

WHO Blood Regulators Network

Terms of Reference

Background

The regulations and standards to be applied in the area of blood and blood products rely on a highly technical foundation and scientific expertise. Notwithstanding differences in the needs and challenges faced by regulatory authorities in responding to their own national and regional requirements, there is an urgent need to improve cooperation among the leading regulatory agencies in light of the globalization of the marketplace and an increasingly mobile global population which heightens the vulnerability of nations to communicable disease threats.

It is envisaged that the establishment of a network of leading regulatory authorities could provide an effective and flexible forum for enabling a rapid dialogue and fostering development of international consensus on effective regulatory approaches. Such a group could provide a high level of competence to enhance the evaluation of, and regulatory approaches to, complex issues in the area of blood, blood products and associated drugs and medical devices including *in vitro* diagnostics (IVDs)

The need for the World Health Organization ("WHO") to establish a global network of regulatory authorities in the blood field was recognized by the WHO Expert Committee on Biological Standardization ("ECBS") during its 55th meeting in Geneva, Switzerland in November 2004. The ECBS recommended that WHO promote cooperation of experienced regulatory authorities and unanimously agreed that a "peer regulators group" should be established on a priority basis as a cooperative action of experienced regulators. The ECBS further recommended that WHO invites countries that have expressed an interest to join the network.

Accordingly, the WHO Blood Regulators Network is established as a group of leading regulatory authorities in the blood and blood products field. In general, each of these authorities will have a well established, demonstrated institutional capacity and national/regional legal standing to address the delineated objectives of the Network.

A. Objectives

Consistent with the recommendations of the ECBS, the WHO Blood Regulators Network (hereinafter "the Network") will address issues related to advancing technical expertise in the areas of blood, blood products and associated drugs and medical devices including *in vitro* diagnostics (IVDs). Its Objectives will be to: (a) identify issues; (b) share expertise and information; (c) promote convergence of regulatory policy and (d) propose solutions to specific issues, especially emerging public health challenges

The Network shall focus on the following areas with a particular emphasis on reacting quickly and flexibly to critical situations:

1. Scientific assessment of current and emerging threats to the safety and availability of blood and blood products;
2. Scientific assessment of the impact (i.e., potential benefits and drawbacks) of new technologies in the field of blood and blood products;
3. Exploration of opportunities among regulatory authorities to cooperatively address emerging public health challenges; and
4. Exploration of opportunities for regulatory collaboration/harmonization, particularly in response to emerging public health challenges (such as, for example, actions to prevent transmission of emerging agents in blood products or tools for removing these agents).

B. Functions of the Network

The Network shall have the following functions for the purpose of furthering its Objectives:

1. Establish a fast and effective mechanism for communication among the Members, and with scientific or other regulatory bodies;

2. Communicate its considerations and recommendations to the ECBS, through WHO, with the aim to advance the work of the ECBS and strengthen its recommendations; and
3. Support WHO in enhancing and assisting regulatory authorities worldwide, as well as the regional networks of regulatory authorities which are to be further developed in all WHO regions.

C. **Members**

1. Initially, the Network will be comprised of a small group of Regulatory Authorities (also referred to as "Members") that have responsibility for the regulation of blood, blood products and related IVDs and the necessary expertise and capacity to address emerging public health challenges. Currently, the Regulatory Authorities invited are the following (in alphabetical order of countries):

- a. Therapeutic Goods Administration (TGA), Australia
- b. Health Canada, Canada
- c. Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS), France
- d. Paul-Ehrlich-Institut, Germany
- e. Food and Drug Administration (FDA), U.S.A.
- f. Swissmedic, Switzerland

2. The Members will each designate a Representative to participate in the Network. The Representatives will themselves have expertise, and have on-going access to colleagues with expertise, in the areas of regulation, standards setting, licensing, batch release, and pharmacovigilance of blood and blood products, including relevant epidemiology. Every Representative should act as a contact person, and should be responsible for communication within the Network, and for the organization of the scientific assessment within his or her own organization, making sure that all the available relevant scientific and regulatory expertise is utilized adequately. An alternative expert should be designated by each Regulatory Authority as a substitute representative, in case the principal Representative is not

available. Each participating Regulatory Authority and WHO should ensure that a rapid contact is always available in case of emergencies.

3. The Chair shall be rotated every two years by consensus of the Members and will work closely with WHO secretariat.

D. Invited Experts

At the request of the Network, the WHO may invite individual relevant experts ("Invited Experts") to participate in certain meetings of the Network, for the purpose of sharing information and/or advising the Network on matters within the sphere of their competence. Invited experts will not, however, be considered as Members.

E. Operations

1. The Network provides the Members and other participants with the opportunity to discuss matters and formulate proposals and recommendations which fall within the Terms of Reference. Those proposals and recommendations addressed by the Network to the ECBS will be transmitted by WHO in a timely manner.
2. The Network may establish Working Groups composed of Invited Experts to support specific areas of expertise, as necessary. A Member of the Network will be elected as a Chair of each Working Group. The Chair of the Working Group will appoint the Invited Experts of the Working Group after consultation with the Chair of the Network and the WHO Secretariat. The Chair of the Working Group will report to the Network the conclusions reached by the Working Group.
3. The considerations and recommendations of the Network will be made by consensus of the Members. Considerations and recommendations of the Network will not legally commit WHO or the participating Regulatory Authorities and will not override the authority of the respective governing bodies of the Members. They will constitute expert advice from which the Members, other Regulatory Authorities and WHO may utilize.

4. The Network is not an independent legal entity, but a collaborative mechanism between the Members. Whereas the Members may freely share the issues discussed and the consensus considerations and recommendations of meetings of the Network, the Network cannot be formally represented by individual participants at any other fora. The Chair of the Network, could however report on the activities of the Network with the agreement of all the Members and the WHO secretariat.

5. The Network shall conduct its activities by any method of communication that is efficient and appropriate to discharge its Objectives, including by in person meetings, videoconference, exchange of written reports and communications, e-mail communications and telephonically.

6. It is understood that Members of the Network have to comply with the rules of their respective authorities regarding confidentiality of privileged information and conflict of interest. It is further understood that the Network will operate under the rules and regulations of WHO applicable to technical advisory groups.

F. Secretariat support

1. Secretariat support for the Network will be provided by WHO, acting through the Department of Medicines, Policy and Standards ("PSM") and the Team responsible for blood and blood products and related biologicals ("QSD") at the Organization's headquarters in Geneva. In this connection, WHO will: (a) coordinate the organization of the meetings and other communications of the Network, and of any Working Groups, (b) prepare and distribute, in consultation with the Chair, draft agendas, meeting reports, progress reports, etc (c) receive and submit applications to the Members for membership in the Network, and (d) receive and inform the Members of notices of termination.

2. In addition, WHO will, as part of its secretariat support for the Network: act as a central repository of information and documentation relevant to the Network (including in particular reports of the Network and Working Groups), and disseminate and distribute such

information and documentation to the regulatory authorities of WHO Member States and the public as appropriate, including through the WHO Web site.

3. The Network's products will be disseminated with appropriate disclaimers, including that the content does not necessarily reflect the views or stated policy of the participating regulatory authorities, organizations, agencies and institutions (including WHO, acting as the secretariat for the Network). A clarification of the nature of the proposals/recommendations put forward in such Network documents, will be included along the following lines: "The name of the Network, including its Members and other participants may not be used for or in connection with commercial or promotional purposes"

G. Financing of, and fundraising for operation of the Network (including the secretariat support)

1. Members and Invited Experts will, in principle, be responsible for meeting their own expenses in relation to the Network (including, but not limited to, travel and subsistence for the attendance of meetings). Subject to the availability of funds, the Members may decide to support the participation of other country organizations or agencies, individuals, and/or of Invited Experts.

2. The secretariat support and related day to day operation of the Network will be financed by WHO. In addition, WHO may raise funds from other sources to support the work of the Network, in accordance with WHO's established policies and principles.

3. The acceptance by WHO of any contributions for the Network from the Members, as well as from other sources will be subject to WHO's established policies and principles and to WHO's financial rules and regulations, administrative procedures and practices.

H. Miscellaneous

1. The Members of the Network and the WHO can propose new candidates for membership. Applications to become a Member will be addressed to WHO secretariat which,

after consultation with the Members of the Network, will inform the applicant about the decision.

2. Termination. Any Member may decide to terminate its involvement in the Network by providing written notice to WHO. WHO shall remove the Member in question from the list of Members and inform other Members of the Network accordingly.

3. Amendments. These Terms of Reference may be modified in writing by consensus of all Members and with the endorsement of WHO.
