



WHO Blood Regulators Network

Terms of Reference

Revised 2016

Background

1. 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 a continuous 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.
2. A network of leading regulatory authorities provides an effective and flexible forum for enabling a rapid dialogue and fostering development of international consensus on effective regulatory approaches. Such a group should 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).
3. 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 invite countries that have expressed an interest to join the network.
4. Accordingly, the WHO Blood Regulators Network was established as a group of leading regulatory authorities in the blood and blood products field. In general, each of these authorities has a well-established, demonstrated institutional capacity and national/regional legal standing to address the delineated objectives of the Network.

A. Objectives

5. Consistent with the recommendations of the ECBS, the WHO Blood Regulators Network (hereinafter "the Network") addresses 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 are:

- a) to identify issues;
- b) to share expertise and information;
- c) to promote convergence of regulatory policy and
- d) to propose solutions to specific issues, especially emerging public health challenges.

6. The Network is focused on the following areas with a particular emphasis on reacting quickly and flexibly to critical situations:

- a) scientific assessment of current and emerging threats to the safety and availability of blood and blood products;
- b) scientific assessment of the impact (i.e., potential benefits and drawbacks) of new technologies in the field of blood and blood products;
- c) exploration of opportunities among regulatory authorities to cooperatively address emerging public health challenges; and
- d) 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

7. The Network has the following functions for the purpose of furthering its objectives:

- a) establish a fast and effective mechanism for communication among the Members, and with scientific or other regulatory bodies;
- b) communicate its considerations and recommendations to the ECBS, through the WHO

Secretariat, with the aim to advance the work of the ECBS and strengthen its recommendations; and

- c) 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

8. The Network consists of a small group of Regulatory Authorities (also referred to as "Members") that have responsibility, in their respective countries, for the regulation of blood, blood products and associated drugs and medical devices including IVDs and the necessary expertise and well established, demonstrated institutional capacity to address emerging public health challenges. A list of the Network Members, which is found as a separate annex, is regularly updated by the WHO Secretariat and is also made available on the WHO Blood Regulators Network website.

9. Each Member shall designate a Representative to participate in the Network. The Representatives themselves have expertise, and have ongoing access to colleagues with expertise, in the areas of regulation, standard setting, licensing, batch release, and pharmacovigilance of blood and blood products, including relevant epidemiology. Every Representative shall act as a contact person, and shall 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 shall be designated by each Regulatory Authority as a substitute representative, in case the principal Representative is not available. Each Member should provide the WHO Secretariat with the curriculum vitae of both the Representative and Alternative experts. Each participating Regulatory Authority and the WHO Secretariat should ensure that a rapid contact is always available in case of emergencies.

10. To ensure that the Network can meet its objectives, it is important to keep its character as a "peer regulators group". The Network needs to maintain a workable size with 12 Members in maximum in order to assure the ability to react quickly and flexibly to critical situations. Consideration should be given to a broad representation of WHO regions.

11. In reviewing membership applications from additional regulatory authorities, the following criteria should be considered:

The applicant:

- a) represents a leading Regulatory Authority that has responsibility for the regulation of blood, blood products and associated drugs and medical devices, including IVDs; has the necessary expertise and capacity to address emerging public health challenges;
- b) has a well-established, demonstrated institutional capacity and national legal standing to address the delineated objectives of the Network;
- c) is able to provide the necessary information and evidence that the criteria are met, by first completing a questionnaire and if necessary by an oral explanation and discussion with the Network upon invitation of a Representative of the applicant authority by the WHO Secretariat;
- d) nominates a designated Representative and/or the substitute Representative of the applicant Regulatory Authority which contributes in providing the necessary information.

12. A Regulatory Authority interested in becoming a Member should send an application letter to the WHO Secretariat, explaining its interest in membership as well as its potential contribution to the Network. Alternatively, the Members of the Network and the WHO Secretariat can also propose new candidates for membership. The WHO Secretariat will then request the applicant Regulatory Authority to provide the necessary information and evidence for meeting the criteria. At the request of the Network, the WHO Secretariat may invite the applicant candidate to partially participate at the meeting as an observer. If the application and the information provided is found acceptable by unanimous recommendation of the Network Members, the WHO Secretariat shall, in consultation with the ECBS members, decide on whether to approve the application of an applicant candidate. The WHO Secretariat shall thereafter inform the applicant of the decision taken.

13. Whereas Membership in the Network is not time limited, any Member may decide to terminate its involvement in the Network by providing written notice to the WHO Secretariat. The WHO Secretariat shall inform other Members of the Network and remove the Member in question from the List of Members accordingly. In addition, WHO reserves the right to terminate the Membership of any Member with the provision of 30 days prior notice in writing.

D. Invited Experts

14. At the request of the Network, the WHO Secretariat 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. Such experts will be required to complete a WHO Declaration of Interests form to be provided and assessed by the WHO Secretariat.

E. Operations

15. A Representative or Alternative is elected by consensus of the Members as Chairperson of the Network. The term of office of the Chair shall normally consist of two years. A Chair should not be elected for more than two consecutive two-year terms. The WHO Secretariat shall facilitate the Chair election procedure. The Chair will work closely with the WHO Secretariat, especially for the organization of the meetings and with regard to reporting on the activities of the Network.

16. 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. Such proposals and recommendations shall be addressed to the WHO Secretariat for its presentation to the ECBS in a timely manner.

17. The Network may establish adhoc 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 report to the Network the conclusions reached by the Working Group.

18. The recommendations of the Network are made by consensus of the Members. Recommendations of the Network shall not be binding on WHO or the participating Regulatory Authorities and are not overriding the authority of the respective governing bodies of the Members or of WHO. They constitute expert advice from which the Members, other Regulatory Authorities and WHO may utilize.

19. 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 or a designated Representative or Alternative, could however report on the activities of the Network with the agreement of all the Members and the WHO Secretariat.

20. 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. The working language of the Network shall be English.

21. 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 operates under the rules, regulations and administrative practices of WHO.

F. Secretariat support

22. Secretariat support for the Network is provided by WHO, acting through the Department of Essential Medicines and Pharmaceutical Policies and the programme responsible for blood products and related biologicals at the Organization's headquarters in Geneva. In this connection, the WHO Secretariat: (a) coordinates the organization of the meetings and other communications of the Network, and of any Working Groups, (b) prepares and distributes, in consultation with the Chair, draft agendas, meeting reports, progress reports, etc, (c) receives and submits applications for membership in the Network to the Members, and (d) receives and informs the Members of notices of termination.

23. In addition, WHO, as part of its secretariat support for the Network, acts as a central repository of information and documentation relevant to the Network (including in particular reports of the Network and Working Groups), and disseminates and distributes such information and documentation to the regulatory authorities of WHO Member States and the public as appropriate,

including through the WHO web site.

24. The Network's products are 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 WHO Secretariat support)

25. Members and Invited Experts are, in principle, 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.

26. The WHO Secretariat support and related day to day operations of the Network are financed by WHO. In addition, WHO may raise and accept funds from other sources to support the work of the Network, in accordance with WHO's established rules, regulations and administrative practices.

H. Miscellaneous

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

Annex

WHO Blood Regulators Network List of Members

The following agencies are Members of the BRN (in alphabetical order of countries):

- Therapeutic Goods Administration (TGA), Australia
- Health Canada, Canada
- Agence nationale de sécurité du médicament et des produits de santé (ANSM), France
- Paul-Ehrlich-Institut, Germany
- Ministry of Health, Labour and Welfare (MHLW), Japan
- Swissmedic, Switzerland
- Food and Drug Administration (FDA), USA