance and encouragement will be required to ensure that all relevant national and regional policy-makers have AMR included in their portfolios of work, as AMR should be clearly considered to be 'everyone's problem'.

High-Level Commission

- 3.25. The High-Level Commission might have a useful role in harnessing and supporting other relevant commitments, agreements and initiatives, for example the 2030 Sustainable Development Goals and commitments for Universal Health Coverage, Health Systems Strengthening and the 2005 International Health Regulations. This would be important to ensure synergies rather than competition between these various action areas. There might be scope for some High-Level Commission members to be drawn from these other areas so that the linkages between them become structural.
- 3.26. The proposed High-Level Commission is time-bound, but it is not clear from the model how long it would exist. Unless it is all the way to the 10-year mark (when a Global Agreement is expected to be secured), it is uncertain how the Global Steering Group and Secretariat would make the leap from working groups and engagement to the establishment of a process which would end in the Global Agreement – unless perhaps that is the role of the Secretariat.
- 3.27. The High-Level Commission would need to represent the interests of both high-income and low- and middle-income countries.

Global Steering Board

- 3.28. The Global Steering Board should synthesise scientific and socio-economic views of the impact of AMR not only on “*human health, animal health and global food production*” (bullet point 4), but also on the environment.
- 3.29. The objective to “*oversee integrated solutions for new products, sustainable supply, equitable and optimal access, quality assured*” (bullet point 6) needs to be developed so that the detail of which precise activities this would include is clearer.
- 3.30. Some of the roles that are described may overlap with those of the High-Level Commission – e.g. sustain momentum, engage with member states. A key requirement will be for the Board to have enough teeth and influence to gain traction.

Standing Secretariat

- 3.31. The UK agrees strongly with the proposal that the Standing Secretariat be composed of a formalised group that is based on both the existing Tripartite but also UNEP.

4. Annex 1: Wider considerations and opportunities identified

Response methodology

4.1. For each of the sub-headings in Annex 1, the UK considered whether there were any gaps in the proposals, and if anything unnecessary had been included.

Comments on sub-sections

a. Wider considerations

- 4.2. Maintaining the links between AMR and the Sustainable Development Goals, the 2005 International Health Regulations and the aspiration to achieve Universal Health Coverage will be an important factor in maintaining the momentum at the WHO level. Formalising the accountability process will be key: organisations must be held to account by member states and civil society.
- 4.3. In Annex 1 there is a suggestion that AMR should be included within UN Development Assistance Frameworks (UNDAF). The UK would strongly support this proposal where it can be agreed with the host Government. UNDAFs are designed to set out the specific priorities and interventions that the UN and host government will be aiming to achieve in country. This proposal was also previously mooted by the UN Deputy Secretary General in discussion with the 'Group of Friends on AMR' in New York. This would highlight the urgency of addressing AMR, ensure that support for developing and implementing National Action Plans is integrated in the country-owned plan supported by all UN agencies, help to capture interlinkages across the 'One Health' agenda and help to strengthen accountability of the agencies as part of the Tripartite+UNEP partnership.
- 4.4. However, this recommendation should be accompanied by detailed guidance to UN country teams to give examples of best practice, including specific examples of interventions/programmes which country offices could take forward, and, where possible, programming aligned with interventions aimed at implementing the 2005 International Health Regulations and Universal Health Coverage as well as strengthening veterinary services (including training for monitoring and surveillance of antibiotic usage in agriculture in supporting implementation of national action plans). Without providing appropriate guidance, this sort of recommendation could result in incoherent, fragmented approaches.

b. Identified opportunities

- 4.5. The UK agrees with the need to identify intermediate actions and outcomes (pending an eventual global multi-stakeholder agreement) and to (re)frame AMR, the latter emphasising the ways in which many of the interventions needed to address AMR themselves relate to and support wider existing priorities for developing countries - such as improving (rather than limiting) access to quality-assured antimicrobials for humans.

- 4.6. There needs to be explicit recognition that in some (especially developing country) circumstances the issue is not so much overuse of antibiotics, as insufficient access, use and quality. Measures to limit or restrict the inappropriate use of antimicrobials in human health through regulation will need to be linked to effective measures to improve access to quality-assured products and to optimise their availability and use, and this will require careful coordination with other initiatives such as the access to medicines roadmap.
- 4.7. The list provided is quite short-term and includes a number of events that have concluded. A longer-term view would be welcome.



August 29th, 2018

The United States Government provides the following feedback on three IACG discussion papers: *Future Global Governance for Antimicrobial Resistance, Reduce Unintentional Exposure and the Need for Antimicrobials, and Optimize Their Use*, and *Meeting the Challenge of Antimicrobial Resistance: From Communication to Collective Action*,

Future Global Governance for Antimicrobial Resistance

General Comments on Report

- There is a remarkable degree of global consensus that currently exists on this topic of combating AMR. We seek to build on that consensus, rather than distracting from it with time-consuming and potentially contentious negotiations. The most practical step is to build on actions and commitments to date, particularly national action plans and stakeholder commitments, as well as UN agency coordination arrangements.
- Consensus from the WHO GAP and the UNGA High Level Meeting is that action lies within the UN system (to coordinate more fulsomely) and with member states (to develop and implement national action plans). We would like to see more concrete steps from IACG to further this needed coordination.
- The United States cannot consider any legally binding instrument proposals. IACG has no mandate to convene a treaty process; only member states can do so. Financial considerations are just one reason. A treaty process would require program and budget implications (PBI) considerations. (PBI is also relevant to calls for a 'membership fee' to fund the tripartite.) Practically speaking, a treaty would be a massive amount of work to negotiate. Far simpler issues have taken years upon years to negotiate; a binding and intersectoral text of this type would take even longer – and pull massive resources away from critical and timely work on the ground.
- Global *coordination* for antimicrobial resistance is a more accurate reflection of the goal and mandate of the IACG. The focus for global coordination should help implement national action plans over guidance setting, as it takes into consideration individual country context, burden of disease, and identifies areas for resource mobilization to help fund NAPs. The paper lacks focus on data sharing and evidence-based policy that should be guiding principles when giving recommendations.
- The document, including annexes, overemphasizes reduced use as the end goal, rather than actions aimed at public health impacts such as reducing AMR or decreasing outbreaks of



disease to improve human, animal, and environmental health. Consideration of a One Health approach in this document could be strengthened by taking into consideration needs to preserve animal health and food security.

- The IACG advocates for applying global standards monitored by a centralized steering board. AMR is a multifaceted problem. It would not be practical to have a centralized steering board of a limited number of stakeholders dictating what is best for various sectors, populations and regions of the world facing different disease challenges, risks, and antimicrobial susceptibilities.
- Regarding global leadership on combating AMR the United States continues to support the tripartite model of WHO, OIE and FAO as the best way forward. We believe it encompasses the stakeholders who are on the frontlines addressing this challenge.
- The report advocates for the precautionary principle by stating that agriculture is doing nothing regarding agricultural uses and awaiting scientific evidence. The paper does not acknowledge that a number of countries including the U.S. have committed to phasing out the use of medically important antimicrobial drugs for growth promotion and bringing other uses of these drugs under veterinary prescription.
- The IACG was tasked with providing practical guidance. The term “precautionary principle” does not do that: It is ill-defined and subject to misinterpretation. The precautionary principle can refer to taking risk management decisions in the absence of data and does not provide countries with any guidance or clarity on how to go about assessing and managing risk. Moreover, the United States often opposes its application on the international plane. In this and other contexts it would be more appropriate to speak of a “precautionary approach” consistent with Rio Principle 15. Under the precautionary approach, when faced with threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent that damage. The precautionary approach, therefore, is less susceptible to misinterpretation both because it has been widely accepted for over 25 years and because it provides some guidance in terms of the qualitative risk that must be present in order to invoke it and the types of measures that should be taken.
- While nearly all use can result in some sort of resistance, there are clearly certain uses that contribute to more public health risk without corresponding health benefits than others. Our challenge is to find those uses that are detrimental, while leaving in place those uses that benefit the health and wellbeing of human and animal populations. We support optimizing use and good stewardship over setting arbitrary limits on use that do not account for changes in disease conditions and animal populations.
- Antimicrobial resistance is a health issue. Licensed human and veterinary medical professionals in many countries use antibiotics to address human and animal health. We believe discussion of antimicrobial use should remain in the realm of science and health.



Specific Comments

Page 5: Specific sector needs:

Animal/Agriculture/Aquaculture/Food

Bullet 1: Recommend deletion of “Global standards/regulations to provide a level playing field”

Justification: Applying global standards is not practical when different health needs must be considered in a variety of situations with different species, risks (pathogens), antimicrobial susceptibility patterns, national governance structures and access to medications. We are dealing with the need for giving human and veterinary medical clinician’s flexibility to exert clinical judgement in varying health conditions.

Bullet 3: Add “safe and efficacious” in front of “alternatives to antibiotics”

Justification: In many countries the regulatory structure for approving efficacy and safety or alternatives to antimicrobials may not be robust or mature. This results in alternative products being marketed that may have unproven efficacy for the claims made or that may not have been evaluated for safety for animal and/or public health. Additionally, some alternatives to antimicrobials may also select for AMR, and that should also be a consideration when recommending their use.

Page 6:

#1: “Have a clear mandate to elevate global action to elevate global action on AMR across human and animal health, agriculture, food, and environment...” “The last sentence in this section mentions holding “Member States to account.” The background states that: The IACG is mandated to provide practical guidance for approaches needed to ensure sustained effective global action to address AMR. Accountability of Member States is not within the mandate of the IACG. pg 43 (a) UNGA AMR Political Declaration: At present, the IACG is consolidating recommendations from a number of initiatives and is recognized at the global level as a key stakeholder. Having been created in 2016 by the UN SG responding to the General Assembly decision to focus on tackling antimicrobial resistance at a global level, the IACG’s role is specifically to: a) provide guidance on the approaches needed to promote sustainable action, b) recommend how to best improve global coordination, especially on the insights brought forth through the GAP, and c) to report back to the Assembly as it convenes for its 73rd session. However, the IACG is not meant to coordinate, implement, govern, or enforce action leaving room for global governance action to take place – be it through a newly created framework or otherwise.

#4 Regarding binding commitments: Antimicrobial drugs are used for health reasons. Restricting a professional’s judgement (human or veterinary medical) when addressing health threats through binding commitments is not practical guidance. Different health needs must be considered in a variety of situations with different species, risks (pathogens), antimicrobial susceptibility patterns, national governance structures and access to medications.



Page 8:

#3, paragraph 2: Did all the experts truly agree to a global, multi-stakeholder agreement, such as a treaty? Proposing a treaty regarding a health issue that has complex challenges and needs seems like an oversimplification of a complex health issue, rather than doing the hard work of trying to identify practical ways to address health needs while minimizing AMR risk.

Page 10:

Global Steering Board, Bullet 4; Second sentence: It is not clear what is meant by "Synthesis should include scientific and socio-economic views on incidence of AMR..." All work should be based on science and risk. What is meant by "socio-economic views"?

Page 11

#3, Bullet 4 regarding use of technical advisory groups: Recent experience is resulting in expert groups not being represented by enough experts across the spectrum of sectors. These expert groups are made to sign confidentiality agreements, are non-transparent, and one would question whether they are truly developing consensus positions. Expert groups appear to be recommending political positions supported by only some countries such as application of the precautionary principle instead of science and risk-based realistic guidance for countries to implement.

Page 17:

2nd and 3rd paragraphs, a comma appears to be missing in the number as written in both paragraphs. The number should read 700,000.

Last paragraph states:

#1, "To date, agriculture has attracted less attention in debates about AMR." This is an inaccurate statement. Agriculture regularly receives the most attention on the AMR issue. This is interesting in that the O'Neil report that predicts the increase in antimicrobial resistant illnesses and deaths and economic burdens relies on analysis of *Klebsiella pneumoniae*, HIV, *Escherichia coli*, Tuberculosis, *Staphylococcus aureus*, and malaria. Agriculture uses could stop tomorrow and have little effect in addressing 4 of the 6 microorganisms/conditions (*Klebsiella pneumoniae*, HIV, TB or malaria).

#2, "The broadly acknowledged lack of scientific evidence and paucity of data is not evidence for no action. Indeed, analysis of previous international agreements that were based on the 'precautionary principle' suggest that the time for global governance for AMR is now and provide lessons for agreeing on an ideal path forward."

The report states that agriculture is doing nothing and awaiting scientific evidence without acknowledging that a number of countries beyond the European Union, including the U.S. have committed to phase out the use of medically important antimicrobial drugs for growth promotion as called for in the WHO Global Action Plan.

Page 18:



First paragraph states: "Several major international reports, and the experience of the European Union (EU), point the way forward." Why is the experience of the EU only relevant? There are other approaches that should be considered. What public health impacts have the EU approaches had?

Page 19:

Regarding "corporate voluntary code of conduct on AMR": We need to ensure unintended consequences such as poor animal health and food security do not result from an economic desire to meet public perception goals that are not grounded in science and risk.

Page 20:

Last paragraph, first sentence regarding "accountability mechanisms": It's equally necessary to come up with reasonable, practical models based on science and risk.

Page 21:

3rd paragraph describes human health being the greatest contributor to AMR followed by agriculture. What other uses are these two ahead of other than companion animal?

Page 22:

2nd paragraph, consider revising the following sentences as follows:

- While overuse is common across many nations, rising use in countries such as India, China, Brazil, South Africa, and Russia (BRICS) accounts for 76% of the overall increase in antibiotics between 2000 and 2010. India and China, in particular, are large contributors.²⁰
- The combination of overprescribing and unregulated use are driven by government, market and health care system failures, regulatory laxity, financial incentives, misguided pressure to use antibiotics from patients, and a desire to be on the "safe side." (changed semi-colon to a comma, and moved the period inside the quotation mark)

3rd paragraph, consider revising the following sentence to avoid using a number at the beginning of the sentence, or write out the words "ten percent." Also, should counties read "countries" (see highlighted text)?: 10% of medical products in developing counties ("countries"?) is substandard or falsified; antibiotics and antimalarials are the most commonly reported.²⁴

Page 28: (b),

Barriers to applying existing...; Regarding mandatory data sharing, it is concerning to have a global board making decisions on data regarding health decisions and a level of granularity a global board could not appreciate, if that is what is being suggested.

Page 29:



Paragraph on “Lack of scientific agreement”; sentence 2: “However a lack of scientific agreement is not a reason for inaction”. Not implementing the precautionary principle does not mean “inaction”. There have been numerous stewardship efforts such as eliminating growth promoting uses and bringing medically important antimicrobial drugs under veterinary oversight. It would be helpful for the authors to acknowledge the progress that has been made.

Page 29:

Last sentence: “Industry lobby groups argue that banning AGP creates financial losses...” The report acknowledges the need to bring stakeholders together but is derogatory toward the very sectors it needs working together to address the problem. It is not all about financial loss or “industry lobbyists”. Demonizing those that do not support this articulation of the precautionary principle by labeling them “industry lobbyists exerting pressure” will not help bring to the table governments who are committed to science and risk-based approaches to balance public health, animal health and food security needs and finding practical guidance that the IACG was tasked to deliver.

Page 30:

First sentence: “Thus, countries with a strong agricultural presence may face domestic pressures against measures such as an AGP ban.” This statement is insulting. It’s not about “pressure”. It’s about making sane, rational, scientifically-based decisions that balance human health, animal health, and food security needs and provide helpful guidance. The precautionary principle is being used here to support a ban regardless of science and risk. How does stating that one must ban medications being used for health needs provide practical guidance to countries trying to find meaningful ways to balance complex needs and varying risks?

Page 31:

End of first paragraph states “...made efforts to raise antibiotic-free meat in response to consumer pressure”. “Antibiotic-free meat” is a misnomer. Are the authors referring to animals “raised without antibiotics”? Animals have to go through a withdrawal period so that antibiotic levels have reduced before the animal is slaughtered and the meat is sold.

Page 32:

Regarding comparisons to efforts to address tobacco: Medication isn’t tobacco. Medication is a health need and should not be treated as an optional issue such as tobacco, the use of which is detrimental to health.

Page 33:

#1, regarding precautionary principle: How is this group advocating for use of the precautionary principle to address AMR? The report appears to be a wholesale adoption of a term without practical guidance as the IACG was tasked to provide.

Page 43:

Paragraph beginning with, “At present...;” states: the IACG’s role is specifically to: a) provide guidance on the approaches needed to promote sustainable action, b) recommend how to best



improve global coordination, especially on the insights brought forth through the GAP, and c) to report back to the Assembly as it convenes for its 73rd session.”

Promoting sustainable action means that all stakeholders need to be brought together. Use of aspirational and non-practical terms like the precautionary principle and global standards for a complex issue will not bring governments or stakeholders together.

Page 43:

Regarding global standards or rules: Instituting global standards and rules in the face of different species, risks, resistances, governing structures and priorities in different countries and local conditions is not practical.

Page 51:

References a U.S.-Cambodia Free Trade Agreement (CAFTA). The report references CAFTA as a free trade agreement between the U.S. and Cambodia. This is incorrect. CAFTA-DR relates to the Dominican Republic-Central American Free Trade Agreement, which covers the following countries – Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and the Dominican Republic.

Page 53:

The elements of the proposed AMR treaty appear to be poorly thought out with little practical guidance as the IACG was asked to provide.

Page 58:

Reference to SDG 2, there appears to be a combining of 2 different targets- 2.3 specifically speaks to doubling agricultural productivity and incomes of small-scale producers while 2.4 talks about resilience and sustainable food production systems

By 2030, double the agricultural productivity and incomes of small-scale food producers, in particular women, indigenous peoples, family farmers, pastoralists and fishers, including through secure and equal access to land, other productive resources and inputs, knowledge, financial services, markets and opportunities for value addition and non-farm employment

By 2030, ensure sustainable food production systems and implement resilient agricultural practices that increase productivity and production, that help maintain ecosystems, that strengthen capacity for adaptation to climate change, extreme weather, drought, flooding and other disasters and that progressively improve land and soil quality



Reduce Unintentional Exposure and the Need for Antimicrobials, and Optimize Their Use,

General Comments on Report

IACG mandate includes cooperation among UN bodies and reinforcement of a One Health approach therefore necessitating an environmental focus that should include increased engagement with UNEP.

Specific Comments

Title Page:

Consider revising the title to read “Optimizing Use of Antimicrobials.” Reducing unintentional exposure and the need for antimicrobials can be addressed in the document narrative.

Page 3:

2nd paragraph - The term “resistance” is negative and does not accurately reflect the multiple influences on behavior. Change “Resistance to” to “The need for”, so that the second sentence will be as follows: “The need for behaviour change among health workers may also be an issue.” 2nd paragraph - The statement about limited effectiveness and cost-effectiveness of IPC interventions is too general and overstated. Need to qualify, e.g., by inserting “some” or “certain” before “IPC interventions”, so the statement will be as follows: “limited evidence about the effectiveness and cost-effectiveness of some IPC interventions to improve patient outcomes”). However, it would be better to be more specific about which interventions are meant. Currently the wording implies any IPC intervention, e.g., hand hygiene, standard precautions, transmission-based precautions, etc., which is too broad.

Pages 10-11:

The challenges and current responses described for low and middle-income countries (LMICs) are similar to challenges often faced by low and middle-income families served by federally funded health centers. Consider using “low and middle-income populations” rather than countries.

Page 12:

3rd bullet - This bullet should pertain to all healthcare settings. Also, community health centres are only one subset of ambulatory care. Therefore, replace “(hospitals, community health centres)” with “(all settings including hospitals, ambulatory care, and long-term care)”.



Page 13:

Consider adding an alphabetical acronym list (“Acronym Glossary”) used throughout this and other documents. This will allow readers to focus on content rather than the acronym’s meaning



Meeting the Challenge of Antimicrobial Resistance: From Communication to Collective Action

Specific Comments

Page 23:

3rd paragraph, the narrative describes the Breakthrough Series, an IHI Collaborative Model that has been successful in training healthcare workers and improving quality of care in hundreds of U.S. organizations. For several years, HRSA's Bureau of Primary Health Care implemented this model to improve diabetes care. I recommend further review to determine successes, challenges and/or lessons learned through implementation of the Breakthrough Series Model in federally funded health centers.

CSOs & NGOs

FUTURE GLOBAL GOVERNANCE FOR ANTIMICROBIAL RESISTANCE

Antibiotic Resistance Coalition
Response to the Interagency
Coordination Group on Antimicrobial
Resistance Public Consultation

August 2018

Signatories:

*Alliance to Save Our Antibiotics
American Medical Student Association
Centre for Science and Environment
Ecumenical Pharmaceutical Network
Food Animal Concerns Trust
Health Action International
Health Care Without Harm
IFARMA
Institute for Agriculture and Trade Policy
ReAct – Action on Antibiotic Resistance
ReAct Africa
ReAct Asia Pacific
ReAct Europe
ReAct Latin America
ReAct North America
Society for International Development
Sustainable Food Trust
Third World Network
What Next Forum*

The IACG commendably has taken up the important issue of global governance for AMR. Interested members of the Antibiotic Resistance Coalition (ARC) convened to develop this joint response to the paper. We understand that this discussion paper represents the work of a subgroup of the IACG members and that this is just a starting point for discussion.

The IACG discussion paper lays out some useful principles, but prioritizing and building upon these might have been informed by applying them to concrete, next steps. How does an engagement of “stakeholders from across the AMR system” result in a “global and true One Health approach” when the incentives faced by some stakeholders may run counter to such measures? How will the governance approach “secure binding global commitment for action, with accountability clearly assigned at every level” when the last and not least principle of “securing and more effectively organising sufficient funding and resourcing to implement and deliver AMR transition initiatives” rings empty? Hopefully, this will emerge from a bottom-up analysis of what is needed to catalyze change rather than solely a top-down exercise.

Civil society advocated for such a governance structure to provide oversight and coordination across UN and intergovernmental agencies when it called for the creation of IACG, but the resulting IACG as a hybrid of part expert commission and part representative body of key agencies (minus UNDP and UNESCO) provides useful lessons. The strengths and limitations of the IACG offer useful insights into how to shape governance. Any governance structure post-IACG must have 1) greater call on technical agency inputs; 2) ability to assess and coordinate inter-agency activities on AMR beyond just the Tripartite and including the environment; 3) a framework to provide guidance to countries on how to prioritize AMR interventions; 4) a framework for monitoring for accountability; and 5) funding and resources commensurate to this charge. The IACG paper on global governance focuses on how a Standing Secretariat, Global Steering Board and High-Level Commission might deliver a global, multi-stakeholder agreement in 10 years. There are certainly various configurations of these structures—defined in such a generic and general way—that might yield the same outcomes.

Equally important, however, would be how the governance structure enables the use of policy levers that strategically could advance an effective response to AMR. Some of these policy levers can be identified from the work of the other IACG subgroups.

Meeting the challenge of antimicrobial resistance: From communication to collective action	AMR Watch
Antimicrobial resistance: national action plans	Prioritization framework for countries to assess return on investment from different AMR interventions
Optimize use of antimicrobials	Leapfrog fund for transitioning agricultural livelihoods
Antimicrobial resistance: invest in innovation and research and boost R&D and access	Procurement facility
Surveillance and monitoring for antimicrobial use and resistance	Monitoring for accountability framework

AMR governance draws upon important norms set by various intergovernmental bodies, including the Tripartite agencies as well as UNEP and Codex Alimentarius Commission. The IACG paper, however, is unclear in how it hopes to ensure policy coherence with these other sources of normative guidance, with ongoing processes like the Global Development and Stewardship Framework for AMR and the Codex standard-setting process, and with the work of the Tripartite agencies (WHO, OIE and FAO). Are there lessons from the standard-setting and priority-setting across treaties in other areas that might inform the approach, particularly in lead up to a proposed treaty?

The IACG might also lay out steppingstones to building the support, particularly among Member States and civil society, towards a lasting governance approach for tackling AMR, perhaps on the road to a treaty. Before global consensus is reached, what are the ways in which a like-minded group of Member States based on clear principles might come together to act decisively and collectively on AMR, without undermining the confidence building that is needed to reach an equitable, multilateral outcome? Defining these approaches might shed insight as to how to build the momentum for a binding global commitment on AMR.

The road to a treaty, however, should not distract or detract from the pace of ongoing efforts to resolve the shortfalls in support of building a surveillance system, rational use, innovation of health technologies, or other measures to address AMR.

1. Defining governance: Moving beyond the institutional boxes

1.1 The rationale outlined for a global forum is a useful start, that is, to:

- Set global standards and targets in human health, agriculture, and the environment
- Conduct surveillance and monitor progress towards goals
- Build norms and public knowledge of the true scale of AMR and the economic consequences
- Finance alternatives and innovations such as new vaccines, diagnostics and therapies for both humans and animals through a pooled fund
- Collaborate with the private sector where possible
- Ensure accountability to consumers and citizens who will be vital drivers of change.

This list in the background paper, of course, captures many of the AMR policy areas worked on in recent years, but neglects key areas, from the innovation of practice, not just technologies, to building the capacity of professional societies and civil society to effect AMR change.

1.2 The “straw man” model devotes too much attention on structure of future global governance of AMR and too little attention to its functions. There are various ways in the institutional boxes in Figure 1 might be arranged, whether they lead to a global, multi-stakeholder agreement or not. More importantly, the IACG should propose a modular approach to governance delivering on key priorities for AMR governance, offering steppingstones to building a global commitment to such governance, and suggesting how like-minded Member States can move this agenda now (bearing in mind the need for clear principles and the need for reaching an equitable, multilateral outcome).

1.3 The “straw man” model is a top-heavy structure that has more appointed officials and committees than clarity of purpose. Perhaps the IACG should consider the potential functions for global governance first and the strategic levers required for effecting such change. These might include modular components such as:

- R&D coordination and financing for innovation of technology and practice, in both human and animal health sectors
- Pooled procurement facility
- Fund for transitioning small-scale food producers and those with agricultural livelihoods at the subsistence level away from production practices reliant on antimicrobial use
- Campaign fund to support communication efforts for collective action, including civil society and professional society mobilization

- 1.4 ARC supports the broadening of governance beyond the Tripartite agencies to include the UN Environment Programme, but also expects greater engagement by UNICEF, UNDP and other UN and intergovernmental agencies in tackling the challenge of AMR. It should not remain the province of just the technical agencies steeped in One Health issues.
- 1.5 Reframing the narrative or “pitch” for AMR as a development issue is important, not only for integrating this work within the Sustainable Development Goals, but also to recognize the potential of AMR-sensitive interventions in advancing AMR-specific goals. For example, WASH (water, sanitation and hygiene) and vaccine campaign interventions could lower the overall burden of bacterial infections, thereby averting the need for antibiotic treatment and the selective pressure on these life-saving drugs.
- 1.6 The consensus building and stakeholder engagement opportunities could better enlist civil society. Yet whether it was establishing the Global Fund for AIDS, Tuberculosis and Malaria or ratifying the Framework Convention on Tobacco Control, it was not industry, but civil society that was the key catalyst in bringing about these changes. Civil society dramatically lowered the price of HIV/AIDS medicines by negotiating generic triple therapy for \$350/year. And for the Framework Convention on Tobacco Control, civil society carried forward much of the country-level advocacy in support of the WHO’s first use of its public health treaty making authority, in opposition to the tobacco industry and its allies.

While the Leeds Castle meeting of stakeholders organized in April 2018 included a range of experts, including some from academia, civil society representation remained very limited as was the paucity of voices from low- and middle-income countries. Given importance of these groups in driving and effecting lasting change, both should be enlisted more prominently in shaping the model for future AMR global governance.

2. **The IACG paper identifies as barriers to a global approach to AMR as “gaps in data, a lack of scientific agreement, private interests with little short-term incentive to alter behaviour or to accept higher regulatory standards; variations in national capacity/capability to participation in a global compact, and other powerful pressures to maintain the status quo.” However, it is unclear how the proposed governance structure would address these barriers.**
 - 2.1 The discussion of “Antimicrobial use and human healthcare” in the background paper (pages 21-22) focuses on overuse, but fails to acknowledge the challenge of underuse in resource-limited settings. Such an oversight suggests a potential blindspot in governance-

the need to ensure access, not just avert excess in the use of antibiotics. Ensuring access involves secured financing, pooled procurement, and measures that capture access to first and second-line antibiotics, not just stewardship of these drugs.

- 2.2 The need for striking the right balance between access and stewardship is underscored by the recent update of the WHO's Essential Medicines List that categorizes antibiotics into Access, Watch and Reserve categories (AWaRe). An important instrument of global governance supporting country-level implementation of the AWaRe strategy might be pooled procurement. The experience of the Global Drug Facility in providing access to second-line TB drugs at lower, negotiated prices in exchange for country program assurances of rational use and scale-up might inform this approach.
- 2.3 The IACG background paper alludes to "other powerful pressures to maintain the status quo" and "private interests with little short-term incentive to alter behaviour or to accept higher regulatory standards." Yet the proposed governance structure does not put in place safeguards to prevent regulatory capture. Regulatory capture refers to the failure of government to act in the public's interest, and instead commercial interests of those the agency is regulating are advanced. Rather representatives of industry are included on the Global Steering Board.

The paper describes a "corporate voluntary code of conduct on AMR" as one of three models that struck the authors "as offering potential." Astonishingly, the description of the "willingness already demonstrated by some parts of industry" ignores how this "willingness" came about as a result of more than a decade of concerted civil society action. This is recounted in the IACG paper on "Meeting the Challenge of Antimicrobial Resistance: From Communication to Collective Action" which describes how civil society organizations across the consumer, environmental and public health fields used a scorecard ranking the top 25 restaurant chains in the United States based on their antibiotic policies. Responding to the Chain Reaction Report, fourteen of these companies have taken steps to improve the sourcing of food animal products without the routine use of antibiotics, up from five companies two years earlier.

Where in this scenario of "industry codes of conduct on AMR" is the support and enabling policy environment needed for civil society to bring about this concerted public pressure? The paper might also have discussed where needed change in AMR might not come from signaling companies by adversely affecting their public reputation or bottom-line through paying markets. Civil society focused its efforts on public-facing brands in the value chain. Why does the analysis fail to recognize not only the incompleteness of these successes, but

the time it has taken to achieve them and the even longer periods yet to implement these voluntary commitments? The authors of the background paper could have also discussed how voluntary corporate commitments may forestall more effective, government mandated monitoring for accountability.

3. **The IACG discussion document as well as the companion background paper calls for a multistakeholder process that sidelines the role that Member States as governments that represent their peoples must play. Key principles for any governance process should include transparency, safeguards against conflict of interest, and fairness of representation.**

The IACG discussion paper on global AMR governance might also be rooted in commitments to key principles of good governance. These include, as repeatedly noted in previous civil society and ARC position statements, a commitment to transparency and an openness of the policy process, safeguards against conflict of interest, and fair representation, particularly of LMIC concerns.

The [ARC input to the IACG](#) from May 2018 highlights the importance of “broad participation among countries, particularly low- and middle-income countries” and “avoidance of any conflicts of interest especially among those who might shepherd a global governance process.” The ARC input also made the point that effective monitoring and evaluation of progress “requires governments to ensure collection and public transparency of relevant data as well as the complementary efforts of civil society to hold key stakeholders accountable.” Similarly, in its [briefing](#) to the 2017 WHO Executive Board, ReAct states that the IACG “embrace the principles of transparency, openness and accountability in its operations and enlist the cooperation of other partners, especially civil society.”

- 3.1 By rooting governance in a rights-based approach and placing Member States at the center of the process, the public’s interest is better centered in the process, conflicts of interest can be minimized, and governments, held accountable. Too often, calls for “multi-stakeholder processes” fail to keep governance free of undue influence from stakeholders that have financial conflict of interest. A multi-stakeholder process accepts that corporations will be at the table, making financial conflict of interest unavoidable.

In fact, the IACG background paper on governance puts forward the idea that the World Economic Forum, which “now has formal status as an International Organization” (page 19), could host such a multi-stakeholder protocol. The background paper authors’ own

engagement with the World Economic Forum (Devi Sridhar on the World Economic Forum Council on the Health Industry and Ngaire Woods as the co-Chair of the World Economic Forum's Global Future Council on Values, Technology and Governance) should have positioned them well to make clearer critique of the shortcomings of such an idea.

- 3.2 Transparency and openness of the policy process are key to ensuring monitoring for accountability to the public's interest. The need for this transparency begins with collecting and making publicly available the data on antibiotic use, drug resistance patterns, price, and measures of access and stewardship. The principle also extends to the policy process. Both the inputs as well as the outputs of the intergovernmental process of shaping AMR governance decisions requires a commitment to transparency, while understandably preventing those with financial conflict of interest from unduly influencing the outcomes of such deliberations. Though more could be done to engage stakeholders effectively, the IACG's recent efforts to post its meeting minutes and submissions to its public consultation process are examples of what should be considered part and parcel of good governance practices of transparency.
- 3.3 Safeguards against conflict of interest are important. Specifically, civil society has concerns over the financial conflict of interest posed by monied interests influencing public policy processes. Disclosure of such financial conflicts of interests can serve as a useful starting point, but does not in and of itself rid the governance process from undue influence from such interests.

Safeguards against conflict of interest must extend to how the policy dialogue is constructed. For example, the proposed "High-Level AMR commission would be led by political, industry, and civil society leaders..." and the diagram of global governance of antimicrobial resistance has industry—alongside civil society, regulators, professionals, and academia—bridging between the Standing secretariat and Global steering board. There is an important difference between recruiting input from industry and having industry involved in the public policy decision making process. The former risks regulatory capture and corruption of the policy process; the latter supports informed decision making. Given the background paper's specific acknowledgement of both "private interests with little short-term incentive to alter behaviour or to accept higher regulatory standards...and other powerful pressures to maintain the status quo," it would be logically incoherent to place these very actors with financial conflict of interest right in the middle of the governance structure.

- 3.4 Fairness of representation in the policy process refers both to how governance bodies are comprised and also how inputs to the governance policy process is enabled. The representation of low- and middle-income countries in the deliberative, policy process is key to addressing this concern.

Fairness also involves protection against donor-dominated processes. If there is going to be Member State buy-in, particularly by those least well-resourced and sometimes in greater need of effecting changes in AMR policy, the process must allow for both perceived and actual fairness in the governance policy process. The IACG governance paper is somewhat silent on how these concerns of fairness in representation might be handled.

And the examples provided from the Global Fund to Fight AIDS, Tuberculosis and Malaria, GAVI and the Joint UN Program on HIV/AIDS suggest lessons, but less so admonishments. The take-away lessons from these case studies fall short of flagging problems that have emerged in these governance structures. For example, GAVI has faced criticism for placing vaccine companies on its board,¹ and this has led to repeated questioning of whether this initiative has effectively negotiated the best prices for affordable vaccines for the countries it serves.

A stronger comparative analysis might have lifted up useful lessons. For example, how has the Country Coordinating mechanism that requires national committees in recipient countries to include representatives from “government, the private sector, technical partners, civil society and communities living with the diseases”² better grounded the work of the Global Fund in local realities or not?

4. Ensuring policy coherence across UN and intergovernmental agencies requires aligning the normative guidance and efforts of these groups, yet the workings of the multi-stakeholder process remain poorly defined in this IACG discussion paper.

- 4.1 The fragmentation of the governance process for AMR across multiple, intergovernmental agencies (Tripartite or Quadripartite) contributes to policy incoherence. Each of these intergovernmental agencies responds to different Ministries within governments. There is a need for a redesigned governance approach that is Member State driven and that can address policy incoherence at its roots. Lessons from the successes and challenges of

¹ Jack A. Conflict of interest fears over vaccine group. *Financial Times*, May 26, 2011. Available at: <https://www.ft.com/content/484e8ada-87c2-11e0-a6de-00144feabdc0>

² The Global Fund to Fight AIDS, Tuberculosis and Malaria, “Country Coordinating Mechanism,” available at: <https://www.theglobalfund.org/en/country-coordinating-mechanism/>

previous efforts, such as the Committee on World Food Security, might inform the IACG's formulation of a governance structure for AMR policy making. Established in 1974, the Committee on World Food Security (CFS) has served as an intergovernmental body and a forum within the UN system on such issues. Its structure includes the CFS Bureau comprised of a Chairperson and twelve Member State countries and an Advisory group, a Plenary, High Level Panel of Experts on Food Security and Nutrition, and a Secretariat housed in the FAO with support from the World Food Programme and the International Fund for Agricultural Development.

- 4.2 A needs-driven, coordinated response to AMR is required. The process for aligning and reconciling normative guidance across UN and intergovernmental agencies within the global AMR governance structure should be spelled out more clearly. The potential for such discordance in global AMR governance is greater because AMR, as a multisectoral issue, cuts across multiple agencies with overlapping jurisdictions. For example, the World Health Assembly likely draws government representatives from health ministries, whereas the FAO and OIE General Assemblies likely recruit government representatives from other Ministries.

Antibiotic resistance is caused and driven by a wide range of factors, including overuse and misuse of antibiotics in humans and animals--lack of access to infection prevention measures like vaccines and basic health care, poor quality water, sanitation and hygiene, to name a few. The tripartite consisting of the WHO, OIE and FAO is able to cover a wide range of human and animal health issues, but the responsibility to tackle antibiotic resistance stretches far beyond those three UN agencies. A global governance system will need to enable a broader remit of action and be able to influence a wider set of relevant policy agendas including (but not exclusively) those on sustainable development and poverty reduction.

- 4.3 The effective engagement of non-State actors might benefit from examining and possibly emulating in some respects the work of the Stop TB partnership . Operating within the guidance laid down by FENSA (WHO's Framework of Engagement with Non-State Actors), the Stop TB partnership has supported civil society organizations through the Challenge Facility for Civil Society. Of note, the Stop TB Partnership moved its Secretariat in 2014 from a hosting arrangement by WHO to the UN Office for Project Services (UNOPS). WHO sits on the Partnership's Coordinating Board and Executive Committee. But the arrangement has served to allow the Partnership to "focus its attention and activities on coordinating the global effort against TB and strengthen its advocacy work" while making it "clear to all how WHO and the Partnership will work both in their respective areas and in

collaboration to accelerate the fight against TB. It will allow both institutions to maximise their respective mandates and comparative advantages.”³ The Partnership includes more than 1000 partner organizations from international and technical organizations, government programmes, research and funding agencies, foundations, NGOs, civil society and community groups, and the private sector.

- 4.4 A staged approach to ensuring countries have the resources and the technical capacity of implementing global norms requires attention in this global governance arrangement. Member States come to the challenge of AMR with varying levels of resource commitments and differing levels of antimicrobial use in their healthcare delivery and food production sectors. How could targets and milestones be linked to the availability of such support?
- 4.5 A key test as to whether policy coherence can be achieved involves how AMR governance bases policy on scientific evidence. Lessons from the accomplishments and the challenges that have faced the Intergovernmental Panel on Climate Change would be instructive. Ensuring the trustworthiness of the knowledge that backs the policy process is critical. Independent assessment of available evidence and the capacity to invest in gap-filling research are important to the process of AMR governance. The integrity of these efforts relies on the independence of its funding. This should be a public good, backed by public resources.

However, available evidence will face inherent limitations, where randomized controlled clinical trials are either not possible nor ethical to conduct. In such cases, policy decision making has to be made on basis of the best analysis of the available evidence. The precautionary principle supports such an approach by stating, “When activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established.”

- 4.6 At the country level, inter-Ministry alignment might be supported by the approach taken through the example of National AIDS Councils, promoted by UNAIDS (page 41). The Councils often were positioned above the Ministries of Health, thereby perhaps enabling greater intersectoral collaboration and inter-Ministerial alignment.
- 4.7 The multiple references to private sector and to civil society are often made imprecisely. In many instances, these labels treat groups comprised of heterogeneous stakeholders with one broad brush. The IACG analysis would benefit from a more careful analysis of the

³ Stop TB Partnership. “The Stop TB Partnership to move its Secretariat from WHO to UNOPS,” July 16, 2014. Available at: http://www.stoptb.org/news/stories/2014/ns14_049.asp

differences among these stakeholders, both in the private sector and civil society. Inviting one civil society representative is not tantamount to representing all of civil society. Focusing on the interests of the research-intensive, multinational drug companies is also not synonymous with the perspective of the pharmaceutical industry sector as a whole. And it almost certainly does not capture the concerns of stakeholders in the healthcare delivery system, insurers, agribusiness, or farmers. In proposing public-private partnerships or enhanced role for the private sector, the IACG also should consider how “to fully engage with the private sector” would be handled. Notably, concerns over financial conflict of interest and risk management need to be in place.

5. Effective governance will not happen unless a strong system to monitor for accountability is in place.

- 5.1 The IACG discussion paper is silent on the need for transparency of key data, the collection and release of which may require a governance structure to mandate. The flow of food products and the use of antibiotics in its production remain hidden by industry, by governments, and by the intergovernmental agencies involved in the data collection.
- 5.2 There is also a critical need for AMR Watch activities. This is a shared responsibility, particularly by those stakeholders without financial conflict of interest. Governments and intergovernmental agencies have a key role building upon the Tripartite Monitoring and Evaluation Framework, the country self-assessment surveys, and Tripartite agency data collection efforts. But the transparency, the interpretation and analysis, and even the strategic collection of these data sometimes fall short. This is where the efforts, particularly of civil society, can significantly complement global watch efforts.
- 5.3 Self-regulation should not be regarded as a substitute for the effective exercise of state authority at both the national and international levels.⁴ While the report by Sridhar and Woods points out “private interests with little short-term incentive to alter behaviour or to accept higher regulatory standards,” it is puzzling that the report places such prominence on the role for self-regulation. Industry self-regulation is not anchored in democratic accountability. At most, it is an imperfect addition to regulation.

The AMR Industry Alliance brings together over 100 companies in the life-sciences industry and makes reference to the shared goals and commitments made in the Declaration on Combatting Antimicrobial Resistance signed in January 2016 at the World Economic Forum.

⁴ Vogel D. The Private Regulation of Global Corporate Conduct: Achievements and Limitations *Business & Society* March 2010; 49(1): 68-87. Available at: <https://iow.eui.eu/wp-content/uploads/sites/28/2017/04/Beckers-03-Vogel.pdf>

Running counter to commitments made on R&D in this Declaration, Sanofi and Novartis recently closed down their research on antibiotics. And only 36 out of 101 Alliance member companies participated in the survey for the Alliance's first progress report.⁵

- 5.4 Monitoring for accountability on AMR should be integrated with the indicators for the Sustainable Development Goals. AMR-specific indicators, both in healthcare and in food production systems, would be important to place the issue of antimicrobial resistance squarely in the framework of accountability of the Sustainable Development Goals. As UN Country Teams work towards producing a United Nations Development Assistance Framework (UNDAF) to meet the goals of the 2030 Agenda for Sustainable Development, the IACG should consider how the goals of AMR governance might be furthered within UNDAF.

⁵ SustainAbility. *Tracking Progress to Address AMR*. Geneva, Switzerland: AMR Industry Alliance, January 2018. Available at: https://www.amrindustryalliance.org/wp-content/uploads/2018/01/AMR_Industry_Alliance_Progress_Report_January2018.pdf

REDUCE UNINTENTIONAL EXPOSURE AND THE NEED FOR ANTIMICROBIALS, AND OPTIMIZE THEIR USE

Antibiotic Resistance Coalition
Response to the Interagency
Coordination Group on Antimicrobial
Resistance Public Consultation

August 2018

Signatories:

*Alliance to Save Our Antibiotics
American Medical Student Association
Centre for Science and Environment
Ecumenical Pharmaceutical Network
Food Animal Concerns Trust
Health Action International
Health Care Without Harm
IFARMA
Institute for Agriculture and Trade Policy
Natural Resources Defense Council
ReAct – Action on Antibiotic Resistance
ReAct Africa
ReAct Asia Pacific
ReAct Europe
ReAct Latin America
ReAct North America
Society for International Development
Sustainable Food Trust
What Next Forum*

We commend the IACG for the goal of this paper: to “reduce unintentional exposure and the need for antimicrobials, and optimize their use” across healthcare, food production and the environment. Members of the Antibiotic Resistance Coalition (ARC) convened to develop this joint response to the discussion paper.

A. THEMES TO EXPLORE FURTHER

While the discussion paper lays out a range of challenges and current responses, we would encourage a deeper analysis of the gaps and the high-yield opportunities going forward. Specific themes that we urge be explored further include:

- **Finding synergy across sectors**
- **Prioritizing a Cross-Sectoral Approach**
- **Emphasizing AMR in the SDGs**
- **Identifying policy Levers**
- **Creating an enabling environment for policy and behavior change**
- **Establishing a tiered stewardship approach**
- **Enabling monitoring for accountability**

Synergy across sectors. Healthcare, food production and the environment are just different lenses to the same underlying challenge in reducing the need for antimicrobials and unintentional exposures. More intentional integration of these approaches ought to result in positive synergies, policy coherence and greater success.

The IACG could usefully look for such cross-sectoral opportunities given its frame of analysis. For example, regardless of the sector, surveillance data can serve as a powerful trigger for policy action. A surveillance system that better integrates information from both healthcare and from food production also could have particular value in safeguarding the food supply from drug-resistant pathogens. Point-of-care diagnostic platforms might have dual markets, both in healthcare and in food production. It could be made a priority to identify where economic incentives fail to align with policy goals around AMR -- from the way that healthcare providers might be reimbursed to how veterinarians working for large food producers might be motivated to use antibiotics. Restrictions on antibiotic marketing also need to be implemented both in healthcare delivery and in the food production sectors. Such steps also may require mobilizing greater resources for intergovernmental agencies to carry out these functions.

Prioritizing a Cross-Sectoral Approach. Despite the opportunity for cross-sectoral synergies, the IACG discussion paper is distinctively sectoral in its organization and approach. Each of the seven sections draws most of its analysis in one sector—healthcare delivery, food production,

or the environment. It is true that capacity and assets, governmental and non-governmental stakeholders, regulatory framework, and root causes for AMR differ quite considerably by sectoral context. However, for a government implementing a NAP on AMR, the IACG could recommend the development of a cross-sectoral prioritization framework that better positions a country to make explicit strategic choices as to where limited resources might be invested to address AMR. For example:

- What guidance could be provided to a country as to whether to invest in “clean water, sanitation and hygiene” as opposed to “prevention and control of human infection”?
- Even across efforts just to prevent and control human infection, are vaccines a better investment than antimicrobial stewardship measures to ensure better rational use of antibiotics? If universally administered, pneumococcal conjugate vaccine could potentially prevent 11.4 million days of antibiotic use in children younger than 5, thereby averting nearly half of antibiotic treatment courses in these children.¹ With a global pneumococcal vaccine coverage of below 50%,² there is much room for improvement.
- If one were focused on prevention and control of animal infection, under what circumstances would veterinary oversight, curbing the use of medicated feed, or improving animal husbandry practices be the most cost-effective point of intervention?

AMR in the Sustainable Development Goals. Mainstreaming AMR into the SDGs is essential. Tackling AMR is a priority that can and should be addressed in SDG2, but also in SDG12, thereby considering reduction of food waste and changes in the food production model. For example, over 30% of food can go to waste within industrial production.³ Meat and dairy farms are also the largest greenhouse gas emitters,⁴ so increasing industrial food production will both facilitate the spread of AMR and contribute to climate change. This will require moving beyond business as usual. The pressure to increase animal density and growth rate in raising livestock and aquaculture will inevitably require more antibiotic use. Unless this production model is changed and a commitment to a more circular economy or virtuous cycle of production is made, this upward spiral in use of antibiotic use will never be broken, and stewardship efforts will make marginal improvements, not reversing root causes.

Policy Levers. Some of the most significant policy levers for tackling AMR extend beyond the bounds of the current approaches currently described in this paper. Specifically:

¹ Laxminarayan R, Matsoso P, Pant S, Brower C, Røttingen J, Klugman K, Davies S, Access to effective antimicrobials: A worldwide challenge, *Antimicrobials: access and sustainable effectiveness*, *Lancet* 2016, 387: 168–75.

² Immunization coverage fact sheet, WHO, January 2018. Available at: <http://www.who.int/mediacentre/factsheets/fs378/en/>

³ High Level Panel of Experts on Food Security and Nutrition, Food losses and waste in the context of sustainable food systems, June 2014. Available at: <http://www.fao.org/3/a-i3901e.pdf>

⁴ GRAIN & Institute for Agricultural Trade and Policy, *Emission Impossible*, July 2018. Available at: <https://www.iatp.org/sites/default/files/2018-08/Emissions%20impossible%20EN%2012.pdf>

1. Behavioral economic approaches to change individual behavior and innovative financing at the institutional level should fall within the scope of potential recommendations.
2. Small-scale producers and resource-limited facilities should be supported technically and financially in making the transition to more sustainable antibiotic use practices.
3. The power of procurement of antibiotics—particularly pooled procurement—in shaping not only access, but also stewardship of these life-saving drugs also warrants careful consideration.
4. Procurement is also a significant lever in shaping the behavior of industry, regardless of sector.
5. Antimicrobial stewardship also requires a vibrant research agenda to test and pilot more effective interventions.

Creating an enabling environment for policy and behavior change. The best practices for cultivating, harvesting and disseminating guidelines and behavior change interventions ought to be a focus for IACG review. By drawing upon exemplars from other fields, an enabling policy environment for supporting efforts in addressing AMR might be created through the recommendations of the IACG. A few examples include:

- Decades of experience in the implementation of the Integrated Management of Neonatal and Childhood Illness;
- Peer-to-peer network approaches like the Institute for Healthcare Improvement’s Breakthrough Collaboratives;
- Insurer use of financial and non-financial incentives; and
- Collective action by professional societies and credentialing organizations, including the “Choosing Wisely” initiative of the American Board of Internal Medicine Foundation.

A Tiered Stewardship Approach. Work also must continue to develop a system for implementing stewardship practices, tiered to the level of resources in those settings. Where there are insufficient prescribers or no laboratory facilities, triage, treatment and referral approaches are still needed. What is the governance structure that would enable those tackling AMR the means to position such strategies for country governments and other key stakeholders to adopt? Similar considerations apply in the agricultural sector, where the experience of extension services and the role played by the Consultative Group on International Agricultural Research might be factored into a recommendation.

Monitoring for Accountability. There should be mandates on governments to collect and share data on antibiotic use in both human and animal sectors. Data collection and sharing are the foundation for ensuring effective monitoring of progress toward meeting targets, and therefore accountability. While the Tripartite efforts to put together a Monitoring & Evaluation

Framework are a useful start, the IACG should make a recommendation that ensures an effective framework across Member States for reporting such information. Civil society can also use data, which must be made transparent, to benchmark stakeholder performance against targets and create comparison scorecards. Another way to ensure that such data become actionable is to support the development of tools that empower them to take measure of effects of AMR in healthcare delivery, food production and the environment. Collectively, such efforts could serve as a Global Watch on AMR.

B. RECOMMENDATIONS FOR THE HUMAN, ANIMAL AND ENVIRONMENTAL HEALTH SECTORS

1. The concerns over antimicrobial stewardship in healthcare delivery span both prevention and control of human infection and optimizing use in humans.

- 1.1 Though plenty of studies document approaches that reduce unnecessary antibiotic use, a Cochrane review suggests that “we do need more research to understand why the most effective behavior change techniques are not more widely adopted within hospital settings. Future research should instead focus on targeting treatment and assessing other measures of patient safety, and different interventions that explore the barriers and facilitators to implementation.”⁵ By comparison, however, to the recognition and research dollars going into developing new antibiotics, global funding to invest into research on implementation of changes in practice also needs to be bolstered.
- 1.2 The connection and complementarity between AMR-sensitive interventions and AMR-specific interventions are key to explore. Conditions of clean water, sanitation and hygiene influence the burden of disease faced by the healthcare delivery system. WASH activities can focus on the potable water supply for communities or the need for sourcing water in health facilities. The IACG might consider how WASH efforts might amplify the response to AMR and what country-level guidance in targeting such initiatives might be offered.
- 1.3 In optimizing the use in humans, underuse as well as overuse must be addressed. Monitoring for effective stewardship, but not for access to life-saving antibiotics would set back antimicrobial stewardship efforts. Local populations would consider a focus on the former, without the latter, evidence that committing to tackling AMR was not to save their lives, but those of others who already had access to antibiotics. Today, global lack of access to essential antibiotics causes more deaths than resistance. Approximately half of the

⁵ Cochrane. “Support for health professionals reduces unnecessary use of antibiotics in hospitals.” Available at: <https://www.cochrane.org/news/support-health-professionals-reduces-unnecessary-use-antibiotics-hospitals>

900,000 children under 5 that die from pneumonia every year could be saved by providing access to correct antibiotics.⁶

1.4 Beyond the various prizes established for bringing a new point-of-care diagnostic forward for AMR, there needs to be greater attention to enhancing the innovation of novel diagnostics suited for resource-limited settings. It is, however, not enough to develop new diagnostics. A strategy for their implementation should be considered and coupled with improvements in care or antibiotic stewardship.⁷ The development of a rapid diagnostic test for bacterial pneumonia suited for use where there is minimal infrastructure could save more than 405,000 lives each year, much of it by reducing overtreatment with antibiotics.⁸ A test for acute lower respiratory infections could save more than 400,000 lives each year⁹. The development of and affordable access to diagnostics suitable for use in developing countries and improved laboratory capacity in LMICs is therefore a top priority.

2. Antimicrobial stewardship must also include the food production system (optimizing use in animals and plants, prevention and control of animal infection, and food safety and food production).

2.1 The need to increase food production from animals is not fully in accordance with SDG2, as ensuring food security is not limited to food animal production. The more animals are raised, the more plant food they will need to consume. Currently over 65% of grains are consumed by livestock in the U.S.,¹⁰ and over 60% are in Europe.¹¹ The paper calls for increased meat and dairy production for growing populations to align with SDG 2, when in countries with the most intensive agriculture, most of the produce is destined to feed animals, not humans. Therefore, in considering strategies to feed the world more efficiently, using more plant products to feed humans alongside meat and dairy production must be considered.

2.2 Meeting the food security goals of SDG 2 also does not necessarily imply increasing production of all food system models. SDG2 mentions increasing production by small-scale

⁶ Laxminarayan, R. et al. Access to effective antimicrobials: a worldwide challenge. *Lancet* 2016; 387: 168–175.

⁷ Wellcome Trust. Four diagnostic strategies for better-targeted antibiotic use. 2016. Available at: <https://wellcome.ac.uk/sites/default/files/diagnostic-strategies-for-better-targeted-antibiotic-use-wellcome-jul15.pdf>

⁸ RAND Research Highlights. Estimating the Global Health Impact of Improved Diagnostic Tools for the Developing World. Santa Monica, California: RAND Corporation, 2007.

⁹ Lim, YW et al. Reducing the global burden of acute lower respiratory infections in children: the contribution of new diagnostics. *Nature* 2006 Nov 23; 444 Suppl 1:9-18.

¹⁰ Cassidy, E. S., West, P. C., Gerber, J. S., & Foley, J. A. (2013). Redefining agricultural yields: from tonnes to people nourished per hectare. *Environmental Research Letters*, 8(3), 034015.

¹¹ Virginia W. Mason and Jason Treat, NGM Staff. Source: Global Landscapes Initiative, Institute on the Environment, University of Minnesota. Available at: <https://www.splendidtable.org/story/solving-the-worlds-food-dilemma-in-5-steps>

producers in a *sustainable way*, but increasing industrial farming for animal production is not sustainable.¹² Thus, sustainable intensification of industrial production does not exist. The agricultural model must take this into account when calling for increased food production. Already, nearly 80% of agricultural land is dedicated to pasture and feed production.^{13,14} Intensification of more industrialized production will only add to that figure. In contrast, smaller scale models of food animal production are less likely to rely on the use of feed grains to raise livestock, as opposed to forage.

- 2.3 In addition to feed grains, more industrialized models of food animal production also tend to use more antimicrobials than less intense production models, making intensive production models to be more significantly driving antimicrobial resistance than less intense food animal production.¹⁵ Intensification would mean increasing the density of animal production, in which case antibiotics would become increasingly necessary. Instead, local growth must be promoted over global intensification. More sustainable food production practices are the solution, not the challenge, to achieving adequate food security and concurrently lowering antimicrobial use in this sector.
- 2.4 The IACG discussion paper does not adequately address key approaches to tackling antibiotic overuse in animals. In discussing optimizing antibiotic use in animals and plants, the discussion paper fails to refer to the [WHO guidelines on the use of medically important antibiotics in food-producing animals](#), which call for a ban on the use of these antibiotics for growth promotion and disease prevention. In doing so, the paper downplays the relevance of the issue of using antibiotics routinely for disease prevention and growth promotion.
- 2.5 While the paper acknowledges the expected 70% increase in antibiotic use in livestock by 2030 with continued intensification, it does not suggest mechanisms for change. For example, the paper does not touch on the use of medicated animal feed.^{16,17} Yet data from the European Medicines Agency estimates that the proportion of antibiotics used in food

¹² Committee on World Food Security. *Sustainable agricultural development for food security and nutrition: what roles for livestock? A report by The High Level Panel of Experts on Food Security and Nutrition*. Rome, 2016.

Available at: <http://www.fao.org/3/a-i5795e.pdf>

¹³ <https://www.globalagriculture.org/report-topics/meat-and-animal-feed.html>

¹⁴ Max Roser and Hannah Ritchie (2018). "Yields and Land Use in Agriculture". *Published online at OurWorldInData.org*. Retrieved from: <https://ourworldindata.org/yields-and-land-use-in-agriculture>

¹⁵ <http://www.saveourantibiotics.org/media/1777/asoa-report-real-farming-solutions-to-antibiotic-misuses-what-farmers-and-supermarkets-must-do.pdf>

¹⁶ Davies, M. & Meesaraganda, R. (January 2018). A game of Chicken: How Indian Poultry Farming is Creating Global Superbugs, *The Bureau of Investigative Journalism*. Accessible at: <https://www.thebureauinvestigates.com/stories/2018-01-30/a-game-of-chicken-how-indian-poultry-farming-is-creating-global-superbugs>

¹⁷ Paliwal, A. & Singh, J. (March 2018) Hatching Superbugs, *Down To Earth*. Available at: <https://www.downtoearth.org.in/coverage/hatching-superbugs-45547>.

animal production for group treatment (including metaphylaxis) varies widely from 90% overall in Europe vs. less than 10% in Sweden.¹⁸ The IACG could address how production practices might be improved to move closer to the antibiotic use levels seen in Sweden and how regional comparisons and targets across countries could be used to identify and motivate the adoption of best practices. For example, standard treatment guidelines could be established for judicious use of antibiotics in animals. Strategies could also include better labelling of feed containing antibiotics, meat raised with antibiotics and antibiotics to increase consumer and purchaser awareness. Finally, better oversight and regulation of imports, online sales and advertising of medicated feed are needed.

2.6 There are good, evidence-based case studies for other countries which, like Sweden, have significantly reduced antimicrobial use in food animal production, by eliminating use of antimicrobials for growth promotion and for routine disease prevention in the absence of disease, as the aforementioned WHO Guidelines recommend. Denmark and the Netherlands, both major food animal producers in Europe, have decreased their use of medically important antimicrobials significantly. Since 2011, overall consumption of those drugs in food animal production has dropped by more than 60% in the Netherlands.¹⁹ And in Denmark, where change happened earlier, antibiotics consumed in pig production fell by more than half from 1992 to 2009, even while productivity increased; the pig sector accounts for 80% of agricultural antibiotic use in Denmark.²⁰ Profiling of outliers in antimicrobial use, as seen through Denmark's Yellow Card Initiative, among both farming operations and veterinarians, and improvements in animal husbandry, nutrition and vaccination, as seen in Sweden's pig production practices,²¹ are useful starting points. However, evaluating such interventions in LMICs requires investment. Barriers to implementing these improvements requires additional study, as does piloting of how best to incentivize changes in behavior and practice in antimicrobial use in a variety of country contexts.

2.7 A "Leapfrog Fund" should be established to help small-scale farmers make the necessary transition to achieve a more sustainable food production approach, to become less reliant on antibiotics, and to abide by efforts to ban medically important antibiotics in farming.

¹⁸ European Medicines Agency, Sales of Veterinary Antimicrobial Agents in 30 European Countries in 2015. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2017/10/WC500236750.pdf

¹⁹ The Dutch figures are at Netherlands Veterinary Medicines Authority (SDa). 2017. Usage of Antibiotics in Agricultural Livestock in the Netherlands in 2016. Published May 29, 2017. Accessed (Dutch language only) at <https://www.rijksoverheid.nl/documenten/rapporten/2017/05/29/het-gebruik-van-antibiotica-bij-landbouwhuisdierenin-2016>

²⁰ Levy, S. (2014). Reduced Antibiotic Use in Livestock: How Denmark Tackled Resistance. *Environmental Health Perspectives*, 122(6), A160–A165. <http://doi.org/10.1289/ehp.122-A160>

²¹ Federation of Swedish Farmers (November 2015). Swedish pig production. Available at: https://www.lrf.se/globalassets/dokument/om-lrf/bransch/lrf-kott/grisnaringen/swedish_pig_production_2015.pdf

The support required would involve both technical and financial aspects in making the transition to more sustainable antibiotic use practices. In certain cases, the continued use of antibiotics can harm farm production, pointing to the need for transition support. For example, feeding certain Gram-positive or broad-spectrum antibiotics orally to farm animals can increase shedding of *Salmonella* or *Escherichia coli*, with implications for food safety and human health.^{22,23,24,25}

- 2.8 The IACG discussion paper notes that economic and population growth will fuel greater demand for meat products, and that this could be an important driver of greater antimicrobial use as well. The trade of food animal products is concentrated into the hands of a few countries, both on the export and on the import sides. The impact of AMR-related trade restrictions by importing countries on the adoption of more sustainable food production deserves further analysis. The WTO allows its Member States to establish trade restrictive measures to protect human health or the environment and encourages them to base these on international standards, guidelines or recommendations.²⁶ In 2017, the WHO established guidelines calling for restrictions on the use of medically important antibiotics in animals. While a harmonized approach to regulation is useful, countries should not be limited by minimal global trade standards but instead have the liberty to establish higher standards based on such guidelines.
- 2.9 R&D investment into bringing new vaccines and diagnostics that improve food animal production is also needed. Where there are market failures to bring forward such technologies, the IACG might consider borrowing lessons from the product development partnerships and public-private partnerships that have addressed such challenges in the R&D for treatments of neglected diseases. The technologies for achieving these aims among small-scale producers may differ from what might be used in large-scale production, and these must be targeted.
- 2.10 Antibiotic use for the treatment of small animals and pet treatment should be better regulated. In many countries, the number of pets is higher than number of livestock

²² Barrow, PA. Further observations on the effect of feeding diets containing avoparcin on the excretion of salmonellas by experimentally infected chickens. *Epidemiol Infect.* 1989 Apr;102(2):239-52.

²³ Delsol, AA et al., The effect of chlortetracycline treatment and its subsequent withdrawal on multi-resistant *Salmonella enterica* serovar Typhimurium DT104 and commensal *Escherichia coli* in the pig. *J Appl Microbiol.* 2003;95(6):1226-34.

²⁴ Evans, MC et al., Antimicrobial growth promoters and *Salmonella* spp., *Campylobacter* spp. in poultry and swine, Denmark. *Emerg Infect Dis.* 2003 Apr;9(4):489-92.

²⁵ Looft, T et al., In-feed antibiotic effects on the swine intestinal microbiome. *Proc Natl Acad Sci U S A.* 2012 Jan 31;109(5):1691-6. doi: 10.1073/pnas.1120238109.

²⁶ WHO, WIPO, WTO. Antimicrobial resistance – a global epidemic. Available at: https://www.wto.org/english/news_e/news16_e/heal_29aug16_e.pdf

animals, excluding poultry, yet medication of pets is often under the radar. Data collection and transparency around what small animal veterinarians are prescribing and for what purposes are needed.

3. Both the healthcare delivery and food production systems generate antibiotic pollution into the environment (environmental contamination).

3.1 Antimicrobial contamination of the environment occurs across the value chain. Targets and standards must be set for all contributors, notably not just pharmaceutical production plants,²⁷ but also farms,^{28,29} sewage treatment plants and hospitals. Benchmarks to lower antibiotic pollution can be (a) set through Good Manufacturing Practice (GMP) standards, (b) incorporated into the National Action Plan, and (c) entered into criteria set by procurement and credentialing agencies.

3.2 UNEP, along with Tripartite agencies, must extend the Monitoring & Evaluation Framework on which the Tripartite agencies have started to include data to be collected on antibiotic pollution and evidence of drug resistance in the environment. In addition, concerns are emerging that antibiotic use may have other environmental effects. Research efforts should focus on environmental risk assessments that can serve as a basis for evidence-based regulations.³⁰ The following examples have been illuminated by new research and underscore the need to evaluate more closely the impact of:

- antimicrobials on potential disruption of ecosystem services provided by dung beetles; antimicrobials on possible increase of methane gas emissions of livestock cattle;³¹
- biocides and metals on the co-selection and promotion of antibiotic resistance;^{32,33}

²⁷ Sinha, R. (May 2017) Bitter Medicine, *Down To Earth*. Available at:

http://cdn.cseindia.org/attachments/0.94770800_1529997685_bitter-medicine.pdf

²⁸ Bhushan, C., Khurana, A. & Sinha, R. (2016). Antibiotic use and waste management in aquaculture: CSE recommendations based on a case study from West Bengal, Centre for Science and Environment, New Delhi.

Available at: <https://www.cseindia.org/antibiotic-use-and-waste-management-in-aquaculture-7906>

²⁹ Bhushan, C., Khurana, A., Sinha, R., & Nagaraju, M. (2017). Antibiotic Resistance in Poultry Environment: Spread of Resistance from Poultry Farm to Agricultural Field, Centre for Science and Environment, New Delhi.

Available at: <https://www.cseindia.org/fst-report-antibiotic-resistance-in-poultry-environment-8851>

³⁰ *Strategic and Operational Guidance on Animal and Environmental Aspects: National Action Plans on Antimicrobial Resistance for Developing Countries*, 2017, Centre for Science and Environment, New Delhi. Available at:

<https://www.cseindia.org/strategic-and-operational-guidance-on-animal-and-environmental-aspects-7858>

³¹ Hammer TJ, Fierer N, Hardwick B, Simojoki A, Slade E, Taponen J, et al. Treating cattle with antibiotics affects greenhouse gas emissions, and microbiota in dung and dung beetles. *Proceedings of the Royal Society B: Biological Sciences*, 2016; 283(1831): 20160150.

³² Romero, JL et al., Resistance to Antibiotics, Biocides, Preservatives and Metals in Bacteria Isolated from Seafoods: Co-Selection of Strains Resistant or Tolerant to Different Classes of Compounds. *Front Microbiol*. 2017 Aug 31;8:1650.

³³ Pal, C et al., Chapter seven – Metal resistance and its association with antibiotic resistance. *Adv Microb Phys*, 2017 Vol 79: 261-313.

- the use of herbicides such as glyphosate which have been shown to change the response of enteric organisms common to foodborne outbreaks to antibiotics, thereby heightening spontaneous mutation to higher levels of drug resistance and potentially undermining antibiotic therapy.³⁴

3.3 Remediation technologies for handling the removal and disposal of antibiotic pollution from the environment need to be developed.

3.4 Procurement and supply chain policies must include environmentally preferable purchasing criteria to guide manufacturers, producers, suppliers, and distributors to be accountable to responsible antimicrobial use and associated pollution. As an example within the healthcare sector, Health Care Without Harm has shown how a virtual global network of hospitals and health systems can work to achieve measurable improvements in greening the practices of these institutions through the “Global Green and Healthy Hospitals” project. Through the [EcoQUIP project](#), Health Care Without Harm and its partners work to support public procurers to secure innovative solutions to “improve the efficiency, quality and environmental sustainability of healthcare.” Through the [Antimicrobial Stewardship Through Food Animal Toolkit](#), Health Care Without Harm and its partners guide health professionals in designing a comprehensive, multi-departmental hospital antimicrobial stewardship program that includes food procurement. Industry could also play a bigger role in supporting stewardship by ensuring safe disposal of unused or expired drugs across the supply chain and implementing drug take-back programs.³⁵

3.5 Greater disclosure by industry, antibiotic and feed manufacturers, farmers and retailers around the amount of antibiotics sold, procured, used and discharged as effluent would enable better regulation of the flow of antibiotics throughout the environment.

3.6 Another forward-thinking dimension of tackling AMR in the environment is the redesign of health facilities to manage better infection control and prevention. Changing the built environment in hospitals can be as straightforward as ensuring air circulation in operating rooms with windows where negative pressure ventilation is not possible. Research into how to make medical instruments with surfaces resistant to biofilm and bacterial colonization might reduce the reliance on handwashing alone to slow bacterial spread.

³⁴ Kurenbach B, Marjoshi D, Amabile-Cuevas CF, Ferguson GC, Godsoe W, Gibson P, et al. Sublethal exposure to commercial formulations of the herbicides Dicamba, 2,4-Dichlorophenoxyacetic acid, and Glyphosate cause changes in antibiotic susceptibility in *Escherichia coli* and *Salmonella enterica* serovar Typhimurium. *mbio.asm.org*, 2015; 6(2).

³⁵ U.S. Food and Drug Administration, Disposal of Unused Medicines: What You Should Know. Available at: https://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/ensuringsafeuseofmedicine/safedisposalofmedicines/ucm186187.htm#take_back

3.7 The best way to mitigate pollution is to avoid antimicrobial use in the first place, both in human medicine and in agriculture. Antibiotic use should only be when necessary, yet much of the use in agriculture and a good portion in human medicine remains unnecessary. Holding practitioners, including physicians and veterinarians, accountable when they prescribe at much higher levels than their peers is important.

MEETING THE CHALLENGE OF ANTIMICROBIAL RESISTANCE: FROM COMMUNICATION TO COLLECTIVE ACTION

Antibiotic Resistance Coalition
Response to the Interagency
Coordination Group on Antimicrobial
Resistance Public Consultation

August 2018

Signatories:

*Alliance to Save Our Antibiotics
American Medical Student Association
Centre for Science and Environment
Ecumenical Pharmaceutical Network
Food Animal Concerns Trust
Health Action International
Health Care Without Harm
IFARMA
Institute for Agriculture and Trade Policy
ReAct – Action on Antibiotic Resistance
ReAct Africa
ReAct Asia Pacific
ReAct Europe
ReAct Latin America
ReAct North America
Society for International Development
Sustainable Food Trust
Third World Network
What Next Forum*

The IACG commendably has taken up the important issue of moving from strategic communication towards collective action to curb the global public health threat of AMR. Interested members of the Antibiotic Resistance Coalition (ARC) convened to develop this joint response to the paper. We understand that this discussion paper represents the work of a subgroup of the IACG members and that it is just a starting point for discussion.

The discussion paper thoughtfully proposes a comprehensive framework with five core components towards focusing communication efforts more strategically and aligning them with the other priority areas of the IACG. The paper outlines a number of examples within these five core components. This ARC response provides a series of key issues where IACG could further expand on its work, emphasizing the need for civil society participation and involvement as key partners in both enacting communication efforts as well as monitoring their progress.

Furthermore, it will be critical that as the IACG moves forward with their recommendations to the United Nations (UN) and Tripartite agencies that there is consideration for securing commitment from Member States and UN agencies to ensure adequate technical and financial resources for awareness, communication, behavior change and related actions that are critically important in ensuring a successful response to AMR.

1. Looking back towards past public health campaigns across developed and developing countries to inform best practices for AMR communication efforts

1.1 The IACG should consider looking to prior communication campaigns across other public health areas in different contexts to identify evidence-based approaches that can be applied to AMR. The discussion paper mentions examples across tobacco control as well as veterinary health but further resources and coordination among the Tripartite agencies already engaged in behavior change work might be targeted towards determining communication strategies that are regionally or locally sensitive. For example, additional lessons might be garnered from successful HIV campaigns conducted in low and middle income countries at the community level that have led to a reduction in stigma around the disease as well as prevention¹. The discussion paper mentions the concept of *sumak kawsay* that has led to ReAct Latin America, an ARC member, to work regionally to address AMR more holistically as this concept suggests. Similarly, the IACG might consider establishing a research agenda that would identify such culturally sensitive approaches in

¹ Karl Peltzer and others, 'Impact of National HIV and AIDS Communication Campaigns in South Africa to Reduce HIV Risk Behaviour.', *TheScientificWorldJournal*, 2012 (2012), 384608 <<http://dx.doi.org/10.1100/2012/384608>>.

coordination with UN agencies such as UNESCO, which has previously been engaged in such work at the regional level for HIV/AIDS education².

- 1.2 Particularly in developing countries where resources may be limited towards investing into AMR-specific campaigns, the IACG should recommend that the Tripartite and other relevant UN agencies at the regional and national level identify where AMR might be integrated into existing development campaigns. As AMR resonates across sectors and issues from universal health access, WASH, nutrition to sustainable agriculture, supporting its integration more horizontally into existing campaigns could help generate best practices and foster more effective communication even with limited resources.
- 1.3 Efforts to identify locally or regionally sensitive strategies should also be aligned with the priority setting process to undertake interventions most relevant or urgent to a specific setting. In addition to developing needs assessment tools and a priority setting decision framework as outlined in the IACG discussion paper, a mapping of existing partners including civil society and others such as faith-based organizations already engaged in public health communication efforts either directly focused on AMR or where AMR-related messaging may be applied, might further maximize existing resources. These groups should also be included in provided critical input and feedback towards identifying and shaping locally and regionally specific communication strategies.
- 1.4 It is also important to reiterate some of the points within the first ARC submission to the IACG submitted this past May. Critical for the success of communication efforts that lead to behavior change will be the involvement and empowerment of local champions, both among providers and patients as well as communities and civil society. Any national action plan implementation or global strategy on AMR should acknowledge the importance of rooting such efforts more sustainably in networks of local champions and advocates³.

2. Developing a global research agenda for setting communication priorities

- 2.1 Moving forward from the UN Declaration on Antimicrobial Resistance, the Tripartite agencies in coordination with the UN must develop global and regional research agendas, securing Member State buy-in and commitment. Similar research agenda processes have been applied to other public health areas such as tuberculosis where the research pillar of

² UNESCO, *UNESCO's Strategy for HIV/AIDS Prevention Education*, 2004 <www.unesco.org/iiep> .

³ Antibiotic Resistance Coalition, *Antibiotic Resistance Coalition and Civil Society Input to the Interagency Coordination Group on Antimicrobial Resistance*, 2018 <<http://abrcoalition.com/wp-content/uploads/2018/06/civil-society-input-to-the-interagency-coordination-group.pdf>>.

the End TB strategy has led to development of global research frameworks⁴, priorities in operational research⁵, and regional research priorities as part of broader roadmaps to implement regional action plans⁶. Such a process can be linked to the objectives already outlined in the global action plan for Tripartite agencies at the global and local level as well as Member States. As an additional example with tuberculosis, the WHO has published a toolkit to support developing national research plans⁷ that similarly could be applied to AMR.

- 2.2 While there has been significant focus on the grave concern of no longer having options for antimicrobial treatment in the future due to AMR and increasing investment towards R&D of such medicines as well as diagnostics and vaccines, the IACG should recommend there be further resources targeted more upstream that would truly curb the use of such treatments in the first place. For instance, further technical and financial resources might also be targeted towards operational research to promote change in practices based on behavioral and communication studies and development of sector and setting specific messaging. Within this area might be a focus on what types of incentive mechanisms would be effective in changing the behavior of a target group. Such studies looking at restricting or enabling incentive mechanisms have been carried out in the context of healthcare providers in the hospital setting⁸. Similar studies should be carried out in other settings such as the pharmacy or outpatient or other sectors such as veterinary health across different country contexts.
- 2.3 Research is also need for providing alternatives to treatment particularly for contexts where out-of-pocket payments are the primary method by which patients access health services. Context-specific research plus guidance from the international level could not only allow for the success of these interventions in a local context, but also allow them to be used and adapted across communities or countries. For example, in Thailand, the Antibiotic Smart Use project provided both education as well as a locally acceptable alternative for

⁴ World Health Organization (WHO), *WHO | A Global Action Framework for TB Research in Support of the Third Pillar of WHO's End TB Strategy*, WHO (World Health Organization, 2016) <<http://www.who.int/tb/publications/global-framework-research/en/>>.

⁵ Stop TB Partnership, The Global Fund and World Health Organization (WHO), *Priorities in Operational Research to Improve Tuberculosis Care and Control WHO Library Cataloguing-in-Publication Data: Priorities in Operational Research to Improve Tuberculosis Care and Control*, 2011 <www.who.int>.

⁶ Masoud. Dara, Colleen. Acosta and World Health Organization. Regional Office for Europe, *Roadmap to Implement the Tuberculosis Action Plan for the WHO European Region 2016-2020: Towards Ending Tuberculosis and Multidrug-Resistant Tuberculosis* (World Health Organization, Regional Office for Europe, 2017).

⁷ World Health Organization (WHO), *WHO | A Toolkit for Developing A National TB Research Plan, in Support of the Third Pillar of the End TB Strategy*, WHO (World Health Organization, 2016) <http://www.who.int/tb/publications/TB_research_toolkit/en/>.

⁸ Peter Davey and others, 'Interventions to Improve Antibiotic Prescribing Practices for Hospital Inpatients', *Cochrane Database of Systematic Reviews*, 2017 <<http://dx.doi.org/10.1002/14651858.CD003543.pub4>>.

both pharmacists and patients that successfully lowered dispensing of antimicrobials⁹. Further investment is needed for such research efforts across sectors to identify where and what alternatives may effect in curbing antimicrobial misuse and overuse with input from key target groups along the antimicrobial value chain.

2.4 A study conducted on the effectiveness of AMR communication interventions showed that those strategies targeting school children and parents have notable potential¹⁰. ReAct Latin America has been employing such interventions that engage school children as the catalysts for change in curbing antibiotic overuse or misuse and that there is a dearth of research in looking at the effectiveness of AMR interventions. The Tripartite agencies might be well positioned to support such work to identify evidence-based approaches targeting communities outside of providers that can be scaled up across settings.

2.5 While extensive modeling of the problem of AMR has been conducted, further modeling is needed to look at where might be most effective points of intervention along the antimicrobial value chain. By modeling different scenarios of behavior change with key target groups in different settings linked to the goals and targets outlined in the global action on AMR, resources might be more strategically targeted. Cost-benefit analyses might also be considered to determine which groups might be best positioned even with limited resources to carry forward communication efforts to enable behavior change. Mapping existing local initiatives may also be a good place to start.

3. Empowering civil society to identify, implement, and measure efforts that communicate AMR effectively

3.1 Civil society and other local partners can also be leveraged to surveil and measure the impacts of communication efforts to see if resulting behavior change has occurred. Thailand's Antibiotic Smart Use project provides a good example of implementing an intervention at a specific point along the supply chain, where antibiotics are dispensed in pharmacy, and the development of both locally-adaptable alternative as well as communications tools to change behavior of both providers as well as the public. Behavior change was measured by quantifying the number of antibiotics dispensed demonstrating the effectiveness of the intervention. In many countries where civil society or faith-based organizations provide health services, these groups are positioned to effectively pilot and

⁹ Nithima Sumpradit and others, 'Antibiotics Smart Use: A Workable Model for Promoting the Rational Use of Medicines in Thailand', *Bulletin of the World Health Organization*, 90.12 (2012), 905–13 <<http://dx.doi.org/10.2471/BLT.12.105445>>.

¹⁰ Lesley Price and others, 'Effectiveness of Interventions to Improve the Public's Antimicrobial Resistance Awareness and Behaviours Associated with Prudent Use of Antimicrobials: A Systematic Review', *Journal of Antimicrobial Chemotherapy*, 73.6 (2018), 1464–78 <<http://dx.doi.org/10.1093/jac/dky076>>.

measure the impacts of such interventions that can then be scaled across different countries.

- 3.2 While modeling would certainly be ideal in helping to determine the impact of such interventions as well as how resources might be most effectively targeted, the lack of data, particularly in low resource settings, will be challenging to overcome. The Tripartite agencies might consider developing a platform to which civil society and other partners might contribute data to inform prioritization efforts as well as results from pilot projects to measure the application of targeted AMR communication efforts.
- 3.3 Communication efforts should make use of existing partners in civil society that can harness adaptable messaging through own channels for reaching key groups along the antimicrobial value chain from patients, health care workers, farmers, veterinarians, consumers, to the general public. Communication efforts should also go further upstream, targeting policy makers, politicians nationally and in local communities, as well as leaders of food production businesses and health care settings.
- 3.4 Civil society can play a critical role in communicating AMR effectively to build public awareness and to target efforts towards strategic interventions that the public and other key groups can be engaged in. Such communication can help build political will for governments and other groups who can allocate, divert, or provide financial and technical resources to do so for AMR. For instance, at a briefing prior to the UN High Level Meeting on AMR in 2016, the South Korean Director of Animal Health Management Division for the Ministry of Agriculture stated that civil society played a pivotal role in making the public aware of the number of multi-drug resistant bacteria found in food animal products at common grocery stores throughout the country¹¹. This prompted the government to then develop a stepwise plan to ban the use of antibiotics important in human medicine from food animal production. Similarly, during a South-East Asian regional meeting in Penang, Malaysia in March 2018, organized by South Centre and Third World Network, the Ministry of Health of Indonesia presented their experience on the recent ban of antibiotics as growth promoters¹². The announcement from the Indonesian health authorities prompted two civil society organizations, participating in the meeting, to establish contact with the ministry officials to talk about monitoring and implementation of the measure. Consumers groups participating in the meeting also discussed about possible campaigns and strategies

¹¹ Every Woman Every Child, 'Experts Discuss Recommendations to Curb Antimicrobial Resistance | Every Woman Every Child' <<http://www.everywomaneverychild.org/2016/06/07/experts-discuss-recommendations-to-curb-antimicrobial-resistance/>>.

¹² Third World Network, *Report on Asian Regional Workshop on Antimicrobial Resistance, Co-Organised by the South Centre and Third World Network* (Penang, Malaysia, 2018).

to push their own governments to enact similar measures. Supporting consumer groups and other NGOs working on health issues could be a way to promote campaigns on behavior and policy change.

4. Ensuring appropriate and practical incentives for particular groups to change practice

- 4.1 Inadequate regulation and control of the sale and use of antimicrobials in both humans and animals through financial incentives targeted to those prescribing or dispensing these treatments has been a major factor leading to the AMR crisis.¹³ Therefore, removing such conflicts of interests among human and veterinary health providers will be critical for behavioral change. Additionally, conflicts of interest also emerge when education efforts for these providers are funded through the pharmaceutical industry that can lead towards messaging around antimicrobial use rather than stewardship of such products. Instead, such education should be independently developed and provided, no depending of funding or participation from the pharmaceutical industry to adequate emphasis on stewardship and evidence-based practice.
- 4.2 Economic incentives across the antimicrobial value chain play a key role in prompting behavior change. For instance, in Denmark where the financial remuneration for veterinarians tied to the volume of antimicrobials sold for food animal production removed and instead, received based on visits to farms, antimicrobial use decreased. In fact, in comparing Denmark to other countries in Europe where such financial incentives for veterinarians still exist, antimicrobial use in food animal production is significantly less.
- 4.3 As mentioned above, a key challenge in this area that remains is the lack of alternatives in human and animal health available. Behavior change efforts may be significantly more effective if aligned with technical assistance from the Tripartite agencies and other partners to study and provide alternatives that can be used across countries.

5. Monitoring for accountability towards effecting AMR change

- 5.1 The UN and Tripartite agencies have recognized the need to address AMR as part of achieving the Sustainable Development Goals (SDGs)¹⁴. To ensure commitment of financial and technical resources from both Member States and UN agencies, the IACG should recommend that AMR be clearly integrated into the SDGs through specific targets and indicators aligned with the goals and targets outlined in the global action plan. This would

¹³ ARC declaration <https://www.reactgroup.org/uploads/ARC-declaration/ARC-declaration-May-22-2014.pdf>

¹⁴ Dusan Jasovsky and others, 'Antimicrobial Resistance. A Threat to the World's Sustainable Development', *Development Dialogue Paper*, 2016.

allow for further participation from Member States and others including civil society already engaged in SDG implementation to monitor progress on AMR. This would also allow for further monitoring of national action plan implementation, providing additional data to Member States and Tripartite agencies of where resources may be better targeted.

- 5.2 Civil society has played a key role in monitoring commitments and catalyzing governments to take important measures in other key health areas. For example, civil society was pivotal in sparking the access to medicines movement and driving down the prices of HIV/AIDS medicine through generic competition for the millions of those dying worldwide. Civil society has also been at the forefront of pushing the food industry to change its antimicrobial use practices through public, consumer campaigns. In the United States, these campaigns have led to companies such as McDonalds, Burger King, KFC, and others to stop the routine use of antibiotics in their supply chains. Harnessing this campaign, the Centre for Science and Environment (CSE) in India has shown its own government that while these companies have made commitments in the United States, they have failed to do so around the world prompting discussions between them and the company leaders¹⁵. Civil society can therefore be positioned and empowered to scale up such efforts worldwide to not only monitor various actors across the antimicrobial value chain, but also generate political will and momentum to bring about change.
- 5.3 There is a significant risk that communication efforts addressing AMR might be used by groups with commercial interests such as the pharmaceutical or food animal production industries to further their own agenda. While it is commendable that some of these groups are taking steps to address AMR through their own industry practices, there must be oversight to ensure that the public interest remains at the forefront. The discussion paper highlights some of these efforts such as the AMR Industry Alliance and Access to Medicines Foundation AMR Benchmark, both of which lack independent oversight. The IACG should also support efforts of independent partners who provide an important role in monitoring these groups and holding them accountable. The discussion paper makes mention of the *Chain Reaction* scorecard developed and carried forward by a coalition of civil society actors. Such efforts are critical in ensuring that action is truly being taken and resources are being allocated appropriately in meeting the challenge of AMR.
- 5.4 Monitoring for accountability can give important impetus for motivating behavior change. Such monitoring requires effective surveillance and data collection, but also a commitment to making such information transparent and actionable by the public, civil society, industry,

¹⁵ Chandra Bhushan, Amit Khurana and Anaya Tewari, *Double Standards: Antibiotic Misuse by Fast Food Companies*, 2007 <<http://dx.doi.org/10.2307/41779574>>.

and policymakers. The IACG should recommend that the Tripartite agencies, Member States, and other key partners make data collected towards curbing AMR publicly available to prompt action from a wide swath of actors.



IDS A

Infectious Diseases Society of America

Infectious Diseases Society of America

2017-2018 BOARD OF DIRECTORS

President

Paul G. Auwaerter, MD, MBA, FIDSA
JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE
BALTIMORE, MD

President-Elect

Cynthia L. Sears, MD, FIDSA
JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE
BALTIMORE, MD

Vice President

Thomas M. File, Jr., MD, MSc, FIDSA
SUMMA HEALTH
AKRON, OH

Secretary

Larry K. Pickering, MD, FIDSA
EMORY UNIVERSITY SCHOOL OF MEDICINE
ATLANTA, GA

Treasurer

Helen W. Boucher, MD, FIDSA
TUFTS MEDICAL CENTER
BOSTON, MA

Immediate Past President

William G. Powderly, MD, FIDSA
WASHINGTON UNIVERSITY SCHOOL OF MEDICINE
ST. LOUIS, MO

Angela M. Caliendo, MD, PhD, FIDSA
BROWN UNIVERSITY/RHODE ISLAND HOSPITAL
PROVIDENCE, RI

Henry F. Chambers, MD, FIDSA
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
SAN FRANCISCO, CA

Victoria J. Fraser, MD, FIDSA
WASHINGTON UNIVERSITY SCHOOL OF MEDICINE
ST. LOUIS, MO

Daniel P. McQuillen, MD, FIDSA
LAHEY HOSPITAL & MEDICAL CENTER
BURLINGTON, MA

Thomas A. Moore, MD, FIDSA
IDC OF KANSAS
WICHITA, KS

Ighowwerha Ofotokun, MD, MSc, FIDSA
EMORY UNIVERSITY SCHOOL OF MEDICINE
ATLANTA, GA

Trish M. Perl, MD, MSc, FIDSA
UT SOUTHWESTERN MEDICAL CENTER
DALLAS, TX

Susan J. Rehm, MD, FIDSA
CLEVELAND CLINIC
CLEVELAND, OH

Tina Q. Tan, MD, FIDSA
NORTHWESTERN UNIVERSITY FEINBERG SCHOOL
OF MEDICINE
CHICAGO, IL

Chief Executive Officer

Christopher D. Busky, CAE

IDS A Headquarters

1300 Wilson Boulevard
Suite 300
Arlington, VA 22209
TEL: (703) 299-0200
FAX: (703) 299-0204
EMAIL ADDRESS:
info@idsociety.org
WEBSITE:
www.idsociety.org

August 30, 2018

Haileyesus Getahun, MD, PhD, MPH

Coordinator and Head

UN Interagency Coordination Group on AMR Secretariat

Avenue Appia 20

1211 Geneva 27

Switzerland

Dear Dr. Getahun:

The Infectious Diseases Society of America (IDSA) greatly appreciates the work of the Interagency Coordination Group (IACG) on Antimicrobial Resistance (AMR) and the opportunity to help inform its efforts. IDSA represents over 11,000 physicians and scientists. Our members care for patients with infections caused by multidrug-resistant organisms; lead antimicrobial stewardship programs and infection prevention and control programs; conduct basic, translational and clinical research on AMR and on the development of new vaccines, diagnostics and therapeutics; and drive public health interventions to prevent, detect and track resistance.

IDSA strongly supports international efforts to advance comprehensive solutions to AMR, including stimulating research and development for urgently needed new antibiotics and diagnostics, implementing infection prevention and stewardship programs, and strengthening surveillance. IDSA has been sounding the alarm on AMR for well over a decade and has helped inform, advance and secure federal funding for the US National Action Plan on Combating Antibiotic Resistant Bacteria. We continue working to advance antibiotic research and development (R&D) incentives in the US Congress. IDSA is eager to assist the IACG, World Health Organization (WHO) or other global partners on any aspect of global AMR efforts. Below please find responses to questions posed by the IACG.

Optimize Use of Antimicrobials

What kind of support (other than financial) is needed to translate the existing guidance into implementable actions?

Individuals who are new to the field of antimicrobial stewardship would benefit greatly from expert support. IDSA recommends the creation of additional opportunities for individuals leading successful stewardship efforts to share their knowledge with other providers. IDSA would be delighted to partner in such an effort and can provide, through our membership, a variety of experts.

IDSA also recognizes that broader efforts to strengthen health systems overall are an important foundation to support the success of stewardship. For example, efforts to expand access to appropriate prescribers will be a critical component to efforts to end over-the-counter sales of antibiotics that are contributing significantly to inappropriate use and the development of resistance.

Inappropriate use of antibiotics in animal agriculture is a major driver of resistance. Messages to better explain the impact of antibiotic use in this setting on human health are very important to drive more responsible use policies.

Finally, IDSA calls for the development of clear targets for reducing inappropriate antibiotic use and reporting antibiotic use to measure progress against targets. Targets are needed in the animal and human health sectors as well as the environment. Caution should be taken to ensure that achieving targets does not impede appropriate access to antibiotics for individuals who need them, especially in resource-limited settings.

How can policy makers be assisted to further develop and implement infection prevention and control in human and animal health and plants and be convinced to invest now to mitigate the escalating and future costs and obtain benefits far beyond preventing AMR?

The WHO and others should develop and promote clear and compelling messages regarding the cost of inaction on infection prevention and control. This should include the generation of additional evidence on the economic cost of AMR for human and animal health and food supply in low- and middle-income countries. These types of economic-based arguments can be particularly convincing for policymakers and can help them better understand the value of investments in infection prevention and control. IDSA is also calling upon countries to commit to sustained investment to support infection prevention and control, including through the Global Health Security Agenda. In addition, better educating the public on AMR and on the individual consequences of antibiotic use will better position individuals to place pressure on policymakers to enact infection prevention and control and other AMR solutions.

What incentives or initiatives are needed for behaviour change towards responsible use in the health sector (hospitals, community health centres) and in the food and animal production sectors (animal and plant health professionals, food producers and manufacturers, consumers).

IDSA has primary expertise in human health. Within this sector, IDSA advocates for policies to require stewardship programs in all health care facilities (appropriately scaled) to provide prescribers with the education and tools necessary to understand and implement best practices with regard to antibiotic use and evidence-based communications tools for patient interactions to reduce inappropriate prescribing. We recommend expanded use of telemedicine technologies to facilitate the adoption of stewardship programs, particularly in settings lacking appropriate expertise. IDSA also strongly recommends increased development, availability and use of rapid diagnostic tests as an important tool in guiding optimal antibiotic use. We encourage more resources for research and development of new diagnostic tests, activities to educate providers on optimal diagnostic use, and efforts to ensure that all settings have access to rapid, point of care

tests. We also recognize the important role of public awareness campaigns about the individual and population risks of inappropriate antibiotic use.

What is needed to generate evidence-based data that link the misuse of antimicrobials and the development and spread of AMR via the environment? How can we use the available data to develop effective policy solutions influence policy makers?

IDSA believes increased funding should be made available for research on AMR in the environment and the link between the environment and human disease

What approaches are needed to ensure the industry and investors manufacture and market antimicrobials responsibly, and not stimulate overuse or contribute to environmental pollution?

IDSA is actively engaged with policymakers to develop and advance economic incentives that are de-linked from the sales and use of antibiotics to remove any financial urge to inappropriately market antibiotics. We also support policies that would require companies receiving substantial economic incentives for antibiotic R&D to adhere to stewardship principles. We believe that antibiotic R&D incentives and stewardship are equally essential pillars of efforts to combat AMR, and policies should reflect these intertwined goals.

Changing practices needs the support of the industry - how can we balance the availability of a public good such as effective antimicrobials, with a private industry perspective?

Efforts to promote the appropriate availability and stewardship of safe and effective antibiotics must be balanced with financial realities—namely, that most pharmaceutical companies have exited antibiotic R&D because it is risky, costly and provides very limited opportunity for return on investment. Broader policies to combat AMR must include as a central component new economic incentives that are de-linked from the sales and use of antibiotics. Such incentives would remove the financial pressure to inappropriately market antibiotics while providing the financial support necessary to generate a robust and renewable antibiotic pipeline.

What are the mechanisms to enhance the availability and utility of global resources for the end user (communities and individuals) to optimize or reduce the need for the use of antimicrobials and mitigate the unintentional exposure to the environment?

Preventing infections is an optimal way to reduce the need for antimicrobials. IDSA strongly supports efforts to scale up access to vaccines and invest in vaccine R&D for unmet needs. In some areas, investments in sanitation and clean water are required as well. Further, we advocate for the adoption of evidence-based infection prevention and control strategies in all healthcare settings.

To limit environmental exposure to antimicrobials, IDSA supports appropriate regulation regarding the handling of pharmaceutical waste resulting from antibiotic manufacturing. Stronger regulation is especially needed in low- and middle-income countries.

Meeting the Challenge of Antimicrobial Resistance: From Communication to Collective Action

How can we best measure and prioritize efforts that communicate AMR effectively, so that limited resources are used optimally?

Effective communications about AMR should be appropriately targeted to key audiences. For example, to measure the effectiveness of AMR messages that target policymakers, WHO should measure policy actions taken to address AMR. Communications that result in the allocation of increased government resources to address AMR, new policies to promote infection prevention or stewardship and new policies to stimulate antibiotic R&D could all be considered successful communications efforts. For messages targeting healthcare providers, WHO should measure antibiotic prescribing and infection rates. Communications that lead to a decrease in inappropriate prescribing or decreased infection rates could be considered successful. With regard to messages targeting the general public, WHO should measure antibiotic use and vaccination rates. Communications that lead to a decrease in inappropriate antibiotic use or an increase in vaccination rates could be considered successful.

What are the major barriers to changes in antimicrobial use and management among priority stakeholder groups and communications recommendations to tackle these?

Healthcare providers need communications tools to better understand and respond to patients' knowledge, beliefs, and outcome expectations about antimicrobial use. Patients' perceptions about the benefits of antimicrobial indication, use, and expected outcomes from antibiotics or alternative strategies need to be adequately addressed by the provider to solicit and sustain adherence as well as build trust. In addition, many providers would benefit from education on the appropriate use and interpretation of diagnostic tests to inform optimal antimicrobial use. Evidence has also demonstrated that regular feedback on prescribing patterns and local antibiotic resistance patterns positively impact prescribing behavior. Increased communications to deepen understanding in the general public regarding the individual and population risks associated with inappropriate antibiotic use will also be extremely important.

Finally, we must keep in mind that many of the barriers to change cannot be addressed by communications alone. For example, to address the inappropriate over-the-counter use of antibiotics, investments in health systems will be critically important to ensure that all individuals have access to appropriate health care providers.

What are appropriate and practical incentives for changes in practice? What lessons might be learned from other areas, from vaccination to WASH (water, sanitation and hygiene) campaigns, that could inform what the IACG might recommend?

In countries with sufficient infrastructure, requirements for stewardship programs and infection prevention and control programs are effective and appropriate for driving behavior change. Vaccine requirements in many countries have been successful in driving and maintaining very high childhood vaccination rates and eradicating or nearly eradicating several infectious diseases.

When those requirements have been weakened, vaccination rates have dropped and infectious diseases have resurfaced.

The success of programs such as PEPFAR in building trust in communities and achieving significantly improved health outcomes have demonstrated that robust, sustainable investments that partner international experts and local experts are a winning strategy. The WHO should consider opportunities to build upon existing infrastructure and human resources such as PEPFAR and similar efforts, to improve AMR communications and implement solutions. AMR is a cross-cutting issue that should be of interest to organizations focused on a wide variety of health care issues, including HIV and maternal and child health. Many of the organizations and programs working on these issues have gained the trust of the local communities and would be effective messengers and partners for AMR efforts.

What research agenda is needed to support efforts to communicate AMR? How might this communications research best be funded and coordinated?

IDSA recommends research to inform communications between healthcare providers and patients and family members, particularly in instances in which a patient or family member is requesting an antibiotic that would be inappropriate. Similarly, research to inform communications between antibiotic stewardship implementers and challenging prescribers would be very beneficial. Research to inform communications with the public at various levels of health literacy in a culturally informed context will also be very important.

What model approaches best mobilize key actors in tackling AMR while raising awareness? How might one best structure a multi-stakeholder platform for AMR communications and a community of practice linking these key communications focal points?

IDSA strongly urges the WHO to utilize existing organizations, including medical societies such as IDSA, to mobilize thousands of members and draw from existing expertise. The infectious diseases physicians and scientists in IDSA membership are committed to tackling AMR and well connected to health care providers in a variety of disciplines and settings. IDSA has already issued numerous reports and other communications to raise awareness about AMR, particularly in the US. IDSA's annual scientific meeting, IDWeek, is already a leading showcase of AMR science and a forum for thousands of infectious diseases physicians and scientists. IDSA would be delighted to explore opportunities for IDWeek to serve a greater role in AMR communications, particularly in coordination with WHO. We would welcome the opportunity to partner with WHO and others on broader AMR communications activities.

We also invite WHO and others to utilize the IDSA-convened Stakeholder Forum on Antimicrobial Resistance (S-FAR) as a conduit for communications to a wide array of stakeholders. S-FAR includes over 115 organizations representing health care providers, scientists, public health, industry, patients and advocates across human health and agricultural sectors. Through S-FAR, IDSA provides these partner organizations opportunities to engage with government and multi-lateral entities on AMR and mobilizes partner organizations for AMR advocacy.

Where and what would be the most strategic opportunities for investing in efforts that communicate AMR? How can the Tripartite agencies and other intergovernmental agencies be supported to carry out this work?

Many global AMR communications have been largely focused on human health. The 2017 World Antibiotics Awareness Week was a welcome step forward in communicating AMR messages related to animal health and the environment as well, and we encourage a continued One Health focus. We also encourage WHO and partners to investigate opportunities to utilize well-known individuals and popular personalities to increase public attention to AMR messaging.

How can we best scale promising strategies for changing individual behavior into collective action to effect AMR change? What groups might be enlisted in these efforts? What role does civil society, professional societies and industry trade associations among others constructively play in these efforts, and how might this be supported?

Professional societies play an essential role. IDSA is already driving a wide variety of efforts to effect AMR change and would welcome the opportunity to more effectively partner with multilateral organizations, other countries and additional global partners.

- **IDWeek:** IDSA's annual scientific meeting brings thousands of ID clinicians and scientists together and already features significant educational opportunities on AMR and stewardship. It would be an ideal venue for collaborative presentations, workshops, and other activities with WHO or other global partners.
- **S-FAR:** IDSA convenes the Stakeholder Forum on Antimicrobial Resistance (over 115 organizations) which is a conduit for information sharing, a forum for receiving feedback on policy proposals, and a vehicle to mobilize advocacy to increase government investment in AMR solutions and drive policies to combat AMR.
- **Expertise and knowledge sharing:** IDSA members possess expertise in many aspects of AMR, including leading stewardship and infection prevention and control programs in a variety of settings; conducting research on AMR, including clinical trials for new antibiotics, diagnostics and vaccines; caring for patients infected by multidrug-resistant organisms; and advocating for policymakers to advance AMR solutions. We would welcome more opportunities to share expertise with individuals across the globe as well as learn from our peers in other countries.

What opportunities are there for enabling effective monitoring for accountability towards effecting AMR change? What enabling conditions are critically important for such efforts, and how can we best ensure that these conditions are met?

It is important to measure rates of resistance and inappropriate antibiotic use in all sectors and all countries to evaluate progress in driving both down. This will require appropriate investment in the necessary surveillance infrastructure. Data should consider aggregate progress as well as

country-level progress, to allow for the identification of best practices in countries as well as countries in need of greater assistance.

It is equally essential to assess the antibiotic R&D landscape, including the overall pipeline, drugs in all stages of development for WHO priority pathogens, and the number of large and small companies engaged in antibiotic R&D. Regular monitoring on these fronts should help drive the implementation of antibiotic R&D incentives and evaluate their impact.

Once again, IDSA greatly appreciates the important work of the IACG and looks forward to opportunities to work collaboratively on global AMR solutions.

Sincerely,

A handwritten signature in black ink, appearing to read "Paul G. Auwaerter", with a stylized flourish at the end.

Paul G. Auwaerter, MD, MBA, FIDSA
President, IDSA



Response to IACG discussion paper “Reduce unintentional exposure and the need for antimicrobials, and optimize their use”

Thank you for your invitation to provide a response to the “*Reduce unintentional exposure and the need for antimicrobials, and optimize their use*” consultation document. On behalf of the Antimicrobial Resistance Centre at the London School of Hygiene and Tropical Medicine (<http://amr.lshtm.ac.uk/>), we enclose the following set of responses, collated from researchers from across our multidisciplinary Centre:

Antimicrobial Resistance Centre Contributors to this response document

Dr Clare Chandler, Associate Professor in Medical Anthropology, Faculty of Global Health and Development. Co-director of the Antimicrobial Resistance Centre.
Dr Richard Stabler, Associate Professor in Molecular Bacteriology, Faculty of Infectious and Tropical Diseases. Co-director of the Antimicrobial Resistance Centre.
Dr Heidi Hopkins, Associate Professor in Malaria and Diagnostics, Faculty of Infectious and Tropical Diseases.
Dr Gwen Knight, Assistant Professor in Mathematical Modelling, Faculty of Epidemiology and Population Health.
Dr Harparkash Kaur, Assistant Professor of Pharmacology, Faculty of Infectious and Tropical Diseases.
Dr Meenakshi Gautham, Research Fellow (Health Systems and Policy), Faculty of Public Health and Policy.
Dr Laurie Denyer Willis, Research Fellow (Medical Anthropology), Faculty of Global Health and Development.
Dr Justin Dixon, Research Fellow (Medical Anthropology), Faculty of Global Health and Development.
Ms Nichola Naylor, Health Economist, Faculty of Epidemiology and Population Health.
Ms Maddy Pearson, Research Assistant (Medical Anthropology), Faculty of Global Health and Development.
Mr Henry Lishi Li, PhD Candidate (Public Policy), Faculty of Public Health and Policy.
Ms Alice Tompson, PhD Student (Medical Anthropology), Faculty of Global Health and Development.

General responses

We were pleased to read this overview of optimizing the use of antimicrobials. This is a critical, and complex challenge. In particular, the focus in the report on the relationship between antimicrobial use and water and sanitation is welcome, as it has often been overlooked, and it is good to see the importance set on improving the evidence base on AMR in the environment. We have some specific areas for suggestions in relation to each of the questions posed for feedback. In addition, we have a number of general comments on the content and requests in the consultation:

- We felt that there was a mis-match between the key messages, the contents of the document and the requested feedback. For example, the document describes the lack of data on how to change prescribing practices and yet the summary suggests this is well known, in ‘a wealth of guidance’. We suggest that the document itself is revisited in order to extract key messages that are consistent with its contents. Moreover, there are issues arising from the document that are not addressed in the consultation requests – which seem to build on the topic into a different direction. Therefore, it was difficult to know how best to respond to the consultation – to the key messages, the briefing document or the requested feedback. Furthermore, the questions posed were challenging due to their broad remit and multiple clauses, which rendered them somewhat ambiguous.

- In response to the timing of the consultation, we suggest that similar future endeavours do not coincide with the summer holiday season, in order to maximise the number and quality of the responses the IAGC receives.
- We welcome the connection between hygiene and antibiotic use, however we believe that more consideration should be given to wider infrastructural issues. We need to look beyond the current focus of WASH and behavioural aspects of hygiene to address structural inequalities, for example regarding access to clean water in informal settlements.
- Although the ‘problem’ is acknowledged to be a social one, this societal level reliance on antimicrobials is often overlooked in the solutions proposed. Regarding animal use of antimicrobials, whilst section three recognises the lack of access to information or veterinarians, the current solution focuses on biosecurity. The response to the challenge of access is to increase the use of diagnostics but surely this needs to be accompanied by an increase in access to antimicrobials for those in need.
- We feel that the referencing and topic integration of the briefing document could be strengthened, especially given the large body of work already supported by the World Health Organisation, for example around post-childbirth prophylactic use of antibiotics.
- We note the current focus on healthcare facilities rather than the community. The model also requires individuals to act as consumers to demand changes with regards to antimicrobial stewardship and biosecurity.

Responses to open questions for stakeholders

1. What kind of support (other than financial) is needed to translate the existing guidance into implementable actions?

The briefing document begins by stating there is a wealth of guidance, however subsequently it states: *“little is known about the effectiveness of guidance”* (p.11). This mismatch illustrates a key knowledge gap: Ensuring guidance is based on – locally applicable – evidence can support implementation. Providing accessible summary tables of evidence and related guidance can help signpost local actors.

Information is needed about the impact of guidance on AMR, rather than surrogate outcomes such as ‘inappropriate’ prescribing as this will provide compelling evidence to act. However, this raises further questions, for example is clinically appropriate antimicrobial use the same as appropriate use for tackling AMR? What are the main drivers of AMR in a given setting?

The incentives for following guidance could be reflected upon. In some situations, restricted access to certain antimicrobials could be considered (rather than advising against their use).

Multi-stakeholder platforms have been successfully used at the top level. Similar partnerships could be considered at national and sub- national levels. This will require further research into how to bring about consensus and compromise between the needs, powers and vested interests of the various stakeholders, especially in LMIC settings where governments may lack the capacity to do this. Third parties like universities, research groups and NGOs could act as intermediaries and test novel strategies to get stakeholders to come together.

2. How can policy makers be assisted to further develop and implement infection prevention and control in human and animal health and plants and be convinced to invest now to mitigate the escalating and future costs and obtain benefits far beyond preventing AMR?

We felt this question was asking for an answer of longer term economic models that can provide more favourable estimates regarding the impact of implementing infection control. Given that this type of data is often not available, we observed that people are increasingly using conjectural forecasts instead of data-based models. It may be noted that the imperative to follow an 'investment' model for AMR can place certain aspects of the problem into the spotlight while obscuring others, such as issues relating to those with limited voice / capital.

An area for further consideration if attempting to convince stakeholders of the importance of IPC for AMR is to accompany/pre-empt country National Action Plans with research programmes that can demonstrate the local value of particular interventions. If a local clinical trial demonstrates infection protection control reduces mortality/ morbidity etc then that may be more convincing than evidence from elsewhere. Funding such research may be more cost-effective than relying on generic standardised studies that have been found to be less convincing locally.

The current top-down approach of developing blue-print national action plans means that on-the-ground issues may not be taken into consideration, and local stakeholders may have limited knowledge or relationship with the national action plans. Developing a bottom-up approach with local support and creative solutions for implementation is required, and this may take longer than the ambitious time frames for generating action plans on this relatively new area of policy.

There is an unwillingness (in countries as well as in WHO) to accept the reality of health system inadequacies including the heterogenous nature of the private sector in LMICs. DHS survey terminology continues with very broad public and private categorisations which do not help LMIC planners to understand the nature of health care seeking and utilisation (see for example here: <https://onlinelibrary.wiley.com/doi/epdf/10.1111/tmi.12471>). In LMICs, health systems strengthening and improved universal healthcare has to go hand in hand with AMR reduction. One of the first steps might be to revisit DHS survey terminology and get more accurate data on healthcare providers, including in 'informal' markets.

In order to mobilise political traction in addressing the issue of AMR in agriculture, more modelling is needed to provide citeable estimates of the problem of AMR in different intervention scenarios. In the first instance, having estimates of the potential longer-term, 'worst-case' scenario costs of AMR to the agricultural sector and wider economies can gain politicians' attention. As seen by the traction gained after the publication of the Jim O'Neill Review's AMR burden estimates, such estimates can galvanise international co-operation and national-level policy change¹. Currently, models that estimate the cost-benefit of reduced antibiotic usage on farms estimate a loss for farmers², therefore providing a financial disincentive for uptake, however these do not model forward into scenarios in which continued use of antibiotics makes antibiotics ineffective, therefore leaving

¹ O'Neill, J. "AMR Review Paper–Tackling a crisis for the health and wealth of nations." *AMR Review Paper* (2014).

² Lhermie, G., Tauer, L. W., & Gröhn, Y. T. (2018). The farm cost of decreasing antimicrobial use in dairy production. *PloS one*, 13(3), e0194832.

farmers with no treatment for sick animals and no benefit from giving antibiotics prophylactically/as growth-promoters.

Additionally, more local level data analyses across the One Health economy are needed to provide robust estimates of the current and potential future burden from national or regional perspectives, such estimates can then be used by policy makers when presenting the case for investment, where this is deemed appropriate.

3. What incentives or initiatives are needed for behaviour change towards responsible use in the health sector (hospitals, community health centres) and in the food and animal production sectors (animal and plant health professionals, food producers and manufacturers, consumers)?

We note the problems with defining and communicating ‘responsible use’ of antibiotics across sectors, and the conflicts this presents. Given that *any* antimicrobial use can contribute to resistance, as stated in the brief, perhaps this question should be orientated around reducing reliance on antimicrobials in these settings. To answer this, another question might be posed as ‘what would it take to run a hospital, health centre, food production unit without recourse to antimicrobials?’ and this would then allow us to understand what changes would be required, and to recognise that these need to go beyond behaviour.

We note the use of benchmarking schemes - such as the UK’s fingertips programme – to provide facility, departmental and individual feedback on their antimicrobial use. This could be carried out in conjunction with support to healthcare professionals in case of any negative (legal) consequences of withholding antimicrobials (which was effective in Australia – Broom et al).

Rather than rejecting patients who do not ‘qualify’ for antimicrobials, consideration could be given for alternative means by which to provide care (for example longer consultations in which to explore their care needs, to provide alternative forms of legitimacy for illness, or to recommend other solutions such as resting). We note that this may need support beyond the moment of consultation – that it would require rearrangements of the ways care is organised in time, and in relation to medicines which are currently often the object of care.

Caution may be needed when raising public awareness about AMR when there is a lack of consensus regarding what they should do about it. Blanket awareness raising can cause fear and unintended behaviours, such as increasing use of next line treatments for fear of resistance.

4. What is needed to generate evidence-based data that link the misuse of antimicrobials and the development and spread of AMR via the environment? How can we use the available data to develop effective policy solutions influence policy makers?

Local surveillance platforms need to be set up in a decentralised manner, and there needs to be increased sub-district capacity for monitoring AMR locally, and in the community setting. This will enable local health authorities to monitor and address AMR independently. It is difficult to motivate stakeholders with only very broad, country level and typically hospital-based AMR data. Training such be given to support the standardisation of platforms and pooling of data.

Consideration such be given as to whether to adopt a flexible one-health approach when appropriate focussing on the identification of tracer data such as *E. Coli* rather than a monolithic surveillance model that considers all strains of resistance in all settings.

Whilst complete integration of surveillance systems across humans and animals may not be feasible, or indeed ideal (due to differences in infections or antibiotics of interest), identifying and then utilising data for infections that are important across these sectors is key. For example, utilising human and animal AMR and infection data relating antibiotic resistant and susceptible *Escherichia coli* infections can help us understand the national and global epidemiology of such infections across human populations and agriculture. Additionally, data on the outcomes of these infections in relation to animals and humans would be useful. Such data could be analysed and combined with the epidemiological data, to model the impact of potential interventions on health and economic outcomes, therefore providing evidence to policy makers that can help in resource allocation decisions.

5. What approaches are needed to ensure the industry and investors manufacture and market antimicrobials responsibly, and not stimulate overuse or contribute to environmental pollution?

Benchmarking has been used to publicly name and commend/shame manufacturers. This could go further in terms of health services not buying from identified environmental polluters for example. This would be especially powerful if environmental pollution levels could be linked to local levels of AMR.

The role of medical representatives providing information in the form of marketing should be closely examined with direct to prescriber/consumer marketing of antibiotics banned. Health authorities should take responsibility for ensuring information is provided rather than relying on industry to provide this information.

Regarding a de-linkage model, an intermediary such as the NHS could decide how to pay for the medicines rather than having the consumer shouldering the cost. This would encourage a ‘push-market’.

6. Changing practices needs the support of the industry - how can we balance the availability of a public good such as effective antimicrobials, with a private industry perspective?

There are multiple private industry perspectives from both the supply (pharmaceutical companies, distributors and retailers) and demand sides (healthcare settings, food production/farming industries, individuals), but none of them are likely to automatically align with the requirements for delivering and sustaining the “public good” that is effective antimicrobials. There has been numerous research detailing stewardship measures that mainly target behaviours and use patterns of organisations and individuals through regulations, and indeed progress has been made in putting these solutions to work through national actions plans especially since AMR became recognised as an imminent problem in recent years. However, the severe lack of initiatives to ensure access (evidenced by the AMR Benchmark 2018 from the access to medicines foundation), the continue exodus of major pharmaceutical companies to pull out of antibiotic R&D despite the introduction of myriad financial initiatives to fix market failure (most recently exemplified by Novartis) signal that the notion of “balancing the availability of a public good...with a private industry perspective” is no longer sufficient. If effective antimicrobials are to be seen as a “public good” (which, in an economic

sense, they're not: antimicrobials are not necessary non-rivalrous and can certainly be non-excludable), then the public sector ought to take greater control and ownership of this vital class of pharmaceutical products by actively pursuing and directing paradigm shifting reforms that fundamentally address systemic drivers of antimicrobial use (such as consumer culture) or even the governing rules of neoliberal economics (for example, greater representation of stakeholder interest in corporate governance). Even an alternative response that recognises the fact that antimicrobials are not a "public good" doesn't involve simply accepting the rule of market economics and the private industry perspective, which will only duly respond to surging demand and rising price signals when effective antimicrobials finally run dry. It is important to recognise that public actors and policies are *part* of the market rather than outside it; they, along with private actors, co-shape and co-create markets. Stronger policy interventions that can actively tilt the current antibiotic market towards sustainability and public health goals seem justified now more than ever.

7. What are the mechanisms to enhance the availability and utility of global resources for the end user (communities and individuals) to optimize or reduce the need for the use of antimicrobials and mitigate the unintentional exposure to the environment?

This raises questions about which 'public' are we (not) talking about when discussing AMR.

Consideration should be given to bridging top-down and bottom-up responses, empowering people to make a 'good' choice about what action to take when ill and what to demand in terms of quality of medicines.

In terms of the reduction in the need for the use of antimicrobials – this is a key question and one that we propose needs to be addressed on the societal level – antimicrobials are relied upon in many ways to enable industrial processes, productive labour forces, not to mention enabling uncontained health care processes such as chemotherapy and surgery. Antimicrobials have become a quick fix for poor hygiene, fractured infrastructures, productivity. Mechanisms to reduce the need for these medicines are crucial in addressing AMR and need to consider the problems that antimicrobials have become a solution to in local and transnational economies, and social structures.

MSF Access Campaign



Rue de Lausanne, 78
CP 116 1211 Geneva 2,
Tel: +41 (0) 22 849 84 05
Fax: +41 (0) 22 849 84 04

access@msf.org
www.msfacecess.org

August 31st, 2018

Response by MSF Access Campaign to the consultation on IACG discussion paper, **‘Future Global Governance for Antimicrobial Resistance’**

MSF Access Campaign welcomes the opportunity to respond to the IACG consultation on future global governance for antimicrobial resistance (AMR). We note that the discussion paper for consultation is ‘based on a small meeting with some IACG members and external participants from the public, private and philanthropic sector and further discussions within the IACG’ and has been developed in order to facilitate wider discussion to inform the IACG recommendations on practical future governance model(s) to the UN Secretary General by Summer 2019.

Our comments focus on the following:

1. The importance of accountability and transparency in global governance for AMR
2. The appropriate treatment of private commercial interests in global governance
3. Minimum requirements for sustainable and successful governance on AMR post-2019
4. The insufficiency of self-regulation

The importance of transparency and accountability in global governance for AMR

The IACG discussion paper sets out ‘ten requirements for effective AMR governance mechanisms’ and presents a proposed global governance structure for AMR. However, these ten requirements do not give sufficient weight to the principles of accountability and transparency in the proposed global governance regime.

Transparency is only mentioned once in the paper, and this is in relation to the metrics and indicators for monitoring progress on AMR. Transparency is a fundamental principle of effective global governance and must be built into proposed structures as a prerequisite for both accountability and legitimacy. We urge the IACG to put a greater emphasis on ensuring transparency within the future global governance model.

The importance of accountability in any global agreement is stressed under requirement 4, 'Secure binding global commitment for action, with accountability clearly assigned at every level'. However, this accountability must also be built into the process leading to the development and formalization of an agreement. It is not acceptable to delegate the responsibility for building an enduring global agreement to a 'group of no more than 10 heads of state and senior directors from other sectors', as proposed in the discussion paper. Any global agreement must come from a Member State led process, as States have a responsibility and legitimacy to account to their citizens.

The appropriate treatment of private commercial interests in global governance

Annex 2, the background report, 'Global Governance of Antimicrobial Resistance – a One Health Approach'¹ makes it clear that including industry in the formulation of regulatory standards is a bad idea,

'The experience of global regulation is that, in the absence of a powerful commercial incentive to accept regulation... the inclusion of industry in formulating regulatory standards is likely to lead to a steady dilution through each phase of the regulatory process. Specifically, once regulation passes from general agreement (when there is a public spotlight on agreements reached) to the less-newsworthy detailed regulation stage, and then to implementation, and finally to enforcement, the risks of dilution become stronger and stronger.'²

This is a critically important finding that has not been adequately dealt with in the discussion paper. Far from distinguishing the roles and responsibilities of the different private, public and civil society stakeholders, the paper simply states that an effective AMR governance mechanism should bring all AMR stakeholders to the table, listing Member States, industry/private sector, professional groups, regulators and civil society. MSF agrees that processes for engaging all relevant actors must be created, but believes it is essential to draw red lines between the roles and responsibilities of different actors. As stated in the background paper³, the regulatory system needs to be protected from private sector lobbying (e.g. of the agricultural and pharmaceutical industries).

¹ Background report to inform IACG discussions on Global Governance of AMR – a One Health Approach, 'Global Governance of Antimicrobial Resistance – a One Health Approach' by Devi Sridhar and Ngaire Woods with the assistance of Conor Rochford and Zia Saleh. Available as annex 2 to the IACG consultation paper

² P.52, Background report to inform IACG discussions on Global Governance of AMR – a One Health Approach, 'Global Governance of Antimicrobial Resistance – a One Health Approach' by Devi Sridhar and Ngaire Woods with the assistance of Conor Rochford and Zia Saleh. Available as annex 2 to the IACG consultation paper

³ P. 19-20, *ibid*.

Further it is unclear whether the discussion paper is proposing to include private sector directors in the 'High Level Commission' responsible for building an enduring agreement on AMR. The phrase used is 'no more than 10 heads of state and senior directors from other sectors'. Not only is the proposal for such a small Commission inappropriate for this task from an accountability and legitimacy perspective, but the inclusion of private sector directors here would be wholly inappropriate.

In the table of 'Specific sector needs' presented on page 5 of the consultation paper it states, 'finding mechanisms to address the restrictions imposed by the WHO Framework of engagement with non-State actors (FENSA)'. No further explanation of this remark is given, but it poses a lot of questions as to what aspects of FENSA are considered problematic.

FENSA was adopted by the World Health Assembly in 2016 with 'the full political commitment of all Member States'. It provides a general framework outlining the due diligence, risk assessment and risk management processes necessary for engagement with non-State actors, as well as specific policies for engagement with nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions. FENSA is guided by 8 overarching principles. Most notably, any engagement must: 'protect WHO from any undue influence, in particular on the processes in setting and applying policies, norms and standards'; 'not compromise WHO's integrity, independence, credibility and reputation'; and 'be effectively managed, including by, where possible avoiding conflict of interest and other forms of risk to WHO'.

FENSA, rather than a barrier to AMR global governance, provides an important framework that has been negotiated and agreed to by WHO Member States and should be followed in the construction of an AMR global governance structure. There is a clear conflict of interest between the economic, commercial and financial interests of private sector pharmaceutical and agricultural companies and the mandate of an AMR global governance structure. In line with FENSA and for the benefit and interest of global public health, therefore, private sector entities should be excluded from negotiations and should not play a part in any decision-making processes of the proposed governance structure. This is essential to ensure the independence, objectivity and impartiality of the global governance structure in setting appropriate targets and developing effective policies, norms and standards.

Minimum requirements for sustainable and successful governance on AMR post-2019

The AMR response has to be global but also flexible and progressively adapted to national realities and contexts. Not all health systems are equally prepared to respond, a key priority has to be to strengthen LMICs' health systems, including laboratory systems strengthening and to support the retention and training

of health workers who form the cornerstone of any AMR response. For MSF it is essential that the needs of developing countries and particularly neglected people are not left behind in future global governance. A transparent, accountable governance structure, led by and inclusive of all member states that provides for civil society engagement, oversight and consultation is the best means to provide this.

At the national level, it is important that AMR mitigation is built into existing programmes and that monitoring and evaluation requirements are streamlined into existing reporting processes. In resource-constrained countries where MSF operates this is particularly the case. Linkages should be made with existing global initiatives, including the Universal Health Coverage (UHC) agenda and SDG implementation reviews of progress to avoid duplication and conflation of reporting processes and implementation work itself. Furthermore, the inclusive approach is necessary in assuring greater buy-in from actors previously not involved in AMR work through existing frameworks and initiatives beyond the WHO's Global Action Plan.

AMR-sensitive interventions such as water, sanitation and hygiene standards improvement, enforcement of infection prevention and control and vaccination are vital to initiate and sustainably establish AMR-specific programmes, such as laboratory and surveillance systems and standard treatment guidelines to inform clinical stewardship measures. Looking for and integrating into existing national level efforts in this regard will provide a solid foundation for the AMR response.

The insufficiency of industry self-regulation

While the discussion paper does not directly propose a corporate voluntary code of conduct on AMR, it is discussed as an option in annex 2. MSF takes this opportunity to highlight the insufficiency of this approach and to reiterate the point made in the background paper, that 'for self-regulation to be effective, it typically needs to exist in the shadow of robust regulatory conditions, such as reporting requirements which are not only enforced, but in which the quality and veracity of reporting is constantly being checked.'⁴ This is particularly relevant given the background paper also acknowledges that the private sector has 'little short-term incentive to alter behaviour or accept higher regulatory standards.'⁵ Self-regulation is no substitute for binding regulations.

⁴ P.49, Background report to inform IACG discussions on Global Governance of AMR – a One Health Approach, 'Global Governance of Antimicrobial Resistance – a One Health Approach' by Devi Sridhar and Ngaire Woods with the assistance of Conor Rochford and Zia Saleh. Available as annex 2 to the IACG consultation paper

⁵ P.18. *ibid.*



August 31st, 2018

Response by the MSF Access Campaign to the consultation on IACG Discussion Paper **‘Reduce unintentional exposure and the need for antimicrobials, and optimize their use’**

The MSF Access Campaign welcomes the opportunity to contribute to this critically-important dialogue on antimicrobial stewardship. While commending the efforts of the IACG Working Group in producing this Discussion Paper, in the section below, we directly address a number of ambiguities and omissions in the document that we request be addressed in its subsequent revisions.

- i) **Quote:** *‘Good guidance is available: There is a wealth of good, relevant guidance that, if put into practice, would lead to a significant, rapid reduction in the inappropriate use of antimicrobials in humans, animals and plants.’* (page 1)

Response: With respect to antimicrobial use in human populations this is only partly true. There are some forms of ‘guidance’ that have the potential to lead to a reduction in such inappropriate use – particularly training for health professionals in distinguishing between aetiologies and severities of infectious illnesses, along with evidence-based clinical guidelines for antimicrobial prescriptions – but the availability of such tools in remote populations and low-resource settings is typically very limited. That, combined with the limited range of antimicrobial medicines available in such settings, means that a broad-spectrum, empirical approach to therapy is often required that relies on selection from a narrow range of agents. We must also acknowledge these constraints and develop ‘guidance’ tools particular to healthcare in severely resource-limited settings.

As the degree of stewardship capacities vary significantly between and within countries, recommended measures to optimize use must reflect on the abovementioned limitations and adopt tools relevant for each of the **tiers of the stewardship** system.

- ii) **Quote:** *'Infection prevention and control measures, supported by adequate water and sanitation infrastructure, will make a difference: Significant WASH improvements and effective strategies to change practices are essential, combined with the application of biosecurity measures.'*

Response: This quote, and the sections in the document devoted to the topic of infection prevention and control (IPC), focus almost entirely on WASH and neglect to address the critically-important role of vaccination, both in human and animal populations (acknowledging that the latter is outside MSF's particular expertise). Given the strong and growing evidence for vaccines as a safe, sustainable and cost-effective means of preventing infections, there should be more clear recommendations regarding vaccines in the paper.

- iii) **Quote:** *'Harmonized approaches to regulation are essential: To ensure effective, science-based regulation on AMR, and to avoid trade friction elicited by different regulatory approaches to AMR, countries must be encouraged to take a harmonized approach based on international standards.'*

Response: The relevant sections of the current draft of the paper focus on 'unnecessary or suboptimal use of antibiotics' as seen from the perspective of informal markets, and also the problem of substandard or falsified medicine. Absent from the discussion regarding legal and regulatory systems is the need to address the phenomenon of irresponsible manufacture and marketing of antimicrobial products, whereby pharmaceutical companies make spurious or inappropriate claims regarding the efficacy and clinical indications for their products and/or manufacture antimicrobials in combinations that are unnecessary, potentially harmful and contribute significantly as drivers of AMR. The nature and magnitude of this on prescriber, supplier and patient behaviours is poorly understood and will need to be a key area of study and work in the regulatory domain.

Some specific responses to the ‘**Open questions for stakeholders**’ posed on the last page of the Discussion Paper are as follows:

- *What kind of support (other than financial) is needed to translate the existing guidance into implementable actions?*
 - Large-scale technical support will be required to develop locally-relevant, epidemiologically-informed clinical guidelines for appropriate antibiotic use.
 - Technical assistance in addressing shortfalls in the legal and regulatory capacity to develop and enforce regulations regarding appropriate antibiotic manufacture, supply, distribution and consumption in many countries.
 - Costing analyses of interventions to mitigate AMR on the various levels, informed by pilot case studies can assist countries in prioritizing and tailoring the interventions based on their varying starting point and the expected outcomes.
 - Similarly, more case studies on successful interventions on AMR from resource-limited settings are needed. This information will be useful in informing local decision-makers on the most effective measures.

- *How can policy makers be assisted to further develop and implement infection prevention and control in human and animal health and plants and be convinced to invest now to mitigate the escalating and future costs and obtain benefits far beyond preventing AMR?*
 - Every effort should be made to identify and adapt existing tools for use in suitable settings, rather than investing time, energy and financial resources into unnecessarily developing new materials.
 - Mainstreaming interventions on AMR across multiple, currently siloed programmatic areas while looking for specific AMR results is recommended. This can amplify the activities' outreach and increase buy-in among healthcare professionals as well.
 - Surveillance data are essential for understanding the magnitude of AMR and therefore convincing policy makers of the need to invest upfront. Further, such surveillance data should be kept updated and provide information that is ‘actionable’ for practitioners in terms of making visible particular local dynamics and trends of resistance that can be taken into account in prescribing practices.

- *What incentives or initiatives are needed for behaviour change towards responsible use in the health sector (hospitals, community health centres) and in the food and animal production sectors (animal and plant health professionals, food producers and manufacturers, consumers).*
 - In hospitals and health facilities, the focus should be on education and training of health professionals to better understand the role of antimicrobials and inform their patients appropriately
 - Engaging and educating community leaders is a key lever in successfully informing the public regarding the optimal use of antimicrobials
 - More research is needed to understand reasons behind the insufficient deployment of economic and social incentives to achieve behavior change on various levels of healthcare system.

- *What approaches are needed to ensure the industry and investors manufacture and market antimicrobials responsibly, and not stimulate overuse or contribute to environmental pollution?*
 - This touches on the point raised above about irresponsible, unethical and/or dangerous marketing practices and links to the need to **regulate** against such harmful practices on the part of pharmaceutical manufacturers.

- *Changing practices needs the support of the industry - how can we balance the availability of a public good such as effective antimicrobials, with a private industry perspective?*
 - There is a clear need for binding regulations to be agreed at a global level in order to both guide the actions of private industry in a manner that optimises public health objectives; and sets a level playing field for these actors.
 - Regulations should be agreed at the supra-national level, but since binding regulations are the sole responsibility of governments, enforcement will need to take place at the national level. Governments will require mechanisms to hold each other to account in this regard.
 - Given the significant conflicts of interest that emerge from the private sector's involvement in the antibiotic lifecycle - from manufacturing sites to the bedside of a patient, it is inappropriate to include private industry in the formulation of regulatory standards or in overseeing their implementation and enforcement.

- Research has exposed unethical practices which both directly and indirectly drive the emergence of resistance¹. However, more understanding is needed in their scope, particularly in resource-poor settings where health system limitations allows for unregulated, third-party involvement.
- *What are the mechanisms to enhance the availability and utility of global resources for the end user (communities and individuals) to optimize or reduce the need for the use of antimicrobials and mitigate the unintentional exposure to the environment?*
 - Reduce the price of vaccines and scale up their use: In addition to the essential tools required to diagnose infections and treat them appropriately, a further key to reducing antibiotic resistance is to prevent infections in the first place. Increasing affordable access to vaccines should be a high priority within the global AMR response. Vaccine coverage remains unacceptably low in many countries where MSF works despite the overwhelming evidence supporting vaccination as an effective, low-cost measure to reduce the burden of both infectious diseases and AMR at every level². For example, it has been estimated that introduction of Haemophilus influenzae type b (Hib) conjugate vaccine and pneumococcal conjugate vaccine (PCV) to 75 developing world countries could reduce antibiotic use for these diseases by 47% and avert 11.4 million days of antibiotic use in children younger than 5 years old each year³. Other vaccines for diarrhoeal and respiratory infections, in particular, have similar potential.
 - Currently, vaccination coverage is unacceptably low in many countries where MSF works. PCV, to take one example, remains unaffordable for a number of LMICs. By May 2018, globally 53 countries (27%) had not introduced a PCV vaccine in their national immunisation programme⁴. Of these 53 countries only 7 are Gavi-eligible countries⁵, which illustrates a trend seen for years whereby low-income countries are introducing new vaccines at a faster pace than middle-income countries (MICs) due to the availability of international donor financial support. The lowest price of ~USD 10 per child is available to those countries that are subsidised by Gavi, the Vaccine Alliance and, since 2017, to humanitarian organizations through the Humanitarian Mechanism, a mechanism for accessing affordable and timely supply of vaccines for use in humanitarian emergencies. Even some Gavi-supported countries are not scaling up PCV coverage

¹ WHO/ Health Action International Collaborative Project, 'Understanding and Responding to Pharmaceutical Promotion, A Practical Guide', First Edition working draft for Pilot Field Testing, <http://haiweb.org/wp-content/uploads/2015/05/Pharma-Promotion-Guide-English.pdf> Accessed 30th August 2018

² Kathrin U Jansen & Annaliesa S Anderson (2018): The role of vaccines in fighting antimicrobial resistance (AMR), Human Vaccines & Immunotherapeutics, DOI: 10.1080/21645515.2018.1476814

³ Laxminarayan R, Matsoso P, Pant S, Brower C, Røttingen JA, Klugman K, Davies S. 2016. Access to effective antimicrobials: a worldwide challenge. Lancet 387:168 175.doi:10.1016/S0140-6736(15)00474-2

⁴ WHO Data, statistics and graphics, http://www.who.int/immunization/monitoring_surveillance/data/en/ Accessed 5th July 2018

⁵ IVAC's digital platforms contain downloadable vaccine introduction maps : <http://view-hub.org/viz/> Accessed 5th July 2018

in their immunisation programmes for fear that they won't be able to sustain an affordable supply once they transition out of Gavi funding and have to pay much higher prices. Global funds such as Gavi, the Vaccine Alliance have been set up by donor governments to support the role out and uptake of much needed medical tools such as vaccines. However, in recent years these funds have insisted on 'transitioning' or 'graduating' middle-income countries out of eligibility for support. As such the usefulness of these funds to address the access issues of a wider range of countries is diminished. The IACG should recommend that any mechanism to expand access to AMR-related health technologies, including vaccines, be global in scope. This could start with revisiting and reversing the current trend towards restricting support for LMICs through 'graduation' and 'transition'.

- Moreover, governments must be supported to address situations of monopolies and high prices where these are barriers to access for needed AMR technologies- drugs, diagnostics and vaccines. This involves avoiding the granting of poor quality patents as well as making use of compulsory licensing to overcome unaffordable prices of monopoly products. Given the unaffordable prices of certain important medical tools that have been shown to reduce the need for the use of antimicrobials, this should be a priority for the IACG.
- If unchecked, **antibiotic shortages** can endanger availability of critically-important antibiotics on a global scale. Addressing issues influencing sustainability of antibiotic supply chain, including lack of producers, extremely centralized production systems, and the need to attract generic manufacturers to produce antibiotics, is central to comprehensive solutions.
- Pooled procurement, as specifically modelled by the Global Drug Facility (GDF), should be explored as a key mechanism for ensuring both lower prices for antibiotics and improved stewardship. The GDF represents a large portion of the market for TB drugs and diagnostics, and uses this to negotiate prices with companies based on larger volumes. GDF's international tenders allow both generic and innovator companies to compete in supplying quality-assured TB health products. It rejects tiered pricing; encourages suppliers to enter into markets; provides forecasting to suppliers as well as providing governments with forecasting assistance and orders (which is important given different shelf lives). It anticipates and addresses global supply issues and provides advice to countries on switching to optimal from sub-optimal formulations. In the area of diagnostic tools, GDF has been able to negotiate improved service and maintenance terms from companies.
- Data generation is essential to diagnose the contours of the problem of availability. **Need to measure access** to antimicrobials - which is a largely unexplored area particularly in settings where MSF operates - is therefore key. Efforts to collect data on consumption should be

complemented with measuring access to first and second-line antibiotics. Similarly, there is a critical need to scale up the body of evidence on access to antibiotics on a country level, including via the use of assessment tools to measure access and develop country case studies and making this data publicly available through publication and submission to global repositories.

World Medical Association & International Federation for Medical Students Associations

WHO AMR Interagency Coordination Group

Introduction

The World Medical Association (WMA) is an organization which represents 9 million physicians from over 110 countries. The WMA has engaged on the AMR agenda and the implementation of the Global Action Plan for the last several years, and we are looking forward to continue our contributions. WMA representatives have participated in various expert groups namely on Communications and Behavior Change, but also on the competencies for the education of Healthcare Workers on AMR. We have collaborated with the IFMSA to generate the comments to the documents that you can find below.

The International Federation of Medical Students' Associations (IFMSA) is a nonpartisan and nonprofit organization recognized as one of the oldest and largest student run organizations in the world. IFMSA has a broad representation of 135 member organizations from 125 countries across the continents of the world, representing a total of 1.3 million medical students. IFMSA has AMR as one of the top priorities of the Federation and is a committed member in the fight against AMR. Recently, IFMSA launched Innovate4AMR, an online innovation competition aiming to engage students and youth from all fields to unite against AMR.

Optimize Use of Antimicrobials

What kind of support (other than financial) is needed to translate the existing guidance into implementable actions?

- Health systems strengthening to ensure access to care, adequate diagnostics for early diagnosis of infections and qualified prescribers.
- Platforms for exchange of expertise and best practices for stewardship implementation
- Generation of locally relevant guidelines for prescribers to follow and establishment of targets for reduction in antibiotic consumption in all sectors, keeping in mind that access should not be jeopardized

How can policy makers be assisted to further develop and implement infection prevention and control in human and animal health and plants and be convinced to invest now to mitigate the escalating and future costs and obtain benefits far beyond preventing AMR?

- Friendly messaging on the cost of AMR both financial and human life, and the link between infection prevention practices and the reduction in AMR, and subsequently costs
- Make the cost-effectiveness case for IPC, which is currently restricted to the scientific literature, available in an easy to understand fashion to policy makers, and ensure that such studies exist for LMICs as well, where the highest need for sustainable investments in IPC is.

What incentives or initiatives are needed for behaviour change towards responsible use in the health sector (hospitals, community health centres) and in the food and animal production sectors (animal and plant health professionals, food producers and manufacturers, consumers).

- Health sector:
 - Establishment and investment in stewardship programs for hospitals and clinics
 - Increase public awareness about the risks of inappropriate antibiotic use
 - Equip care teams and prescribers with the knowledge and tools to commit to appropriate prescribing
 - Increased availability and use of rapid diagnostics
- Animal and agriculture sector
 - Increase the knowledge base of veterinarians on the risks of misuse of antibiotics in animals
 - Clear targets for antibiotic use and a mandatory reporting mechanism
 - Sustainable farming practices which would decrease the need for antibiotic use for disease prevention
 - Publicize success stories in farming and productivity without antibiotic use

What is needed to generate evidence-based data that link the misuse of antimicrobials and the development and spread of AMR via the environment? How can we use the available data to develop effective policy solutions influence policy makers?

- Increase funding availability for environmental AMR and to investigate the link between the environment and human disease

What approaches are needed to ensure the industry and investors manufacture and market antimicrobials responsibly, and not stimulate overuse or contribute to environmental pollution?

- Provide economic incentives that are de-linked from the sales and discourage inappropriate promotion of antibiotics
- Require companies receiving economic incentives for antibiotic R&D to commit to stewardship with a clear action plan prior to the reception of the funds

Changing practices needs the support of the industry - how can we balance the availability of a public good such as effective antimicrobials, with a private industry perspective?

- Provide economic incentives that are de-linked from the sales and use of antibiotics and providing the financial support necessary to generate a robust and renewable antibiotic pipeline that targets priority pathogens according to the WHO priority pathogen list

What are the mechanisms to enhance the availability and utility of global resources for the end user (communities and individuals) to optimize or reduce the need for the use of antimicrobials and mitigate the unintentional exposure to the environment?

- Increased investment in water, sanitation and hygiene, and in infection control practices in all healthcare settings.
- Regulate handling of pharmaceutical waste in particular those resulting from antibiotic manufacturing especially in LMICs
- Availability and affordability of rapid, point of care diagnostics
- Engage healthcare professionals and healthcare students at all levels to support the AMR agenda and stewardship practices locally

Meeting the Challenge of Antimicrobial Resistance: From Communication to Collective Action

How can we best measure and prioritize efforts that communicate AMR effectively, so that limited resources are used optimally?

- For healthcare professionals, measure antibiotic use (once a unified measurement for antibiotic use is agreed upon) and infection rates as proxies for successful messaging and compliance with IPC practices in selected target countries.
- For messages targeting veterinary professionals and farmers, measure antibiotic use as a proxy for effective messaging in selected target countries.
- Can also consider surveying public knowledge once again particularly on the aspect of antibiotic use in the animal and agricultural sector, building on the survey done in human health.

What are the major barriers to changes in antimicrobial use and management among priority stakeholder groups and communications recommendations to tackle these?

- Many issues cannot be tackled by communications alone, including access to a qualified healthcare professionals and healthcare facilities, pushing people to seek advice and antibiotics from shops and over the counter.
- The AMR language is very difficult for the general public and sometimes even for certain healthcare cadres. Language should be simplified and spread in a culturally competent way, and at various levels of health literacy, building on the innovative ways to educate the public about HIV.
- In certain healthcare settings, antibiotics may be the only available tool to treat severely ill patients, so healthcare system strengthening with the availability of diagnostic tools are crucial to overcome barriers to antibiotic overuse.

What research agenda is needed to support efforts to communicate AMR? How might this communications research best be funded and coordinated?

- Research to inform communication about AMR with professionals in the animal, agricultural and environmental sectors
- Research to inform communication between patients/public and prescribers around AMR
- Research to inform communications with the public at various levels of health literacy in a culturally informed context.

What model approaches best mobilize key actors in tackling AMR while raising awareness? How might one best structure a multi-stakeholder platform for AMR communications and a community of practice linking these key communications focal points?

- Utilize professional groups including student groups such as the WMA, IFMSA, and others, to bring in their expertise to existing platform, and facilitate collaborations between interested parties.
- Increase the number of communities of practice available for healthcare and animal health professionals to exchange knowledge and expertise, drawing from the experience of the existing community of practice for National Action Plans.

Where and what would be the most strategic opportunities for investing in efforts that communicate AMR? How can the Tripartite agencies and other intergovernmental agencies be supported to carry out this work?

- AMR communications has been very restricted to human health for the most part with the exception of the last WAAW. Investment in communications about AMR should be an equal priority to OIE and FAO, as it is to WHO, to increase buy in and the momentum around AMR, which is desperately needed in these organizations. Opportunities to bring familiar popular faces for public AMR messaging across sectors should be investigated.
- Again, professional organizations, student bodies, potentially consumer and patient organizations can be used to spread the message to a wider audience.
- Most healthcare undergraduate curricula do not provide enough formal education on AMR, leaving future healthcare providers with insufficient skills to tackle AMR during their professional careers. Highlighting the importance of AMR in curricula would translate into a whole generation of future AMR champions

How can we best scale promising strategies for changing individual behavior into collective action to effect AMR change? What groups might be enlisted in these efforts? What role does civil society, professional societies and industry trade associations among others constructively play in these efforts, and how might this be supported?

- Healthcare Professionals' groups and healthcare student groups play a crucial role in the AMR agenda. The WMA and the IFMSA, have committed to fight AMR and to use their wide international network to spread awareness and to engage national medical and medical students' associations, and have contributed significantly to various aspects of the GAP implementation. They also have knowledge and expertise that they can share with other organizations and groups. It is essential to keep them engaged moving forward, and to try to replicate the same model with professional groups in the animal and agricultural sector.

What opportunities are there for enabling effective monitoring for accountability towards effecting AMR change? What enabling conditions are critically important for such efforts, and how can we best ensure that these conditions are met?

- Surveillance is essential and requires investment in an infrastructure to allow for informative data. Resistance rates should be used as proxy measurement of adequate IPC and appropriate antibiotic use, while antibiotic use indicators and targets are agreed upon.
- In the animal and agricultural sector, surveillance is also crucial both at baseline and after interventions to reduce antibiotic use.
- Both of the above elements require investment in a sustainable surveillance infrastructure.



WORLD VETERINARY
ASSOCIATION

World Veterinary Association

PRESIDENT

➤ Dr Johnson CHIANG (Taiwan)

PRESIDENT ELECT

➤ Dr Patricia TURNER (IACLAM)

IMMEDIATE PAST PRESIDENT

➤ Dr René CARLSON (USA)

COUNCILLORS FOR AFRICA

➤ Dr Gani ENAHORO (Nigeria)
➤ Dr Clive MARWICK (South Africa)

COUNCILLORS FOR AMERICA (NORTH)

➤ Dr Troy BOURQUE (Canada)
➤ Dr Cassandra TANSEY (USA)

COUNCILLOR FOR AMERICA (LATIN)

➤ Dr Maria Nelly CAJIAO (Colombia)
➤ Dr Jannet VELEZ RIVAS (Perú)

COUNCILLOR FOR ASIA and OCEANIA

➤ Dr Said GUL SAFI (Afghanistan)
➤ Dr Takeo SAKAI (Japan)

COUNCILLOR FOR EUROPE

➤ Dr Maaïke VAN DEN BERG (The Netherlands)
➤ Dr Olafur ODDGEIRSSON (Iceland)

COUNCILLOR FOR MIDDLE EAST and NORTH AFRICA

➤ Dr Mohammed BAKKOURY (Morocco)
➤ Dr Hani GOHAR (Egypt)

COUNCILLOR FOR INTERNATIONAL REGIONAL ORGANIZATIONS

➤ Dr Sira Abdul RAHMAN (CVA)

COUNCILLOR FOR INTERNATIONAL DISCIPLINE-CENTRED ORGANIZATIONS

➤ Dr Harutyun AVSAROGLU (IACLAM)

WORLD VETERINARY ASSOCIATION (AISBL)

Avenue de Tervueren 12
1040 Brussels, Belgium

T +32 2 533 70 22
E secretariat@worldvet.org

www.worldvet.org

WVA/18/doc/033 (FINAL)

Brussels, 17 August 2018

The World Veterinary Association (WVA), representing the global veterinary profession, wishes to commend the Interagency Coordination Group on Antimicrobial Resistance on the development of the Discussion papers *“Reduce unintentional exposure and the need for antimicrobials, and optimize their use”*, *“Future Global Governance for Antimicrobial Resistance”* and *“Meeting the challenge of Antimicrobial Resistance from Communication to Collective Action”*.

The WVA is pleased to have the opportunity to give feedback on these discussion papers and wishes to offer the following comments:

Future Global Governance for Antimicrobial Resistance

- In general, the governance document brings many interesting ideas together but at the same time it very much gives the impression of being “work in progress”. It contains valuable elements, but more should be done to increase the paper’s consistency and internal coherence. Goals, expectations, and structures amongst others could be made more explicit.

- From an Animal Health point of view, WVA believes it is important that a Future Global Governance for AMR will be able to balance the needs of the professions and stakeholders that apply a One Health approach. For each sector unnecessary or inappropriate use of antimicrobials should be avoided as much as possible. It is important to emphasize infection prevention rather than denying access to antimicrobials. This applies to both human health care and equally to animal health and welfare. In large parts of the world, especially in LMICs, many people are very much depending on their animal husbandry, including livestock, poultry and fish farming.

- It is essential that a proposed new governance structure will be synergistic to structures that are in place already. Special attention has to be given to the mandate member countries have given to the existing intergovernmental organisations OIE, WHO and FAO, and to make sure that these mandates and a mandate for the new governance structure will be well coordinated and aligned.

- In addition to striving for a new Global Agreement, initiatives that have been taken in different countries in recent years and have proven to be effective should be fostered and promoted. The development of a Global Agreement will take many years. In the meantime current best practices should be promoted as much as possible.
- Another point that, WVA believes, has to be taken into consideration is the continuing good connection between the proposed Global Governance Structure and the institutions and organisations that will be responsible for the implementation of the future Global Multi-stakeholder Agreement.
- The fact that the three elements Risk Assessment, Risk Management and Risk Communication are not clearly separated is a point of concern, which could undermine the credibility of the proposed governance structure.
- Regarding the Key Messages presented on page 2,
 - For transparency, we would have appreciated it if there had been an overview of the participants of the “small meeting” in Leeds Castle.
 - The connection between the ten requirements for effective AMR governance mechanisms that emerged from the meeting and the possible future governance model should be made more clear. It would be helpful to indicate for each requirement how it will be covered in the governance model.
 - Is the High Level Commission only meant to exist during the startup of the Global Steering Board? How is the participation of the private sector in the High Level Commission assured? What is the relation between the High Level Commission (2 years) and the delivery of the Global Multi-Stakeholder Agreement?
- In the table on page 4, in the second paragraph, “what are the needs for practical future global governance of AMR?” specific sector needs are presented at very different levels and in an unbalanced way. Where the Human Health Sector focuses on WHO internal and administrative hurdles, the other two Sectors - Animal /Agriculture/Aquaculture/Food and the Environment Sectors – take a broader view on what the requirements are for making global governance successful for the Sectors. In addition, items listed under Shared One Health address the overall topic at very different levels.
- Set of minimum requirements for an effective AMR Governance mechanism (pages 6,7 and 8)
 WVA agrees with the importance of points 1 to 10, however as they are presented in the discussion paper they are a complete mixture of “what”, “how” and “by which resources”. It would be helpful if the more or less separate points would be put together in a more consistent order, for example in one clear “Terms of References document”. Risk assessment, risk management and risk communication elements should be clearly identified and allocated.

- WVA agrees that a clear mandate, regulating what is expected to be done, and what not, is important. WVA certainly supports the importance of engaging stakeholders, worldwide and in all sectors and academic disciplines. Such engagement is critical for linking policy with practice and vice versa.

- Figure 1, page 9.

The figure is not sufficiently explanatory. It shows the different actors but it is not clear what role they have and how these functions are linked together. The “Delivering a Global Multi-Stakeholder Agreement” is in our view a deliverable and as such it is not part of the governance structure.

It is also not clear how the minimum requirements 1 to 10 on the previous pages are addressed and incorporated in the presented scheme.

Reduce unintentional exposure and the need for antimicrobials, and optimize their use.

Open questions for stakeholders

Q: What kind of support (other than financial) is needed to translate the existing guidance into implementable actions?

A: Existing guidance documents should be translated into very easy to understand action points that can be implemented step by step. For many people guidance documents are too large and the wording too cumbersome for them to be understood and implemented all at once. Defining milestones will be helpful to make progress. The inclusion of figures and decision trees would promote understanding. It could also be helpful to bring people together at local level to share best practices, and to encourage and teach each other.

Many guidance documents take a very technical approach. Input from other academic disciplines, like social and behavioral sciences, could be very helpful.

Q: How can policy makers be assisted to further develop and implement infection prevention and control in human and animal health and plants and be convinced to invest now to mitigate the escalating and future costs and obtain benefits far beyond preventing AMR?

A: Probably there is not one single answer to this question. Politicians and other policy makers will judge the investments they can make against other priorities they see and against tangible goals that can be achieved. In most cases the time line politicians oversee are relatively short. Especially in countries with limited resources AMR will have to compete with many other topics. It would be helpful if policy maker initiatives could be combined with bottom-up initiatives. Raising awareness is a key success factor. Policy makers can be meaningfully influenced by civil society organisations with a track record in the domain of antibiotic stewardship. Such organisations must continually

liaise with regulatory authorities, but more importantly develop a forum between industry and government departments, or public private partnerships to talk to each other and advance the objectives of the GAP, NAPs and country-specific strategy documents.

It will be important to keep communicating the importance of AMR to avoid that after a period of time the topic will fade in the background.

Q: What incentives or initiatives are needed for behavior change towards responsible use in the health sector and in the food and animal sectors?

A: critical point here is that those whose behavior is to be changed are generally not the same as those who will benefit from these changes. It is important to try to bring the two groups closer together. An example from the animal sector that appeared to be very effective was imposing quarantine measures on people who are in close contact with farm animals (farmers, slaughter house staff) when they have to go to a hospital. Another example is industry-driven initiatives to do residue testing on animal derived food such as milk and meat where government funded residue testing programmes do not exist. Such programmes managed by large food companies for example can include both severe penalties for non-compliance and incentives for compliance

Q: What is needed to generate evidence-based data that link the misuse of antimicrobials and the development and spread of AMR via the environment? How can we use the available data to develop effective policy solutions influence policy makers?

A: when evaluating the development and spread of AMR it will be very difficult to differentiate between what is caused by misuse and what by correct use. Probably the best option is to change conditions for use from “yes, provided that...” to “no, unless ...”

Q: What approaches are needed to ensure the industry and investors manufacture and market antimicrobials responsibly, and not to stimulate overuse or contribute to environmental pollution?

A: Society should not rely on the good-will of pharmaceutical companies for the availability and proper use of medicines in food animals. Active involvement is required. Public Private Partnerships where different stakeholders, in particular veterinarians and farmers, work together can be helpful to identify common interests and goals.

Q: Changing practices needs the support of the industry – how can we balance the availability of a public good such as effective antimicrobials, with a private industry perspective?

A: see answer to previous question.

Q: What are the mechanisms to enhance the availability and utility of global resources for the end user (communities and individuals) to optimize or reduce the need for the use of antimicrobials and to mitigate the unintentional exposure to the environment?

A: There is no single answer to this complex question. A silver bullet that would solve the issues is not available. Probably the best way forward is to facilitate and foster initiatives taken by different stakeholders at different levels. It is important that all parties involved take action within their

spheres of influence and do not wait for others to step forward first. Where possible, initiatives should be brought together to increase synergism.

Meeting the challenge of antimicrobial resistance: from communication to collective action

Q: How can we best measure and prioritize efforts that communicate AMR effectively, so that limited resources are used optimally?

A: Probably the best way to measure and prioritize actions is by measuring the real effect, in terms of antimicrobial use and antimicrobial resistance that occur after the communication action is launched. In the field of animal health and welfare it has been shown that substantial reductions in antimicrobial usage can be achieved in a relatively short period of time. Such reductions have led to a significant reduction in AMR. A great deal of research has focused on the development of antibiotic alternatives to maintain or improve health and productivity.

Q: What are the major barriers to changes in antimicrobial use and management among priority stakeholder groups and communications recommendations to tackle these?

A: Important barriers are economic and commercial barriers. In the food market there is a high competition on price and animal owners are under high market pressure to produce at low costs. This makes it difficult for them to invest in for example better housing conditions for the animals. The barrier to overcome is to get buy-in from management that it is possible to increase farm profitably when applying strict antibiotic stewardship in the overall biosecurity programme, an approach that has already been proven in several large production units in many countries. In general there is little incentive or recognition for individuals who have taken positive actions.

Q: What are appropriate and practical incentives for changes in practice? What lessons might be learned from other areas, from vaccination to WASH (water, sanitation and hygiene) campaigns, that could inform what the IACG might recommend?

A: In addition to distributing technical information it is important to find role models that advocate the desired behavior that will help to arrive at the tipping point from where certain behavior is not acceptable anymore. Peer pressure will encourage those who have stayed behind to move forward.

Q: What research agenda is needed to support efforts to communicate AMR? How might this communications research best be funded and coordinated?

A: Using antimicrobials is only partially based on knowledge and medical need. Probably as important are social and cultural factors. It is important that the research agenda includes those aspects.

Q: What model approaches best mobilize key actors in tackling AMR while raising awareness? How might one best structure a multi-stakeholder platform for AMR communications and a community of practice linking these key communications focal points?

A: A way forward could be to work at different levels for example with different expert panels and stakeholder groups, that deal with general and more specific questions and whose opinions are brought together at a higher and overarching level.

Q: Where and what would be the most strategic opportunities for investing in efforts that communicate AMR? How can the Tripartite agencies and other intergovernmental agencies be supported to carry out this work?

A: An important point for communication is through the education of children, youngsters and students. It requires time and a long term view, but probably they are the group that can make a real difference. They can help to spread the message to other people.

Q: How can we best scale promising strategies for changing individual behavior into collective action to effect AMR change? What groups might be enlisted in these efforts? What role does civil society, professional societies and industry trade associations among others constructively play in these efforts, and how might this be supported?

A: Professional societies and their members can play a key role at the interface between policy makers, academia and the day to day practice. They can help to explain measures that are taken and the reasons behind such measures. They can also feedback experiences from the field, what does work and what not and for what reasons.

Q: What opportunities are there for enabling effective monitoring for accountability towards effecting AMR change? What enabling conditions are critically important for such efforts, and how can we best ensure that these conditions are met?

A: Probably most important is setting SMART (Specific, Measurable, Attainable, Realistic, Timely) goals that people can commit to.

Private

IACG Consultation

IACG Working document: Discussion paper with preliminary analysis Future Global Governance for Antimicrobial Resistance

I. General Comments

- The danger of antimicrobial resistance moving across borders demands the strengthening of global governance arrangements; no country can avoid the consequences if antimicrobials become ineffective. We welcome the proposal for an AMR global governance mechanism and look forward to engaging with the IACG in defining and progressing its implementation, as we believe the pharmaceutical industry is a key stakeholder in global efforts to address AMR.
- Within this governance, we appreciate the establishment of a Global Steering Board which will consist of a multi-sector, multi-stakeholder group. The industry has a key role to play in combatting AMR, thus it is important to include representatives from the various life sciences industry subsectors in the Global Steering Board.
 - a. AMR is an important issue that requires a multi-sectoral approach. The UN IACG should formally engage with the private sector as it develops its findings and recommendations to ensure solutions leverage all capabilities and achieve maximum impact. Any future permanent AMR governance structure should also include the private sector as a full partner.
 - b. We recommend that the goals of the Global Steering Board be expanded to include education and increasing general public awareness. We therefore suggest the following: (i) the Global Steering Board will make sure that educational programs for health workers are developed and implemented on a global scale, taking into account local specificities and (ii) the Global Steering Board will develop and support global awareness campaigns and ensure that member states utilize them effectively.
- Balancing flexibility in expectations in acknowledgement of differing levels of capacity available in different countries while preserving some collective goals will be a challenge. It would have been helpful to see this challenge discussed more fully in terms of the ways in which it could be addressed by the different governance mechanisms profiled in the accompanying report. We suggest that the Global Steering Board could encourage exchanges of best practices and experiences to especially address the most urgent situations and the needs of LMICs.
- Development of evidence-based targets that will be reported and tracked will be important to establish and maintain momentum for reduction in antimicrobial resistance. The AMR Industry Alliance recommends that the reporting on AMR, its trend and its social, medical, environmental and economic consequences will be based on cross-sectorial, local and international surveillance networks.

IACG Consultation

II. Specific comments on the draft paper

Page, column, paragraph	"Specific Text" from the draft paper	Comment/Suggested Edit	Importance L, M, H
p.5, section 1	[Shared One Health needs section] – "to fully engage with the private sector"	The AMR Alliance appreciates the inclusion of the full private sector engagement in the section cited. However to achieve that, a new approach to collaboration may be required, and a clear model defined. The EU for example, recognized the same issue in its AMR Action Plan. <i>"Actions against AMR cannot succeed without the sustained involvement of stakeholders, including industry, civil society, academia, and non-governmental experts throughout policy development and implementation. The Commission takes note of existing commitments and collaborative efforts such as the declaration by the pharmaceutical, biotechnology and diagnostics industries on combating AMR. It provides a roadmap for further collaboration efforts between industry, governments and non-governmental organizations in the global fight against AMR."</i>	H
	[Shared One Health needs section]	Consider adding in specific reference the R&D pharmaceutical companies and the diagnostic sector, and the need for incentives. <i>Suggested wording: Sustainable investment into the research and development of novel antibiotics, vaccines, and antibiotic alternatives."</i>	H
p.5, section 2	[Specific sector needs] – "Precautionary but pragmatic approach"	Precautionary measures must also be science/evidence-based, and be both proportionate and capable of global application.	M
p.7, point 8	"Be a credible and respected voice, synthesizing evidence and adding weight to global negotiations."	Reliance on the evidence as a basis for policy-making will be particularly important to the credibility of the review role described.	M
	"These must be supported by clear metrics for evaluating progress, harmonizing existing indicator mechanisms where available"	We reiterate the importance of the development of an accountability mechanism for both the public and private sectors. While we welcome the creation of the Tripartite Global monitoring of country progress on addressing antimicrobial resistance, we are disappointed that the	M

IACG Consultation

		Objective 5 of the WHO GAP (Investments in new medicines, diagnostic tools, vaccines and other interventions) was excluded from the questionnaire and is therefore not currently monitored. The Tripartite should include this objective in its monitoring to support information exchange and enable accountability among governments related to progress against Objective 5 of the WHO GAP. Any future accountability mechanism should capture the full range of actions governments should be taking.	
p.8, point 3, paragraph 2	“Overall, the experts agreed ... within the next 10 years.”	The paper should make clear that the 10-year timeframe refers to the global treaty. The proposed Secretariat and Global Steering Board should be put in place within the next year to minimize loss of momentum. Additionally, the challenge of educating the wider audience could be better emphasized.	L
		We support the goal-oriented approach proposed for the new governance system. It is however important that such agreements are supported and ratified by all countries, especially those where the burden of AMR is high.	L
p.8, point 3.1, paragraph 2	[Reference to the Global Steering Board]	The board structure should be inclusive of the industry.	H
p.8, point 10	“For example, setting standards, <i>influencing regulation</i> , strengthening surveillance systems, supporting capacity building, and supporting pilot programmes.”	Consider changing to “... <i>influencing regulation and facilitating regulatory alignment</i> ...” to reflect the scope for improving consistency of regulatory practice.	L
p.9, figure 1	[Reference to the High Level Commission]	The IACG should preferably propose the structure to the Board and then work to implement it over the next 5 years (see above).	L
p.12, b), point 2	A “pitch” for AMR	The AMR Alliance welcomes the inclusion of developing an AMR pitch and views it as essential.	L
p.13	[References to profile-raising opportunities]	We would suggest for the IACG to consider whether annual events related specifically to AMR should be developed to act as a focal point for assessing progress.	L

IACG Consultation

p.13, bullet point 2	“Consensus building opportunities (including, but not limited to)”	All the listed items are government bodies, while it should also be considered how to strengthen the engagement and support of the private sector.	H
p.18, number (4)	“Finance alternatives and innovations such as new vaccines, diagnostics ...”	In addition to supporting the development of new vaccines, we need to ensure that National Action Plans and government policies are supportive of increased access and utilization of vaccines. If the access environment is not strengthened then investment in the R&D for vaccines could be impacted.	M
p.28-30	“Barriers to applying existing solutions and best practices”	The paper could benefit from more strongly highlighting the barriers described. In particular, the ability to conduct surveillance and regulate markets in resource-poor settings represent a baseline enabler of future governance. To quote from the EU Action Plan <i>“A comprehensive, collaborative and coordinated collection and analysis of data from multiple domains, i.e. a One Health AMR surveillance system, is therefore essential to understand the magnitude of the problem, identify trends, determine how the use of antimicrobials and AMR are linked, evaluate policies and set priorities”</i>	M

IACG Consultation

IACG Working document: Discussion paper with preliminary analysis Reduce unintentional exposure and the need for antimicrobials, and optimize their use

I. Key Messages

General

- The AMR Industry Alliance agrees that the fight against antimicrobial resistance (AMR) is a major public health challenge all around the globe, impacting the health of people, animals, and ecosystems. We support the holistic “One Health” approach proposed in the discussion paper “Reduce unintentional exposure and the need for antimicrobials, and optimize their use.”
- Industry is a key stakeholder in addressing AMR and should be formally included as a full partner in multi-sectoral mechanisms to optimize use of antimicrobials. AMR Industry Alliance members are making progress addressing manufacturing discharges, along with many other contributions to R&D, stewardship and access. However, urgent progress is needed to strengthen the economic foundation that supports these activities. We urge the IACG to play a role in ensuring that dialogue involves industry, is balanced and informed by facts.
- The paper does not seem to include references to diagnostics, which play a key role in the fight against AMR and specifically, in reducing inappropriate use.
- Currently, vaccination is only referenced in the animal health section. Given the importance of vaccines in addressing AMR (preventing infections, reducing inappropriate use of antibiotics), we propose a dedicated section on AMR and vaccines.
- A key component of any response to address inappropriate use should be measuring the impact on patient outcomes. There is a focus on restrictions and limiting antibiotic use, instead of antimicrobial stewardship: right drug, right diagnosis, right patient, right duration. This paper should explicitly define stewardship and inappropriate use.

Environment

- The multiple potential sources of antibiotics/antibiotic resistant genes require a collaboration by all the stakeholders to limit the spread of AMR. The AMR Industry Alliance welcomes the reference to its work on “setting target values for the pharmaceutical industry based on an assessment of risk for the development of resistance in the environment. The AMR Industry Alliance has already released its Common Antibiotic Manufacturing Framework and continues to work with environmental experts to set discharge limits associated with antibiotic manufacturing.
- A small but visible proportion of antibiotics discharged into the environment result from poor manufacturing processes. Industry is committed and actively working to reduce manufacturing discharges from our sector, through the AMR Industry Alliance.

Infection prevention

- Immunization has a key role to play in infection prevention. To ensure vaccines can have a multi-dimensional impact on AMR reduction, measures must be taken to ensure wider use of existing vaccines – through a life-course approach to National Immunization Programs, the implementation of National Actions plans for AMR as well as hospital and health care facility stewardship programs.

The use of diagnostics

- The paper does not seem include references to diagnostics, which play a key role in the fight against AMR and specifically, in reducing inappropriate use. Their utility includes:
 - In human health, (i) to identify pathogens, their sensitivity and acquired resistance to multiple-antibiotics, (ii) to ensure that antibiotics are prescribed only when it has been proven that they are required, (iii) to personalize antibiotic treatment and (3) to use properly and sparingly any novel antibiotics or extended-spectrum antibiotics to avoid the emergence of new resistance;
 - In animal health, to promote the use of antibiotics for therapeutic reason and, in particular, to test the sensitivity prior to the use of critical antibiotics as well as to ban them as a growth promoter or as a preventive treatment;
 - In R&D, to better select the patients in novel anti-infective clinical trials;
 - In the food industry, to help control the microbiological quality of products, raw materials and production environment (particularly targeting microorganisms whose multi-resistance is emerging);
 - In surveillance programs, diagnostics are the only tool that enable surveillance, at local, national and international levels, on the basis of a strong cooperation between human and animal health surveillance networks
- Despite such significant benefits, diagnostics are still too often underused, as clinicians often only take into consideration the additional cost of utilization, rather than the overall value of diagnostics. In many cases, the diagnostic is more expensive than the antibiotic leading to incentives that result in underuse of diagnostics while overusing antibiotics. This incentive structure must be addressed to help ensure appropriate and optimal use of antibiotics. Evidence-based health economic outcomes research studies on a local and global basis need to be conducted on the value of diagnostics. In order to improve access to diagnostic tests, we recommend the IACG include in their recommendations for member states to do the following:
 - Embed the use of diagnostic tests into prescribing practices in order to decrease reliance on empiric antibiotic utilization.
 - Modification of reimbursement systems to include diagnostic tests would critical. The development of member states regulations where antibiotics should not be prescribed without a diagnostic test would be desirable.
 - Strengthen initiatives to boost national, regional, and local laboratory capacity so that there is enhanced access to diagnostic tests and testing facilities in all countries.
 - Provide support to resource-limited settings and health care facilities on training for performing tests, analyzing the results, and issuing reports.
 - Align reimbursement and market access regulation with public health goals to drive more timely and accurate diagnosis of infectious diseases with an acceptable Return on Investment (ROI) for diagnostic companies.
 - In animal health, harmonize diagnostics regulation in order to ensure the same quality level, limit registration fees, and reduce overall development costs.
- In addition, raising awareness and driving behavior change in AMR is critically important. We recommend that there must be an increased effort to educate clinicians, laboratorians, veterinarians, pharmacists, and students on the role of diagnostic tests in improving antibiotic prescribing and usage.
- While efforts are being made to track raw antibiotic consumption, the clinical context of this data is not currently taken into consideration and continues to be cited as a weakness of this type of feedback data.

Therefore, initiatives should be supported to improve our understanding of clinical appropriateness of antimicrobial use and what the optimal variables are for risk adjusting antimicrobial consumption data. In this way, comparisons of antibiotic use can be normalized and qualified in a manner that may mitigate drug resistance further upstream at the “prescriber level.”

II. Responses to open questions posed by the UN IACG

p.12, Q5: “What approaches are needed to ensure the industry and investors manufacture and market antimicrobials responsibly, and not stimulate overuse or contribute to environmental pollution?”

- The role of the payers/buyers and regulators in the value chain must be addressed. Payers/buyers of antibiotics should consider the environmental angle of pharmaceutical production when evaluating tenders rather than focusing solely on reducing price. There is a paradox in the increasing downward pressure on antibiotic prices and increasing expectations regarding manufacturing practices.
- An important challenge is that the countries in which environmental pollution is most of concern are countries which have a large and growing chemical/pharmaceutical industry and generally less well developed environmental protections.
- The National Action Plans for India and China should reflect their special role as the manufacturing hub of antibiotics/antimicrobials for the world. We urge the WHO and other global agencies to continue to engage governments, and provide support when appropriate, to facilitate the implementation of National Action Plans in particular in countries with a key role to manage the risk of environmental pollution.
- Industry also has a role to play by developing widely adopted manufacturing environmental expectations. Purchasers and investors can recognize and encourage additional efforts through pricing and investment decisions.

p.12, Q6: “Changing practices needs the support of the industry - how can we balance the availability of a public good such as effective antimicrobials, with a private industry perspective?”

- Tender mechanisms could help better support the security of supply by reflecting a fair cost and therefore allowing for sustainably-made antibiotics. As detailed in the Access to Medicine paper on Stockouts and Scarcity antibiotics provide a slim margin when sold in tenders can hinder companies from competing in lower value markets. “Further, governments with high purchasing power are using increasingly stringent tendering processes focused on price, creating competition among producers that puts further pressure on already slim margins.”
- With regards to reducing antibiotic discharge in the environment, part of the potential may lie in greater partnerships between organizations like WHO and industry, collaborating on common global goals. While there are some examples of industry inclusion (e.g. Society of Environmental Toxicology and Chemistry (SETAC) and the Canadian Society of Microbiology meetings/workshops and their output; JPI-AMR Environmental Dimension of AMR workshop and paper with research priorities), the exclusion of industrial expertise from some activities is counter-productive. Advancing research to answer the question of “What is the biggest environmental contribution to clinically relevant AMR?” would be particularly informative.
- Reimbursement reform is needed to enable appropriate access to novel antibiotics and stabilize the economics of antibiotic R&D. Reimbursement reform can complement and reinforce key antimicrobial stewardship components, including the use of diagnostics, de-escalation, regimen monitoring, and surveillance.

III. Specific comments on the draft paper

Page, column, paragraph	<i>"Specific Text" from the draft paper</i>	Comment/Suggested Edit	Importance L, M, H
p.2, section 1	1. Prevention and control of human infection in the provision of health care	The section does not mention the importance of governments ensuring access to vaccines. It needs to be ensured that vaccines are seen as having an important role. Stewardship plans, including government and hospital stewardship plans, should support strengthened access to vaccines as relevant. Vaccines provide a very cost-effective prevention strategy. Vaccines are one of the most cost-effective health tools; every dollar spent on immunization is estimated to provide returns of \$44 in economic and social benefits ¹ .	H
p.8, section 6	6. Environmental contamination	The concrete and catalytic work of the AMR Industry Alliance on the topic should be recognized.	H
p.8, section 6, paragraph 2	"Other challenges include the lack of routine, standardized monitoring to determine the trends in AMR from environmental sources, and difficulty in defining the intersecting environment and therefore in designating	Another big gap is understanding the current relevant sources of environmental contamination. These need to be known so that policies and mitigation strategies can be prioritized. e.g. human waste, hospital waste, agriculture, manufacturing.	H

¹ Ozawa S, et al. Return On Investment From Childhood Immunization In Low- And Middle-Income Countries, 2011–20. Health Affairs. 2016; 35(2)

	leadership and responsibility. There are high risks of duplication and of neglect of important areas.”		
p.8, section 6, paragraph 3	[Current Responses]	There is important work currently ongoing in India - India’s Central Pollution Control Board is already working on drafting antibiotic standards for industrial effluent, which are expected to be released soon for public comments. These could globally be the first enforced regulations for controlling antibiotic residue in pharmaceutical waste.	M
p.8, section 6, paragraph 4	“The Joint Programming Initiative on Antimicrobial Resistance (JPI AMR) promotes research and shared knowledge about the causes and consequences of AMR in the environment include.”	The sentence seems to end prematurely	L
p.10, section 7, paragraph 5	“This often results in unnecessary or suboptimal use of antibiotics ...”	There is also suboptimal use of vaccines in many countries, especially in adult populations, in large part due to government policies. The AMR Industry Alliance believes we need to ensure vaccine policies support increased use and access.	H
p.12 Question n°6	“how can we balance the availability of a public good such as effective antimicrobials, with a private industry perspective”	The use of the terminology “public good” is inaccurate and should be deleted. A public good is defined as a product that one individual can consume without reducing its availability to another individual, and from which no one is excluded. "Antimicrobials" do not meet these criteria and cannot be classified as a global public good.	H

		The World Bank characterizes "AMR containment" ² as a global public good which is both more accurate and more aligned with global public health interest.	
--	--	--	--

² Drug-Resistant Infections, A Threat to our Economic Future. World Bank Report. March 2017.

IACG Consultation

**IACG Working document: Discussion paper with preliminary analysis
Meeting the Challenge of Antimicrobial Resistance:
From Communication to Collective Action**

I. General Comments

- The “Key Questions for Stakeholders” seem highly relevant to the issue of communicating about AMR, but are not easily relatable to the subsequent content of the paper. We would suggest that the setting out of a strategy development process (involving all stakeholders and aiming at alignment) would be a better point of departure for this important exercise, rather than a consultation.
- This discussion paper proposes five core components to help frame and connect the range of activities needed to make strategic communications an effective tool to address AMR. There is limited background information on how these components were selected and the structure it provides does not particularly lend itself to a discussion of how an effective communications campaign can be built or how the IACG might support National Governments.
- We suggest the partial restructuring of the paper as it does not clearly distinguish between different target audiences and might also benefit from a discussion of the utility of different communication strategies in relation to those target groups.

II. Comments per key components

Targeting Priorities

- It's not clear how "surveillance of antimicrobials at the level of drug manufacturers" relates to the Targeting Priorities component of strategic AMR communication. This type of sales data is commercially-sensitive and may not correspond to antibiotic use (or even supply) due to bulk purchasing, distribution agreements, and parallel trade. We suggest it is deleted.

Raising Awareness

- This section contains a number of relevant examples or campaigns led by the public sector. The section would benefit from a more extensive and systematic discussion of the learnings from these initiatives.
- While direct healthcare and patient communication by industry is governed by many codes and rules, companies can still raise awareness and serve as valuable resources to the appropriate use of antibiotics. For instance, several companies are active in continuing medical education, activities that help to maintain or increase the knowledge and skills of healthcare professionals. Doing so in collaboration, or together with independent

IACG Consultation

accredited providers, minimize potential conflicts of interest. A number of Alliance members – companies as well as associations – support WAAW each year with public health campaigns, conferences, events and other activities. For example, Alliance members participated to an AMR Awareness Fair on Capitol Hill partnering with 20 stakeholder organizations to educate Capitol Hill staff on the impact of AMR. Other examples of what AMR Alliance members are doing to raise awareness on AMR can be found at <https://www.amrindustryalliance.org/in-action/>

Supporting Behavior Change

- This section contains numerous relevant examples focused on regulating prescribing and dispensing behavior. The AMR Industry Alliance suggests that there could be a clearer emphasis in this section on strengthening prudent use without compromise to patient care. We recommend to further emphasize evidence-based “enablement” techniques to support physician decision-making, as opposed to rigid restrictions on use which could undermine access to the right treatment at the right moment.
- The description of the London School of Hygiene & Tropical Medicine (LSHTM) and the Royal Veterinary College study carried out in six LMICs (page 15) captures the complex influences on prescribing behavior, ranging from structural issues (lack of diagnostics or stockouts) to social/behavioral issues (pressure to prescribe). These issues should be unpacked further to highlight the opportunities and limitations to behaviour change communication in absence of longer-term progress on health and water/sanitation systems strengthening.
- We agree with the UN IACG’s paper that incentives — both financial and non-financial — have an important role in shaping behaviour change. Pharmaceutical promotion provides valuable information to providers, but should be done in a way that supports appropriate use and reduces inappropriate use. The AMR Industry Alliance recognizes that sales and marketing activity focused on driving volume of sales risks being counter to what is appropriate for antibiotics.
- According to the 2018 AMR Benchmark from the Access to Medicine Foundation, four companies are already taking steps to adjust incentives for sales teams to decouple them from antibiotic sales volume: GSK, Shionogi, Pfizer and Novartis. One other company (Johnson & Johnson) is carrying out no direct promotion of a specific product.

Enabling Collective Action

- It is not clear what place the discussion of pooled procurement (Global Drug facility for TB drugs) has in this paper. We suggest deletion of the paragraph.

Monitoring for Accountability

- The AMR Industry Alliance agrees that any communications strategy should contain a feedback mechanism so that communications efforts can be fine-tuned in the light of outcomes. It is suggested that the feedback should come through surveillance of antibiotic use. This seems restrictive. Use may be affected by many factors unrelated to public understanding, including clinical need. We would suggest that the feedback loop could also include other forms of assessment that would be more appropriate to the measuring communications effectiveness in changing public attitudes.
- The draft states “As key stakeholders begin to take collective action, monitoring for accountability adds another important dimension to communicating AMR”. We reiterate the importance of the development of an accountability mechanism for both the public and private sectors. While we welcome the creation of the Tripartite Global monitoring of country progress on addressing antimicrobial resistance, we are disappointed that the Objective 5 of the WHO GAP (Investments in new medicines, diagnostic tools, vaccines and other interventions) was excluded from the questionnaire and is therefore not currently monitored. The Tripartite should include this objective in its monitoring to support information exchange and enable accountability among governments related to progress against Objective 5 of the WHO GAP.
- The draft cites the WHO-HAI price surveys as a potential model for promoting access to medicines (page 28). While these surveys can provide an important snapshot on availability and affordability in the retail sector, they should be interpreted in the broader health system context. These surveys may be appropriate for outpatient antibiotics, but not for second-line antibiotics since a whole host of financing and stewardship interventions also influence availability.
- While we appreciate the reference to the AMR Industry Alliance progress report, the current construction on page 30 appears to undermine this report by highlighting differences with the 2018 AMR Benchmark. That is, it gives the impression that the AMR Benchmark had different findings than the AMR Industry Alliance Progress report. There are key methodological differences between these reports and they include different sets of companies. These differences should be clearly highlighted and the discussions separated.

TO: UN Interagency Coordination Group on AMR
FROM: Animal Health Institute
DATE: August 31, 2017
RE: Future global governance for antimicrobial resistance

Dear IACG Secretariat,

The Animal Health Institute (AHI) is a non-profit membership organization that represents companies in the United States with an interest in veterinary health. Our members develop and produce the medicines that help keep pets and livestock healthy. By keeping animals healthy, their medicines also help improve the health and well-being of humans and keep the food supply safe. Antibiotic resistance is an important public health threat, and animal health companies in the U.S. have worked with Federal agencies to implement the national action plan and federal guidelines.

AHI strongly supports the comments submitted by HealthforAnimals in response to the three discussion papers published by the UN Interagency Coordination Group on Antimicrobial Resistance: 1) Future Global Governance for Antimicrobial Resistance, 2) From Communication to Collection Action and 3) Optimize Use of Antimicrobials.

AHI is particularly concerned about several proposals within the global governance discussion paper. The 2016 United Nations Political Declaration on antimicrobial resistance (A/RES/71/3) requested the Secretary-General to establish an inter-agency coordination group to provide practical guidance. But, this proposal falls short of that goal and instead seeks to instill a layer of bureaucracy that would further limit communication and transparency within the IACG. We therefore encourage the IACG to focus on practical recommendations and guidance to improve coordination, especially for existing work streams, and not pursue an expanded governance model.

Policies should be based on scientific evidence. Likewise, the IACG's final report should place emphasis on science-based guidance for standards and exclude reference to the precautionary principle or "level playing fields." Such statements can be both confusing and reflect a political agenda thus failing to uphold high scientific standards. The precautionary principle is considered risk avoidance due to the strong political desire for a zero-risk approach. Ultimately the precautionary principle is neither practical nor based on scientific or risk-based standards and assessments. Similarly, the *level playing field* concept reflects a political agenda not a scientific standard. It also directly conflicts with Member State obligations to the World Trade Organization (WTO), specifically, Article 2.2 of the SPS Agreement. AHI recommends the final report exclude any reference to the precautionary principle, level playing field or recommendations that conflict with WTO obligations.

Thank you for the opportunity to provide input.

Sincerely,

Rachel Cumberbatch, DVM
Director, Regulatory Affairs, Animal Drug Section
Animal Health Institute

Animal Medicines Australia



Animal Medicines Australia
ABN 76 116 848 344 | ACN 116 848 344
18 National Circuit
Barton ACT 2600, Australia
P: +61 2 6257 9022
animalmedicinesaustralia.org.au

30 August 2018

The Secretariat
Interagency Coordination Group on Antimicrobial Resistance

By email only: iacg-secretariat@who.int

Regarding the Interagency Coordination Group on Antimicrobial Resistance (IACG) paper on Future Global Governance for Antimicrobial Resistance

Thank you for the opportunity to provide feedback on this discussion paper. Animal Medicines Australia (AMA) is the peak body representing the leading animal health companies in Australia. AMA member companies are the local divisions of global innovators, manufacturers, formulators and registrants of a broad range of veterinary medicine products that prevent, control and cure disease across the companion animal, livestock and equine sectors.

The 2016 United Nations Political declaration on antimicrobial resistance (A/RES/71/3) requested the Secretary-General to establish an inter-agency coordination group *"to provide practical guidance for approaches needed to ensure sustained effective global action"* in consultation with the World Health Organization (WHO), the United Nations Food and Agricultural Organization (FAO), and the World Organization for Animal Health (OIE), collectively the Tripartite, among other objectives.

The mandate for *practical guidance* is not well represented in the discussion paper and proposed governance model. Below are comments and suggestions for improvement.

- 1. The mandate of the political declaration does not request recommendations on governance, but requests practical guidance on "options to improve coordination," (par. 15.) The IACG should consider developing its options to improve coordination within existing structures and models.**

A most practical approach would seem to build on the existing contributions, work streams, and expertise of the Member States and the Tripartite. The creation of a new organization, steering board, or bureaucratic layer will divert financial, political, and expert resources from the development and implementation of pragmatic interventions to reduce the incidence of bacterial disease treatment failure and provide related public health outcomes.

The Tripartite agencies would benefit from improvements in the collaboration and coordination of work. In the past year, there are several instances where they have not coordinated or “staying in their lane”. Coordinating activity needs to be intentional and requires these three to work together to leverage expertise and resources. The most notable exceptions to collaboration are the WHO paper in November 2017 on the use of antimicrobials in food producing animals and the FAO’s DG Statements on eliminating prevention uses. Both recommendations and the associated communication materials were inconsistent with the OIE Terrestrial and Aquatic Codes on antimicrobial use. Options to improve coordination should start at the top of the organizations.

The final report should include recommendations and practical guidance to improve coordination, especially for existing work streams, and not pursue an expanded governance model.

2. The discussion paper should include options to improve Member State collaboration.

There are significant policy and legal differences on the methods of monitoring for resistance, the definition of antibiotics, definition of therapeutic uses, the development of interventions, regulating animal health products, incentivizing innovation, and many more topics that would benefit from Member State collaboration. The discussion paper and background do not expand on existing programs or competencies of Member States and ways in which to leverage them (i.e: NARMS, CLSI, CIPARS). For example, for comparing public health and veterinary data, it is far more appropriate to use Clinical Laboratories Standard Institute (CLSI) methods instead of other entities. Only susceptibility testing, disc diffusion, and MIC methods that have been standardized and validated by internationally recognized organizations such as CLSI should be used. This would allow comparability of results (e.g. with human data) and to allow the analysis of resistance patterns over the time.

The final report should include recommendations and practical guidance for Member States to collaborate.

3. The discussion paper inventory of existing actions and models was very limited and excluded significant work streams of Tripartite or Member State entities. For example, there was only one reference to Codex Alimentarius Commission and no mention of its Task Force on Antimicrobial Resistance. There was no mention of the OIE Ad-hoc Group on Antimicrobial Resistance, yet their recommendations on AMR were the most discussed topic at the OIE’s General Session in May 2018. Lastly, the background report was heavy on animals and agriculture, yet there was no reference to the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR).

The final report recommendations should disregard the governance model recommendation or legal instruments included in this discussion paper and focus on improvements in coordination to enable technical coherence and help countries without national action plans to make informed, science-based decisions.

The IACG should acknowledge that progress is occurring in programs to understand the resistance pressures in Member States (ex. NARMS, CIPARS), improve responsible use of antibiotics, and develop new non-medically important antimicrobial products for infectious disease in animals. Since the UN adopted the political declaration, the number of countries with national action plans has more than doubled. The OIE's 2017 antimicrobial survey show significant progress toward more capacity and regulation of antimicrobial medicines in agriculture. The data shows less of a need for governance model and more of a need for coordination and coherence.

The final report should include recommendations and practical guidance to improve coordination, especially for existing work streams, and not pursue an expanded governance model.

4. The discussion paper wrongly includes an Animal/Agriculture/Aquaculture/Food sector specific need for “global standards/regulations to provide a level playing field.”

Policies to benefit public health should be based on scientific evidence, not on political agendas that seek to perpetuate interventions that lack scientific evidence of efficacy or efforts to advance a single model to deliver public health outcomes.

The *level playing field* concept directly conflicts with Member State obligations to the World Trade Organization (WTO). Specifically, Article 2.2 of the SPS Agreement enumerates core obligations of all WTO Members. It provides that Members shall “ensure” that any SPS measure is “applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence....” The WTO Appellate Body has ruled that “the obligation in Article 2.2 that an SPS measure not be maintained without sufficient scientific evidence requires that there be a rational or objective relationship between the SPS measure and the scientific evidence”.

The conditions of each Member State vary and they should be able to address their public or animal health circumstances based on scientific evidence instead of distorting their animal health or biosecurity regiments to comply with policies of a third country that are counter to their SPS Agreement obligations.

The adoption of ineffective interventions in the interest of *levelling the playing field* can contribute to increased antimicrobial resistance, foodborne disease, food insecurity, and reduced animal welfare among other risks. Further, The WHO AMR Global Action Plan, undersigned by all countries, agreed that when implementing measures to address AMR, this should be done at the Member State level considering the prevailing circumstances.

The final report should exclude any reference to level playing field or recommendations that conflict with WTO obligations.

5. The discussion paper places consensus before scientific evidence in Environment section of sector specific needs (pg 5).

Consensus is an important part of the scientific process; however, its use on page 5 is a political application without appreciation for the costs or public health benefits or consequences that may accrue from the standard(s). Most UN Member States count on the UN and Tripartite agencies to provide scientific advice because their resources are very limited, and they can ill afford to adopt ineffective policies or interventions that conflict with their prevailing conditions.

The final report should place emphasis on science-based guidance for standards. Consider changing the sentence to “mechanism to develop science-based standards.”

6. The discussion paper should promote scientific risk analysis rationale instead of including the ‘precautionary principle’ term in Environment section of sector specific needs, “Application of precautionary principal in short-term whilst evidence base is established.”

The precautionary principle is a regional concept contained to the European Union. The discussion paper does not recognize the significant unfamiliarity of the concept outside of Europe and the great potential for misapplication and adoption of costly and ineffective interventions. The European Union has struggled to define the concept. Practical guidance for its application does not exist and will not serve Member States well.

The precautionary principle is considered risk avoidance due to the strong political desire for a zero-risk approach. Such an approach is inconsistent with the political declaration desire to support practical guidance and recommendations.

Further, due to significant differences of the prevailing conditions and legal structures of the non-European Union Member States, the adoption of the precautionary principle in this context could harm the advancements of *Sustainable Development Goals*. Member State’s environmental protection and land management policies play important roles in protecting water resources, food security, climate, rural economic opportunity, gender opportunity, and poverty alleviation.

A better way to deliver the public health objectives as set forth in the political declaration for the environment is to support efforts by the Tripartite and others to develop environmental data, conduct risk assessment, and then apply appropriate and proportionate risk management interventions.

The final report should exclude any reference to the precautionary principle.

7. The discussion paper should give greater value to the role of the private sector and public private partnerships, especially in low and middle-income countries (LMIC).

The animal agriculture community is very diverse globally and plays an important public health function in protecting the health of animals, the safety of food, and the sustainability of food production.

The political declaration speaks very specifically about involving multiple sectors to support the outcomes of the declaration, yet the discussion paper is highly selective and critical of the private sector's roles as part of the solution. In many countries, private sector food producers and processors contribute greatly to ensuring that safe food from healthy animals is available to consumers. These contributions can vary with the prevailing regulatory resources of a Member State. It seems natural that the private sector should be involved in the global process to contribute to AMR-related programming and consultations. The paper really misses the contributions of global, regional, and national associations as well as specific company efforts to drive changes and support their national action plans. The overwhelming majority of global food animals and related processors are privately held persons or entities. The language in this section is alienating to the private sector, which is counter to the language of the political declaration.

The final report should include recommendations and practical guidance to support involvement of the private sector and public private partnerships in AMR-related programming.

8. The discussion paper report wrongly idealizes the removal of antimicrobials from food production as a solution.

The statements presented are anecdotal and limited to U.S. marketing programs. Eliminating medicine does not eliminate disease. The anecdotal statements included companies that still utilize medicine, including medically important antibiotics, to care for the health of their animals and ensure safety of the food. It would be beneficial for the discussion paper to consider actual outcome-focused data versus marketing programs as a constructive way to inform recommendations for countries.

The final report should exclude food marketing programs of highly developed countries as a means of delivering AMR-focused public health outcome and include support for work of the OIE or Codex Alimentarius Commission's Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (GL 77) as practical guidance for Member States to utilize.

9. The discussion paper and report miss the importance of healthy animal's contribution to food safety and societal benefit of animal welfare.

Healthy animals are critical to ensure a safe food supply. Clinical and subclinical illness in food producing animals has been shown to contribute to greater prevalence of foodborne pathogens. This is why many countries require a veterinarian to monitor animals before presentation for slaughter. Eliminating medicine does not eliminate disease, and the complete removal of medicine from some production systems for marketing programs has

increased mortality and decreased liveability conditions of animals. These are public health risks that must be evaluated when contemplating interventions.

The final report should include recommendations and practical guidance to support the contributions to public health from healthy, well cared for animals.

10. The discussion paper should strike the reference to a treaty and recommendations for an international legal agreement.

Effective action and science-driven public health outcomes will be delayed if resources must shift to conduct an international agreement negotiation. The co-chairs would benefit from practical recommendations to improve coordination of effort, the coherence of scientific advice, and political openness to evidence-driven solutions. The development of a legal structure would shift this challenge from a public health matter to a legal burden and sanction avoidance. The evidence shows that international action on public health is more effective through collaboration than coercion. A more practical method to enable collaboration would be to support the political declaration and the existing work of the Tripartite, Codex Alimentarius Commission, and similar efforts of Member States.

In summary, the final report should exclude any reference to a treaty or recommendations for an international legal agreement on antibiotics or antimicrobial resistance. Instead, it should focus on practical, on-the-ground work to implement the wealth of guidance available (as discussed in the IACG Discussion paper on optimising use). Focus should be on the provision of practical guidance on collaboration and utilization of existing structures and authorities.

Yours sincerely,



Ben Stapley

Executive Director

Health for Animals

HealthforAnimals comments on IACG paper: Future Global Governance for Antimicrobial Resistance

HealthforAnimals www.healthforanimals.org is the international non-profit association that represents the animal health sector - manufacturers of veterinary vaccines, pharmaceuticals and other animal health products. We represent 200+ companies on all continents - 85% of the animal health sector.

Introduction

The 2016 United Nations Political Declaration on antimicrobial resistance (A/RES/71/3) requested the Secretary-General to establish an inter-agency coordination group “...to provide practical guidance for approaches needed to ensure sustained effective global action” in consultation with the World Health Organization (WHO), the United Nations Food and Agricultural Organization (FAO), and the World Organization for Animal Health (OIE), collectively the Tripartite, among other objectives. The mandate for *practical guidance* is not well represented in the paper and the proposed governance model. Below are comments and suggestions for improvement.

1. The mandate of the political declaration does not request recommendations on governance, but requests practical guidance on “*options to improve coordination*” (par. 15.) The IACG should consider developing its options to improve coordination within existing structures and models.

A most practical approach is to build on the existing contributions, work streams, and expertise of the Member States and the Tripartite. The proposal to create a new organization, steering board, etc., creates a new bureaucratic layer that will divert financial, political and expert resources from the development and implementation of pragmatic interventions to reduce (or eliminate) the incidence of bacterial disease treatment failure and provide related public health outcomes.

The Tripartite agencies would benefit from improvements in the collaboration and coordination of work. There are several recent instances where they were not coordinated or “*staying in their lane*”. The most notable exceptions to collaboration are the WHO paper in November 2017 on the use of antimicrobials in food producing animals and the FAO’s DG Statements on eliminating prevention uses. Both recommendations and the collateral materials were inconsistent with the OIE Terrestrial and Aquatic Codes on antimicrobial use. Options to improve coordination should start at the top of the organizations. Fortunately, the May 2018 Tripartite shows this is happening. **Recommendation:** The IACG final report should include recommendations and practical guidance to improve coordination, especially for existing work streams, and not pursue an expanded governance model.

2. The discussion paper should include options to improve Member State collaboration. There are significant policy and legal differences in the methods of monitoring for resistance, the definition of antibiotics, definition of therapeutic uses, the development of interventions, regulating animal health products, incentivizing innovation, coordinating outreach in low and middle-income countries and many more topics that would benefit from Member State collaboration.

The discussion paper and background fail to expand on existing programs or competencies of Member States and ways to leverage them (i.e. NARMS, CLSI, CIPARS). For example, for comparing public health and veterinary data, it is far more appropriate to use Clinical Laboratories Standard Institute (CLSI) methods instead of other entities. Only susceptibility testing, disc diffusion, and MIC methods standardized and validated by internationally recognized organizations such as CLSI should be used. This would allow comparability of results (e.g. with human data) and to allow the analysis of resistance patterns over time. **Recommendation:** The

final report should focus on including practical recommendations and guidance for Member States to collaborate.

3. **The discussion paper inventory of existing actions and models is incomplete and fails to mention significant the work stream of the Tripartite or of Member State entities.** For example, there is only one reference to the Codex Alimentarius Commission, yet there is no mention of the Codex Task Force on Antimicrobial Resistance, nor of the OIE Ad-hoc Group on Antimicrobial Resistance - two intergovernmental groups where many Member State governments are investing significant efforts. The background report is heavy on animals and agriculture yet makes no reference to the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR), another group in which many Member States and organizations are heavily engaged. **Recommendation:** The final report recommendations should focus on improvements in implementation to enable technical coherence and help countries without national action plans to make informed, science-based decisions.

The IACG should acknowledge that progress is occurring in programs to understand the resistance pressures in Member States (ex. NARMS, CIPARS), improve responsible use of antibiotics, and develop new non-medically important antimicrobial products for infectious disease. Since the UN adopted the Political Declaration, the number of countries with national action plans has more than doubled. The OIE's 2017 antimicrobial survey shows considerable progress toward more capacity and regulation of antimicrobial medicines in agriculture. The data show less of a need for a governance model and more of a need for coordination and coherence.

The same point is made in the recently released OIE/WHO/FAO tripartite document "*Monitoring Global Progress on Addressing Antimicrobial Resistance*", which showed that countries are implementing a range of surveillance programs consistent with their resources. The report reveals that lack of sufficient guidance is not a limitation to the development of a national surveillance program. **Recommendation:** The final report should include recommendations and practical guidance to improve coordination between existing entities, especially for existing work streams, and not pursue an expanded governance model.

4. **The discussion paper wrongly includes an Animal/Agriculture/Aquaculture/Food sector specific need for "global standards/regulations to provide a level playing field."** Policies to benefit public health should be based on scientific evidence not on political agendas to perpetuate interventions that lack scientific evidence of efficacy or efforts to advance a single model to deliver public health outcomes.

The *level playing field* concept directly conflicts with Member State obligations to the World Trade Organization (WTO). Specifically, Article 2.2 of the SPS Agreement enumerates core obligations of all WTO Members. It provides that Members shall "ensure" that any SPS measure is "*applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence...*" The WTO Appellate Body has ruled that "*the obligation in Article 2.2 that an SPS measure not be maintained without sufficient scientific evidence requires that there be a rational or objective relationship between the SPS measure and the scientific evidence*".

The conditions of each Member State are different, and they should be able to address their public or animal health circumstances based on scientific evidence instead of distorting their animal health or biosecurity regiments to comply with policies of a third country that are counter to their SPS Agreement obligations.

The adoption of ineffective interventions in the interest of *leveling the playing field* can contribute to increased antimicrobial resistance, foodborne disease, food insecurity, and reduced animal welfare among other risks. Further, The WHO AMR Global Action Plan, undersigned by all countries, agreed that when implementing measures to address AMR, this should be done at the Member State level considering the prevailing circumstances. **Recommendation:** The final report should exclude any reference to level playing field or recommendations that conflict with WTO obligations.

5. **The discussion paper – in the Environment section on page 5 – placed consensus before scientific evidence; and includes the precautionary principle concept.** Consensus is an important part of the scientific process; however, its use on page 5 is a political application without appreciation for the costs or public health benefits or consequences that may accrue from the standard(s). Most UN Member States count on the UN and Tripartite agencies to provide scientific advice because their resources are very limited, and they can ill afford to adopt ineffective policies or interventions that conflict with their prevailing conditions.

The precautionary principle is a regional concept mainly contained to the European Union. Some UN Member States actively reject the phrase due to its occasional misapplication or justification for costly and ineffective interventions. Other UN Member States outside of Europe are not familiar with the phrase and concept. The precautionary principle is considered risk avoidance due to the strong political desire for a zero-risk approach. Such an approach is inconsistent with the desire expressed in the Political Declaration to support practical guidance and recommendations. Practical guidance for its application does not exist and therefore it does not serve UN Member States well. Further, due to significant differences in the prevailing conditions and legal structures of the non-European Union Member States, the adoption of the precautionary principle in this context could harm the advancement of *Sustainable Development Goals*. Member States' environmental protection and land management policies play important roles for protecting water resources, food security, climate, rural economic opportunity, gender opportunity, and poverty alleviation.

A better way to deliver the public health objectives as set forth in the Political Declaration for the environment is to support efforts by the Tripartite and others to develop environmental data, conduct risk assessment, and then apply appropriate and proportionate risk management interventions. **Recommendation:** The final report should place emphasis on science-based guidance for standards; i.e. change the sentence to “*mechanism to develop science-based standards.*” It should exclude reference to the precautionary principle.

6. **The discussion paper should give greater value to the role of the private sector and public private partnerships (PPP), especially in low- and middle-income countries (LMIC).** The Political Declaration speaks very specifically about involving multiple sectors to support the outcomes of the Declaration, yet the discussion paper is highly selective and critical of the private sector's roles as part of the solution.

The animal agriculture community is very diverse globally and plays an important public health function in protecting the health of animals, the safety of food, and the sustainability of food production. There is a stark contrast between the human health and agricultural worlds which is not well reflected in the paper. In the human health/medical sector, there is significant state/government involvement, investment, and therefore capacity to control. This does not really exist in agriculture.

Except for some non-democratic countries, in almost all countries, most agricultural activity is undertaken on a private basis by individuals, organizations, co-ops or companies – and not by

the public sector. From farm to fork, it is private people or entities that farm and harvest land and animals, create/distribute inputs (fertilizers, seed, breeding stock, medicines, feed, etc.), process plant/animal harvests into high value products, transport and sell final produce.

In many countries, private sector food producers and processors contribute greatly to ensuring that safe food from healthy animals are available to consumers, in conjunction with government regulations and standards. These contributions can vary with prevailing regulatory resources of a Member State. Because public investment in animal health is significantly less than in human medicine, private organizations lead the charge for discovering and developing new innovative approaches. This not only results in the private sector having expertise on emerging technologies, but also a strong understanding of local markets and production systems, both of which are critical for developing strong AMR programs. The animal health industry invests between 6-10% of its revenues in R&D. In many countries, public-private partnerships are well established and successful. Engaging the private sector through PPPs is a best practice that should be better utilized, not villainized.

It is natural that the private sector should be involved in the global process to contribute to AMR-related programming and consultations. The paper really misses the contributions of global, regional, and national associations as well as specific company efforts to drive changes and support their national action plans. The language in this section is under-appreciative, under-cognizant and in places unnecessarily alienating of the private sector. This is counter to the language and intent of the Political Declaration. **Recommendation:** The final report should include recommendations and practical guidance to support involvement of the private sector and public private partnerships in AMR-related programming.

7. **The discussion paper and report wrongly idealize the removal of antimicrobials from food production as a solution.** The statements presented in the paper are anecdotal and limited to U.S. marketing programs. *Eliminating medicine does not eliminate disease.* The anecdotal statements included companies that still utilize medicine, including medically important antibiotics, to care for the health of their animals and safety of the food. It would be beneficial for the discussion paper to consider actual outcome-focused data versus marketing programs as a constructive way to inform recommendations for countries. **Simple volumetric reduction targets of use in animals falsely appear like progress, but lack human pathogen justification. Over two decades into the AMR discussion, it is time that AMR risk reduction strategies start showing that they have contributed to ameliorating the AMR problem in human medicine.** **Recommendation:** The final report should exclude food marketing programs of highly developed countries as a means of delivering AMR-focused public health outcomes and include support for work of the OIE or Codex Alimentarius Commission's Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (GL 77) as practical guidance for Member States to utilize.
8. **The discussion paper and report miss the important contribution of healthy animals to food safety and the societal benefit of animal welfare.** Healthy animals are critical to a safe and productive food supply. Clinical /subclinical illness in food producing animals has been shown to contribute to greater prevalence of foodborne pathogens. Therefore, many countries require a veterinarian to monitor animals before presentation for slaughter. Eliminating medicine does not eliminate disease. The complete removal of medicine from some production systems for marketing programs has increased mortality and decreased livability conditions of animals - a point highlighted by NGOs and academia working for humane animal treatment.ⁱ These are public health risks that must be evaluated when contemplating interventions. **Recommendation:** The final report should include recommendations and practical guidance to support the contributions to public health from healthy, well cared for animals.

9. The discussion paper should strike the reference to a treaty and recommendations for an international legal agreement. Effective action and science-driven public health outcomes will be delayed if resources must shift to conduct an international agreement negotiation. The Tripartite co-chairs would benefit from practical recommendations to improve coordination of effort, the coherence of scientific advice, and political openness to evidence-driven solutions. The development of a legal structure would shift this challenge from a public health matter to a legal burden and sanction avoidance. The evidence shows that international actions on public health are more effective through collaboration than coercion. A more practical method to enable collaboration would be to support the Political Declaration, existing work of the Tripartite, Codex Alimentarius Commission, and similar efforts of Member States.

The IACG Discussion paper on “Optimal use” is very clear “...*there is a wealth of guidance available*” but “...*implementation is key.*” **Recommendation:** Energy should focus on doing that practical on-the-ground work - for which there are ample coordination mechanisms and implementers. The final report should exclude reference to a treaty or recommendations for an international legal agreement on antibiotics or antimicrobial resistance. Instead it should focus on delivering the challenging but impactful practical guidance on collaboration and utilization of existing structures and authorities.

ⁱ “IMPACT OF NO ANTIBIOTICS EVER / RAISED WITHOUT ANTIBIOTICS PRODUCTION ON ANIMAL WELFARE”, Randall Singer et al, <http://animalagalliance.org/images/upload/NAE%20Welfare%20Report%20Final.pdf?>

Health for Animals

HealthforAnimals comments on IACG paper: Reduce unintentional exposure and the need for antimicrobials and optimize their use” .

HealthforAnimals www.healthforanimals.org is the international non-profit association that represents the animal health sector - manufacturers of veterinary vaccines, pharmaceuticals and other animal health products. We represent 200+ companies on all continents - 85% of the animal health sector.

Introduction

The 2016 United Nations Political Declaration on antimicrobial resistance (A/RES/71/3) requested the Secretary-General to establish an inter-agency coordination group “*to provide practical guidance for approaches needed to ensure sustained effective global action*” in consultation with the World Health Organization (WHO), the United Nations Food and Agricultural Organization (FAO), and the World Organization for Animal Health (OIE), collectively the Tripartite, among other objectives.

The comments below are intended to address the mandate for *practical guidance* for animal related topics in the discussion draft to reduce unintentional exposure and the need for antimicrobials and optimize their use. Below are comments and suggestions for improvement.

Topic 3. Optimizing use in animals and plants

The characterization of the current response in this category is good and includes many of the key activities that are occurring. **Recommendation:** Additional items to include in the final report are:

- 1) Guidance on responsible antimicrobial use should be made with an understanding of the prevailing conditions for each Member State. OIE’ s terrestrial or aquatic animal health codes as well as the WHO’ s Advisory Group on Integrated Surveillance provide tools to help veterinarians practice medicine within these prevailing conditions. The final report would be wise to keep decisions and recommendations on the practice of veterinary medicine as close to the OIE as possible to help enable coherence of strategy.
- 2) GL 77. The dominant Codex document remains Commission’ s Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (GL 77). This document and its application are used by regulators, veterinary pharmaceutical firms, and industry stakeholders. Its value is largely derived from its clear, scientific advice on applying risk analysis principles for antimicrobial resistance. The final report should consider that this current guidance is widely utilized, scientifically relevant, and beneficial for Member States and private parties.
- 3) It is worth mentioning the considerable number of responsible use guidances created by global and national livestock associations/groups, as well as those of the larger global operators. These often build further upon public guidances – providing even more practical useful detail. They are easily and frequently updated, rapidly distributed to antibiotic users and well adopted in many markets.
- 4) The use of the term ‘optimize’ is desirable in this context. Antimicrobials and all animal health products should be used responsibly and complement good farm management and animal husbandry. There are many unmet medical needs in animal health and the potential

for global institutions to support elimination of use(s) is very concerning. Eliminating medicine does not eliminate disease. These products do require stewardship and we encourage the final report to continue to use the term optimize.

Topic 4. Prevention and control of infection in animals.

The document rightly includes a description of vaccines in the role of preventing and controlling infection in animals. Vaccines play a critical role in keeping animals healthy and supporting their immune system to avoid the need for an antimicrobial. **Recommendation:** In addition to vaccines, it is important to highlight the role of good nutrition, housing, and the use of certain feed additives, to protect the health of animals and avoid infections. Attempts to change housing or access to certain feed additives can have negative implications on the health of animals. The final report should consider keeping these decisions at the OIE and similar level.

Topic 5. Food safety and food production.

Recommendation: Any revision to this section should consider the Codex Alimentarius Commission's Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (GL 77). Combined with the risk assessments that any Member State require as a condition of registration of a veterinary medicine would help provide a more data-driven conversation about use, food safety, and risks from food production.

Topic 6. Environment contamination.

Recommendation: The final report should consider encouraging the development of data and conducting risk assessment prior to recommending risk management for Member States.

Health for Animals

HealthforAnimals comments on IACG paper: Meeting the Challenge of Antimicrobial Resistance: From Communication to Collective Action

HealthforAnimals www.healthforanimals.org is the international non-profit association that represents the animal health sector - manufacturers of veterinary vaccines, pharmaceuticals and other animal health products. We represent 200+ companies on all continents - 85% of the animal health sector.

Introduction

The following comments correspond to questions presented in the discussion paper on page 2.

- 1. How can we best measure and prioritize efforts that communicate AMR effectively, so that limited resources are used optimally?** The focus of prioritizing communication should follow the process of risk assessment, risk management and then risk communication. Improving the science-based awareness and understanding of antimicrobial resistance (AMR) can help mobilize resources to address this challenge. Therefore, grounding communication based on risk assessment and science-based will be most effective.

To help prioritize, the focus should rely on leveraging the work of the World Health Organization (WHO), the Food and Agricultural Organization (FAO), and the World Organization for Animal Health (OIE), collectively the Tripartite. Programs should focus on AMR amelioration actions that are directed towards pathogens identified in the WHO's priority pathogen list. Global entities are reminded that communications efforts are a competency best reserved for Member States - they know their markets and they can tailor content.

Recommendation: The final report should consider encouraging vigilance when communicating risk or conducting a campaign to advance coherence, focus and understanding of AMR objectives and programs. AMR can be a confusing topic. Efforts to simplify risk can lead to undesirable consequences.

- 2. What are the major barriers to changes in antimicrobial use and management among priority stakeholder groups and communications recommendations to tackle these?** **Answer:** The implication of risk management in the question is problematic since these should be the outcome of the agencies. This question is mixing assessment, management and risk communication. For clarity:
- Risk assessment - by scientific assessors, to gauge safety, efficacy, etc.
 - Risk management - by managers (administrators), to set rules and practices of use
 - Risk communication - by communicators, to communicate the rules and practices of use the risk managers deem appropriate
- 3. What are appropriate and practical incentives for changes in practice? What lessons might be learned from other areas, from vaccination to WASH (water, sanitation and hygiene) campaigns, that could inform what the IACG might recommend?** **Answer:** Public campaigns should communicate risk management practices based on risk assessments. Campaign that promote risk management unconnected with risk assessments can mislead the public and provide a false sense of security.

Communications should focus on the lowest hanging fruit where that have most impact. For example, the two most effective things that people can do to avoid foodborne bacteria (resistant or not) is to wash their hands and cook their meat properly. Yet there are very few communications campaigns focused on these types of practical yet highly impactful actions.

Precision of language is important. Care should be taken about the terms ‘antibiotic’ versus ‘antimicrobial’. And actions should be targeted at the areas of most concern (so antibiotics and not the wider group).

4. What research agenda is needed to support efforts to communicate AMR? How might this communications research best be funded and coordinated? **Answer:** See questions 1 and 3.
5. What model approaches best mobilize key actors in tackling AMR while raising awareness? How might one best structure a multi-stakeholder platform for AMR communications and a community of practice linking these key communications focal points? **Answer:** This already exists with the Tripartite. There is no need for a new legal structure, agreement or treaty that will needlessly divert resources away from public health outcomes to negotiation, litigation, and sanction avoidance.

Developed countries have risk assessments, risk managements and risk communications in place. The challenge is assisting developing countries where resources are lacked. The question should be how the global community can help LMIC countries adapt risk management and risk communication practices without further straining their minimal resources. The answer is by investing in modernizing animal agriculture infrastructure like the Bill and Melinda Gates Foundation does. Communications campaigns targeted at farmers in LMIC telling them not to use ABs when a third or more of their animals are sick or dying will have little impact, unless such campaigns also talk about the tools, and make the help (financial and otherwise) available for them to prevent death and disease, and the ensuing poverty.

Message: In animal agriculture, in LMIC, all the communications in the world are pointless unless the underlying problem – animal disease and its devastating consequences – are diminished.

6. Where and what would be the most strategic opportunities for investing in efforts that communicate AMR? How can the Tripartite agencies and other intergovernmental agencies be supported to carry out this work? **Answer:** Science-based public communication can help the public and the intended audience distinguish between hazard and risk. Therefore, risk communication is instrumental in gaining the public’s trust and having more impact to promote change. Risk communication would be the most impactful when it is based on risk assessment.
7. How can we best scale promising strategies for changing individual behavior into collective action to effect AMR change? What groups might be enlisted in these efforts? What role does civil society, professional societies and industry trade associations among others constructively play in these efforts, and how might this be supported? **Answer:** It should be understood that policy driven by perception should not get ahead of science and risk assessment. Perception should not supersede risk assessment to ease or skew public view of risk. Communication to the public around risk assessments and risk managements should ease the public’s perception of risk. This is a competency best reserved for Member States.
8. What opportunities are there for enabling effective monitoring for accountability towards effecting AMR change? What enabling conditions are critically important for such efforts, and how can we best ensure that these conditions are met? **Answer:** The work of the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR) should be applied here to enable effective monitoring and not duplicate efforts of the Tripartite. Again, it needs to be emphasized that the purpose of policy is not to get ahead of science and risk assessment to have perceived effects on change, but to support science and provide meaningful guidance for the animal health and food animal industry. Taking away medicine will not take away disease and

protect food safety. Risk assessment and risk management will guide production practices and animal health practitioners to prevent disease and food borne illnesses.

There is no need for a new legal structure, agreement or treaty that will needlessly divert resources away from public health outcomes to negotiation, litigation, and sanction avoidance.

International Dairy Federation



IDF comments to the work of the United National Interagency Coordination Group (IACG) on Antimicrobial Resistance (AMR)

(dated 22 August 2018)

General Comments:

The discussion paper provided by the IACG group should take into consideration the central role of the International Dairy Federation in promoting good practice in use of antibiotics along the dairy sector.

Paper *Future Global Governance*:

The International Dairy Federation has a central role in promoting good practice in use of antimicrobials in the dairy sector as it assures the coordination and collaboration of all stakeholders along the dairy chain. The IDF cooperates with FAO and OIE on antimicrobial resistance. While the engagement with private sector is mentioned several times as important, a closer relationship of IACG with IDF could be considered.

This report indicates that private sector and industry leaders need to be involved (page 50), and therefore IDF should be engaged at the start of the process. The work carried by IDF should be taken into consideration.

The IDF has a key role on the monitoring of antibiotic use. In most countries regulation and commercial incentives strictly control antimicrobial agent use in dairy. The dairy industry conducts extensive monitoring of antimicrobial agent use, including testing, to ensure unacceptable residues are not present in milk. By killing micro-organisms, heat treatment of milk provides an effective control measure to assist the management of foodborne AMR.

The IDF encourages good farm management. The 2011 FAO/IDF joint guidelines promote best farming practices to support the production of safe, quality-assured milk and dairy products.

The IDF encourages good animal health and welfare and therefore the prudent use of antimicrobials. Examples of this guidance are the Guide to Prudent Use of Antimicrobial Agents in Dairy Production (2013) and the IDF Factsheet on control and detection of antimicrobials residues in milk and dairy products (2014). On the drafting of these documents, IDF took into consideration the *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005) and *Guidelines on Risk Analysis of Foodborne Antimicrobial Resistance* (CAC/GL 77-2011). The IDF Factsheet on guidance on antimicrobial resistance from the dairy sector (2017) outlines dairy sector guidance on prudent use of AA and defines the global dairy position on AMR. Moreover, IDF is actively participating on the Codex Alimentarius electronic working group revising the *Code of Practice to Minimize and Contain Antimicrobial Resistance* and drafting of *Guidelines for the integrated monitoring and surveillance of foodborne antimicrobial resistance*.

Paper *Optimizing Antimicrobial Use*:

The IDF would like to strengthen the importance of movement of people in the prevention and control of human infection in the provision of health care. This topic is neglected on this document.

The IDF would like to strengthen the importance of life animal trade on animal disease. While the paper mentions that *OIE has prepared disease-specific standards to avoid infection through trade*, this is quite limited. Further consideration is needed.

This paper should also recommend avoiding the treatments of chronic infected cases which would not be cured, and where prolonged treatment would lead to selection of AMR pathogens.

Good management should be highlighted more than alternative medication. Good management leads to healthy animals, with less need of antibiotics.

The IDF is aware of the great differences in different countries and regions of the world. Thus, there should be different actions adapted to the present situation in these regions.

This paper should further consider the importance of food safety and food production to reduce the need for antimicrobial therapy and prevent the spread of AMR. Recommendations should not only cover food production, but also food processing, storage, transport, retail and distribution. This guidance should refer to the already existing good practices, such as the Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004). For clarity and better understanding, some examples of food borne AMR could be cited.

Paper *Communicating for change*

The IDF finds very positive the existing examples from The Netherlands and Denmark regarding a collective action. Highlighting efforts and good practice is important. Other examples could be cited, for instance, the reduction in Norway of the prevalence of mastitis by 60 % since 1994 without any detrimental effect of food quality and animal welfare.

Individual

Comments on the IACG Document *Interagency Coordination Group on Antimicrobial Resistance: Future Global Governance for Antimicrobial Resistance*, for public consultation

From: Jennifer Cole, PhD

1. Research Fellow, AMR, Royal Holloway University of London
2. Public Health Policy Advisor, Rockefeller Economic Council on Planetary Health, Oxford Martin School, Oxford University
3. Associate Fellow, Resilience and Emergency Management, Royal United Services Institute for Defence and Security Studies

Page 2 – re: Global Steering Board: It should be made clear that such a group **must** ensure equal participation from developing nations – particularly India and China – in order to fully consider the implications of changes to AMU in the healthcare sector and agricultural sector structures within these countries and to ensure the challenges posed by their level of development (e.g. levels of hygiene; food standards; pharmaceutical regulation and so on) are addressed. While this is covered later in the main body of the report, highlighting and ‘upfronting’ it earlier would show that including developing nations is essential, not just lip service.

Page 5 – Shared One Health Needs: There may also be a need here to consider very carefully how well prepared/able a country or regional setting is to cope with a post- or reduced- antibiotic era, for example hygiene and infection control in housing and in hospital settings; sanitation systems and waste treatment; availability of diagnosis; availability of regulated healthcare. There is a danger that over-regulation could leave some parts of the world, and low socio-economic groups within more affluent regions, with significantly reduced access to antibiotics and limited access to mitigating healthcare/hygiene alternatives.

Page 6, Point 4: I wonder whether the text suggests too strong a focus on nations rather than industries and multinational private sector key players who may be more able to act quickly?

Page 7, Point 8: More important than ‘globally respected’ may be the need for such a body to have some real teeth to, for example, impose trade sanctions etc.

Page 30, incentives: re – the statement “...However, incentives cannot be achieved by increasing prices or sales volumes as such measures would undermine access and conservation...”: There could be more consideration here of linking measures and incentives to improving public health in general, e.g. reducing meat consumption in general will be accompanied by a reduction/avoidance of increase in obesity and related NCDs. AMU reduction could be framed within/alongside other public health strategies and draw on corporate social responsibility to enable a healthy society. Such an approach could also position antibiotic-free meat as (individually and on a societal level) as aspirational and characteristic of development and affluence (c.f. How public health messages in India have positioned the installation of household toilets as aspirational – see <http://www.inclusivebusinesshub.org/beyond-building-toilets-complete-aspirational-and-sustainable/>)

Page 33: Restoration: Re: “the Ozone layer is expected to return to 1980 levels...”

An important difference between antibiotics and the Ozone layer is that the efficacy of antibiotics cannot 'return' in the same way. Once an antibiotic has gone, we have lost it forever. This is a key distinction between other health crises in which the pharmaceutical and medical sector has been involved and needs to be noted. Lessons from conservation and species extinction may have some value as an alternative. Also, the 'containment' of the cause within one industry sector, with a major multinational stakeholder willing to act, may not be quite the same for AMR - it will involve pharmaceutical companies, the veterinary profession, farmers and food producers. All will have to benefit equally from alternatives but – unlike with the tobacco industry – there will be no single 'loser', which should help the potential solution providers to self-incentivise.

Page 37, point (d): Important to note that HIV/AIDS emerged in LMICs; there was no healthcare available in many of the areas worse affected - part of the challenge was providing this and building healthcare systems alongside public health campaign around sexual health. The challenge with AMR comes from the opposite end of the scale — too much use. How would the new drugs be protected from overuse in LMIC regulation-poor settings?

Page 40, AIDS: A key factor in the AIDS crisis was the 'immediacy' of the issue - how 'in your face' it was. Most people knew someone (or knew of a celebrity or someone) who died of AIDS. There has not yet been a similar level of AMR casualty to grab public attention - recognising how to identify and 'grab' a key 'event' that might trigger such a change could be valuable.

Page 42: Re the statement "AMR moves across borders", While this is true, I feel it is also important to make a distinction between AMR and other cross-border 'pollution' issues, such as air, plastics, PICs and POPs etc in that AMR is self-replicating. It is not a case of 'dumping', 'moving' or 'migration' of pollution, but of reproduction and dispersal magnifying the problem as it moves. AMR both remains at the point of release *and* travels to others. It is as much about the control of the 'plague' that resistant bacteria will cause than the control of antibiotics as pollutants. This gives the issue a unique dual nature not seen in other health crisis (where the key issue is distribution of more drugs) or pollution issues (where the key issue is limiting the movement of the pollutants). It needs to be remembered that the 'Global public good' being provided by better antibiotic governance and regulation is the abstract quality good health – enable through products but not the product itself (though it could be commoditized and how this might help to conceptualise the issue may have value).

Page 46: Incentives for action: An approach here may be to consider what behavioural nudges could be used to influence different sectors - e.g. could research show that farmers' families are more impacted by AMR? Do they suffer more deaths from infection in elderly relatives/neonatal mortality? What shock tactics might galvanise different sectors to action? The individual nudges that join up into collective action may help to support a concurrent strategic top-down approach. Moral pressure on the highest users may have a strong impact – cf. the naming and shaming in the recent Aviva AMR report.

Page 47: Standards: Worth noting that standards in one major industry player can provide a benchmark for smaller businesses even if they are not required to adhere to them legally. This can be particularly important if they want to trade/deal with those who do. An analogy could be drawn with Fairtrade coffee/chocolate symbol.

Page 52: While an analogy can be drawn between the tobacco industry and AMR, it is important to note that the tobacco industry could only really lose from the FCTC - they had no alternate profit structures to explore as they could only provide the challenge, not the solution. This is not the case for the pharma industry, which provides both the problem (antibiotics) but also potential solutions (e.g. vaccination as an alternative) and therefore can help to influence the direction of change.

Muhammad-Bashir Bolajoko

From: [muhammad bolajoko](#)
To: [IACG-secretariat](#)
Subject: FEEDBACK: AMR Interagency Coordination Group Discussion Papers
Date: 31 July 2018 16:56:04

Hi,

Below are my contributions as requested.

Future global governance

My concern here is how to put all regions and/or countries of the globe on the same level of awareness of antimicrobial resistance (AMR) and this why there is need for a robust and sustainable global governance for AMR. This is worrisome as many counties do not really understand the increasing development and risk of AMR to global one-health.

Optimize use of antimicrobial

Again, I am considering my practical and field experiences here in Nigeria, where majority of animal health providers and poultry farmers are not aware of the problems and/or implications of unnecessary and increase exposure of animals to antimicrobial and as such see no need to reduce or optimize their use. Whereas those stakeholders that are aware naturally ask for a replacement that is affordable and effective to replace the use of antimicrobial. The question is what we do about this population of the world with such perception of AMR.

Communication for change

I am very happy with recommendation of this paper and I am positive this will meet the intended objective. However, a sustainable and effective monitoring and evaluation of the communication measures to be adopted is very crucial to ensure that it sustainably meets the global challenges of AMR, as increasingly the factors predisposing to AMR are CONTINUOUSLY dynamic AND relates highly to socio-economic and cultural disposition of the global public. If success is achieved with the communication for change, then success with global governance of AMR and optimize global use of antimicrobial will follow suit as well.

I hope this contributions add value. Thank you for the opportunity.

Best wishes,
Bashir

--

Muhammad-Bashir BOLAJOKE, DVM, PhD
Preventive Veterinary Medicine/Epidemiologist,
National Veterinary Research Institute, Vom, Nigeria.

Marco Haensszen

From: [Marco Haensszen](#)
To: [IACG-secretariat](#)
Subject: Public Consultation Feedback: IACG Discussion Papers
Date: 26 August 2018 14:35:28

Dear IEAG Secretariat,

With reference to the Public consultation on discussion papers informing the report of the Interagency Coordination Group to the UN Secretary-General, I am responding to document **“6. Meeting the challenge of antimicrobial resistance: from communication to collective action”** and specifically to the questions,

- “1. How can we best measure and prioritize efforts that communicate AMR effectively, so that limited resources are used optimally?”
- “2. What are the major barriers to changes in antimicrobial use and management among priority stakeholder groups and communications recommendations to tackle these?”
- “4. What research agenda is needed to support efforts to communicate AMR? How might this communications research best be funded and coordinated?”

My response addresses population behaviour change through awareness raising, but also relates more broadly to behaviour change in the medical and agricultural professions. The main challenge in these questions is that they equate changes to population behaviour with communication. I do not plea to drop education and awareness raising altogether because they evidently have a role to play, but education and awareness raising alone are insufficient and potentially detrimental to address the behavioural dimension of AMR. The document rightly raises the limitations of the “knowledge deficit” model, but it fails to seriously consider behaviour change approaches that go beyond common health policy approaches.

My case it as follows: The current AMR policy emphasis on public behaviour change through education and awareness raising is dangerously deficient. One the one hand, it is implausible that education and awareness raising alone will fundamentally alter population health behaviours in relation to antimicrobial use (either in isolation or in conjunction with other elements of the Global Action Plan). The simple thought experiment of raising awareness among every single person globally fails to achieve fundamental changes in behaviour, because it is not merely an absence of information that shapes health behaviour. This should not come as a surprise and had been established in the social sciences for several decades; and the document itself acknowledges limitations of the “knowledge deficit model.” My own current social research on health behaviour in Southeast Asia confirms that increased knowledge does not typically translate into improved behaviour. My first point therefore is that information provision alone is insufficient to alter population behaviours to a sufficient degree.

On the other hand, the provision of information for a subject as complex as antimicrobial use can and will have unintended behavioural responses, like scaring people off life-saving medicine. “Simple messages” around antibiotic use can be misinterpreted if they do not correspond to people’s understanding of illness, of medicine, and of treatment, and they can easily be misappropriated for other purposes (e.g. stigmatisation, politicisation). My own research provides ample evidence of this point, for example an educational activity that shared information about antibiotic use in line with WHO recommended messages, following which villagers started *selling* antibiotics informally. My second point therefore is that information provision has unintended side-effects.

My third point is that the insufficient policy response can be overcome by addressing not only the individual but also the structural factors underlying people’s health behaviour. However,

this requires us to go beyond conventional ideas of “health policy” and its customary mechanisms, and rather define AMR as “development policy.” Poverty, stress and precarity, discrimination, access to physical infrastructure, distrust in the political system, and many more structural and interpersonal factors shape health behaviour. Development interventions like social protection schemes, cash transfers and access to finance, infrastructure development, or labour rights programmes might be unintuitive but plausible avenues alongside universal healthcare programmes to promote behaviour change. However, we are at an early stage in this agenda, and my third point therefore is that we need to explore development policy solutions to AMR and not waste precious time and resources with a deficient and outdated focus on communication as the sole tool for behaviour change.

In light of the guiding questions above, it is a mystery why the document (and the global response to AMR more generally) should put such a wasteful emphasis on communication and not consider a comprehensive set of behaviour change strategies that take account of the formidable limitations and side-effects of AMR-related communication. We need an urgent diversification of behaviour change policy that draws on development policy and long-standing experience from the social sciences. Disciplines like medical anthropology, development economics, and development studies have several decades of knowledge on the options and limitations of behaviour change campaigns and are therefore in a favourable position to aid the search for and development of innovative *social interventions* that address structural and social aspects of behaviour (for an example, please see this recent [blog](#)). This follows recent pleas from *The Lancet* and the innovation foundation Nesta to overcome the “biomedical bubble.” As a step in this direction, I propose the establishment of a cross-sectorial consortium led by UNDP or the World Bank to coordinate population behaviour change agendas. Should the Secretariat wish to discuss these points further and be willing to explore alternative avenues for research and behaviour change intervention priorities, then I will be at your disposal.

Sincerely yours,
Marco J Haenssger

Marco J Haenssger

Postdoctoral Scientist – Health Policy and Systems
Research Associate – Green Templeton College

Centre for Tropical Medicine and Global Health, Nuffield Department of Medicine
Peter Medawar Building for Pathogen Research
CABDyN Complexity Centre, Saïd Business School

OPEN CONSULTATION BY THE WORLD HEALTH ORGANIZATION ON ANTIMICROBIAL USE

- *What kind of support (other than financial) is needed to translate the existing guidance into implementable actions?*

Strategic support in form of developing an Intergovernmental Panel on Antimicrobial Resistance (IPAR) akin to that in climate change is needed. Such a panel under the auspices of the United Nations should be flexible by allowing individual countries form their own panels under the global umbrella. The objectives of the IPAR should include provision of sound scientific view on antimicrobial resistance (AMR) and its socio-economic impact. The panel can be supported by scientists and experts on a voluntary basis via contributing to writing and reviewing reports, which are then reviewed by governments. In terms of composition, the panel can have different working groups for example working group 1 assesses the scientific aspects of AMR, working group 2 assesses the socio-economic impact of AMR and working group 3 assesses options for minimizing or optimizing antimicrobials. At the local level, professional support should be provided to doctors, veterinarians, farmers and consumers on how best to optimize antimicrobial use; ideally economists and AMR experts should be involved in helping doctors, veterinarians, farmers and hospitals determine the most cost-effective ways of treating ailments or conducting surgeries as this will optimize antimicrobial use.

- *How can policy makers be assisted to further develop and implement infection prevention and control in human and animal health and plants and be convinced to invest now to mitigate the escalating and future costs and obtain benefits far beyond preventing AMR?*

Policy makers should be provided with robust economic evaluations on the immediate and future impact of AMR. This should include both the impact of AMR at the micro and macro level. Also, policy makers should be assisted in developing and utilising affordable technologies for mitigating AMR such as point of care diagnostics.

- What incentives or initiatives are needed for behaviour change towards responsible use in the health sector (hospitals, community health centres) and in the food and animal production sectors (animal and plant health professionals, food producers and manufacturers, consumers).

Attempts to change individuals' behaviour take many and varied forms, including upstream measures such as laws and regulations and downstream measures such as information and education campaigns. Mandatory stewardship programmes is an example of an upstream approach and should be introduced in hospitals, healthcare centres and veterinary clinics. The stewardship programme can be part of accreditation. Hospital accreditation should equally be mandatory in all the United Nations member countries to avoid the issue of free riders. At the downstream, pharmacies especially in developing countries, where drugs are massively dispensed over the counter, should be encouraged to record the drug, name and mobile number of their customers and this can be used as part of pharmacy accreditation. Recording names will indicate to the customer that dispensing of drugs is a professional process as opposed to buying goods from the shop thus will act as a way of changing their behaviour. Multifaceted mass media and educational campaigns targeting both the public and healthcare professionals, but culturally tailored to the particular community, should be held with active engagement of all levels of authority. This should be performed in a coordinated and comprehensive manner that addresses all aspects of behaviour such as capability, opportunity and motivation given changing health behaviour is difficult and requires significant and sustained commitment and investment. Additionally such campaigns should include encouraging consumers to only use accredited health centres or pharmacy.

In the animal health sector, education and training of professionals and farmers should be done at the national level as part of a multimodal campaign. This can involve changing prescription patterns of professionals through education on importance of veterinary oversight and legislation, responsible use of antibiotics, dose rates and withholding periods. Targeted advocacy messages should be developed to highlight the financial feasibility of alternatives to antimicrobials.

As for the manufacturers, corporate social responsibility (CSR) scheme should be developed for drug companies and tax incentive (i.e. reduction in tax) offered. This will encourage global investments in consumer awareness and advocacy campaigns.

- *What is needed to generate evidence-based data that link the misuse of antimicrobials and the development and spread of AMR via the environment? How can we use the available data to develop effective policy solutions influence policy makers?*

The environment is the single largest source and reservoir of resistance. Soil, aquatic, atmospheric, animal-associated, and other ecosystems are home to microbes that harbor antibiotic resistance elements and the means to mobilize them. Therefore understanding the evolution of resistance in the environment, its diversity, and mechanisms is critical to the management of the current antimicrobials. However, given the vastness and the microbial richness of the environment, next generation sequencing can play an important role in detecting and tracking environmental antibiotic resistome. This should be coupled with phylogenetic studies to determine the origin of the microbe i.e. humans, livestock or environment. Furthermore, collection and analysis of AMR data should be done jointly between human and animal health sectors using the One Health principle and outcome presented to policymakers.

- *What approaches are needed to ensure the industry and investors manufacture and market antimicrobials responsibly, and not stimulate overuse or contribute to environmental pollution?*

Appropriate legislation and taxation of manufacturers polluting the environment should be done. Environmental pollution is an externality which in most countries is internalized by taxing the polluters. Inappropriate advertising of antibiotics should be discouraged and penalized with the help of consumer oversight authorities.

- *Changing practices needs the support of the industry - how can we balance the availability of a public good such as effective antimicrobials, with a private industry perspective?*

Antimicrobial resistance is both a public health and economic issue. From an economic view, optimization of antimicrobial use entails minimizing the bad effects such as AMR and maximizing on the good effects e.g. effective treatment and good returns for producers. Surveillance, infection control, stewardship and governance all play an important role in mitigating AMR which is an externality emanating from antimicrobial use. However, currently the returns from investing in drug manufacturing has been reported to be low leading to lack of investment in new antibiotics. Therefore the private sector will require robust financial incentives. Examples of such financial incentives include tax credits (which can be non-refundable or refundable depending on the country or drug to be manufactured), cash

innovation inducement prizes, public-private partnerships, patent buy-outs, end-prize payments, extended patency or market exclusivity, de-linkage business model among others.

- *What are the mechanisms to enhance the availability and utility of global resources for the end user (communities and individuals) to optimize or reduce the need for the use of antimicrobials and mitigate the unintentional exposure to the environment?*

Access to effective antimicrobials is a critical component in reducing AMR and is linked to supply of antimicrobials. Antimicrobial supply chain should adopt high standards of procurement and inventory management practices to ensure steady supply of essential medicines. Additionally, safe and well researched alternatives to antimicrobials should be made available to communities and individuals.

Céline Pulcini

From: [Celine Pulcini](#)
To: [IACG-secretariat](#)
Subject: Feedback on IACG papers
Date: 31 August 2018 11:57:28

To whom it may concern

Please find below some feedback on the recently posted IACG discussion papers, that are very interesting to read.

Future Global Governance

- It is written that "At the national level, any governance structure should support coordination and reduce duplication", and I fully support this. I also believe that such coordination efforts are needed at regional (e.g. WHO regions) and international level, as much duplication and redundancy in efforts is happening right now, and this is a waste of precious resources.

Reduce unintentional exposure and the need for antimicrobials, and optimize their use

- the human and animal parts are not aligned regarding IPC. In the human part, IPC is mostly dealing with healthcare acquired infections, whereas in the animal part, IPC includes all prevention of infection and transmission efforts (community and healthcare settings), including vaccination. I believe that a definition of IPC is needed, clarifying the place of vaccination, and of prevention of infections (in its broad sense), in all settings.
- page 3 last line: I would replace "gastrointestinal disease, increasing even further the need for antibiotic treatment", by "increasing the number of antibiotic prescriptions", since most of these antibiotic prescriptions are unnecessary (most gastrointestinal diseases being self-limited and benign).
- section 7: a definition of antimicrobial stewardship would be useful (e.g. set of actions aiming at responsible antibiotic use)
- page 10, section 7, second paragraph: information on the appropriateness of antibiotic prescriptions is also dearly missing

Best regards,

Prof. Céline PULCINI

MD PhD

Member of the executive committee of the French Infectious Diseases society

(http://www.infectiologie.com/site/_spilf_presentation.php)

Chair of ESGAP (ESCMID Study Group for Antimicrobial stewardship)

(<https://www.escmid.org/index.php?id=140>)

Associate Editor for Clinical Microbiology and Infection (<http://www.journals.elsevier.com/clinical-microbiology-and-infection/>)

CHRU de Nancy, Service de Maladies Infectieuses et Tropicales /

Dons en ligne pour soutenir les travaux de recherche de l'équipe ANTIBIOVAC en sélectionnant 'Programme ANTIBIOVAC'

Michael Ryan

From:

Sent: Tuesday, 07 August 2018 10:55

To:

Subject: RE: We need your input! AMR Interagency Coordination Group Discussion Papers

Dear Chris,

Many thanks for the opportunity to comment on these documents. The documents pull together a lot of interesting information and data and outline an interesting roadmap for the future work and collaboration on the challenges in dealing with AMR globally. I have reviewed the documents from the agricultural perspective and have briefly outlined some issues that came to mind. In particular, I think there needs to be a stronger emphasis on the economic dimension especially with respect to AMU in food animal production.

1. A greater emphasis should be given to the risks associated with AMR and the potential impacts on the global food supply chain, in particular the availability of animal proteins for human consumption. A critical goal in this context is getting the right balance the issues of food safety and food security in the context of AMU/AMR.
2. Most of the focus appears to be on regulations and regulatory structures and enforcement, however, I think it is also important to emphasise the economic incentives, especially in food animal production that would encourage farmers adjust their current animal production systems to more sustainable systems. Also, in this context, it is important to clarify the benefits /costs of antimicrobials to food animal producers in the short run (there is a perception of short term net gains in some systems), and in the medium-long run (the evidence shows that the costs clearly outweigh the benefits).
3. The issue of negative externalities to society and human health from AMU in animal production may need to be better developed and explained as this is an area that is not well understood at present.
4. From a global perspective, perhaps the first crucial step is to phase out the use of antibiotics as AGPs in animal production. Many countries have achieved this goal with no adverse effects on production (EU phased out AGPs in 2006), but today a large proportion of antimicrobials are still used for growth promotion especially in the BRIICS. In effect, it would appear from the limited data available that the bulk of antimicrobials are still used for animal growth promotion in many parts of the world.
5. Another issue relates to the use of antibiotics for disease prevention especially in high density intensive production systems. It think it is important to show that there are several alternative cost effective ways (better nutrition, breeding, management, biosecurity, etc.) to prevent a disease outbreak in animals, apart from antibiotics.
6. Globally, to complete the AMU/AMR picture it would also be useful to include some discussion on companion animals and wildlife. The use of antibiotics on companion animals is high and growing in many high income countries.
7. Overall, finding the right balance between regulations (which are properly enforced) and economic incentives is the key to optimising the use of antimicrobials in livestock production and in developing sustainable food animal production systems.

I hope that these brief comments are helpful.

With kindest regards

Michael

Ellen Silbergeld

From: Ellen Silbergeld

Sent: Monday, 30 July 2018 20:33

To: FAO on Antimicrobial Resistance

Subject: RE: We need your input! AMR Interagency Coordination Group Discussion Papers

Actually the comments i sent on governance apply to all the papers. There is a lack of understanding as to the variability among countries, agriculturalists, and resources. Suggest more consultation with stakeholders on all topics

Ellen K Silbergeld PhD

Professor, Environmental Health and Engineering

Johns Hopkins Bloomberg School of Public Health

From: Ellen Silbergeld

Sent: Monday, 30 July 2018 20:31

To: FAO on Antimicrobial Resistance

Subject: RE: We need your input! AMR Interagency Coordination Group Discussion Papers

Thank you for sending these papers. I strongly endorse the intention of the concept of global governance, but I also have some concerns based on my service on the WHO guidance development group on AMR in agriculture.

1. I do not think that there is international consensus on the goals of such governance, and in fact three of the major food animal producing countries dissented from our guidelines
 - a. While there is always lack of full consensus, the likely nonparticipation of these large sectors will make it difficult to achieve the over all goals given the transnational flow of AMR
2. From my experience, effective policies and actions vary greatly across countries and regions based on resources, agricultural practices, and sociocultural factors. This document is a very top-down expert driven approach: more stakeholder participation is essential. In addition, policies that may be appropriate and achievable for high incomes countries with largely highly integrated and intensive production will be different from middle and lower income countries with larger sectors of small entrepreneurial farmers and fewer resources for monitoring and reporting. The existence of resources for effective policies for controlling clinical uses also vary.

FURTHER NOTES ON OTHER DOCUMENTS TO COME

Rick Watkins

From: [Rick Watkins MD](#)
To: [IACG-secretariat](#)
Subject: IACG
Date: 22 August 2018 18:23:08

Dear Secretary,

I have enjoyed reading the discussion papers on AMR. They are interesting, timely and well-written. I am an infectious disease physician and clinical researcher with a keen interest in antibiotics and AMR. Please let me know if there are any opportunities to help with the efforts of the IACG, such as committee service or helping with report writing. Thanks in advance for your consideration, I am sure you have many individuals making similar requests.

Kind regards,

Rick Watkins

Richard R. Watkins, MD, MS, FACP, FIDSA
Associate Professor of Internal Medicine
Northeast Ohio Medical University

Division of Infectious Diseases
Cleveland Clinic Akron General

Martin Wierup

From: Martin Wierup

Sent: Tuesday, 28 August 2018 10:40

To: FAO on Antimicrobial Resistance

Subject: SV: We need your input! AMR Interagency Coordination Group Discussion Papers

Dear Chris,

Please find my comments in attached document.

It would be interested to know the further development of the documents and the view on my major comment – need for data on the use of antimicrobials.

To note, in my country Sweden we have such data since 1980 in animals and it would have been impossible to evaluate and document our ban of antimicrobials for growth promoting in 1986 without those data. The same experiences are now made in other countries and to provide such data are the way to be a harmonized demand for all EU MS.

All the best and kind regards

Martin

Martin Wierup, DVM, PhD, Dipl. ECVPH, Dipl. ECPHM

Senior/Emeritus Professor

Dep. Biomedical Sciences

and Veterinary Public Health (BVF)

Swedish University of Agricultural Sciences (SLU)

To FAO Antimicrobial Resistance Communications

Respond from Martin Wierup, Sweden; member of JEMRA Committee; August 28, 2018.

Dear Chris

As requested in your mail of 30 July 2018 from FAO/ please find my comments on the three documents as below.

General

I have with great interest studied the three documents and found them to be excellent, balanced and well written and, based on a good and comprehensive summary of the current situation, propose concrete and specified ways forward. I welcome that they all focus on such ways and do not, as was not uncommon in previous years, pointing out possible uncertainties that need to be cleared out before actions are taken. It is also clarified that the current actions; status quo is not enough. I have one major problem (data on the use of antimicrobials as specified below) but in addition and generally only limited comments to add in particular when considering that the text need to be short.

1. **Future Global Governance for Antimicrobial Resistance – including comprehensive appendix**

The approaches and suggestions and key messages made seem fine and logic to me although I do not find myself to have enough expertise to forward any further specific suggestions on the global implementation and associated governance

2. **Reduce unintentional exposure and the need for antimicrobials, and optimize their use**

To strengthen that position I would suggest you to consider a modification on the following two points:

1. Under second paragraph of the heading 3 on “*Optimizing use in animals and plants*” I would like to highlight the following sentence: “*Intensification of animal production, however, is predicted to increase the use of antimicrobials in livestock by nearly 70% by 2030 (data still correct?) if production methods do not become more sustainable*”.

I would suggest a more sensitive wording because the predicted increase in livestock production, i.e. to ensure optimal food security have traditionally been used as an argument for continuous use antimicrobials for growth promoting – thus blocking actions to reduce the usage. As in the rest of the document I find it to be of importance to introduce a new agenda also on this point.

2. In the text under the heading of “6. *Environmental contamination*” I would suggest you to consider to include a sentence with the message that suggested actions previous in the feed and food and chain will decrease also those risks associated with the dissemination AMR in the environment although the impact of those risks need to be further evaluated. My reason is to avoid that the need for research in this area is claimed to be required before actions are taken.

3. I also find it important and justified to clearly mention that measuring the use of antimicrobials, a key tool and cornerstone for success. In EU, no or very limited progress was made before the use of antimicrobials was measured by appropriate methods. Without that data all countries and industries can claim and have claimed that they apply a proper use. The same experiences was made in the EU for the prevention and control of infectious diseases, e.g. food borne Salmonella.

To note, historically in Europe which I also have experienced during recent years in e.g. the US, the industry have and still may claim that they cannot disclose industrial secrets although these data generally are well available within the industry. All developed countries have detailed data on its industrial production (cars, food and so on) and from a one health perspective the production and use of antimicrobials should be of highest priority. AND without those data it is hard or impossible to monitor and access the prevalence and variation of the prevalence of different pattern of AMR including if a possible decrease in AMR can be related to interventions done.

See also my comments on Communications below.

3. **Meeting the Challenge of Antimicrobial Resistance: From Communication to Collective Action**

Again (see above) I would emphasize that the text on monitoring in clear words must include appropriate data on the use of antimicrobials and not only as I now read it focus only on accountability.

Accordingly my strong suggestion is that:

- The first bullet points in “Key message” should add “Data on the use of antimicrobials” as a second or first cornerstone.
- The first bullet point in the “Key takeaways” make little sense if the flow of antimicrobials is not based on hard data on the use of the drugs.

In addition I suggest that:

- under the heading of “Open questions for stakeholders” in first paper and if found appropriate also in the other two papers, is included a question on ways to ensure appropriate and solid data on the use of antimicrobials – on a country base and also different animal productions (my focus) and on farms. Such data now exists in different EU countries and it is not a rocket science to provide, although the approach can differ between countries.

Other

Medicines for Malaria Venture

From: [Silvia Ferazzi](#)
To: [IACG-secretariat](#)
Subject: Comments from Medicines for Malaria Venture to IACG on AMR Paper: Future Global Governance for Antimicrobial Resistance
Date: 31 August 2018 14:45:25

Dear Madam, Dear Sir,

On behalf of the organization Medicines for Malaria Venture, I have the pleasure to submit the following comments to the above paper informing the report of the Inter-Agency Coordination Group to the UN Secretary-General.

Yours faithfully,

Silvia Ferazzi
Director, Advocacy,
Medicines for Malaria Venture

General comment

1. This paper almost solely focuses on antibiotic resistance. Anti-parasitic (e.g. antimalarial) resistance and anti-fungal resistance are largely overlooked. The paper justifies this approach by stating that “antibiotic resistance is of particular concern given that it is the greatest contributor to global risk and the limited selection of antibiotics available”. However, antimalarial resistance is not a minor threat: in the absence of new drugs and an efficient response, failure of the current five artemisinin-combination therapies for malaria could lead to the 1970s mortality level in countries, so an additional mortality of around 2 million per year. This easily matches the forecasts for anti-bacterial resistance, which predict that the world would be facing an additional 50 million deaths by 2050 in the absence of a new generation of drugs.

2. Some issues and challenges which are mentioned in specific reference to antibiotic resistance are in fact common to other forms of AMR – notably access to underserved populations and importance of scaling up diagnostics development for prevention of drug misuse. These commonalities could be much better reflected in this paper.

Question: What are the needs for practical future global governance of AMR?

The mention of Product-Development Partnerships, which are key actors in the current global R&D - and access - response to AMR, is missing as potential stakeholders among public-private partnerships in the future governance for AMR.

This email and any attachments may contain confidential information. If you are not the intended recipient, please delete the email and any attachments and notify the sender

Medicines for Malaria Venture

From: [Silvia Ferazzi](#)
To: [IACG-secretariat](#)
Subject: Comments from Medicines for Malaria Venture to IACG on AMR Paper: Reduce unintentional exposure and need for antimicrobials and optimize their use
Date: 31 August 2018 14:47:14

Dear Madam, Dear Sir,

On behalf of the organization Medicines for Malaria Venture, I have the pleasure to submit the following comments to the above paper informing the report of the Inter-Agency Coordination Group to the UN Secretary-General.

Yours faithfully,

Silvia Ferazzi

Director, Advocacy,

Medicines for Malaria Venture

Question: Changing practices needs the support of the industry - how can we balance the availability of a public good such as effective antimicrobials, with a private industry perspective?

- 1. In the reference to the threat of AMR to children ("challenge" section on Chapter 5), the fact should be better emphasized that children are a highly vulnerable and neglected population, and that getting the formulations, doses and the market access right is very important in this context. It should be noted the in most countries in Africa even the frontline antibiotics are not available today in child-friendly formulations.*
- 2. As a priority, first-line antibiotics and other antimicrobials needs to be protected in countries where they still work by ensuring the highest quality versions of these first-line medicines, including child-friendly formulations, through the WHO Prequalification process.*

-
-

Medicines Patent Pool Submission to the discussion paper “Reduce unintentional exposure and the need for antimicrobials, and optimize their use”

The MPP is a United Nations-backed public health organization funded by Unitaid, working to improve access to affordable and appropriate HIV, hepatitis C and tuberculosis medicines in low- and middle-income countries. The MPP has previously worked on antimicrobial resistance in the context of HIV and TB. In HIV, the MPP holds several licences on second-line antiretrovirals – i.e. antiretrovirals used in patients whose HIV infection has developed resistance to first-line treatment – as well as products such as dolutegravir, which was recommended by the WHO for first-line use in countries with high levels of pre-treatment resistance to one class of medicines¹. In TB, the licence signed by MPP and the Johns Hopkins University on sunitinib includes provisions to ensure that commercialization of the product follows proper stewardship. Recently, the MPP has expanded its mandate to work on other patented essential medicines, including future new antibiotics of public health priority that could contribute to addressing antimicrobial resistance.

The submission below will try to answer some of the questions included in the consultation paper “*Reduce unintentional exposure and the need for antimicrobials, and optimize their use*” focusing on questions 5, 6 and 7 and the potential role that the Medicines Patent Pool (MPP) could play as part of the AMR response, with a particular focus on how the MPP could contribute to good stewardship of new antimicrobials while facilitating affordable access. These points were also included in the MPP’s submission to the IACG discussion paper on “Antimicrobial resistance: Invest in innovation and research, and boost R&D and access”, where we focused on the use of licensing approaches to support innovation, access and stewardship. However, given that these points are particularly relevant in the context of this new discussion paper, we are hereby re-submitting them for consideration by the relevant IACG working group.

The MPP’s Experience in Supporting Innovation, Access and Stewardship

Currently, the MPP holds licenses on 16 medicines for HIV, HCV and TB with nine patent holders, including pharmaceutical companies, universities and public research organizations. These licenses enable 25 partner generic companies and one product development partnership to develop, register, manufacture, and supply WHO-recommended products in a large number of LMICs. The MPP’s work has delivered 17 million patient years of treatment and resulted in \$535 million in savings from the procurement of more affordable quality-assured medicines.

The experience of the MPP in HIV has provided a concrete example of how licensing and patent pooling can contribute to addressing some of the innovation and access challenges relating to health technologies.

As mentioned in the introduction, antimicrobial resistance was already part of the work of the MPP in HIV, hepatitis C and TB. The MPP is therefore already implementing, monitoring, and enforcing stewardship-related obligations in its current licenses with drug manufacturers. These

¹ World Health Organization. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection, 2nd edn. WHO Press, 2016
http://apps.who.int/iris/bitstream/handle/10665/208825/9789241549684_eng.pdf;jsessionid=939637CE96EB31

practices include the careful evaluation and selection of licensees through its Expression of Interest system, strict quality requirements, and provisions for pharmacovigilance. Through these binding requirements and close monitoring of licensees' compliance, the MPP has demonstrated success in ensuring its licensees adhere to such obligations and has sought remedies up to and including termination of licenses for those who fail to perform. However, the model may also require significant adaptation in the AMR field beyond HIV.

The potential role of the MPP in contributing to innovation, access and stewardship for new antimicrobials, including new antibiotics

Recent high-level reports have recommended that the MPP could play an important role in new mechanisms for financing antimicrobial R&D. The Review on Antimicrobial Resistance chaired by Jim O'Neill recommended that incentive mechanisms such as market entry rewards should be linked to requirements to ensure access and stewardship – for example, by requiring recipients of payouts to license their discovery to the MPP under appropriate provisions.² Analyses from Chatham House, a prominent international affairs think tank based in the United Kingdom, and DRIVE-AB, a consortium supported by the European Innovative Medicines Initiative, made similar recommendations.^{3 4}

Last May, the MPP released the results of the feasibility study exploring the possibility of expanding its mandate to work on other patented essential medicines, including new antibiotics of public health priority.⁵ In the study the MPP looked at its role in relation to new antibiotics taking into consideration the categorization made by the WHO Committee on the Selection and Use of Essential Medicines on antibiotics for Access, Watch and Reserve.⁶ MPP licenses could be tailored to the specific public health needs that a new antibiotic can contribute to addressing while ensuring a proper balance between innovation, access and stewardship. Stakeholder feedback during the conduct of the feasibility study, confirmed that there could be a role for MPP to play, through its licences, in promoting good stewardship practices while enabling affordable access to new antimicrobials. For example, a number of stakeholders pointed out that many of the developers of pipeline antimicrobials identified in the WHO Pipeline Report were smaller biotechnology companies, with little to no presence in LMICs and no current plans for stewardship or access in these countries. Indeed, the AMR Benchmark published recently by the

² The Review on Antimicrobial Resistance Chaired by Jim O'Neill. Tackling drug-resistant infections globally: final report and recommendations. 2016. [https://amr-review.org/sites/default/files/160525_Final paper_with cover.pdf](https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf) (accessed Feb 18, 2018).

³ Chatham House. Towards a New Global Business Model for Antibiotics Delinking Revenues from Sales: Report from the Chatham House Working Group on New Antibiotic Business Models. 2015.

⁴ DRIVE-AB. Revitalizing the antibiotic pipeline: Stimulating innovation while driving sustainable use and global access. 2018. <http://drive-ab.eu/wp-content/uploads/2018/01/DRIVE-AB-Final-Report-Jan2018.pdf> (accessed Feb 19, 2018).

⁵ The Medicines Patent Pool Foundation. Exploring the expansion of the medicines patent pool[s] mandate to patented essential medicines: a feasibility study of the public health needs and potential impact. <https://medicinespatentpool.org/uploads/2018/05/Feasibility-Study-Expansion-of-the-MPP-Mandate-And-Appendix-2018.05.24.pdf> (accessed July 9, 2018)

⁶ World Health Organization. Global priority list of antibiotic-resistant bacteria to guide research, discovery, and development of new antibiotics. <http://www.who.int/medicines/publications/global-priority-list-antibiotic-resistant-bacteria/en/> (accessed July 6, 2018).

Access to Medicine Foundation found that only two of 28 antibiotics in late stages of clinical development had any access or stewardship plans in place⁷.

An access and stewardship licensing framework for the AMR context would build upon the substantial work that the MPP has already completed in exploring how stewardship-related practices could be integrated into its licensing model.⁸ The development of such a framework would begin with the recognition that many of the most important measures for ensuring proper stewardship of new antimicrobials lie outside of the licensing context; for example, strengthening regulatory systems in LMICs, expanding the availability of proper diagnostics, and developing and implementing sound treatment guidelines will be key to achieving good stewardship but cannot be addressed in a license agreement with a manufacturer. However, MPP could nevertheless make an important contribution by addressing certain aspects of stewardship that can be influenced through licensing agreements, while contributing to facilitating access to needed new antibiotics in LMICs. Potential areas in which antimicrobial stewardship could be promoted through MPP licensing are explored further below:

- *Quality standards*

Ensuring that a drug meets quality standards, that it is safe and effective, contains the correct amount of active ingredient, has a stable shelf-life, and is manufactured in accordance with current Good Manufacturing Practices (cGMP) – is a central pillar of ensuring responsible antimicrobial stewardship⁹. In its licenses for HIV and HCV products, the MPP requires that all licensees manufacture the product in a manner consistent with WHO pre-qualification (PQ) or stringent regulatory authority (SRA) standards, or approval through an Expert Review Panel (ERP).¹⁰ This is consistent with the standards used by the Global Fund, Unitaaid and the Global Drug Facility (GDF). The MPP would continue to implement strict quality standards in any licenses for new antibiotics.

- *Release of active pharmaceutical ingredients into the environment*

The O'Neill Review on AMR observed that improper treatment of wastewater by manufacturers of antimicrobial active pharmaceutical ingredients (APIs) and the resultant release of the APIs into the local environment can act as a “driver for the development of drug resistance, creating environmental ‘reservoirs’ of antibiotic-resistant bacteria.” MPP licenses in antimicrobials could

⁸ The Medicines Patent Pool Foundation. TB Stewardship Report. 2016.

https://medicinespatentpool.org/uploads/2017/07/STEWARDSHIP-REPORT_FINAL-1.pdf (accessed March 8, 2018)

⁹ Laxminarayan R, Duse A, Wattal C, *et al.* Antibiotic resistance—the need for global solutions. *Lancet Infect Dis* 2013; **13**: 1057–98.

¹⁰ For example, the quality provision in the MPP-ViiV Form Sublicense for dolutegravir, in section 4.2, provides as follows: “Licensee agrees that it will manufacture Raw Materials and Product in a manner consistent with (i) World Health Organization (“WHO”) pre-qualification standards; or (ii) the standards of any Stringent Regulatory Authority (“SRA”), defined as regulatory authorities which are members, observers or associates of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, as may be updated from time to time. Where such approvals are not yet available, the Licensee will obtain temporary approval through a WHO Expert Review Panel, as appropriate and if applicable.” A similar provision could be included in MPP licences covering other antimicrobials.

seek similar commitments from its licensees regarding environmental discharge and incorporate rigorous standards for acceptable levels of discharge once these are developed in the coming years.

- *Marketing and promotional practices*

It would be appropriate to have strict controls on the sublicensee's promotion and marketing for antibiotics that have been (or are likely to be) classified as "Watch" or "Reserve" in the WHO EML. In order to ensure that MPP sublicensees do not engage in inappropriate promotional activities, the MPP could, as part of its Expression of Interest (EOI) process, ask potential sublicensees to submit marketing plans that are in line, for example, with the recommendations in the WHO's Ethical Criteria for Medicinal Drug Promotion, or other relevant standards, and in line with national laws and regulations. Such plans could then become binding obligations as part of the licensing agreement.

- *Selection of licensees and affordability*

Unlike with MPP-licensed products with high sales volumes, such as medicines used in first-line HIV treatment, where the MPP seeks a large number of licensees in order to generate market competition, in antimicrobials the MPP may need to limit the number of licensees in order to better control the medicines' use in line with good stewardship. Under this practice, because the number of licensees – and thus competition – would be limited, there may be a need for additional measures to ensure that the end product is made available at an affordable price. This could be done, for example, by specifying a 'cost-plus' formula that establishes the maximum allowable price based on the manufacturer's production costs, while ensuring a sustainable profit margin for the licensee.

- *Definition of permissible buyers*

If the WHO EML recommend that an antimicrobial licensed to the MPP is used only in restricted settings (e.g. only in hospitals), it may be appropriate for the MPP to define in sublicense agreements the types of entities to whom sub-licensees may sell the product. This would be in line with the AMR Industry Alliance Roadmap, in which the signatories have committed to "collaborate with governments, their agencies and other stakeholders to reduce uncontrolled antibiotic purchase, such as via over-the-counter and non-prescription internet sales".¹¹

- *Limitations on irrational combinations and use*

The inappropriate use of antimicrobials, including in irrational combinations, can contribute to the development of resistance. Recently, for example, an alarming proliferation of irrational fixed-dose combinations of antibiotics has been reported in India.¹² New antimicrobials may also have potential applications in veterinary use, but such use may not be conducive to good

¹¹ Industry Roadmap for Progress on Combating Antimicrobial Resistance –September 2016. 2016.

¹² McGettigan P, Roderick P, Kadam A, Pollock AM. Access, Watch, and Reserve antibiotics in India: challenges for WHO stewardship. *Lancet Glob Heal* 2017; 5: e1075–6.

stewardship. In close consultation with the WHO and other experts, MPP licences could define permissible uses and permissible combinations.

Conclusion

The increased focus on the need to respond to rising antimicrobial resistance will likely translate to a growing pipeline of new drug candidates to target priority pathogens in the coming years. Within the new categorization systems for antibiotics adopted in the Essential Medicines List in 2017, the MPP may be uniquely positioned to implement and enforce access and stewardship obligations which can contribute to support the appropriate use of antibiotics for newly developed antibiotics. Licences could be tailored to different antibiotics of public health priority depending on whether they fall under the Access, *Watch* or *Reserve* categories of the WHO. New incentive mechanisms for the development of new antibiotics could be linked to licensing via the MPP to support access and stewardship of the end of the product.

The MPP is already implementing, monitoring, and enforcing stewardship-related obligations in its current licenses with drug manufacturers in the fields of HIV, hepatitis C and TB. These practices include the careful evaluation and selection of licensees through its EoI system, strict quality requirements, and provisions for pharmacovigilance. Through these binding requirements and close monitoring of licensees' compliance, the MPP has demonstrated success in encouraging its licensees to adhere to such obligations. Further areas would likely need to be considered in the AMR context, as described above.

In the context of efforts to support the development of new antibiotics it is important that due consideration be given to ensuring that any new antibiotics of public health priority are available to those who need them in LMICs. Support to overcome innovation challenges in AMR should therefore integrate access considerations, as well as considerations relating to appropriate use, from the outset. Public health oriented licensing via the MPP can be a mechanism to supporting these objectives, particularly if combined with incentives for the clinical development and manufacturing of new antibiotics.



Response by the South Centre to the consultation on IACG discussion paper, ‘Future Global Governance for Antimicrobial Resistance’

31 August 2018

The South Centre is pleased to have the opportunity to provide comments to the IACG on the public consultation document “Future Global Governance for Antimicrobial Resistance”. In addition to this submission, the South Centre associates itself with the submission made by the ARC Coalition.

About the South Centre:

The South Centre is the inter-governmental policy research institution of developing countries, with currently 54 developing country member States from Africa, Asia and the Pacific, and Latin America and the Caribbean. The South Centre promotes more effective South-South cooperation and coordination, supports developing countries in participating in and voicing their development interests and priorities more effectively in various multilateral and regional development policy-related issues and fora, and provides policy advice and technical assistance to governments on their national development-related policies.

The main activities of the Centre are policy research and analysis, convening of meetings and conferences for developing countries to share views and experiences, and technical assistance and capacity building activities. The issues taken up by the Centre include international and regional trade policy, global macroeconomic and finance issues, global public health, innovation and intellectual property policy, climate change, environment and sustainable development, international economic issues including tax policy, external debt and international investment policy; human rights policy; global governance for and North-South relations, South-South cooperation, and global governance for development. The South Centre has three major institutional pillars: The Council of Representatives in which the Member States are represented; the Board comprising a Chairperson and members who act in their individual capacities and provide guidance to the Secretariat; and the Secretariat headed by the Executive Director which implements the activities of the South Centre. The Secretariat is accountable to and works under the guidance of the Board and the Council.

For any information concerning this submission, or the work of the South Centre, please contact Ms. Xin Cui, office of the Executive Director, Dr. Carlos Correa.

I. The goal of the governance structure

- A global treaty with binding commitments

The consultation document states that the ultimate goal of the governance structure should be the delivery of a global, multi-stakeholder agreement – such as a treaty – within the next 10 years. It was felt that only this kind of high - level political agreement would provide sufficient mandate to act in accordance with the needs identified, providing the authority to coordinate resource, engage stakeholders and secure binding commitment for action (pg. 8).

The South Centre agrees that a high level political agreement – in the form of a treaty – would increase the accountability and the engagement by country governments to place and sustain AMR as a priority at country level, across sectoral agendas –human health, animal health, food chain, environment- and bring together multiple agencies in the UN system and other stakeholders to support the necessary country-level actions.

- An intergovernmental treaty with stakeholder participation

The South Centre is of the view that the governance model should be an intergovernmental agreement with multi-stakeholder participation, as opposed to a multi-stakeholder agreement.

A global binding treaty with cross-sectoral AMR commitments can only be legitimate through a multilateral process that requires negotiation primarily among member States and their buy in. Given the complexity and multi-sectoral aspects of AMR, emphasis should be kept on mobilizing member States of the UN system in first instance.

Stakeholder engagement to support an intergovernmental negotiation is critically important – of civil society and industry actors - and more efforts should be made to mobilize them at national and regional level, and to the extent possible, at global level (such as through participation as observers to member State negotiations in multilateral fora).

- Scope and fora for the treaty negotiations

There is a need to be specific about what should be the objective of global commitments to be negotiated in the context of the UNGA, as opposed to the domain of individual UN bodies and other international agencies with AMR related activities such as the OIE, the FAO-WHO Codex Alimentarius Commission and the World Bank. The call for global negotiations must also take into account related processes to ensure synergy and avoid unnecessary duplication which could over-burden member States and cause negotiating fatigue.

There are a number of multilateral negotiations with multi-stakeholder involvement that are ongoing in many of these agencies, including the WHO. The most notable process being the work towards a global Development and Stewardship Framework for AMR on a one-health approach, under the WHO in collaboration with FAO and OIE.¹ Progress has been slow, due

¹ The UNGA High Level Political Declaration on AMR, A/RES/71/3, “calls upon the World Health Organization, together with the Food and Agriculture Organization of the United Nations and the World

to various factors including the complexity of the area, disagreements among member States on the objective and scope, insufficient prioritization given to the process within the lead institutions (i.e. no high level officials in WHO and in the FAO and OIE are leading the negotiations) and as a result lack of visibility among member states of the process and their limited engagement.

As several of the WHO and other UN agencies already have legitimacy to do a range of work on AMR, including norm-setting in their respective areas of work, the scope of the work that the global treaty process would encompass needs to be better described. What a global process needs to accomplish is to 1) increase the coordination among the work of agencies (for example to promote the translation of the recommendations of the WHO guidelines on use of medically important antimicrobials in food-producing animals into national and international standards or guidance such as those of the WHO-FAO Codex Commission), 2) identify and take action to fill the gaps in current agency work and global commitments and actions at national level, 2) to scale up support, - political, technical and financial- for key agencies to give proper guidance to countries on AMR and for developing countries to increase their capacity to take effective action on AMR.

It is expected that the IACG should provide guidance to UNGA on what are the current gaps in the existing structures that are to provide support to countries on AMR to enable them to scale up their commitments to AMR actions, as well as to improve coordination among all relevant agencies party to the UN system and others, such as OIE and World Bank. This analysis is essential to understand what are the best mechanisms, including governance models, to increase and sustain global action on AMR, which is at the heart of the IACG mandate.

The South Centre agrees that some of the main gaps is the need for greater coordination and coherent policy development and guidance among WHO, OIE and FAO on AMR and for UNEP to take a greater role on addressing the environmental aspects of the AMR challenge, as well as for greater involvement of the United Nations Development Group (UNDG) of agencies, including UNDP, in including AMR in the support they provide countries in national development plans, identifying priorities and potential means for financing.

Organization for Animal Health, to finalize a global development and stewardship framework, as requested by the World Health Assembly in its resolution 68.7, to support the development, control, distribution and appropriate use of new antimicrobial medicines, diagnostic tools, vaccines and other interventions, while preserving existing antimicrobial medicines, and to promote affordable access to existing and new antimicrobial medicines and diagnostic tools, taking into account the needs of all countries and in line with the global action plan on antimicrobial resistance” (Para 13).

II. The governance model

The South Centre agrees that leadership by member States -some championing and enabling funding- and heads of UN agencies is necessary to ensure AMR is in the political agenda in the UN at the highest level and there is continued commitment to treaty negotiations, relevant agencies coordinate amongst each other towards achieving common objectives, that sufficient technical expertise and evidence-base is be available to inform the process, and all the relevant stakeholders are included in the process in order to achieve the necessary changes required.

The discussion document by the IACG devotes significant attention to describing a proposed model for the delivery of a global multi-stakeholder agreement. The proposed functions of the model are high level: to build enduring global agreement on AMR, provide high level advocacy and keep AMR on the political/heads of state agenda and to integrate AMR into the SDGs and successor systems. The South Centre supports these objectives. However, it is not unclear from the discussion document how the proposed governance structure would lead to these objectives, otherwise described as “functions”.

The South Centre suggests, therefore, that the IACG, while developing a proposal for governance models for sustaining global actions on AMR, give more attention to:

- 1) describing in an evidence-based manner what are the current gaps and challenges to achieving these objectives, in particular the integration of AMR various multilateral processes, including the global Development and Stewardship Framework for AMR led by WHO in collaboration with OIE and FAO, and with the overall UN development framework;
- 2) strategies to build further support by member States of the UN system to a global agreement on AMR and what should be the substantive elements of a global agreement within the UN framework.

The establishment of a Global steering Board, if composed of only a selected number of member States in addition to selected stakeholders, would appear to lack legitimacy to drive member State negotiations at the UNGA level where the process must necessarily be placed to take into account the full range of considerations and needs of all UN member States and their stakeholders, in particular of developing countries, in order to guarantee and sustain commitments.

It is also unclear where the multilateral negotiations would take place within the “straw-man” model that is suggested.

- Potential conflict of interest in the governance model

The South Centre supports an intergovernmental treaty with ample space for stakeholder participation. Attention needs to be given to determining how appropriate measures would be instituted to avoid, mitigate or manage conflict of interest in any governance arrangement, in particular the role that industry would play in such a model.

The “multi-stake holder” agreement as proposed in the discussion paper, by nature would face potential conflict of interest. Hence, accountability and monitoring mechanisms would need

to be established for all parties involved, in particular for private actors where such accountability mechanisms are non-existent.² Annex 2 of the background report also provides an assessment of why the private sector inclusion could be consider problematic particularly when discussing regulations.³

III. Other considerations

- AMR as a development issue

The discussion document states as one of the 10 requirement as a minimum set for AMR governance, the need to “intergrate with the wider global development agenda to better align on an mobilize actions that create common good”. The South Centre agrees with this objective.

The objective of a global treaty on AMR must be closely aligned to the development mandate of the UN. It would be important for the IACG to recommend ways in which the AMR agenda can be linked more closely to the sustainable development agenda and further strengthened, including by providing appropriate resources and integrating AMR in development activities across the UN system. As noted above, there is need for greater involvement of the United Nations Development Group (UNDG) of agencies, including UNDP, to include AMR in their agendas within the scope of the support they provide countries in national development plans, in identifying priorities and potential means for financing.

- Bring in the environment

The South Centre agrees with the proposition to widen the tripartite to include the United Nations Environment Programme (UNEP) to include a mandate to act on environmental aspects of the AMR challenge, and to strengthen and formalise the relationship between WHO, FAO, OIE and UNEP via agreement of a Memorandum of Understanding (MoU). The recent May 2018 MoU among the tripartide did not include UNEP. More importantly, member States will need to agree to provide more resources to the institutions for AMR, in

² The following explanation by an expert on conflict of interest provides a helpful insight for why potential conflict of interest must be carefully considered: “Professionals working in the private sector can have conflict of interest when they serve on government commissions, advisory boards, and/or offer expert advice to public officials. Under these circumstances, these professionals perform public functions and therefore are expected to act as if they were performing their work as public employees. Yet these professionals might have financial interests that can be affected by the outcome of their public decision. Consequently, they might be in situation where they can perform their public sector functions in ways that promote their private interests.” Professor Marc A Rodwin, presentation on conflict of interest at the South Centre on July 23, 2018.

³ “The experience of global regulation is that, in the absence of a powerful commercial incentive to accept regulation... the inclusion of industry in formulating regulatory standards is likely to lead to a steady dilution through each phase of the regulatory process. Specifically, once regulation passes from general agreement (when there is a public spotlight on agreements reached) to the less-newsworthy detailed regulation stage, and then to implementation, and finally to enforcement, the risks of dilution become stronger and stronger.” P.52, Background report to inform IACG discussions on Global Governance of AMR – a One Health Approach, ‘Global Governance of Antimicrobial Resistance – a One Health Approach’ by Devi Sridhar and Ngaire Woods with the assistance of Conor Rochford and Zia Saleh. Available as annex 2 to the IACG consultation paper

particular for UNEP to increase in-house expertise to effectively develop and scale up in-country support.



**SUBMISSION TO INTERAGENCY COORDINATION GROUP ON ANTIMICROBIAL
RESISTANCE**

**DISCUSSION PAPER: FUTURE GLOBAL GOVERNANCE FOR ANTIMICROBIAL
RESISTANCE**

*Empowered lives.
Resilient nations.*

16 AUGUST 2018

1. Building on the United Nations Development Programme (UNDP) presentation to the IACG in January 2018 and the response to the April 2018 United Nations Foundation mapping for the Sub-Group 5, UNDP is submitting the following contribution on the July 2018 **“Future Global Governance for Antimicrobial Resistance”** discussion paper.¹
2. The discussion paper provides an excellent overview of the main governance challenges in terms of the need to better align UN, governmental and other relevant stakeholders’ initiatives, priorities and funding to bolster the urgent need to address AMR as well as the need to effectively address the multifaceted, multi-sectoral and multi-stakeholder dimensions of an appropriate AMR response.
3. Based on UNDP’s experience in the negotiation and implementation of several health and environment related global agreements, a global agreement could be beneficial in terms of promoting global norms and commitments in certain aspects of the AMR response, if appropriately designed and negotiated.
4. A Global Steering Board hosted in an existing organization and led by a time-limited High-Level AMR Commission could be a useful endeavor if the Terms of Reference are appropriately focused and ambitious, the membership of both the Board and the Commission inclusive and an open process for public and expert consultation is created.
5. The current tripartite governance structure (WHO, FAO and OEI) would benefit from increased engagement with UNEP and environment stakeholders. Increase multi-sectoral engagement, including of neglected sectors in the AMR response such as environment², should be a key priority in any governance reform.
6. Overall, there is a need for a stronger link with the 2030 Agenda for Sustainable Development (2030 Agenda) and the Sustainable Development Goals (SDGs). Although the discussion paper recognizes the need to integrate AMR within the wider global development agenda it is unclear what specific governance reforms are proposed to achieve that, apart from creating AMR indicators and integrate AMR as an outcome in development assistance frameworks such as UNDAFS that seem both sensitive proposals. Strengthening the linkages between AMR and the 2030 Agenda could additionally be done through inclusion of AMR in existing review processes, including Voluntary

¹ IACG Discussion Paper on Future Global Governance for Antimicrobial Resistance, http://www.who.int/antimicrobial-resistance/interagency-coordination-group/IACG_Future_global_governance_for_AMR_120718.pdf?ua=1

² Frontiers 2017 Emerging Issues of Environmental Concern. United Nations Environment Programme UNEP (2017) https://wedocs.unep.org/bitstream/handle/20.500.11822/22255/Frontiers_2017_EN.pdf



*Empowered lives.
Resilient nations.*

National Reviews (VNRs), as well as through national strategies for the achievement of the SDGs.

7. The complexity and multidimensionality of AMR and the one health approach that governments have committed to, requires greater coordination, stronger governance and partnerships as called for by the Agenda 2030. A robust and multi-sectoral governance of AMR responses is central to achieving many of the goals and targets of the 2030 Agenda and the SDGs.
8. There is a need to mainstream AMR within sustainable development responses and support the development and implementation of global and national action plans and strategies with a one health and multi-sectoral approach. There is a lack of recognition of poverty and unmet development needs as drivers of AMR. As also recommended by the Members of the Antibiotic Resistance Coalition and its civil society partners³, there is a need to mainstream AMR into broader universal health coverage, sustainable development, food system and environment agendas. Technical support is needed to support NAP implementation and to address global policy incoherence and governance misalignment and fragmentation.
9. The proposed Governance Structure (figure 1) proposes the creation of a Standard Secretariat that builds on current WHO, FAO, OEI structure and expands to UNEP. As recognized and planned by the IACG Framework for Action, AMR needs of an effective multi-sectoral and multi-dimensional response, therefore such a secretariat and the governance structure must be able to engage a broader UN approach which articulates a clear role for other development partners beyond possible membership to future Technical Advisory Groups. The UN response to AMR should engage all relevant agencies and partners from headquarters to country offices.
10. Governance reforms should also focus on national and regional strategies. Governance reforms should not only focus on the benefits of global norms and coordination, a better governance system should consider the governance needs from a country perspective and also support national and regional governance reform strategies that are key to the necessary sustained technical and financial investment, for example, through the promotion and creation of national multi-sectoral dialogues and platforms and partnerships to ensure whole-government and whole-society responses to AMR.
11. The proposal for governance reform could benefit from an explicit strategy to facilitate increased engagement by developing countries governments and civil society, as AMR is a global priority and

³ Consolidated comments on first set of IACG discussion papers,
http://www.who.int/antimicrobial-resistance/interagency-coordination-group/Comments_on_IACG_discussion_papers_1st_set_270718.pdf?ua=1



*Empowered lives.
Resilient nations.*

the response should be tailored and adapted to the specific national realities and needs, including effective and evidence-driven responses. AMR is a global challenge that cuts across borders, and affects all countries, across all regions and levels of development. But not all countries and systems are equipped to respond. Thus, AMR responses need to be tailored to the specific country needs, context and capacities, especially those of developing countries, conflict-affected settings and challenging operating environments.

12. Governance of the response to AMR could benefit from increased recognition of the benefits of right and development-based frameworks. This includes paying explicit and systematic attention to human rights principles, commitments and safeguards, including in the discussion papers.
13. There is a need to pay much greater attention to tuberculosis (TB) which remains the world's leading cause of death from an infectious disease. Drug resistant TB responses are severely neglected, with important gaps in prevention, diagnostic, access to treatment and research and development for new regimes. Through the work of the IACG, there is a need and an opportunity to better integrate AMR and DR-TB programmes, responses and governance frameworks.
14. In conclusion, UNDP is not currently a member of the IACG but remains committed to supporting the IACG, Member States and other development partners in multi-sectoral approaches to AMR which pay much need attention to the development dimensions of the response to AMR.
15. In line with our [Strategic Plan 2018-2021](#), UNDP could support the integration of AMR responses within the development system, as well as the creation of national multisectoral platforms and governance strategies at the country level to strengthen the inclusion of development, environment, financing, human and animal health, food, agriculture and trade governmental sectors, as well as other relevant partners and stakeholders including affected communities, civil society, academics, professional societies, and the private sector. While not all are specific to AMR, UNDP already has a portfolio of capacity, expertise and projects across the global, regional and country levels relevant to AMR responses. AMR-specific and sensitive activities are relevant for several teams across UNDP, including apart from the HIV, Health and Development Group of the Bureau for Policy and Programme Support (BBPS), the environment and natural capital teams of the Sustainable Development Group.



*Empowered lives.
Resilient nations.*

Snapshot of UNDP work relevant to AMR responses:

As a founding co-sponsor of the [Joint UN Programme on HIV/AIDS \(UNAIDS\)](#), UNDP has a proven track record of ensuring that sectors beyond health are engaged in HIV responses. UNDP has traditionally convened government stakeholders including ministers of finance, trade, industry, justice, foreign affairs and social protection as well as other key partners from civil society, academia and the private sector to jointly respond to HIV in a coordinated and coherent manner. For example, UNDP served as the secretariat of the Global Commission on HIV & Law and together with governments, civil society and UN partners has supported 89 countries to implement the Commission's recommendations.

UNDP's partnership with the [Global Fund to Fight AIDS, Tuberculosis and Malaria](#) focuses on three areas of work: policy, implementation support, including procurement of health technologies, and capacity development. UNDP serves as an interim Principal Recipient in some of the most challenging operating environments and is currently managing grants in 19 countries as well three regional grants covering an additional 27 countries. TB is already a component in 12 of the UNDP-managed grants.

Through the public and private partnership [Global Healthcare Innovation Technology \(GHIT\) Fund](#), UNDP supports research and development for new health technologies for neglected diseases. 50% of the GHIT portfolio is relevant to AMR, providing grant funding to support research for TB medicines and diagnostics.

UNDP supports governments to build resilient health systems, including through the provision of technical support and the convening multisectoral taskforces to strengthen legal, policy and regulatory frameworks, strengthen national procurement and supply chain systems and remove barriers to access to medicines and other health technologies. For example, leading the [Access and Delivery Partnership \(ADP\)](#), UNDP works with WHO, PATH and the Special Programme for Tropical Disease Research (TDR) to strengthen health systems to facilitate appropriate introduction of health technologies for TB, malaria and neglected tropical diseases. In addition, through its partnership with Gavi, the Vaccine Alliance and the Government of India, UNDP is rolling out an [Electronic Vaccine Intelligence Network \(eVIN\)](#) and improving immunization coverage and capacities of immunization systems.

UNDP supports countries and development partners to implement solutions that simultaneously consider the health of people and the planet. Some of the partnerships/initiatives that aim at improve environmentally respectful and resilient systems and strategies include work in sustainable health procurement, health-related waste management and reduction of use of mercury and other pollutants like for example UNDP-hosted [Sustainable Procurement in the Health Sector Initiative \(SPHS\)](#), UNDP Global Fund [Healthcare Waste Management Toolkits](#), UNDP's partnership with the [Health Care Without Harm \(HCWH\)](#) and the [Global Environmental Facility](#) and UNDP's overall work on [planetary health](#).



*Empowered lives.
Resilient nations.*

For further information please contact:

Name:	Mandeep Dhaliwal and Tenu Avafia
Position:	HIV, Health and Development Group
Organisation:	UNDP
Email:	