Terms of Reference for the “Coalition of Interested Parties”
WHO Network for Regulatory Systems Strengthening

These Terms of Reference (ToRs) apply to a newly established WHO network for regulatory systems strengthening, named the “Coalition of Interested Parties, WHO Network for Regulatory Systems Strengthening” (hereinafter, the “Network”). These TORs establish the framework for collaboration between the World Health Organization (WHO) and participants in the Network in order to provide more effective support to regulatory systems strengthening, with a view to enhancing access to safe, effective and quality medical products¹.

1. **Context**

Resolution WHA67.20 on *Regulatory system strengthening for medical products*, which was approved by the Sixty-seventh World Health Assembly in May 2014, recognizes that effective regulatory systems are an essential component of health system strengthening, contribute to better public health outcomes, and are necessary to the implementation of universal health coverage. The Resolution also recognizes that inefficient regulatory systems can be a barrier to access to safe, effective and quality medical products.

WHO’s objectives in the area of regulatory system strengthening are to:

1. promote cooperation on regulatory matters, convergence and transparency through networking, work-sharing and reliance; and
2. build capacity in Member States consistent with good regulatory practices.

These objectives are intended to facilitate the availability of safe, effective and quality medical products by assisting countries reach and sustain a level of regulatory oversight that is effective, efficient and transparent.

WHO understands that an increasing number of entities are involved in efforts to strengthen regulatory systems at country-, regional or global level. WHO also recognizes the value of networks, collaboration and coordination (particularly given limitations in resources) in achieving the aforementioned objectives, in enhancing the effectiveness of regulatory support outcomes and, conversely, in avoiding fragmented or uncoordinated support to Member States.

2. **Purpose and Objectives of the Network**

The purpose of the Network is to establish and promote a unified strategic and coordinated approach to strengthening national and regional regulatory systems, thereby contributing to the implementation of Resolution WHA67.20 as well as the common objectives of the Network participants. The Network also aims to increase the effectiveness of collective efforts and desired impact in countries and regions.

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¹ As used in these TORs, “medical products” include medicines, vaccines, blood and blood products and medical devices, including diagnostics.
More specifically, the objectives of the Network include:

a) the more effective use of resources directed at strengthening regulatory systems, consistent with good regulatory practices;
b) enhancing the capacity, consistency and sustainability of regulatory support interventions;
c) promoting the sharing and adoption of best practices between participants in the Network; and
d) reducing burden on regulatory authorities caused by uncoordinated, duplicative and potentially incongruous support activities.

These ToR set forth, among other things, the nature of and framework for the collaboration among the participants in the Network, eligibility criteria for parties wishing to participate in the Network, categories of participation and the Network’s governance mechanisms.

Collaboration and operationalization within the Network may also be supported by specific operating procedures, templates and training, as deemed necessary by participants with a view to enhancing the efficiency and effectiveness of the Network.

3. **Scope**

The Network’s activities span the lifecycle of regulatory system strengthening efforts, including:

a) the benchmarking of regulatory systems to generate and analyze evidence of regulatory system performance;
b) assisting in the formulation and implementation of institutional development and strategic plans as well as regional development plans;
c) providing technical support to national regulatory authorities or regional regulatory networks as well as governments to address the identified gaps and/or to achieve the defined objectives;
d) monitoring the progress of the regulatory system(s) at defined milestones.

4. **Status**

The Network a WHO voluntary collaborative mechanism for enhancing coordination among interested parties for regulatory systems strengthening. The Network is not a legal entity and therefore not intended to create legally binding obligations on parties but rather to operate through the commitment to work in good faith in achieving the shared purpose and objectives as outlined in these TORs.

As a WHO’s network, the activities and operations of the Network shall be administered and housed in WHO in accordance with the WHO Constitution and its General Programme of Work, WHO’s Financial and Staff Regulations and Rules, WHO’s manual provisions, and applicable WHO policies, procedures and practices.

The Network will only operate within and according to these Terms of Reference. Recommendations and proposals by the Network are non-binding on WHO and other participants in the Network and are only intended to serve as a reference point for action to improve the collective support provided to Member States. Each participant is responsible for implementing recommendations and activities subject to and in accordance with its own mandate, internal rules, regulations, procedures and priorities.

The Network is not a regulatory network but takes account of and can lend support to networks of regulatory authorities by strengthening regulatory systems in individual Member States, and by supporting reliance and work-sharing in a more coordinated and effective manner. Towards this end, as and where appropriate, the Network will leverage existing regulatory networks to address regulatory gaps in countries and regions with a view to enhancing access to safe, effective and quality medical products.
5. Guiding Principles of the Network

The following principles will guide the work of the Network.

a) Coordination between WHO and the Network participants to support the strengthening of regulatory systems is essential to enabling complementary, coherent action and optimal outcomes in Member States;
b) The sharing and use of confidential and/or proprietary information in connection with the implementation of the Network’s activities will subject to the Network participants’: (i) obtaining the prior written consent of the owner of such confidential and/or proprietary information which may include, without limitation, the relevant national regulatory authorities (NRAs) and/or Ministries of Health (MOHs); and (ii) prior signature of, and compliance with the terms and conditions contained in, the Confidentiality Undertaking set forth in Annex I to these TORs;
c) The Network’s support is directed at the country and/or regional level(s), and will be coordinated through the designated Network country and/or regional focal persons from each participating organization;
d) Operationalization of the coordinated Network support for regulatory system strengthening in a country or region must be led by the NRA(s) if it is to have the desired country impact; and
e) The work of the Network will be conducted in a manner that is objective and impartial, without favour to any Network participant or other party, and that avoids actual or apparent conflicts of interest, unfounded bias or improper influence of stakeholders.

6. Areas of Collaboration

The overall aim of the WHO Network is to establish and promote a unified, strategic and coordinated approach to strengthen national and regional regulatory systems to a level commensurate with stable, well-functioning and integrated systems as outlined in Resolution WHA67.20. This level of regulatory functioning represents maturity level 3 (ML 3) according to WHO classification of regulatory systems and functions, under which regulatory functioning may range from maturity levels 1 (no formal system) to 4 (advanced level of performance and continual improvement).

The nature and scope of collaboration among relevant Network participants in a particular country or region will be set forth in an agreed written plan of support (hereinafter a “Support Plan”), which will, among other things, define roles and responsibilities of each Network participant based on its competencies, and establish the specific activities, expected outcomes, priorities, timelines and available resources under such Support Plan.

Based on Resolution WHA67.20, the WHO five-step capacity building model (Fig.1) will also guide the roles and activities of the Network participants, including under such Support Plan:

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Steps in supporting the regulatory systems strengthening in a country or regional network should normally involve the following:

a) Based on a written request from relevant NRA(s) and/or national Ministries of Health (MOH), conduct benchmarking of the regulatory system using the WHO The Global Benchmarking Tool (GBT) to establish development needs of national or regional regulatory systems;

b) Elaborate an Institutional Development Plan (IDP), a national strategic plan, and/or a regional development plan, as applicable, defining the gaps to be addressed and objectives to be achieved. Document regulatory gaps from an NRA benchmarking and capacity-building efforts conducted to date to develop recommendations and activities under the IDP, the national strategic plan or regional development plan;

c) Identify and confirm Network participants interested in contributing to the project and their potential roles. The contribution of other organizations who are not Network participants will be assessed on a case by case basis in line with WHO’s policies and rules;

d) Develop a comprehensive road map and budget, including resources necessary to implement the IDP, national strategic plan and/or regional development plan. The road map will include all capacity building activities and any other relevant activities, including the establishment of milestones for monitoring progress and reporting to the NRA/MOH and concerned stakeholders. The roadmap will also confirm leads and supportive parties for each prioritized activity/task;

e) Convene meetings to discuss and agree upon the IDP, national strategic plan or regional development plan and roadmaps, the related implementation costs and funding, as well as the roles and responsibilities of each party. This would include a draft accountability framework to implement the roadmap as well as a communication mechanism and would normally begin with a ‘kickoff’ meeting led by WHO involving Network participants involved in the project, the NRA(s)/MOH(s) and other interested stakeholders (Governmental entities; non-State actors: non-governmental organizations, academic institutions, philanthropic foundations, international and regional business associations and individual experts) on a case by case basis; and

f) Implement activities and monitor progress under the roadmap and accountability framework, making adjustments as necessary.
7. Membership

7.1 Parties Eligible to become Participants

Entities need to apply to become participants in the Network. Categories\(^3\) of entities eligible for participation are:

a) intergovernmental organizations, including the United Nations and its specialized agencies;
b) government bodies such as MOHs and NRAs;
c) non-governmental organizations;
d) academic institutions; and
e) philanthropic foundations.

It is recognized that some entities may be active only in certain regions and/or countries based on their priorities and mandates.

7.2 Application Criteria for Participation in the Network

The following general and specific criteria must be cumulatively met.

*General criteria*

In order to become a participant in the Network, each entity must (i) fall within one of the eligible categories set forth under Section 7.1 above; and (ii) fulfil the following general application criteria:

a) Demonstrate a clear commitment to advancing public health;
b) Agree to these Terms of Reference and its Annexes (including, but not limited to, the Confidentiality Undertaking attached hereto), and any future amendments hereto or thereto;
c) Commitment to provide ongoing support to the Network’s regulatory system strengthening activities; and
d) Nominate focal person(s) for matters relating to the Network and its activities.

*Specific Criteria*

In addition to the aforementioned general criteria, eligible entities must also fulfil the following technical criteria:

a) Demonstrated adherence to and compliance with relevant international technical norms and standards, especially those established by WHO; and
b) Demonstrated engagement in regulatory strengthening activities.

Regulatory authorities operating at ML 3 or above are, in principle, eligible to provide technical support as a party of the Network.

Areas of technical support are categorized according to the regulatory functions and overarching enabling system defined by the WHO Global Benchmarking Tool (GBT)\(^4\).

7.3 Commitments/obligations of participants

Once a participant has been admitted to the Network, such participant undertakes to respect the following obligations:

\(^3\) Categories c, d and e are defined as per paragraphs 9, 11 and 12 of the Framework of engagement with non-State actors (FENSA)

a) Adhere to and comply with these Terms of Reference and its Annexes (including, but not limited to, the Confidentiality Undertaking attached hereto), and any future amendments hereto or thereto;

b) Actively participate in, observe and support the Network’s purpose, objectives, guiding principles, work and activities;

c) Share information (as and where appropriate, and subject to the protection of confidential and/or proprietary information) in an open and transparent manner for the fulfilment of Network’s objectives and activities;

d) Attend and actively participate in annual and ad hoc Network meetings;

e) Take responsibility for its actions (and those of its employees, contractors, agents and representatives), and make meaningful contributions in connection with the work and activities of the Network;

f) Conduct itself and its work in a manner that is ethical, transparent, avoids conflicts of interest and displays integrity; and

g) Not engage in activities or actions that would prejudice the objectives and/or activities implemented by the Network; and

h) If such entity will provide technical support as part of its participation in the Network, then such entity also agrees to adhere to and comply with applicable international technical norms and standards including, without limitation, those established by WHO.

7.4 Parties Eligible to become Observers

The Network may invite entities and/or individual experts who do not meet the criteria for participation in the Network, but who are otherwise involved in activities which are relevant to all or have experience and expertise in the activities considered the Network, to attend designated meetings of the Network in their capacity as observers.

Subject to and without limiting the foregoing, categories eligible to be observers of the Network are:

a) Umbrella regional or international business associations; and

b) Individual experts not affiliated to organizations otherwise represented in the Network.

Each observer will be required to sign and return to WHO a Confidentiality Undertaking (in the form of Annex I attached hereto) prior to attending any meetings of the Network.

For the avoidance of doubt, observers will not have any role in the Network’s decision- and/or recommendation-making process.

7.5 Application Procedure for Participants; Decisions

The application process to become a participant in the Network is set forth in Annex II which is attached to and constitutes an integral part of these TORs.

Eligible entities who are interested in joining the Network as a participant must submit an application through the Web-based platform (see chapter 10.2). Applications to become a participant in the Network must be addressed to WHO. Interested applicants must provide, in reasonable detail, adequate and sufficient information to enable WHO to evaluate the application.

WHO will conduct due diligence and review applications in accordance with the applicable eligibility criteria set forth in these TORs, as well as WHO’s rules, regulations, policies, procedures and practices including, without limitation, WHO’s Framework for Engagement with Non-State Actors (FENSA)\(^5\) with respect to

\(^5\) [https://apps.who.int/wha/pdf_files/wha69/a69_r10-en.pdf](https://apps.who.int/wha/pdf_files/wha69/a69_r10-en.pdf)
applications submitted by Non-State Actors (NSAs). In addition, those non-State actors will be screened every two years to ensure that they still meet FENSA requirements.

WHO will submit the results of its review and screening of applications that meet the eligibility both general and specific criteria to the relevant Steering Group for discussion. Notwithstanding the foregoing, however, WHO will retain the final decision on whether any application to become a participant in the Network is accepted. Decisions are not appealable.

7.6 Termination of participation/involvement

Each participant in the Network has the right to withdraw from participation in the Network at any time, subject to providing WHO with at least three (3) months’ prior written notice and to the orderly conclusion of any ongoing activities.

WHO also has the right to terminate the participation/involvement of any participant and/or observer of the Network at any time, upon providing written notice thereof to such participant/observer. Without limiting the foregoing, WHO shall have the right to terminate the participation of any participant in the Network if such participant: (a) no longer subscribes or adheres to the goals, objectives, guiding principles and/or other terms and conditions applicable to the Network and/or its participants, as described in these Terms of Reference and its Annexes; (b) ceases to meet the criteria for participation the Network, as set forth in these Terms of Reference; and/or (c) acts in any manner which, in WHO’s discretion, is or could be perceived as prejudicial to the Network and/or its reputation or activities.

8. Governance

The Network’s governance structure will be comprised of a Global Steering Group (GSG) at the global level, as well as by Regional Steering Groups (RSGs) that may also be established at each WHO Region. Each of the GSG and RSGs will, in turn, be supported by a Secretariat.
8.1 Global governance structure

Global Steering Group

The Global Steering Group (GSG) will be responsible for establishing, monitoring and facilitating of the overall strategic direction, strategic planning, priorities and effectiveness of the Network at the global level.

The GSG will be composed of representatives of WHO and of each participant in the Network, as well as the chairs of each Regional Steering Group (see Section 8.2 below). Each of WHO and the participants in the Network will nominate one (1) representative to participate, on its behalf, in the GSG.

All actions, decisions and recommendations of the GSG shall be approved by consensus. In the event that a consensus is not reached, the Secretariat of the Network will take a decision in consultation with the chair of the GSG.

The GSG will have a chair and vice-chair elected from among its members for a period of two (2) years. To the extent possible, geographic rotation and gender equity will be taken into consideration when electing the chair and vice-chair of the GSG.

The GSG’s major function is to oversee that the Network’s work and activities are conducted according to these Terms of Reference, the agreed strategic plan and annual work plans for the Network, and WHO’s applicable technical recommendations, guidance and standards.

In addition to the foregoing function, the specific responsibilities of the GSG are to:

a) Establish, approve, monitor, review and facilitate the Network’s overall strategic direction, priorities and effectiveness;

b) Establish, approve and review the Network’s annual plan and activities at the global level;

c) Identify and approve recommendations on areas for improvement concerning the activities of the Network at the global, regional and/or country levels;

d) Review and note or approve, as applicable, (annual) reports produced by the Network;

e) Review and provide input regarding applications for participation in the Network for approval by WHO;

f) Review and approve recommendations concerning revisions to the Network’s operating procedures and Web information-sharing platform described in Section 10.2 below;

g) Consider, make recommendations and provide guidance on issues arising from the operations of the Network at the global level; and

h) Establish time-limited working groups to undertake work related to Network activities or the development of products of the Network, in each case, at the global level; and

i) Consider and make recommendations regarding the financing and sustainability of the Network and its activities at the global level;

j) Oversee that recommendations made by the GSG are implemented.

8.2 Regional governance structure

Regional Steering Groups

A Regional Steering Group will be established in each of the WHO Regions participating in the Network (hereinafter, “RSGs”).

Each RSG will be composed of representatives of WHO and of each participant in the Network from the WHO region concerned (hereinafter “regional participant(s)”). Each of WHO and the regional participants
will nominate one (1) representative to participate, on its behalf, in the applicable RSG; it being agreed that, unless otherwise determined by WHO, WHO shall be represented by a staff member from the applicable WHO Regional Office (WHO RO). Staff from WHO HQ may attend RSG meetings.

All actions, decisions and recommendations of each RSG shall be approved by consensus. In the event that a consensus is not reached, the Secretariat of the Network will take a decision in consultation with the chair of the RSG.

Each RSG will have a chair and vice-chair elected from among its members for a period of two (2) years. To the extent possible, geographic rotation and gender equity will be taken into consideration when electing the chair and vice-chair of each RSG.

The RSG’s major function is to oversee that the Network’s work and activities in the region are conducted according to these Terms of Reference, the agreed development plan, and WHO-recommended guidance and standards.

The specific responsibilities of the RSG within the relevant WHO region are as set forth below:

a) Establish, monitor and facilitate the overall regional strategy, plans, priorities, operations and effectiveness of the Network for the region (provided that such regional strategy, priorities and operations shall be consistent with, and shall not prejudice, the overall global strategy, plans and priorities established by the GSG at the global level);

b) Establish, approve and review the Network’s annual plan and activities for the relevant region;

c) Identify and approve recommendations on areas for improvement concerning the activities of the Network within the relevant region;

d) Review and note or approve, as applicable, (annual) reports produced by the Network within the relevant region;

e) Review and provide input regarding applications for participation in the Network within the relevant region for decision by WHO;

f) Review and provide recommendations to GSG concerning revisions to the Network’s regional operating procedures and any regional Web information-sharing platform, if any is established;

g) Consider, make recommendations and provide guidance on issues arising from the operations of the Network within the relevant region; and

h) Establish time-limited working groups to undertake work related to the Network’s activities or the development of products of the Network, in each case, within the relevant region;

i) Consider and make recommendations regarding the financing and sustainability of the Network and its activities in the relevant region;

j) Oversee that recommendations made at the Regional General Meeting are implemented.

8.3 Secretariat

WHO serves as Secretariat of the Network (in accordance with WHO’s rules, regulations, policies and procedures.

The Secretariat’s role will be to oversee the day-to-day management and administrative support of the Network.

As such, the Secretariat is responsible for:

a) Serving as the interface between the Network and its participants and observers;

b) Serving as the general point of contact for all matters related to the Network, including interest in participation;
c) Providing administrative and budget management support to Network participants on matters related to the Network:
d) Preparing agendas and documents for GSG and RSG Meetings, in collaboration with respective chairs;
e) Organizing and providing secretariat support for aforementioned meetings;
f) Preparing GSG and RSG meeting reports, in collaboration with respective chairs and rapporteurs:
g) Drafting the Network’s annual plan of work for review and approval by the Global Steering Group and/or Regional Steering Groups;
h) Drafting other reports and documents related to the Network, as and where appropriate and as requested by the GSG and/or RSGs, for the review and approval by the Global Steering Group and/or Regional Steering Groups;
i) Developing operating procedures for the Network’s activities, for submission to and approval by the GSG and/or RSGs, as appropriate;
j) Monitoring and reporting on the implementation of the Network activities and recommendations;
k) Bringing issues that require action to the attention of the GSG and/or RSGs, as appropriate; and
l) Hosting and managing the Network’s databases and web platform.

8.4 Meetings

The GSG shall meet in person at least once a year at WHO’s headquarters in Geneva or at such other venue as may be decided by the GSG.

Each RSG will meet in person at least once per year at WHO’s Regional Office for the region concerned or at such other venue as may be decided by the relevant RSG.

The GSG and RSGs may each determine the increase the frequency of their meetings or to allow for such meetings to take place via teleconference or videoconference.

8.5 Decisions and recommendations

To the extent that the Network or any of its governance groups issue any decisions or recommendations, such decisions and recommendations: (i) shall be made by consensus of the Network’s participants comprising the Network and/or such governance groups, as applicable, and (ii) shall not be binding on either WHO or any other participant in the Network.

As a WHO-led network, the activities and operations of the Network shall be administered in accordance with the WHO Constitution, regulations, rules, policies, procedures and practices.

9. Code of Conduct

Each Participant and observer must adhere to the following code of conduct as a condition for its initial and continued participation or involvement in the Network:

a) Refrain from using its participation or involvement in the Network or any of its activities for any advertising, promotional, commercial, illegal or unethical purposes or gain;
b) Refrain from using the name, acronym or emblem of WHO or any participants or observers without express written authorization of WHO or such other party, as applicable;
c) Refrain from representing itself as an agent or representative of WHO or any participants or observers;
d) Refrain from representing itself or its activities, products or services as certified, approved or endorsed by WHO or any participants or observers;
e) Refrain from making any false or misleading statements or claims about itself or its activities, products or services; and
f) Refrain from engaging or supporting, whether directly or indirectly, any fraudulent, illegal or unethical practices or activities.

10. Confidentiality

A Confidentiality Undertaking with WHO must be signed by each Network participant, as well as by each observer, as a condition to participation/involvement in the Network (see Annex I).

Without limiting or prejudicing the terms and conditions of such Confidentiality Undertaking, each participant in the Network agrees to:

a) maintain the confidentiality of (and refrain from disclosing to any third parties) any confidential information and materials shared by or on behalf of WHO and/or any Network participants, except when expressly indicated otherwise in writing by WHO;

b) to maintain the confidentiality of (and refrain from disclosing to any third parties) any views or opinions expressed by WHO and/or any Network participant, as well as of any deliberations and discussions held in the context of Network or any of its activities, except when expressly agreed otherwise in writing by WHO; and

c) to not make or issue any public statements/materials or press releases concerning Network, its work or any of its activities, or on behalf of WHO, unless specifically requested or authorized to do so in writing by WHO.

10.1 Consent of national regulatory authorities to share confidential information

The Network participants acknowledge and agree that the successful functioning of the Network is dependent on obtaining the consent of beneficiaries (e.g., NRAs and/or regional regulatory networks) for WHO and Network participants to use and share confidential and/or proprietary information related to such beneficiaries and/or their activities for purposes of carrying out the Network’s regulatory strengthening activities.

WHO and each of the Network participants will use their reasonable efforts to obtain the aforementioned prior consents of the NRAs or regional regulatory network. For the avoidance of doubt, neither WHO nor Network participants shall use or share (with each other or any third parties) any confidential or proprietary information pertaining to any aforementioned authority/network until its written consent has been secured.

10.2 Information-Sharing Platform

Network participants agree to use a common, secure Web platform for sharing confidential information related to regulatory system strengthening activities, including reports and findings related to country missions and operational plans. WHO will host the web platform to be used for this purpose.

Each party is responsible for clearly designating as “Confidential” any documents or information that it uploads (or provides the Secretariat for upload) to this platform.

Access to confidential information pertaining to the NRA will be on a need to know basis, restricted to those parties providing support to the NRA through the Network, as agreed to by the responsible authority in the NRA or MoH.

The Web information-sharing platform is a key enabler of the Network. It consists of (i) a public (external facing) Web (ii) pages and secure private pages restricted to Network parties. Information on the platform is
organized at three levels: global, regional and country. The platform serves to facilitate planning, coordination, communication and advocacy. It also serves as a convenient portal for members to access reports, meetings, events, products of the Network, profiles of parties and observers, as well as confidential information pertaining to the regulatory system strengthening of countries and regions. Details on the structure and functioning of the platform are described in separate documents.

11. Financing of the Network

Each Network participant shall be responsible for covering all costs and expenses relating to its participation in the Network’s governance, work and activities including, but not limited to, travel and subsistence expenses in connection with attendance at meetings. When possible and at its sole discretion, WHO may provide financial support to Network participants for specific Network activities. The above does not prejudice or preclude separate funding arrangements, if any, entered into between the WHO and Network participants.

Subject to the availability of sufficient financial resources for this purpose, the day-to-day routine operations of the Secretariat to the Network will initially be financed by WHO.

WHO may also, in its sole and absolute discretion, seek to raise funds or accept financial and/or in-kind contributions from external sources to support Network operations, in accordance with WHO’s rules, regulations, policies, procedures and practices.

12. Amendments

These Terms of Reference may be amended from time to time by WHO following discussion with parties.

13. Use of Names and Emblems

The use of the Network’s name, acronym and emblem is restricted to WHO and/or Network participants, but only with prior express written approval of WHO.

Network participants and observers shall not use the name, acronym or emblem of WHO in any manner or for any purpose, without prior written consent by WHO.

14. Public Communications and Publications

Publication of reports and other information products from the Network should be in peer-reviewed journals and in accordance with open access policy.

As a general rule and subject to its discretion, WHO shall be responsible for issuing all public communications and publications relating to Network’s work and activities. In this regard, Network participants shall not make or issue any public statements/materials or press releases concerning the Network, its work or any of its activities, or on behalf of WHO, unless specifically requested or authorized to do so in writing by WHO.

The contributions to the Network made by its participants will be acknowledged by WHO in accordance with its applicable rules, regulations and procedures.

Any publication relating to Network’s work or activities (hereinafter “Publications”) shall be subject to WHO’s rules, procedures and practices on publications, and shall be published by WHO in accordance with the same.
As a general rule and subject to its discretion, WHO shall be responsible for issuing all Publications. All decisions about the preparation and dissemination of any Publications shall be made by WHO. For the avoidance of doubt, any publication and/or dissemination of any Network materials shall be made exclusively by WHO, or as otherwise decided by WHO on a case-by-case basis.

Copyright in any Publication made by WHO shall be vested exclusively in WHO. Likewise, WHO shall exclusively own all copyright in any work prepared or published by WHO including, but not limited to, any compilation of works by Network members and/or any work prepared with input from any Network members. Copyright in any specific separate work prepared exclusively by any Network participant shall remain vested in that participant (or remain in the public domain, if applicable).

Any Publications by any Network member(s) shall be subject to WHO’s review and written approval prior to their publication and shall contain appropriate disclaimers as determined by WHO including, but not limited to, a disclaimer to the effect that the content of such Publication does not necessarily reflect the views or stated policies of WHO.

15. **Monitoring**

The progress made on the activities in order to achieve the overarching objectives of the Network is continuously monitored by the Secretariat. An annual report is prepared on the information on the outcome of the monitoring and is presented to the GSG and the RSGs as applicable for consideration (see also section 8.3 h, j).

16. **Amicable Resolution of Disputes**

Any dispute or disagreement between any of the Network’s participants will be resolved through direct and amicable negotiations.

17. **Privileges and Immunities**

Nothing contained in or relating to these Terms of Reference and/or any work or activities relating to the Network shall constitute or be deemed to be a waiver of any privileges or immunities enjoyed by WHO under any national or international law, treaty or convention, and/or as subjecting WHO to any national court jurisdiction.

18. **Termination of activities of the Network**

WHO may terminate the activities of the Network at any time upon providing the participants at least sixty (60) days’ prior written notice thereof. Upon the issuance of such written notice, WHO and the Network’s participants will work collaboratively and in good faith to wind down and bring to a conclusion the activities of the Network by the termination date. Notwithstanding the termination of the Network’s activities, the provisions of these Terms of Reference which are, by their nature, intended to survive such termination will do so indefinitely.

Annexes:

I. Confidentiality Undertaking
II. Application process
Annex I – Confidentiality Undertaking

(Set forth in next page.)
CONFIDENTIALITY UNDERTAKING

1. The World Health Organization (WHO) has established a WHO network for regulatory systems strengthening at the regional, national and country levels, named the “Coalition of Interested Parties, WHO Network for Regulatory Systems Strengthening” (hereinafter, the “Network”).

2. In connection with the Network, participants and observers in the Network may gain access to confidential and/or proprietary information, documents and other materials which are disclosed by WHO and/or other third parties collaborating in the Network (including, without limitation, participants, observers, national regulatory authorities and Ministries of Health) and which are clearly stated or marked by such disclosing party(ies) to be confidential (“collectively, “Confidential Information”). To safeguard the confidentiality of such Confidential Information, each participant and observer in the Network (including, without limitation, the Undersigned) is required to sign the Undertaking set forth in this document.

3. The Undersigned hereby undertakes to treat the Confidential Information as confidential and proprietary to WHO and/or third parties collaborating in the Network, and to use the Confidential Information solely for purposes of carrying out the activities, meetings and recommendations of the Network at the global, regional and/or country levels (collectively, the “Purpose”), and no other purpose. The Undersigned also agrees to take all reasonable measures to ensure that Confidential Information is not used, copied, disclosed or otherwise transmitted, whether in whole or in part, by or on behalf of the Undersigned to any third parties; except for third parties who have a need to know the Confidential Information for the Purpose and who are bound by obligations of confidentiality and restrictions on use which are substantially similar to those contained in this Undertaking.

4. The Undersigned shall not be bound by any confidentiality obligations or restrictions on use contained herein if and to the extent that the Undersigned is clearly able to demonstrate that the Confidential Information: (a) was known to the Undersigned prior to its disclosure to by WHO or any third parties collaborating in the Network; or (b) was in the public domain at the time of disclosure to the Undersigned by WHO or any third party collaborating in the Network; or (c) becomes part of the public domain through no fault of the Undersigned; or (d) becomes available to the Undersigned from a third party not in breach of any legal obligations of confidentiality or restrictions on use.

5. The Undersigned undertakes not to communicate any of the materials, discussions, outputs, results or recommendations of the Network or any of its governing bodies or working groups to any third parties, except as authorized in writing by WHO.

6. Upon WHO’s request, the Undersigned shall promptly return to WHO or third parties collaborating with the Network, as applicable, any and all copies of their respective Confidential Information which are then in the Undersigned’s possession or control.

7. The obligations of the Undersigned pursuant to this Undertaking shall survive the termination of the Undersigned’s participation in the Network.

8. Any dispute relating to the interpretation or application of this Undertaking shall, unless amicably settled, be subject to a conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or,
in the absence of agreement, with the rules of arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.

9. Nothing contained in or relating to this Undertaking shall be deemed or construed as a waiver of any of the privileges and immunities enjoyed by WHO, or as submitting WHO to any national court jurisdiction.

Agreed to and accepted by the Undersigned as of the date set forth below.

FOR AND ON BEHALF OF

[INSERT FULL NAME OF ENTITY]

Signature: ______________________________
Name: ______________________________
Title: ______________________________
Date: ______________________________
Annex II - Application process

Process of application for participation in the Network:

1. WHO will publish on the Network’s (external-facing) website the criteria for participation in the Network as well as the relevant form/information that must be completed and provided to WHO by parties wishing to become participants in the Network. WHO may also send announcements to third parties whom WHO is aware would be interested in becoming participants in the Network; provided, however, that any such announcement shall not be construed as WHO granting the recipient thereof any right, benefit or advantage, including with respect to the Network’s application process.

2. Parties interested in participating in the Network must complete and submit an initial application form, via the Web-based Network platform and must clearly indicate that such interested party wishes to become a participant in the Network.

3. Following receipt of an initial application, WHO will perform a preliminary screening to determine whether the applicant meets the eligibility criteria set out in the TORs for participation in the Network.

4. Should the application pass this screening step under 3 above, WHO will provide the applicant with a copy of the Network Terms of Reference (including, but not limited to, the Confidentiality Undertaking contained in Annex I thereto), as well as a more detailed application form (together with the list of the additional information and documentation concerning the application which WHO requires in order to assess the application).

For an application to be considered, the applicant will be required to submit adequate information and documentation regarding its legal status, membership, mandate, aims and objectives, sources of funding (including list of donors and sponsors) as well as a summary of its activities (nature and scope) as they relate to the criteria to become a participant in the Network. Non-State actors would be required to sign the tobacco-arms disclosure statement.

5. Following receipt of the detailed application and all supporting materials/documentation, WHO will review the same and determine whether the applicant meets, in principle, the eligibility criteria, the general criteria and, if applicable, the specific criteria set out in Sections 7.1 to 7.2 of the TORs for participation in the Network. WHO will request further clarification from the applicant, should it be necessary to determine whether any such criteria are met.

6. If WHO determines that an applicant meets, in principle, the aforementioned criteria for participation in the Network, then WHO will circulate a summary of each application, together with a provisional decision of acceptance thereof and supporting rationale on eligibility and criteria, to the Global Steering Group or Regional Steering Groups, as applicable, for their input. For the avoidance of doubt, WHO will retain the final decision on whether or not any applicant (i) meets the eligibility, general and/or specific criteria required for participation in the Network, and/or (ii) is formally accepted to join the Network as a participant (see below). WHO’s decisions concerning the foregoing are not open to appeal.

7. Following consultations with and input from the applicable Steering Group(s), WHO will determine whether an applicant will be formally accepted to join the Network as a participant, and will inform successful applicants of the same in writing.

8. Successful applicants will be required to agree to, sign and return to WHO a copy of the Terms of Reference of the Network, as well as of the Confidentiality Undertaking attached as Annex I thereto, as a condition precedent to their participation in the Network.