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

Contents

In focus

Pursuant to decision WHA70(10) (2017), document A71/24 (2018) and decision WHA71(11) (2018), the Director-General will submit a report on measures taken to implement the requests contained therein (EB144/23).

The various issues reported on in EB144/23 have long and braided genealogies which are not clearly presented in this report. These genealogies need to be traced back, at least, to the 2016 PIP Review Group report.

Implementing the recommendations of the 2016 PIP Review Group

The report of the 2016 PIP Review Group was conveyed to the Assembly in A70/17.

In Decision WHA70(10), para 8(a) the DG was requested to take forward the recommendations of the Review Group.

In para 5 of A71/24 the Secretariat reported to WHA71 on progress on this request and in para 19(a) committed to completing the implementation of the recommendations of the 2016 PIP Review Group before WHA72. This recommendation was endorsed in Decision 71(11).

In EB144/23, para 2, the Secretariat reports that this has been completed

Strengthening critical pandemic preparedness (and the Partnership Contribution Implementation Plan 2018-2023)

In Section 6.3 the PIP Review Group commented on the Partnership Contribution implementation (see findings 48- 55 of the PIP RG report).

In Decision WHA70(10), para 8(c) the DG was requested to “continue supporting the strengthening of regulatory capacities and carrying out burden-of-disease studies, which are fundamental foundations for pandemic preparedness” .

In paras 10-11 of A71/24 the Secretariat responded to this request highlighting the importance of the Partnership Contribution Implementation Plan 2018–2023 and in para 19(c)(i) undertook to continue the implementation of the Plan to this end. This undertaking was endorsed in Decision WHA71(11). In EB144/23, para3, the Secretariat reports on the implementation of the Partnership Contribution Implementation Plan 2018–2023.

Concluding Standard Material Transfer Agreements 2 and the collection of annual PIP Partnership Contributions

Key findings regarding SMTA2s are summarised in findings 34-42 of the Review Group report (in A70/17) leading to recommendations 18-22. Findings 43-45 deal with the collection of the PC leading to recommendations 23-24.

In Decision WHA70(10), para 5, the Assembly recognised the progress being made and in para 8(d) the DG was requested “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”. The Secretariat reported in A71/24 para 13, on progress regarding this request. In A71/24, para 19(c)(ii), the Secretariat undertook to conclude more SMTA2s. This was endorsed in WHA71(11), Annex (c)(ii). In EB144/23, para 4, the DG refers to the reporting of PIP PCs in the June 30, 2018 Progress Report and through the Programme Budget portal.

Engagement with the secretariats of the Convention on Biological Diversity and other relevant international organizations

Findings 70-73 and recommendation 36 of the Review Group concern the relationship of the PIP Framework to the Nagoya Protocol of the CBD.

In WHA70(10), para (6) the Assembly decided to “recognize the ongoing consultations and collaboration between WHO and the Secretariat of the Convention on Biological Diversity and other relevant international organizations” and in para 8(f) requested the DG to “continue consultations with the Secretariat of the Convention on Biological Diversity and other relevant international organizations, as appropriate”.

In paras 17-18 of A71/24 the Secretariat advised the Assembly of progress in response to this request and in para 19(c)(iii) undertook to continue such engagement. This was endorsed by the Assembly in WHA71(11), Annex (c)(iii).

In para 5 of EB144/23 the Secretariat reports that such engagement is ongoing (see report of June 2018 Consultation).

Implementing the recommendations of the External Auditor

The Review Group reported concerns and misunderstandings regarding the collection and use of partnership contributions (PCs), see pp 18-19 of A70/17. In para 8(e) of WHA70(10) the Assembly asked the Secretariat to organise an audit of the PCs.

In para 15 of A71/24 the Secretariat reported on the outcomes of this audit and in WHA71(11), Annex (d) the Assembly endorsed the undertaking of the Secretariat to implement the auditor's recommendations.

EB144/23, para 6, reports that the recommendations of the Auditor have been implemented.

The sharing of seasonal influenza viruses and genetic sequence data

In Finding 11, the Review Group reported receiving wide-ranging views from key informants, including Member States, industry and civil society, on including seasonal influenza under the PIP Framework, with strong views both for and against, and judged that the implications of including seasonal influenza need to be studied further. Rec 3 was that "the Director-General should undertake a study to determine the implications and desirability of including seasonal influenza viruses in the PIP Framework". More detailed discussion in Section 3.2.1 from page 34.

The Review Group's summary of its findings and recommendations (12-17) regarding the sharing of GSD are quite specific.

In WHA70(10), para 8(b) the Assembly decided to request the DG:

> *regarding the PIP Framework Review Group's recommendations concerning seasonal influenza and genetic sequence data, to conduct a thorough and deliberative analysis of the issues raised, including the implications of pursuing or not pursuing possible approaches, relying on the 2016 PIP Framework Review and the expertise of the PIP Advisory Group, and transparent consultation of Member States and relevant stakeholders, including the Global Influenza Surveillance and Response System;*

In A71/24, para 19(b), the Secretariat advised the Assembly that "The Secretariat intends to complete the analysis in order to submit a comprehensive draft to the Seventy-second World Health Assembly through the Executive Board at its 144th session". This was endorsed in WHA71(11) and in EB144/23 (paras 7-24) the development of the draft analysis is described; the outcomes of the October 2018 consultation are summarised and the finalised analysis is referenced.

The issues associated with the possible inclusion of seasonal influenza under the PIP Framework were discussed by the PIP Framework Advisory Group from October 17-19, 2018. The Advisory Group's considerations and recommendations are contained in paras 43-52 of the report of the October meeting.

The Advisory Group's considerations regarding the treatment of genetic sequence data under the PIP Framework and related recommendations are contained in paras 53-65 of the report of the October meeting.

Draft decision

The draft decision at para 25 of EB144/23 includes a broad request to continue to work on uncertainties arising between the PIP Framework and the Nagoya Protocol and some specific initiatives (the search engine, the principle of acknowledgement, and the amended footnote).

Background

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.

The implementation of the Nagoyal Protocol under the Convention on Biological Diversity (see EB140/15) has complicated the operations of the PIP Framework:

- national implementation legislation appears in some cases to have created obstacles to the sharing of biological materials as provided for under the PIP Framework;
- consideration of access and benefit sharing in relation to seasonal influenza and other pathogens and in relation to genetic sequence data are complicated by inconsistencies between the PIP Framework and the Nagoya Protocol;

More about PIP on WHO website here.

See Tracker links to previous discussions by WHA and the EB of the PIP Framework.

PHM Comment

The principles of access and equitable benefit sharing are simple but the implementation issues are extremely complex. The draft decision provides for continued exploration and incremental change.

Notes of discussion at EB144

- EB144/23

Chair: The board is invited to note the report and consider the draft decision contained in the report

Romania : On behalf of EU. Ready to approve the decision with few amendments. Request for addition/deletion/modifications of words in different paragraphs of the document. Following are few examples. “Reads out the whole changed paragraphs, so it is difficult to follow it”

1. Want to add words in paragraph 1

2. In second para want to add same amendment EB144/23

3. Para OP1.a; to urgently work with global partners as countries implement Nagoya article

4. To explore next steps and to present such additional steps to be presented to the PIP advisory group.

5. New OP3: to work collaboratively with WHO to raise awareness among MSs of the implications of the implementation of the Nagoya Protocol, etc.…

6. Former OP3 will become OP4.

Gabon: On behalf of 47 African nations. The PIP report demonstrates the progress and strengthening of labs and surveillance. Raises inequalities in terms of sharing viruses. Welcome the updates arising due to Nagoya protocol which offer challenges and opportunities. Insisting on the fair share of the benefits. Takes note of the report and support the draft decision

Japan: Appreciate the WHO effort with the report; inclusion of seasonal influenza and genetic sequence data: concern about their inclusion into the PIP Framework; seasonal influenza: range of challenges, because seasonal influenza vaccine will be difficult to manufacture and will pose challenges in the implementation of the PIP framework; need HR burden in this regard; genetic sequence data: should be freely available and without charge: we should not hinder this practice; they are in favour to keep the PIP as it is now; support the draft resolution;

Indonesia: Appreciates report particularly to address seasonal influenza and sharing of genetic material. More discussion with MSs and partners whether to include seasonal influenza. Develop separate mechanism for seasonal influenza in line with Nagoya protocol. Sharing of genetic data should be included in PIP and as biological material. Draft decision is premature and need more discussions which are transparent. So decision should be made before next WHA.

Djibouti: On behalf of EMRO; welcome the report; draft decision should be transmitted to the WHA72; decisions have been obtained after the consultation of MS; they agree with the draft decision, but the implementation Nagoya protocol present challenges and opportunities; challenges especially with regard to the share of the benefits of seasonal influenza and genetic sequence data; we need to protect the fair sharing of the benefits provided, in particular with regard to LMICs; sharing of viruses should be encouraged by the PIP framework and Nagoya protocol;

***Brazil*:** Welcomes report. Satisfied with results of implementation. Comment efforts for inclusion of seasonal influenza into PIP framework. Acknowledge challenges due to sharing seasonal influenza and Nagoya protocol and wish for more time for discussion and intersessional work.

Mexico: Welcome the report; improving and maintaining PIP framework should be WHO priority; CBD: WHO should strengthen communication with the CBD secretariat, in particular with the view to implement the Nagoya Protocol and on the document (results of some research) presented on the last Nagoya meeting; interesting to hear the view of the Secretariat on those two documents (CBD and Nagoya); the initial text is acceptable, but would deserve some improvements (seem not to agree fully with EU amendments, but seems open to discussion).

***US*:** PIP framework are unique and important. Important that all countries share seasonal influenza, and genetic biological data. Don't support reopening of PIP framework. DG should raise awareness about barriers emerging due to Nagoya protocol. Recognise by PIP advisory group. However regarding OP2 there has been insufficient revision. Modification in annex-2 is too broad and can lead to unwanted consequences.

Amendments “over” Acceptance of EU amendments (so that they are not duplicated)

1. Para 1 of OP1: propose adding sharing of these findings with WHO

2. OP1 sub point 2: inconsulation with MSs

3. OP2: deleting it whole and adding quick discussion with MSs

4. OP1 d) to explore, in consultation with MS,

5. OP2: delete the part of amending the footnote: to work with states and relevant stakeholders;

Bahrain: Welcome the DG report; appreciate the progress made in improving the PIP framework, in particular in capacity building; the sharing of benefits should be equitable (prices and accessibility of vaccines);

Germany: Aligns with EU statement. Thank secretariat for inclusive process. Research on virus material should continue. Strongly support current PIP framework, they don't want to add the items on genetic biological materials and seasonal influenza in the PIP. Support draft amended by EU.

Chile: Welcome the progress made; strong supporter of the sharing of influenza viruses; recommendations must be broadly disseminated; participated in technical cooperation between MOH and other organizations; talking about national measures to improve equipment, sharing of viruses, capacity building for surveillance, sharing of information;

Australia: Welcome report. Any inclusion of genetic sequence data and seasonal influenza should not compromise current PIP framework. We support WHO that addresses uncertainty with Nagoya protocol. Support EU amendment but need more time to study same.

China: China share the influenza virus through PIP and share genetic sequence data (GSD); they manufacturers in China signed transfer agreement with WHO; PIP is useful to manage access to viruses and the sharing of benefits; we support the work of WHO on this document, some of the discussions are going beyond the scope of the PIP; There are thing in Nagoya protocol which should be discussed by MS.

Non-EB members.

Thailand: Welcomes report. Concerned with leaving out seasonal influenza from PIP framework. Support Romania and EU.

Dominican Republic: Welcome the document; recognize the PIP has an effective tool to dealing with issue related to access and benefit sharing in preparing for pandemic; turning to sharing seasonal influenza in the PIP: recognize the progress achieved in implementing the recommendations included in WHA 71.11; The Nagoya protocol is also relevant when we are talking about surveillance and capacity building; need more information on seasonal influenza; They will address the proposals made by EU;

Norway: Important that DG to work with other partners on uncertainties on sharing of genetic data and implementation of Nagoya protocol. Support EU amendment. What is relevance of amending SMT at this point? question to secrétariat.

Iran: The issue of widening the scope of PIP need further deliberations any hasty decision can have a devastating effect on such an important tool ; most capacity building are around surveillance and strengthening laboratories;

Panama: Endorse Brazil, Mexico and US and continue deliberations as they are important for global public health.

Russia: Appreciate the work made to implement the framework; global influenza system if functioning effectively; it is essential that the scope of the PIP has a negative impact on the global influenza surveillance system; we should not expand the scope to the PIP; Russia spent a great deal of money to vaccinate people against influenza; no objection to the proposals made in annex 1 and 2;

India: Broadly endorses the report. WHO should ensure concurrence with Nagoya protocol. Implementation issues are complex. We request further deliberations on amendments suggested by EU and USA.

Republic of Korea: During last discussion, they took part to the consultations; urge the secretariat to address benefit sharing in footnote 1 and 2.

Switzerland: Fully supports PIP framework. Need more coordination like on information of GSD. In light of Nagoya protocol benefit sharing in regards to GSD becomes controversial. Reservations on modifications of SMTA2.

Non-state actors

International Federation of Medical Students' Associations

International Federation of Pharmaceutical Manufacturers and Associations

Medicus Mundi International

ADG WHE: PIP framework is a successful instrument. Must ensure continuous effective mechanism of virus sharing. We must try to seperate PIP framework from other broader issues, made for only one patogen with pandemic ability. Nagoya protocol is very imortantant but also must insure it supports sharing during acute……Access and benefits: need more structured discussions with MSs.

DG: The Nagoya protocol is bigger than PIP; Nagoya can be used for other viruses, bacteria, etc. ; We should do everything we can with regard to PIP and address the potential negative impact; with regard to PIP, we have to be very serious, we have to understand the consequences, we have to uphold the principle of solidarity to the maximum; we are very

vulnerable: if you take Ebola, it's lousy, it's nothing compared to influenza; the reasons for the PIP is to prevent any disaster; we are making progress; actions that we take can save us now;

Chair: proposes to suspend this item and to take action later, because there are many amendments; the secretariat will prepare a conference paper and we would have an intersessional process;

Conf paper EB144/CONF./10 Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. Draft decision proposed by Secretariat with amendments by Member States

It is not clear from WHO Watch notes or from the video records how this discussion evolved. The governing bodies website lists EB144(6) as one of the decisions adopted by the EB but this text as published remains full of drafting disagreements and presumably was not adopted in this form.

Perhaps it is scheduled for further intersessional consultation.