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Director-General's consultation with Member States

Proposals to finalize remaining elements of the "Pandemic Influenza Preparedness Framework for sharing influenza viruses and access to vaccines and other benefits"

BACKGROUND

1. The Sixty-second World Health Assembly, through resolution WHA62.10, requested inter alia that the Director-General "facilitate a transparent process to finalize the remaining elements [of the Pandemic Influenza Preparedness Framework], including the Standard Material Transfer Agreement (SMTA) and its annex, and report the outcome to the Executive Board at its 126th session in January 2010".

2. The process adopted in order to respond to the Health Assembly's mandate included:

- review and analysis of the positions expressed during the Intergovernmental Meeting on the key outstanding issues
- production of this document (the "Paper") setting out specific proposals for finalizing the remaining issues
- a two-day consultation with Member States to discuss the proposals.

3. Analysis of the remaining elements to be finalized in the Pandemic Influenza Preparedness Framework for sharing influenza viruses and access to vaccines and other benefits[1] shows that they fall into one of the following areas:

- SMTA and relations with influenza vaccine manufacturers
- intellectual property rights
- other matters.

4. The Paper presents proposals to resolve the two key remaining issues, namely SMTA and intellectual property rights. Both of these issues cover core public health concerns related to pandemic influenza preparedness, including, in particular: the continued ability of WHO Network laboratories to assess the risk of pandemic influenza, and the uninterrupted and expeditious development and supply by influenza vaccine manufacturers of pandemic influenza vaccines, a goal being to provide developing countries in need with access to these vaccines.

[1] Document A62/5 Add.1, Appendix.

PROPOSALS

SMTA and relations with influenza vaccine manufacturers

5. Discussions at the Intergovernmental Meeting highlighted two substantially divergent approaches related to SMTA: one perspective espoused a binding, all-encompassing agreement, covering both virus and benefit sharing, while the other perspective supported an agreement limited to virus sharing.

6. The proposed approach would create two documents: (a) an SMTA that covers the sharing, use and transfer of PIP Biological Materials *within the WHO Network*; and (b) Guiding Principles for the development of benefit sharing arrangements with influenza vaccine manufacturers. Drafts of these documents are attached as Annexes 1 and 2.

(a) ***The SMTA:*** This document would apply to all laboratories in the WHO Network. The terms for the use of PIP Biological Materials by WHO Network laboratories are those contained in their WHO Terms of Reference. Through the SMTA, providers of PIP Biological Materials consent to the transfer of such Materials within the WHO Network, subject to continued application of the SMTA. The SMTA would become applicable to WHO Network laboratories upon their acceptance of their new WHO Terms of Reference (for laboratories already in the WHO Network) or upon designation or recognition of a laboratory by WHO as a member of the WHO Network (for new laboratories joining the WHO Network). By accepting a designation or recognition by WHO, a laboratory would be automatically bound by the SMTA and this would continue as long as that designation or recognition was in effect. The SMTA also includes a provision on resolution of disputes.

(b) ***Guiding Principles for the development of benefit sharing arrangements with influenza vaccine manufacturers:*** Individual arrangements would be sought with influenza vaccine manufacturers based on a set of Guiding Principles to be agreed by Member States. This approach is based closely on that which was used to develop consensus on the WHO Terms of Reference for WHO Network laboratories (i.e., Member States agreed on "Guiding Principles for the Development of WHO Terms of Reference" which guided the Secretariat in its preparation of said Terms of Reference). Given the potentially unlimited number of laboratories outside the WHO Network that may request PIP Biological Materials, and the practical impossibility of WHO entering into arrangements with all of them, the solution proposed is to limit individual arrangements to influenza vaccine manufacturers. All arrangements with influenza vaccine manufacturers would reflect the same Guiding Principles, notably benefit sharing, intellectual property rights and dispute resolution, but also allow flexibility to recognize the differences between manufacturers.

Intellectual property rights

7. During the discussions at the Intergovernmental Meeting, two different perspectives emerged: one supporting no restriction on the right of parties handling PIP Biological Materials to seek intellectual property rights with respect to inventions developed with these Materials, and the other seeking to limit or restrict pursuit of intellectual property rights.

8. The proposed text represents a compromise between these positions. The essence of the proposal is to ensure that neither the Framework nor the SMTA impede research and development that could result in improved technologies or medicines for the detection and/or control of influenza. Additionally, the proposal seeks to ensure equitable rights of all laboratories that handle and use PIP Biological

Materials, permitting all laboratories to seek intellectual property rights derived from the use of such Materials, regardless of the laboratories' legal status (for example, designated WHO Collaborating Centre or public, private, for-profit or non-profit entity).

9. The proposal is thus to allow any entity receiving PIP Biological Materials to pursue intellectual property rights derived from the use of said Materials, and urge such entity to grant to WHO a non-exclusive, royalty-free, sub-licensable licence with respect to such rights, to the extent that such grant is not prohibited by law, regulation or third-party obligation (which obligation exists before the receipt of the PIP Biological Materials). Licences to WHO would be subject to certain terms and conditions, including but not limited to: commitment, ability and readiness of a potential recipient to use the sub-licence, and agreement on the territorial application of the sub-licence.

10. This proposal aligns with the intellectual property provision used in a recent public-health-related agreement, namely the Collaboration for AIDS Vaccine Discovery.[1] The proposal is attached as Annex 3 to this Paper.

Other matters

11. Finalization of a small number of outstanding elements may be completed in due course following consensus on the seminal matters discussed above. These remaining elements include:

(a) preambular paragraphs, notably on the relationship between the Framework and the Convention on Biological Diversity;

(b) the name of the WHO Network; and

(c) definitions on "genetic materials" and "clinical specimens".

[1] The Collaboration for AIDS Vaccine Discovery (CAVD) was launched by the Bill & Melinda Gates Foundation in July 2006 and now funds a total of 19 three-to-five year grants which support more than 450 investigators across 100 institutions in 21 countries. More information on the CAVD, including access to the legal agreements may be found at: http://www.cavd.org/Pages/default.aspx. The intellectual property clause used as the model may be found in Annex C, 1.b.iii of the CAVD Data & Materials Sharing Agreement using the following link: http://www.cavd.org/SiteCollectionDocuments/CAVDDataMaterialsSharingAgreement.pdf.

Annex 1

Draft Standard Material Transfer Agreement

In furtherance of the Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (the "Framework"), this Standard Material Transfer Agreement ("Agreement" or "SMTA") has been developed.

THE PARTIES TO THIS AGREEMENT HEREBY AGREE AS FOLLOWS:

ARTICLE 1 – PARTIES TO THE AGREEMENT

1.1 Parties to this SMTA are limited to influenza laboratories that have been designated or recognized by WHO and have accepted to work under agreed WHO Terms of Reference. In this Agreement:

- The Provider is the laboratory sending PIP Biological Materials, as herein defined,

and:

- The Recipient is the laboratory receiving PIP Biological Materials.

1.2 Provider and Recipient are hereafter collectively referred to as "Parties".

ARTICLE 2 – SUBJECT MATTER OF THE AGREEMENT

PIP Biological Materials (hereinafter "Materials") transferred from the Provider to the Recipient are subject to the provisions of this Agreement. PIP biological Materials, for the purposes of the SMTA, include human clinical specimens,[1] virus isolates of wild-type human H5N1 and other influenza viruses with human pandemic potential; and modified viruses prepared from H5N1 and/or other influenza viruses with human pandemic potential developed by WHO Network laboratories, these being candidate vaccine viruses generated by reverse genetics and/or high growth re-assortment.

ARTICLE 3 – RIGHTS AND OBLIGATIONS OF THE PARTIES

3.1 The Provider and Recipient undertake the following with respect to the Materials:

3.1.1 To comply with their respective WHO Network Terms of Reference.

3.1.2 To use best efforts to ensure that the Materials are handled in accordance with applicable WHO guidelines.[2]

[1] "Clinical specimens" means biological materials such as swabs and aspirated fluid, blood, serum, plasma, faeces, and tissues, collected from humans/[and non-human sources/animals] for diagnostic purposes, study or analysis.

[2] "WHO Guidance on Regulations for the Transport of Infectious Substances" and "WHO Guidelines for the collection of human specimens for laboratory diagnosis of avian influenza infection".

3.1.3 To comply with the following provision concerning intellectual property rights:

If intellectual property rights are obtained on inventions derived from the use of PIP Biological Materials, the holder of such rights should grant to WHO a non-exclusive, royalty-free, sub-licensable licence with respect to such rights. Licences to WHO shall be subject to the following terms:

(a) WHO shall, upon request, have the right to grant sub-licences of said licence (hereinafter "WHO sub-licences") for public health purposes;

(b) WHO may subject WHO sub-licences to appropriate conditions based on sound public health principles.[1]

3.2 As a member of the WHO Network, Recipient recognizes that Materials are provided to facilitate implementation of Recipient's agreed WHO Terms of Reference. Recipient further agrees that the Materials will be used solely for the purposes stated in said Terms of Reference. Recipient agrees that any use of the Materials beyond those purposes will require specific authorization from the Provider.

3.3 The Provider agrees to the onward transfer and use of the Materials, to all members of the WHO Network, on the same terms and conditions as those provided in this SMTA.

3.4 The Provider consents to the onward transfer of the PIP Biological Materials to influenza vaccine, diagnostics and pharmaceutical manufacturers, on the condition that such influenza vaccine manufacturer has or is developing with WHO a benefit sharing arrangement based on the *Guiding Principles for the development of benefit sharing arrangements with influenza vaccine manufacturers*. WHO shall make available, as appropriate, information regarding such arrangements.

3.5 The Provider and the Recipient acknowledge that any intellectual property rights existing as of the date of adoption of the Framework by the World Health Assembly will not be affected by this SMTA.

ARTICLE 4 – DISPUTE RESOLUTION

In the event of a dispute under this SMTA, Parties shall first seek an amicable settlement. Should this fail, the dispute may be submitted to the Director-General who will review the circumstances and may consider appropriate action in response to the dispute which may include the suspension or revocation of the WHO designation of the relevant laboratory.[2]

ARTICLE 5 – ACCEPTANCE AND APPLICABILITY

With respect to laboratories in the WHO Network at the time of the adoption of the Framework by the World Health Assembly, acceptance by such laboratories of their revised WHO Terms of Reference, as contained in the Framework, constitutes acceptance of this SMTA. Following the adoption of the Framework, designation or recognition by WHO of other laboratories as laboratories in the WHO Network will constitute acceptance of this SMTA by such laboratories. This SMTA shall cease to be applicable only upon suspension or revocation of designation or recognition by WHO or upon formal withdrawal by the laboratory of its participation in the WHO Network. Such a suspension, revocation or withdrawal shall not relieve a laboratory of pre-existing obligations under this SMTA.

[1] For example, the commitment, ability and readiness of a potential recipient to use the sub-licence; and agreement on the territorial application of the sub-licence.

[2] As provided in Section 7.3.4 of the Framework.

Annex 2

Guiding Principles for the development of benefit sharing arrangements with influenza vaccine manufacturers

1. In their collective action for global public health, WHO Member States have committed to share, on an equal footing, PIP Biological Materials and the benefits derived from the use of such Materials.

2. Arrangements shall contain provisions on at least the following issues:

(a) Commitment to *share* benefits: In return for access to PIP Biological Materials, a vaccine manufacturer commits to share with WHO benefits derived from the use of such Materials. Examples of benefits that may be shared with WHO include, but are not limited to:

(i) donations of pandemic influenza vaccine to WHO for use in developing countries in need

(ii) development and signing of an advance purchase agreement with WHO for pandemic influenza vaccine

(iii) tiered pricing arrangements for real-time, affordable access by developing countries to pandemic influenza vaccines

(iv) financial contributions to WHO for purchase of pandemic influenza vaccines on behalf of developing countries in need

(v) transfer of influenza vaccine manufacturing technology under the WHO Global Action Plan to Increase Pandemic Influenza Vaccine Supply to qualified developing country private or public sector manufacturers, as appropriate, subject to appropriate technical and feasibility studies.

(b) Intellectual property rights:

(i) A Recipient that obtains any intellectual property rights derived from the use of PIP Biological Materials should grant to WHO a non-exclusive, royalty-free, sub-licensable licence with respect to such rights. Licences to WHO shall be subject to the following terms:

(a) WHO shall, upon request, have the right to grant sub-licences of said licence (hereinafter "WHO sub-licences") for public health purposes;

(b) WHO may subject WHO sub-licences to appropriate conditions based on sound public health principles.[1]

(c) Other clauses: A Recipient commits to accept additional provisions as may be required by WHO consistent with its current practice regarding agreements with the private sector including donations of pharmaceutical products. These may include, but are not limited to, provisions addressing dispute resolution, privileges and immunities, manufacturers' warranties and indemnification.

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[1]For example, the commitment, ability and readiness of a potential recipient to use the sub-licence; and agreement on the territorial application of the sub-licence.

Annex 3

Proposed Text on Intellectual Property Rights

For inclusion as Section 5.5 of the Framework:

5.5 Intellectual property rights

Member States should urge entities that receive PIP Biological Materials and obtain intellectual property rights derived from the use of said PIP Biological Materials to agree to grant to WHO a non-exclusive, royalty-free, sub-licensable licence with respect to such rights, to the extent that this is not prohibited by law, regulation or third-party obligation (which obligation exists before the receipt of the PIP Biological Materials). To the extent that such prospective grants are prohibited by law, regulation or pre-existing third-party obligation, the recipient will in good faith consider requests from WHO for the right to use such intellectual property rights and explore ways to enable such use in a similar cost-limited manner. Licences to WHO should be subject to the following terms:

(a) WHO shall, upon request, have the right to grant sub-licences of said licence (hereinafter "WHO sub-licences") for public health purposes

(b) WHO may subject WHO sub-licences to appropriate conditions based on sound public health principles.[1]

[1] For example, the commitment, ability and readiness of a potential recipient to use the sub-licence; and agreement on the territorial application of the sub-licence.