12.7 Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits

Contents

In focus

A71/24, A71/24 Add.1 and A71/42

A71/24 reports on progress made in implementing decision WHA70(10) adopted in May 2017 after consideration of the report of the 2016 PIP Framework Review Group (A70/17) and the report of the Secretariat on collaboration with the Secretariat of the Convention on Biological Diversity (A70/57).

WHA70(10) requested the DG to:

- 8(a) take forward the recommendations of the PIP Framework Review Group (A70/17);
    - A71/24 reports that this is underway;
    - **Secretariat plans** to have completed required actions by WHA72;
- 8(b) conduct a thorough and deliberative analysis of the issues raised by the Review Group's recommendations concerning seasonal influenza and genetic sequence data;
    - A71/24 reports on:
        - the development of Scoping Paper;
        - consultations undertaken in Nov 6-7, 2017 on the inclusion of seasonal influenza and genetic sequencing data;
        - the information session scheduled for April 2018;
    - **Secretariat plans** finalise this analysis in time for EB146 and then WHA72;
- 8(c) to continue supporting the strengthening of regulatory capacities and carrying out burden-of-disease studies;
    - A71/24 reports that:
        - regulatory strengthening and burden of disease studies included in Partnership Contribution Implementation Plan (2018-2023);
        - publication of regulatory preparedness guidelines will facilitate timely marketing authorisation;
    - **Secretariat plans** to:
        - continue implementing the PC Implementation Plan (2018-2023);

        - conclude more SMTA2s;
        - continue engagement with secretariat of CBD and other secretariats on access and benefit sharing;
        - reporting to WHA72 through EB144;
- 8(d) to continue encouraging manufacturers and other relevant stakeholders to engage in PIP Framework efforts, including, where applicable, by entering into Standard Material Transfer Agreements 2 and making timely annual PIP Partnership Contributions;
    - A71/24 reports that progress is being made;
    - see **Secretariat plans** above;
- 8(e) to request the External Auditor to perform an audit of PIP Partnership Contribution funds;
    - A71/24 reports approval in general by the External Auditor with some recommendations which have been accepted and are being implemented;
    - see **Secretariat plans** above;
- 8(f) to continue consultations with the Secretariat of the Convention on Biological Diversity regarding, in particular, the relationship between the PIP Framework and the Nagoya Protocol, (see EB140/15 and WHO webpage on WHO negotiations with the Secretariat of the CBD);
    - A71/24 reports on:
        - on-going discussions involving secretariats of WHO, CBD, FAO and OIE;
        - Qs and As document prepared by the four secretariats on the application of Nagoya;
        - workshop planned for June 2018;
    - see **Secretariat plans** above.

The Secretariat proposes a Decision approving the Secretariat plans as noted above.

A71/42 provides the Executive Summary of the biennial implementation report for 2018 (in full here). The report covers:

- laboratory and surveillance capacity;
- global pandemic influenza vaccine production capacity;
- agreements with industry;
- use of partnership contribution revenues;
- review of experience in using the definition of PIP biological materials (handling of genetic sequence data).

The Assembly is invited to note the report.

Background

About the Pandemic Influenza Preparedness Framework (PIPF)

The pandemic influenza preparedness framework (here) was developed because of concern regarding inequities that had emerged in the context of WHO influenza sharing through what was then known as the Global Influenza Surveillance Network (GISN). Countries shared influenza viruses with WHO linked laboratories, which in turn shared candidate vaccine viruses with vaccine manufacturers, but no benefits were returned to WHO or the countries that shared the influenza viruses. In fact countries that shared the influenza viruses often were not able to gain access to the vaccines, either because there were unavailable or because they were unaffordable. Discussions over the inequities peaked in 2007, leading to intensive negotiations and finally a Framework for virus and benefit sharing in 2011.

Under this Framework recipients of viruses have to share benefits. Benefits are shared through two channels: SMTA agreements and partnership contributions.

Recipients of biological materials are required to enter into an agreement with the WHO known as the Standard Material Transfer Agreements (SMTA) to indicate how the benefits of accessing these materials are to be shared with the WHO. Two different SMTAs are provided for. SMTA1 is for entities within the GISRS receiving materials. SMTA2 is for entities outside the GISRS receiving materials. The benefits shared under SMTAs are largely in kind benefits. (See details of SMTAs in Annex 1 & 2 of the PIP Framework.)

Entities outside the GISRS are also expected to make 'partnership contributions' to WHO to help support the Global Influenza Surveillance and Response System (GISRS). See Financial Report at Annex 1 of 2016 PIP Framework Partnership Contribution 2013-16 Annual Report. The distribution of the partnership contribution obligation is determined in accordance with rules (8 May, 2013) here. The use of the partnership contribution is governed by Decision EB131(2) from May 2012: broadly 70% is to be used for preparedness (laboratory and surveillance) and 30% reserved for to support response capability. See PC webpage for more.

An Advisory Group was set up to monitor implementation of the PIP framework. This Group meets twice a year.

More about PIP on WHO website here. See in particular the detailed discussion of genetic sequencing data (GSD).

See Tracker links for previous discussions of the PIP Framework.

PHM Comment

PHM urges member states to adopt the decision proposed in A71/24 and and to note A71/42.

Genetic sequence data should be treated in the same way as the viral isolate under the PIP Framework. Access to and use of genetic sequence data should trigger benefit sharing.

Databases that wished to host sequence data should implement a standard user agreement that applies the Framework's benefit-sharing obligations to users accessing sequence data and allows such users to be tracked.

The partnership contribution paid by manufacturers should be updated, given that the current running costs of the Global Influenza Surveillance and Response System is estimated to be US$122 million.

Member States should ensure that access to seasonal influenza viruses is balanced by fair and equitable benefit sharing. Preferably this is achieved by creating a new instrument to govern the sharing of seasonal influenza virus, rather than taking action that might undermine the PIP Framework.

The PIP principles of virus sharing and benefit sharing should be applied to other pathogens accessed by WHO during times of emergencies but how this might be operationalised requires further study and discussion.

Notes of discussion at WHA71

Fourth meeting of Committee B

The Chairman opened the subitem and invited comments from the floor. The Secretariat responded to questions raised and the Committee approved the decision contained in document A71/24 as amended.

Indonesia: supports the full implementation of the framework.

Nigeria on behalf of AFRO:

Endorse the report on the Framework

Consider

Japan: Endorse the report on the framework

Bahrain: Have carried out studies on virus isolates in line with WHO standards

Pakistan: Welcomes the report; Pakistan follows WHO recommendations in preparedness for response to pandemic influenza

Panama: Have a national influenza center that works with the region to monitor the program, in line with the WHO recommendations. Collaborating with other Latin American countries to reduce the pandemic.

Indonesia: Supports the full implementation of the PIP framework

Support the recommendations made by the PIP advisory group increase the budget

Acknowledge the recommendation by the PIP advisory group to expand the framework to include genetic and vaccine research and development in the framework.

Biosecurity, biosafety and intellectual property rights will have to be handled properly.

Genetic sequence data needs to be recognised as valid data under the framework

Paraguay:

Monitoring required

Flexible funding needed

An appropriate distribution of financial resources

Brazil:

Scope of biological material under the framework needs to be dealt with in line with the Mumbai agreement on biological materials.

Amendment proposed to the framework to provide the data on progress in next year's assembly instead of 2020.

Malaysia, Senegal and Australia have given short statements on support of PIP and work of WHO in this arena.

Botswana:

Aligns with Nigeria. PIP might be a lesson for other public health interventions.

Iran:

Supports the proposition to define distribution of funds inside PIP. Some countries have received less support than others regardless of local successes. Iran has developed early response system, and has developed guidelines for cases of pandemic emergencies.

Tanzania:

Glad to see that the secretariat has been on top of this topic. Has recorded record results in laboratory activities and asks for further funds to sustain great things done. Welcomes recommendation and supports Brazil's idea.

USA:

We should work to improve response to PIP and invites DG to additionally develop system of samples sharing. Urges for continuation with PIP measures and evaluation. Supports Brazil's report.

Mexico:

Priority should be sustain and develop PIP, strengthening countries to be able to provide rapid response in cases of pandemics. Antiviral reserves and training of health workers, working together. Participation of regions will ensure that potential problems in implementation are tackled.

Afghanistan:

At high risk of influenza because of high migration rates. We should all work on strengthening all aspects of PIP framework.

Burundi:

Aligns with Nigeria/AFRO. MS should support PIP by building national capacities and share biological materials with WHO research centres. Implementation of vaccination programme.

Thailand:

Aligns with Indonesia/SEARO. IP knows no boundaries: supports genetic sequencing; close collaboration with actors in field; production of vaccines (WHO support capacities of LMIC to produce vaccines).

Saudi Arabia: (tech problems) Supports exchange of biological materials. Supports partnership with production sector, increasing vaccine accessibility. Makes all necessary efforts to secure territory, particularly in season of influenza. Report does not support new tech enough.

Niger:

Aligns with AFRO.

Russia:

Welcomes report. Supports the idea of national plans for PIP. Not so happy with treatment of genetic sequencing, more specific proposal should be made on that.

Iraq:

Elaborated framework for vaccination in influenza season. Welcomes WHO support.

NSA statements: https://extranet.who.int/nonstateactorsstatements/meetingoutline/6

Secretariat:

Great progress since 2016. Move report to WHA72 instead of WHA73. Decision A71/42, para 19 “and requested that the final text of the analysis be submitted to WHA72 through EB144”.