WHO BioHub System technical consultation sessions

Access and benefit sharing and the WHO BioHub System

Background note and discussion questions
I. Introduction

In the context of the continued development of the World Health Organization (WHO) BioHub System, the WHO Secretariat is continuing the series of technical engagements to collate considerations on the design of key elements of the WHO BioHub System. The aim is to gather views and ideas on specific topics that will support WHO’s work on the BioHub System, to ensure that the system meets its global public health objectives. An important topic to explore is the access and benefit sharing (ABS) and the WHO BioHub System.

This background document aims to provide information to facilitate discussions on different ABS considerations and approaches that could be developed for the WHO BioHub System. It seeks to enrich the discussions by providing information that promotes a greater understanding of certain concepts or existing relevant initiatives, recognizing that participants will bring varying levels of knowledge about these. It does not present a conclusive view or reflect the position of WHO on any specific subject or topic, and is meant solely to spark ideas towards wider discussions that are to be had during the technical consultation session.

The discussions are expected to trigger reflections on the merits and drawbacks of different approaches, their potential attractiveness for different stakeholders that could engage with the System, and alignment with national and international obligations that could result from use of the WHO BioHub System by Member States or Qualified Entities. Stakeholders that are anticipated to participate in this consultation include Member States, the medical and scientific community, and laboratory and surveillance networks as well as industry and civil society.

In providing input, participants should be mindful of the WHO BioHub System’s guiding principles, which are the bases for its development and operation. Particularly relevant for this topic is the principle of equity and fairness.

This background note provides:

- examples of benefits that could be provided through the WHO BioHub System;
- questions for discussion, intended to steer the consultation towards identifying key considerations regarding access and benefit sharing building blocks in the context of the WHO BioHub System.

Participants may wish to review previous technical consultations on the subjects of: researcher’s needs and contributions; approaches to handling genetic sequence data; and intellectual property with the WHO BioHub System. Recordings and related materials for each of these sessions can be found here: [https://www.who.int/initiatives/who-biohub#events](https://www.who.int/initiatives/who-biohub#events).
II. Type of benefits that could result from the WHO BioHub System

The WHO BioHub System aims to provide a trusted, rapid, secure system of sharing biological materials with epidemic or pandemic potential. This consultation is meant to explore an equitable sharing pathway for benefits arising from such sharing.

Benefits in the context of the WHO BioHub System are to be defined.

To facilitate discussions, participants are invited to reflect on three categories of benefits set out in Figure 1 below: 1) public health tools and information; 2) laboratory and capacity strengthening support; and 3) medical and other products. These categories and the benefits listed thereunder were identified using other access and benefit sharing arrangements, such as the Pandemic Influenza Preparedness Framework (PIP) (see Annex for more information). They are provided for illustrative purposes only, showing some of the potential benefits that could arise from the WHO BioHub System.

Figure 1 Overview of potential benefits which may be provided through access and benefits sharing arrangements

- **Public health tools and information**
  - Public health information and tools to perform risk assessment
  - Regular and timely surveillance updates and situation reports
  - Access to genetic sequence data (GSD) through one or more relevant, publicly accessible databases
  - Timely updated and evidence-based vaccine recommendations

- **Laboratory and capacity strengthening support**
  - Reagents and reference biological materials
  - Training, mentoring and capacity strengthening (funds or in-kind training towards building laboratory and/or surveillance capacities in developing countries)
  - Research – participation and acknowledgement of Provider scientists, especially those from developing countries, in scientific projects

- **Medical and other products**
  - Access to medical and non-medical countermeasures or products (through donation tier pricing or normal pricing)
  - Grant to manufacturers in developing countries licenses on mutually agreed terms on technology, know-how, products and processes for which it holds IPR for the production BMEPP medical products.
  - Grant royalty-free licenses to interested manufacturers in developing countries or grant to WHO royalty-free, non-exclusive licenses on IPR, which can be sublicensed, for the production of BMEPP medical products.
  - Transfer of technology, know-how and/or processes for production of BMEPP medical products.

The providers of benefits will vary depending on the nature of the user and the benefit being provided.
III. Questions for discussion

Participants are invited to consider the following questions for discussion, bearing in mind the guiding principles and core objectives of the WHO BioHub System (i.e. promoting rapid and timely sharing of BMEPP, facilitating rapid characterization of such pathogens and rapid risk assessments, facilitating the development of safe, protective countermeasures and other public health products and ensuring fair and equitable access to such products by all countries based on public health needs):

1. What type of ABS modalities should be included as the core components of the WHO BioHub System?

2. If applicable, what are the benefits that your stakeholder group would find most difficult to provide, or would most wish to receive?

3. What are potential access and benefit sharing arrangements that would advance public health goals in an epidemic or pandemic situation?

4. Are there any constraints that may affect the design of a potential BioHub - ABS model, including from the scientific, legal, and/or operational perspective(s)?
Annex: Further information on other mechanisms

Different approaches may be used to facilitate access to different benefits and thereby advance equity of access to them. This annex presents some information on two existing mechanisms that may be useful reference points and may facilitate better understanding of possible design features for the WHO BioHub System.

1) Pandemic Influenza Preparedness Framework

The Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (the PIP Framework) is an access and benefit sharing instrument that was adopted by the World Health Assembly in 2011. It brings together WHO Member States, industry, civil society and other stakeholders and WHO to work together towards pandemic influenza preparedness and response.

The PIP Framework has two main objectives, that are to be pursued on an equal footing: 1) improve the sharing of influenza viruses with pandemic potential with the Global Influenza Surveillance and Response System (GISRS) by strengthening GISRS, and 2) achieve more predictable, efficient, and equitable access to benefits arising from the sharing of such viruses, notably vaccines and antiviral medicines. GISRS is a network of public health laboratories specializing in influenza; it has operated for over 70 years, performing year-round, continuous influenza virus surveillance, detection, sharing, risk assessment, and pandemic & epidemic response. Currently there are 122 Member States supporting 153 GISRS laboratories.

Under the PIP Framework, Member States are expected to share influenza viruses with pandemic potential with GISRS, in return for which benefits arising from such sharing are to be fairly and equitably shared through the PIP Framework. The PIP Benefit Sharing System aims to provide a range of benefits such as: surveillance & risk assessment information, technical assistance to strengthen key capacities including national pandemic influenza response capacities, and equitable access to vaccines, antivirals and other critical pandemic response supplies.

Industry supports the global pandemic influenza preparedness and response efforts through two principal benefit sharing mechanisms under the PIP Framework:

a. Signing Standard Material Transfer Agreements 2 (SMTA 2 - PIPF Annex 2): Through the PIP SMTA2, non-GISRS recipients of PIP biological materials commit to provide to WHO access to future pandemic influenza response products (e.g. vaccines, antivirals, diagnostics) as and when they are produced.

b. Paying the Partnership Contribution (PC) (PIPF section 6.14.3): The PC is an annual payment to WHO from influenza vaccine, diagnostic and pharmaceutical manufacturers that use GISRS. These funds are used by WHO in three different ways: 1) to increase preparedness & response capacities in countries, 2) establish a Response Fund to ensure there are funds available for future pandemic response and 3) support PIP Secretariat.

More details on the PIP Framework are found [here](#).
2) Access to COVID-19 Tools (ACT) Accelerator and COVAX

The Access to COVID-19 Tools (ACT) Accelerator was launched during the COVID-19 pandemic with the aim of bringing together governments, global health organisations, manufacturers, scientists, private sector, civil society and philanthropy, to provide innovative and equitable access to COVID-19 diagnostics, treatments and vaccines.

The ACT Accelerator has three pillars. The vaccines pillar is called COVAX and its objective is to accelerate the development and manufacture of COVID-19 vaccines, and to ensure their delivery. In the COVAX pillar, the mechanism that is designed to facilitate access to vaccines is called COVAX Facility. The design of this mechanism delinks access to biological materials from benefits and relies on negotiating advance deals with several vaccine manufacturers. By bringing together self-financing countries’ resources and donor funding (which should support countries with limited purchasing power) the mechanism aims to create sufficient demand to secure needed doses. Therefore the COVAX Facility functions on the principle of pooling resources to strengthen purchasing power in the race to secure doses from vaccine manufacturers. More details on COVAX Facility are found here.