Terms of Reference for the Advisory Group on Blood Regulation, Availability and Safety

Medicinal (medical therapeutic) products derived from human donations of blood and plasma, including whole blood and other blood components for transfusion, and plasma-derived medicinal products (PDMPs) play a critical role in health care and are fundamental for achieving universal health coverage. Safe, effective and quality-assured blood products contribute to improving and saving millions of lives every year. To ensure access to safe, effective and quality-assured blood products, a functioning national blood system is required. A robust national and regional blood service and blood regulator, with effective haemovigilance and pharmacovigilance systems for monitoring the safety of blood donations and blood product use, is also key to building and strengthening national and regional capacities to respond to emerging infectious threats.

Since 1975, the World Health Assembly has highlighted the global need for blood safety and availability through the adoption of several resolutions that have given greater priority to the issue within global and national health agendas. Key resolutions include:

- WHA28.72, Utilization and supply of human blood and blood products (1975);
- WHA56.30, Global health-sector strategy for HIV/AIDS (2003);
- WHA58.13, Blood safety: proposal to establish World Blood Donor Day (2005);
- WHA63.12, Availability, safety and quality of blood products (2010); and
- WHA 67.6, Hepatitis (2014).

However, progress in blood regulation and availability has been slow in many parts of the world. A major imbalance exists between higher-income and lower-income countries in access to safe, effective and quality-assured blood products. For that reason, the WHO Action Framework to advance universal access to safe, effective and quality-assured blood products 2020–2023 was developed. The framework gathers recommendations on the WHO programmes on quality of blood products and blood transfusion safety and WHO partners’ global efforts to address present barriers to the safety and availability of blood products. It aims to provide a unified global strategic direction to ensure access to safe blood products worldwide.

To this effect, it is proposed that the Advisory Group for Blood Regulation, Availability and Safety support technical advisory functions of the WHO blood products programme and scale up the implementation of WHO policies and strategies to strengthen blood systems, and advance universal access to safe, effective and quality-assured blood products in the world. The role of this Advisory Group is to advise and support WHO at all levels on regulation and technical aspect of blood system.

The Advisory Group (the “AG”) for Blood Regulation, Availability and Safety will act as an advisory body to WHO in this field.

I. Functions

In its capacity as an advisory body to WHO, the AG shall have the following functions:

1. To advise on the development of WHO norms, standards, technical guidelines and high-level strategic recommendations on ensuring safety, quality and availability of blood products.
2. To advise on scaling up the implementation of existing WHO policies, strategies, including innovative strategies and tailored approaches; as well as strengthening the national systems for blood supply and regulation to achieve the goal of universal access to safe, effective and quality assured blood products.

3. To provide scientific assessment of current and emerging threats to the safety and availability of blood and blood products; advise on the recommended measures and actions to be taken by the Member States in preparedness for and in response to the emerging public health threats.

II. Composition

1. The AG shall have up to 25 members¹, who shall serve in their personal capacity to represent the broad range of disciplines relevant to blood regulation and blood transfusion medicines. In the selection of the AG members, consideration shall be given to attaining an adequate distribution of technical expertise, geographical representation and gender balance.

2. Members of the AG, including the Chairperson, shall be selected and appointed by WHO following an open call for experts. The Chairperson's functions include the following:

- to chair the meeting of the AG;
- to liaise with the WHO Secretariat between meetings.

In appointing a Chairperson, consideration shall be given to gender and geographical representation.

3. Members of the AG shall be appointed to serve for a period of 2 years and shall be eligible for reappointment. A Chairperson is eligible for reappointment as a member of the AG, but is only permitted to serve as Chairperson for one term. Their appointment and/or designation as Chairperson may be terminated at any time by WHO if WHO's interest so requires or, as otherwise specified in these terms of reference or letters of appointment. Where a member’s appointment is terminated, WHO may decide to appoint a replacement member.

4. AG members must respect the impartiality and independence required of WHO. In performing their work, members may not seek or accept instructions from any Government or from any authority external to the Organization. They must be free of any real, potential or apparent conflicts of interest. To this end, proposed members/members shall be required to complete a declaration of interests form and their appointment, or continuation of their appointment, shall be subject to the evaluation of completed forms by the WHO Secretariat, determining that their participation would not give rise to a real, potential or apparent conflict of interest.

5. Following a determination that a proposed member’s participation in an AG would not give rise to a real, potential or apparent conflict of interest, the proposed member will be sent a letter inviting them to be a member of the AG. Their appointment to the AG is subject to

¹ Members serve as full participants and partake in the decision-making process of the meeting in which they are involved.
WHO receiving the countersigned invitation letter and accompanying terms and conditions. Notwithstanding the requirement to complete the WHO declaration of interest form, AG members have an ongoing obligation to inform the WHO of any interests real or perceived that may give rise to a real, potential or apparent conflict of interest.

6. As contemplated in paragraph II.4 above, WHO may, from time to time, request AG members to complete a new declaration of interest form. This may be before an AG meeting or any other AG-related activity or engagement, as decided by WHO. Where WHO has made such a request, the AG member’s participation in the AG activity or engagement is subject to a determination that their participation would not give rise to a real, potential or apparent conflict of interest.

7. Where an AG member is invited by WHO to travel to an in-person AG meeting, WHO shall, subject to any conflict of interest determination as set out in paragraph II.6 above, issue a letter of appointment as a temporary adviser and accompanying memorandum of agreement (together ‘Temporary Adviser Letter). WHO shall not authorize travel by a AG member, until it receives a countersigned Temporary Adviser Letter.

8. AG members do not receive any remuneration from the Organization for any work related to the AG. However, when attending in-person meetings at the invitation of WHO, their travel cost and per diem shall be covered by WHO in accordance with the applicable WHO rules and policies.

III. Operation

1. The AG shall normally meet at least once each year. However, WHO may convene additional meetings. AG meetings may be held in person (at WHO headquarters in Geneva or another location, as determined by WHO) or virtually, via video or teleconference.

AG meetings may be held in open and/or closed session, as decided by the Chairperson in consultation with WHO.

(a) Open sessions: Open sessions shall be convened for the sole purpose of the exchange of non-confidential information and views, and may be attended by Observers (as defined in paragraph III.3 below).

(b) Closed sessions: The sessions dealing with the formulation of recommendations and/or advice to WHO shall be restricted to the members of the AG and essential WHO Secretariat staff.

2. The quorum for AG meetings shall be two thirds of the members.

WHO may, at its sole discretion, invite external individuals from time to time to attend the open sessions of an advisory group, or parts thereof, as “observers”. Observers may be invited either in their personal capacity, or as representatives from a governmental institution / intergovernmental organization, or from a non-state actor. WHO will request observers invited in their personal capacity to complete a confidentiality undertaking and a declaration of interests form prior to attending a session of the AG. Invitations to observers attending as representatives from non-state actors will be subject to internal due diligence and conflict of interest considerations in accordance with FENSA. Observers invited as
representatives may also be requested to complete a confidentiality undertaking. Observers shall normally attend meetings of the AG at their own expense and be responsible for making all arrangements in that regard.

At the invitation of the Chairperson, observers may be asked to present their personal views and/or the policies of their organization. Observers will not participate in the process of adopting decisions and recommendations of the advisory group.

3. The AG may decide to establish smaller working groups (sub-groups of the AG) to work on specific issues. Their deliberations shall take place via teleconference or video-conference and the outcome of their deliberations will be submitted to the AG for review at one of its meetings.

4. AG members are expected to attend meetings. If a member misses two consecutive meetings, WHO may end his/her appointment as a member of the AG.

5. A yearly report shall be submitted by the AG to WHO (the Assistant Director-General of the responsible Division). All recommendations from the AG are advisory to WHO, who retains full control over any subsequent decisions or actions regarding any proposals, policy issues or other matters considered by the AG.

6. The AG shall normally make recommendations by consensus. If, in exceptional circumstances, a consensus on a particular issue cannot be reached, minority opinions will be reflected in the meeting report.

7. Active participation is expected from all AG members, including in working groups, teleconferences, and interaction over email. AG members may, in advance of AG meetings, be requested to review meeting documentation and to provide their views for consideration by the AG.

8. WHO shall determine the modes of communication by the AG, including between WHO and the AG members, and the AG members among themselves.

9. AG members shall not speak on behalf of, or represent, the AG or WHO externally or to any third party.

IV. Secretariat

WHO Blood and other Products of Human Origin Teams shall provide the secretariat for the AG, including necessary scientific, technical, administrative and other support. In this regard, the WHO Secretariat shall provide the members in advance of each meeting with the agenda, working documents and discussion papers. Distribution of the aforesaid documents to Observers will be determined by the WHO Secretariat. The meeting agenda shall include details such as: whether a meeting, or part thereof, is closed or open; and whether Observers are permitted to attend.

V. Information and documentation

1. Information and documentation to which members may gain access in performing AG related activities shall be considered as confidential and proprietary to WHO and/or parties
collaborating with WHO. In addition, by counter signing the letter of appointment and the accompanying terms and conditions referred to in section II(5) above, AG members undertake to abide by the confidentiality obligations contained therein and also confirm that any and all rights in the work performed by them in connection with, or as a result of their AG-related activities shall be exclusively vested in WHO.

2. AG members and Observers shall not quote from, circulate or use AG documents for any purpose other than in a manner consistent with their responsibilities under these Terms of Reference.

3. WHO retains full control over the publication of the reports of the AG, including deciding whether or not to publish them.