TECHNICAL CONSULTATION ON PREVENTING AND MANAGING GLOBAL STOCK OUTS OF MEDICINES

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World Health Organization

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FIP is the global organization gathering 137 national associations of pharmacists and pharmaceutical scientists. It is a non-governmental organization (NGO) in official relations with the World Health Organization. Its mission is to "improve global health by advancing pharmacy practice and science to enable better discovery, development, access to and safe use of appropriate, cost-effective, quality medicines worldwide."

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Executive summary

The meeting recognized that shortages and stock outs of medicines and technologies are of concern to all countries and that there is a need for coordinated and global action on approaches to managing them. One single approach or action is unlikely to be effective – it was recognized that an approach across the health system (end-to-end) is needed.

The following areas for further work and actions were proposed:

- Key principles for responding to shortages/stock outs

The impact of a shortage or stock out of medicines is lack of access to medicines for patients, with resulting poor health outcomes. Therefore, a patient-centred approach to managing shortages and stock outs is needed. Transparency should be at the core of the approach, ensuring information is available to all stakeholders and that there is effective communication throughout the value chain.

Noting the increased frequency of shortages that have global impact (for example, benzathine penicillin), there is also a need to develop coordinating mechanisms at the national, regional and global level with a view to promoting transparency, the exchange of information and effective communication. Communications should also focus on preemptively managing shortages to avoid a pending stock out.

- Product identification, products at risk

Several examples of shortages and stock outs of 'vulnerable' products and product groups illustrate the characteristics of products that have been and may be in short supply. It was considered useful to develop a consolidated list of these products, and to start to analyse systematically the reasons for shortages of supply. Sharing validated information about products in short supply was considered to be critical and mechanisms need to be developed to do this (see below). Consolidating product specifications for some of the medicines in repeated short supply might also be productive. Coordination with manufacturers about these products at risk would potentially help to reduce the risk of future shortages.

- Reporting, data, definitions

Examples of good practice of databases for reporting products in short supply were presented. It was agreed that it would be essential to harmonize definitions of 'stock outs' and 'shortages' (noting that work has commenced on this in some groups) and then establish standards for reporting that can be used for databases generally. It was noted that current databases have different approaches and harmonizing on best practice would be desirable. The value of having public access to databases as well as public reporting and availability of information was clearly recognised. Data on current stock (outs) throughout the supply chain must inform decisions to resolve the issue.

- Manufacturers

Without engagement of manufacturers in resolving shortages, there will be no progress. Examples of how individual or groups of manufacturers have responded to shortages for individual products could be used to establish a general approach. As noted above, a mechanism for an effective global discussion between manufacturers, authorities and stakeholders should be established.

- Regulation

A number of examples of current response mechanisms by national medicines regulatory authorities illustrate the potential value of establishing good practice for regulators in response to manufacturing issues, as well as understanding the interaction and impact of regulatory decisions on shortages. Best practices for regulators in responding to shortages should be collected, where possible harmonised, and provided as guidance to others.

- Financing

Adequate financing is a prerequisite for preventing shortages of medicines. Strategies such as credit facilities that would promote consistency and predictability of cash flows would help reduce stock outs in some systems.

- Prices

The challenge of ensuring a fair, viable and affordable price for some products is recognized. It was considered that more transparency about the basis for prices, such as cost of production, would be helpful to allow a constructive dialogue between manufactures and procurement groups. It was accepted that it is important to ensure that prices paid are sufficient to promote quality products and help to reward the guarantee of a continuous supply, but that they must also be affordable.

- Procurement

It was recognized that different tender practices can have a significant impact on product availability. For example, finding balance between short, flexible tenders versus longer term contract periods or multi-party tenders versus single source tenders is important in all procurement environments. A further systematic evaluation of the impact of tender practices on shortages would be useful. Similarly, the experience in some regions of pooled procurement mechanisms suggests that these can have a positive effective on shortages and prices of some medicines. In addition, the question of the impact of large purchasers on the global availability of products, especially those where there is a limited manufacturing base, needs to be evaluated. Procurement practices may also result into transferring the issue from one country to another.

- Supply Chain

The importance of promoting efficient and effective supply chain management throughout the supply chain cannot be overemphasized. Supply chains must be aware and able to distinguish whether a shortage or stock out is indeed a supply chain issue or if it is a

manufacturing level problem. Supply chains can contribute to preventing and managing stock outs and it was noted that IT systems that facilitate both upstream and downstream collection of information need additional support. That is, systems that allow early prediction of shortages as well as management information systems, electronic tracking of products through supply chains, accurate forecasting and quantification of need. Rapidly advancing the use of standardized bar coding was acknowledged as important and feasible. The shortage of reliable data from peripheral levels of the supply chain was noted as a persistent problem.

- Demand

Understanding global and national demand, especially for some of the 'vulnerable' products such as benzathine penicillin, was recognized as an important issue, especially given the experience of market shaping by global organizations. Using the experience to develop a systematic approach to assessing demand would be important to retain these products on the global market.

BACKGROUND

Shortages and stock outs of essential medicines have been increasing in recent years. The problem has become a global problem, with documented supply failures of antibiotics, anaesthetics, chemotherapy medicines and many others. It has been described in high-, middle- and low-income countries and is increasingly related to shortages at the manufacturing level, versus well-documented supply chain and financing challenges.

There are limited data to quantify the full extent of the burden of medicines stock outs, but as stock outs increase, country health systems incur extra costs in managing them as well as the problems that arise in patient care. Clinical outcomes for patients may be adversely affected as a result of non-treatment, under-treatment and possible medication error from attempts to substitute missing medicines.

Global information

Numerous publications over the last five years have described problems with shortages of medicines in high-, middle- and low-income countries. The reasons for these shortages are complex. First of all, there is a global increase in demand for medicines in countries that have historically not been exposed to the global market for pharmaceuticals. This demand to increase availability of medicines in countries has led to increased manufacturing consumption and competition for active pharmaceutical ingredients (API). Changes in API consumption may have adverse consequences in the market relationship between production and medicine availability.

In established markets, business and economic decisions regularly halt the manufacturing of medicines, either temporarily or permanently. Factors such as poor financial incentives, introduction of generic medication, patent expiration, change in clinical demand, regulatory compliance requirements and expenses to correct manufacturing errors can decrease availability of medicines. Regulatory authorities generally are unable to influence business and economic decisions taken by manufacturers.

Required reporting notifications of medicines stock outs across markets is poorly regulated and in many low- and middle-income countries (LMIC) is not yet required.High-income countries reporting shortages include the USA, Canada, Germany, France, Switzerland, UK, Spain, Greece and Italy. However, the causes of the 'shortages' identified in these countries were not necessarily consistent with the definition of a shortage as lack of product, and may be due to the inability of hospitals/purchasers to pay for medicines because of financial problems, rather than the inability to obtain a specified product.

The reports from low-income countries (e.g., Uganda, Tanzania, Kenya) have to date mostly been about the impact of inadequate financing of treatment programmes, which like the situation in high-income countries in the financial crisis, leads to problems with continuity of supply simply because bills are not paid.

The types of medicines identified as being in short supply have varied: for example chemotherapy products (e.g. bleomycin, cytarabine, leucovorin, 5-fluoruracil), anaesthetics (propofol); and antibiotics (gentamicin, streptomycin).The characteristics of products in short supply include sterile intravenous injections, as well as off-patent medicines. There have also been isolated reports of shortages of nuclear medicines products (Technetium 99).

High-income and low-income countries may have different reasons for shortages in relation to supply chains, but payment systems for products can cause problems in both settings. Sudden changes in payment structures or systems that provide perverse incentives to use expensive products seem to cause as much trouble as not having sufficient funds. Rigid or inadequate tender processes may also contribute to the problem and while there may be strategies to limit the risks (e.g., penalties for failure to supply) it would be useful to know how effective these have been in reducing shortages in different settings.

Overall, the reports illustrate that the medicine shortages are increasing in frequency, prompting significant international concern about long-term supply of key medicines. The factors that contribute to the problem have been identified in many studies. The common assessment is that medicines in short supply are mostly old, off patent, difficult to formulate products, that have a tightly defined shelf life with few manufacturers, or sole manufacturers. These characteristics combine with characteristics of supply systems to worsen any interruption in manufacturing – the use of 'just in time' inventory control to minimize the amount of buffer stock held in a supply chain, combined with low prices and small profit margins as well as the requirement for large contracts through tenders.

Mechanisms for pooling notifications for global scrutiny could be investigated. As supply of pharmaceuticals is a multinational business, it is hardly surprising that if a factory is closed in Canada, the product may be in short supply in the USA, Australia, Mexico and the Netherlands, for example. Similarly, if there is only one manufacturer of the active pharmaceutical ingredient globally, the risk of the product disappearing if anything disrupts that API is high. National reporting mechanisms exist in some countries, but a single point of notification or database that could provide global information makes sense. The question of how to establish such a system is much more complex.

Whether it is possible to identify a core set of medicines that there is international agreement about is one question, but payment systems for products can cause problems in maintaining production of critical products. Methotrexate is crucial to the treatment of many oncological and immunological conditions – yet this is a product that has been reported as in short supply repeatedly. Would an agreed global minimum price that is commercially attractive help keep it on the market? How would such a price be set?

The targeted, well-financed and long-term interventions that have improved access to priority diseases of malaria, TB and HIV/AIDS are rich in experiences that could in part contribute to solutions for other medicines; however, it is important to consider that the related medicines are mostly those with single indications that are managed under specialized treatment programmes. Applying these approaches across long lists of medicines would likely fail, considering that many of the medicines in shortage have indications across several categories of general medicine.

In summary, it seems that shortages of key medicines are likely to be continue to be a problem. A systematic international approach to methods to reduce the shortages of key medicines, to minimizeundesirable effects on health care systems may be needed.

MEETING OBJECTIVES

To support the development of solutions for shortages and stock outs, a global technical consultation was hosted by WHO. The main objectives of the consultation were to:

1. Discuss the details of the bottlenecks and problems that are the main contributing factors in shortages and stock outs at global or manufacturing levels;
2. Define and consider the details of existing solutions that exist at national levels and through specialty programmes to mitigate stock out and shortages;
3. Consider which, if any of the national, programme or other existing solutions would have an impact if brought to global scale;
4. Examine those that have potential to create solutions at an international level or other alternatives, suggest the modifications or other means that would be necessary to make them effective at global levels.

SUMMARY OF EXPERT PRESENTATIONS

Analysis of the problem of global shortages and stock outs

The presentations from experts were intended to examine existing problems and solutions. Individual presentations can be made available on request.

Overview, International Pharmaceutical Federation (FIP):
Overview information from FIP (the global pharmacists association) provided a summary of problems, including a summary of information on the impact of shortages as well as the recommendations from the 2013 Summit on Medicines Shortages. Examples included active shortages in USA which, at the time of the presentation, included over 219 different products. The duration of stock outs from European countries that reported information noted that 63.3% of stock outs lasted a number of weeks. The reported causes included manufacturing or other supply problems but almost half, or 47% were unknown causes. According to FIP, costs of stock outs are significant, and an example of US hospitals was cited where the cost of shortages was $416 million, including $200 million to purchase more expensive alternatives and $216 million in labour costs. Medicines most commonly in shortage included generic sterile injectables, other off-patent products, cancer medicines and paediatric formulations.

The recommendations from the Summit in 2013 were presented to remind meeting participants of the actions that had previously been proposed. [1]

Country experience, South Africa:

Shortages in South Africa had received recent media attention. An analysis of key problems suggested that irregular financing and inflexible tendering systems that did not allow purchasers to respond to problems in a sufficiently rapid manner were an issue. Another concern, which other countries acknowledged was prevalent in the majority of low-income countries, was lack of technical capacity of staff. Trends to decentralize procurement

[1] http://www.fip.org/files/fip/publications/FIP_Summit_on_Medicines_Shortage.pdf

systems have benefits, but one of the disadvantages noted was that it reduced visibility in?? centralized data where trends and summary detail would be useful in proactive management of shortages and stock outs. National monitoring programmes are being put into place in South Africa, with the support of the Department of Health, civil society and international organizations.

Country experience, ACAME:

ACAME (Association Central d'Achat des Medicaments) is a network of procurement agencies, primarily of western francophone African countries. Its purpose is to share information and reinforce the availability and affordability of medicines through coordinating procurement specifications, pricing information and regulatory harmonization. Similar to the discussion from South Africa, lack of timely access to finances, strict procurement procedures and lack of high-level coordination of policies across ACAME members often challenges their commitment to ensure effective procurement and access to medicines. Noting the need to continue to expand initiatives such as ACAME to promote coordinated responses to medicines needs, ACAME has encouraged international donors to assist in resolving this problem.

Analysis from WHO Model List of Essential Medicines

A preliminary analysis of the WHO Model List of Essential Medicines was presented, as a first step in defining a potential global list of 'vulnerable' essential medicines. The analysis compared the WHO EML with some of the current published databases (from high-income countries) of medicines in short supply. Based on this comparison, it was noted that adrenaline (epinephrine) and atropine sulfate are listed in all the databases reviewed, and many antibiotics – especially the cephalosporins – are listed in three out for four of the databases. Prices for the medicines in short supply generally have been decreasing over the past decade, but there are limited data available to assess whether volumes of use have also been declining.Further work is needed to ensure that a potential list of 'vulnerable medicines' includes medicines that are in short supply for global procurement agencies as well as LMIC.

Case studies, WHO and UNFPA on benzathine penicillin

Three UN procurement agencies reported chronic shortages of benzathine penicillin. This case study illustrated an example of a product where few, if any, alternatives are available. As the first-line treatment for syphilis, congenital syphilis and preventing mother to child transmission of syphilis, and rheumatic heart disease (RHD), benzathine penicillin is an important medicine. The case study provided a global quantification based on burden of disease, to the degree that estimates are reliably available. The global needs are noted at more than 3 million treatments per year for syphilis and RHD; however, the actual demand remains undocumented, creating challenges in negotiating solutions to the chronic shortage.

Experiences of global procurers, GDF and UNICEF:

Internationally funded procurement mechanisms have provided assistance primarily to low- and middle-income countries to procure quality medicines. The support is generally limited to priority diseases (HIV, TB and malaria and reproductive health), although UN agencies also procure emergency kits and other kit based supplies. The Global Drug Facility

aggregates demand to solve the problems of small and fragmented markets, especially for procurement of TB-, HIV- and malaria-related medicines and products. They procure on behalf of donor programmes and also for countries or other buyers that need access to the medicines targeted by GDF. The challenges faced by both UNICEF and GDF include lack of sources for quality assured products and also lack of up-to-date guidance on specific medicines management questions. A particular example of medicines management included guidance on shelf life. In its original definition, guidance on shelf life helped countries respond to inappropriate practices of suppliers that provided short-dated products. The applicability of that guidance in the context of a fragmented market can be counterproductive. Specialized products with normally short or more complex shelf life issues may fall outside of the guidance, leaving procurers at impasse between the guidance and a sound procurement strategy. This all can lead to manufacturers refusing to participate in tenders for products. It can also lead to manufacturers holding orders and waiting for full batch quantities to avoid holding an aging inventory.

Industry perspective:

The perspective from industry was provided by the Indian Generic Manufacturers Association with comments from IFPMA. Sustainable pricing is a challenge for manufacturers when aggressive procurement practices drive prices down below levels where quality manufacturing can be maintained. Poorly administered price controls systems have also led to situations where manufacturers were faced with selling product at a loss. For smaller manufacturers, even a short-term loss can mean closing a production facility.

An example of a challenge was the case of chloramphenicol for treating infections. With a fragmented market and chronic shortages, a reaction to replace it with ceftriaxone – a more expensive product – became the response. This example highlights how irrational responses to shortages and fragmented markets can be costly to health care systems.

Frequent?? mergers and acquisitions can also lead to manufacturers abandoning medicines that are not financially attractive. While industry is ultimately responsible for ensuring quality of products, regulators sometimes cannot keep up with the pace of new registrations, creating delays in market authorizations for important products. In addition to regulatory capacity, industry members have encountered situations where there were questions regarding the level of objectivity of regulatory inspectors. If regulatory standards change frequently, it can be challenging for industry to meet the standards required.

More could be done to reinforce and support quality in production. Transparency of information would be beneficial for manufacturers, including demand and problem tracking. Time-bound regulatory practices would make market entry more predictable and less costly.

Analysis of existing solutions (at global and national levels and vertical programmes)

Compulsory licensing and TRIPS:

In certain cases, patented medicines are not sufficiently available to populations that need them. The problems with patented medicines can include high prices, failure to produce sufficient quantities or restricting access to financially lucrative markets by the manufacturer, anti-competitive practices and others. In situations like these, the TRIPS agreement provides for a remedy for a national government to issue a compulsory license to another manufacturer during the patent period, for example, the intervention used in some LMIC to ensure access to HIV/AIDS medicines. The use of compulsory licensing assumes that a national government has made efforts to negotiate with the patent holder to develop a mutually agreeable solution but without success. The costs and implications of using compulsory licensing are significant, so this option would be reserved to limited cases where the feasibility, costs and legal implications are carefully considered.

Regulatory solutions, reporting mechanisms:

Notification schemes and reporting mechanisms used in a number of countries were presented and discussed. In Norway, legislation mandates that manufacturers notify the agency about impending shortages, at least two months before they occur, or as quickly as possible if they occur unexpectedly. In the event of a shortage, the manufacturer will re-allocate its own product from other countries to Norway. If this is not possible, the Norwegian Medicines Agency contacts wholesalers for an alternative product. If there is no alternative product available, the agency works with healthcare specialists on deciding on a therapeutic alternative. Similarly, in the USA, manufacturers are also required to report shortages, and the information is published on the USFDA website. The role of the EMA is different as it has no national responsibility; it has been working on approaches to managing shortages that are due to manufacturing problems. Importantly, it was noted that it is essential to consider the impact of regulatory actions on critical products and make an explicit risk/benefit assessment of the risk of non-supply versus supply of a product of questionable quality. Penalties for failing to report were also described for each agency.

The potential value of a global reporting mechanism was discussed. Any approach that enhanced early warning of a shortage would potentially facilitate management of the problem. A common knowledge of medicines in potential short supply could facilitate sharing of information about inspections and harmonize requirements. It might also facilitate global market shaping activities, such as those routinely used by the global procurement agencies. Finally, establishing 'good practices 'for reporting mechanisms, knowing what works and what is feasible, would enable countries without an existing mechanism to establish one.

National supply chains:

The need for effective management of supply chains at the national level was discussed in the context of the impact on global markets. Fragmentation of national supply chains, such as has been created by parallel donor programmes in many countries, was highlighted as a fundamental problem that needs to be overcome to improve shortages. Having high quality and real time data that traces product flows as well as funding flows was recognized as essential, as well as having capacity to analyse and develop interventions in response to data showing shortages. Forecasting need accurately without accurate data was recognised to be almost impossible. Techniques such as the use of bar code tracing for products, as recently introduced in South Africa were described, and the change management approach need for personnel was emphasized. The issue of government and public sector ownership

and operation of supply chains was also raised as a cause of failures in product availability at the point of care; examples of successful private sector involvement in these activities in many countries and the benefits achieved for product availability were provided.

National tender and procurement practices were identified as one potentially correctable cause of stock outs. Extreme examples, such as the Danish tender process where the tender for generics is reissued every two weeks, and long-term sole supply contracts such as a single supplier for five years, were recognized as approaches that could increase the risk of shortage of supply. While there may not be a single perfect solution, it was recognized as necessary to consider the nature of the product, the available alternatives on the market as well as market demand in establishing tender conditions.

Ethical frameworks for managing shortages:

The approaches used to ensure an ethical approach to management of shortages were discussed. Examples from specialist areas of medicine, such as paediatric oncology, as well national experiences including in Canada, could be used to form the basis of a global approach. Principles should be based on:

- The need to optimize and efficiently use supplies to reduce the likelihood and mitigate the effects of future shortages through clinical decisions about use based on rigorous evidence and optimal resource utilization, noting the challenges of inadequate evidence;
- Agreed criteria for prioritization of the use of medicines in short supply, noting that this may be controversial;
- Agreed approaches to minimize 'hoarding' noting that using the 'grey market' to obtain supply of medicines can be associated with risks with respect to quality of products;
- Managing access to medicines fairly across different populations, including clinical trial patients, and those commencing versus those continuing treatment.

Ideally, agreement on a management approach should be reached *before* shortages occur, so that all stakeholders involved are aware of it and can plan accordingly.

DISCUSSION

Discussions in plenary and in technical groups focused on the issues in the expert presentations and prioritized key issues.

Need for harmonisation of definitions

It was noted that the definitions of shortages were not consistent across countries' reporting mechanisms and programmes. While definitions may be needed at multiple levels in the overall value chain, consistent definitions would be important.

Shortages had a range of causes from supply of API, quality problems, lack of visibility into demand and rigid responses from procurement systems. A stock out in many cases could be a managed shortage with proactive approaches and the availability of information. An important contributing cause was the lack of quality data to reliably analyse trends and indicators that would predict products at highest risk of global stock outs or shortages.

Importance of effective communication

Communication, especially the lack of an appropriate forum for exchanging information about impending stock outs in a rational and responsible manner was noted as a significant problem. It was recognized that having effective communication across all stakeholders requires a long-term approach and a commitment to as much transparency as possible, and information sharing.

Supply chains

While supply chains are most often focused on responding to supply chain-related shortages, their impact in managing and preventing global shortages and stock outs was recognized. Some interventions, such as bar coding and the urgent move towards data systems that provide more reliable information are clear. Other interventions would involve a review of the paradigm of government procurement of supply chain services, noting that government policies and practices have often not evolved to benefit from modern market conditions, capacities and best practices. Government is often requested to invest in supply chain capacity and procurement, but does not systematically demand performance as a commercial client might do, nor are they assured of the skills, processes and frameworks for effectively procuring and managing best price, best quality services from private sector supply chain service providers. The lack of reliable data noted that efforts to adopt a common standard in bar coding, such as GS1, would be useful. Discussions also noted the existing successes of bar coding in other sectors.

Early warning and reporting mechanisms

While many early warning and reporting systems exist at national levels, a global reporting mechanism could provide more valuable insight given the development of the global medicines market. Prioritizing a list of medicines to monitor based on a set of characteristics of the products and market, identification of best practices and options to respond would be key in a successful approach. Additionally, data contributed to a global reporting mechanism would need to be from verified sources and must be validated in order to remain credible and useful in a response.

Management options

Preventing and managing shortages and stock outs could include risk-based approaches that prioritize medicines needed by public health systems. Industry risk-management principles may also be useful in determining an overall risk-based approach. Ethical considerations and rational clinical management must be part of any response.

Civil society and professional associations

Civil society and professional associations should continue to play a role in preventing and managing global stock outs. With their position in communities and other forums, they frequently have access to information that would be useful in responding to a global shortage.

PRIORITIES FOR WHO

1. Develop consolidated list of medicines that are in short supply and are critical for use in medicine (from the WHO EML) or are at risk of short supply.

2. Develop an approach to market shaping for these medicines in collaboration with global partners.

3. Facilitate harmonisations of definitions of terms used in relation to shortages.

4. Consider development of a global shortage notification system, resources permitting.

5. Facilitate development of global best practices for regulatory authorities in relation to notification and management of shortages, including data standards, database management and regulatory/legislative strategies to minimize impact of shortages.

6. Work with partners such as global industry representatives and professional associations to develop good practice standards in managing shortages.

7. Work with global partners to develop consolidated volume and consumption data for 'vulnerable' medicines.

8. Work with partners to develop appropriate pricing strategies to ensure supply of 'vulnerable' medicines.

9. Continue to support countries, with global partners, to improve supply chain management, including up to date guidance and policies.

Annexes

Annex A. List of participants

Annex B. Meeting agenda

Name	Organization
Tabi Nkeng	Association Central d'Achat des Medicaments
Thomas Spies	Bayer
Namrata Singh	Clinton Health Access Initiative
Caroline Middlecoat	Clinton Health Access Initiative
Maya Matthews	Delegation of the European Union to the United Nations in Geneva
Akinbisehin Abisola	Department of Food and Drug Services, Federal Ministry of Health, Nigeria
Mirfin Mpundu	Ecumenical Pharmaceutical Network
Kristin Raudsepp	Estonian Regulatory Agency
Brendan Cuddy	European Medicines Agency
Martha Gyansa-Lutterodt	Food and Drug Authority, Ghana
Jon Pearman	Gavi
Dilip Shah	Generic Manufacturers Association
Brenda Waning	Global Drug Facility
Joanne Garrah	Health Canada
Brendan Shaw	IFPMA
Ian Barton	Imperial Health Sciences
Luc Besancon	Internatinal Pharmaceutical Federation
Zuzana Kusynova	Internatinal Pharmaceutical Federation
Samuel Okanda	Kenya Medical Supplies Authority
Jérémie Gallien	London School of Business
Elodie Jambert	Médecins Sans Frontières
Marc Biot	Médecins Sans Frontières
Silverani Padaychee	Medicines Control Council of South Africa
Yuan Xuedan	Ministry of Health, China
Khadija Jamaloodien	National Department of Health, South Afrcia
Anban Pillay	National Department of Health, South Afrcia
Samson Adebayo	Nigerian Agency for Food and Drug Administration
Tor Arne Hotvedt	Norweigen Medicines Agency
Peter Mamacos	Office of Global Affairs, Department of Health and Human Services
Catherine Palmier	Permanent Mission of Canada to Geneva
Niloofar Zand	Permanent Mission of Canada to Geneva
John Skibiak	Reproductive Health Supples Coalition
Pascal Bijleveld	RMNCH Strategy and Coordination Team
Anna Halén	Swedish Health Attache to Geneva
Charles Senessie	Swiss Medic
Steve Hornsby	The Global Fund
Mariatou Tala Jallow	The Global Fund
Sophie Logez	The Global Fund
Tony Gill	Therapeutic Goods Administration, Australian Government Department of Health
Gitanjali Sakhuja	UNDP
Seloi Mogatle	UNFPA
Franciso Blanco	UNICEF
Helen Petach	USAID
Christophe Rerat	WHO
Lisa Hedman	WHO
Suzanne Hill	WHO
Hitesh Hurkchand	WHO
Swathi Iyengar	WHO
Vincent Habiyambere	WHO
Boniface Dongmo Nguimfack	WHO
Cecile Mace	WHO
Patrick James Lydon	WHO
Stephanie Mariat	WHO
Mark Mcdonald	WHO
Abisola Olasumbo Akinbesehin	WHO
Xiulei Zhang	WHO
Peter Bayer	WHO
Adrian Barojas	WHO PAHO
Analia Porras	WHO PAHO
Andries Seitar	World Bank Group

World Health Organization

Provisional Agenda
Technical Consultation on Preventing and Managing Global Stock Outs of Medicines
World Health Organization, Geneva Switzerland, December 8th-9th

Day 1 – Tuesday December 8th

Time	Agenda Item	Presenter/Facilitator
Chair for morning session: Sophie Logez, The Global Fund		
08:45 – 09:15	***Introductions and opening of technical consultation*** • Welcome and Opening remarks • Review of agenda and objectives of the technical consultation • Administrative updates	WHO
09:15 – 10:45	***Problem definition: trends in global stock outs of essential medicines*** • Research to date, global causes of medicines shortages • Country experience – South Africa • 'Vulnerable' essential medicines – a review of the WHO EML • Q&A	Luc Besancon, FIP Dr. Khadija Jamaloodien, SA NDoH Sue Hill, WHO
10:45 – 11:00	**Break**	
11:00 – 12:00	***Contributing causes of global stock outs – what we know*** • Case study: Benzathine penicillin • Examples of shortages, solutions, and challenges with maintaining production capacity • Q&A	Seloi Mogatle, UNFPA, Xiulei Zhang, WHO Dilip Shah, GMA
12:00 – 13:00	**Lunch**	
Chair for afternoon session: Dr. Samson Adebayo, National Agency for Food and Drug Administration and Control		

13:00- 13:45	***Contributing causes of global stock outs – what we know*** • Experiences of global procurement agencies • Q&A	Brenda Waning, GDF Francisco Blanco, UNICEF
13:45 – 14:15	***Patented medicines and shortages*** • Dealing with intellectual property • Q&A	Peter Beyer, WHO

14:15 – 15:15	***Reporting Mechanisms*** **Existing mechanisms in measuring and monitoring stock outs,** • National reporting mechanisms on stock outs to national regulatory authorities (Norway) • Case study • Brief reactions from regulatory agencies regulatory agencies from participating countries on reporting mechanisms, successes and limitations o *What are the most effective elements of reporting in terms of enforcement and impact on availability* o *What elements of national, programmatic, or other reporting mechanisms would be of benefit in a global reporting mechanism*	Tor Arne Hotvedt, Norwegian Medicines Agency Dr. Marc Biot MSF Country regulatory agencies, facilitated by Lisa Hedman, WHO)
15:15 – 15:30	**Break**	
15:30 – 17:00	***Role of National Supply Chain*** • PAHO strategic fund and examples of a country led scheme • Examples from national supply chains on costs and visibility into global stock outs • Regional cooperation • Q&A	Adrian Barojas, PAHO Dr. Jérémie Gallien London Business School Dr. Tabi Nkeng ACAME

17:00 – 18:00	***Role of National Supply Chain***
	
	• *Brainstorming discussion: National procurement agencies*
	  ○ *What roles can national procurement supply chains play in responding, preventing and managing stock outs?*
	  ○ *What are the most effective elements of reporting in terms of enforcement and impact on availability*
	  ○ *What elements of national, programmatic, or other reporting mechanisms would be of benefit in a global reporting mechanism*
	• Wrap up
		Lisa Hedman, WHO
		Country procurement agencies

Day 2 – Wednesday December 9th

Time	Agenda Item	Presenter/Facilitator
Chair for morning session: Charles Senessie, Afro-European Medical and Research Network		
08:45 – 10:00	***Case studies of specific products*** • BCG and other vaccines ***Regulatory challenges in management of shortages (brief comments from regulators)*** ○ *What are the most significant quality issues with managing substitutions and fast track approvals for substitutions* ○ *What are the most promising solutions?* ○ Q&A	Patrick Lydon, WHO Brendan Cuddy, EMA
10:00 – 10:30	**Break**	
10:30 – 11:00	***Programmatic efforts to secure access to targeted commodities*** • Role of global collaborations: RMNCH Trust and GFF • Q&A	Pascal Bijleveld, RMNCH TF
11:00 – 12:00	***Plenary discussion*** • Brief reactions from procurement agencies • What is the most effective use of procurement, pricing, guarantees and other existing mechanisms to address global shortages of essential medicines? • Q&A	Pascal Bijleveld RMNCH TF
12:00 – 13:00	**Lunch**	
13:00 – 14:00	***Plenary discussions*** • What ethical considerations must be included in managing and monitoring global shortages and stock outs • Other options that need to be developed in terms of managing global stock outs and management of shortages of essential medicines	Sue Hill, WHO Health Canada

Chair for afternoon session: Lisa Hedman, WHO		
14:00 – 14:30	**Group Work: Key question: In moving from current national and programmatic based reporting and demand consolidation, which national and programme-based mechanisms can be adapted to be part of a global response? How must they be adapted? What are the limitations and challenges?** • Which commodities are at highest risk • Reporting Mechanism • Fast track approvals for substitute products • Commodity security initiatives • Role of country supply chains • Role of industry • Roles of other actors (civil society)	Group Facilitators
14:30 – 15:00	**Break**	
15:00 – 16:15	Continuation of group work	Group Facilitators
16:15 – 17:15	**Final Panel Round Up** • Reports from work groups? • How do we define and monitor the increasing problem? • What are the most important next steps for management of global stock outs and shortages of essential medicines?	Group Facilitators
17:15 – 17:30	**Wrap up and next steps**	Lisa Hedman, WHO