Comments on Reports Requested under Decision WHA72(12)

(reports available at http://www.who.int/initiatives/pandemic-influenza-preparedness-framework/governance/implementation-of-decision-wha72(12))

Submitted by: Third World Network

Comments on Reports Implementing Decision WHA72(12)

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6. Please provide your comments on the following three reports, available at https://www.who.int/influenza/pip/governance/wha72-12/en/:

Comment on Report on influenza virus sharing (OP1(a)

Seasonal Virus Sharing

The report is very unbalanced when addressing seasonal virus sharing and rather biased against national access and benefit sharing legislation. In paras 10-13, several reasons are given for the delays in virus sharing, and yet most of the discussion and emphasis is on delays due to ABS legislation. For instance there is no discussion on the challenges due to the EU's General Data Protection Regulation where in influenza viruses containing genetic material cannot be shared. No information has been provided on the instances where this was a challenge.

It is also very surprising that 23 non-GISRS academic or public private institution that responded did not report delays in receiving the viruses but non-GISRS vaccine producers did. Interestingly only half of the 19 vaccine producers that responded said that there were delays and these delays were linked to delays obtaining export and import permits, lack of clarity on availability of CVVs and national ABS legislation. This means that the delays due to national ABS, where such delays exists is rather small. Important to note is that the evidence presented is anecdotal.

Of particular concern is that the structure of the survey and the responses received undermine national rights under the Convention of Biological Diversity and the Nagoya Protocol as well as national sovereignty. The current sharing of seasonal viruses is voluntary and any action on the part of WHO has to reflect this as well as the rights that WHO Member States are entitled to under the CBD and the Nagoya Protocol.

In this context, we find the proposed solutions in para 22 very problematic. WHO must take into account the following objections:

(i) On para 22(a): WHO must ensure that its guidance does not undermine the rights WHO member states have under the CBD and the Nagoya Protocol.

(ii) On para 22(d): This proposed solution undermines the rights WHO member states have under the CBD and the Nagoya Protocol. The solution is also unbalanced as there is no mention of fair and equitable benefit sharing. Without fair and equitable benefit sharing, there cannot be a public health response. So just advocating that Ministries of Health only address rapid virus sharing is unethical and undermines public health. The primary responsibility of Ministries of Health is to ensure a public health response and a crucial aspect of that response is the timely availability and accessibility of affordable health products such as diagnostics, vaccines and anti-viral and this is only possible with fair and equitable benefit sharing. Hence Ministries of Health need to emphasize that any virus sharing has to be accompanied with benefit sharing.

(iii)On para 22(e) and (f): There is no basis for WHO to encourage countries to exclude seasonal influenza viruses from ABS requirements. In fact if WHO were to do it, it would be interfering in domestic matters, with the national sovereignty of a WHO member state in implementing national ABS legislation. WHO's actions would be in direct conflict with the requirements of other international instruments. With respect to para (f) it is really a matter of national legislation and procedures.

(iv) On para 22(g): WHO's implementation of a standardized WHO MTA between CCs and NICs is bypassing WHO's governance structure and the rights countries have under the CBD and the Nagoya Protocol. Of notable concern is that there is no benefit sharing requirement from non-GISRS entities. The proposed ad hoc approach to virus sharing will not ensure that there will not be delays but merely serves to undermine fair and equitable benefit sharing from non-GISRS laboratories and the putting in place of an accountable and transparent mechanism for sharing of seasonal flu viruses and fair and equitable benefit sharing.

(v) On para 22(h): The recognition of GISRS as a specialized international ABS instrument makes a mockery of the principles and objectives of the Convention on Biological Diversity and the Nagoya Protocol. There are NO benefits being received from non-GISRS laboratories such as anti-viral and vaccine producers, although with the support of NICs seasonal flu viruses are being collected and shared with diagnostic, vaccine and other pharmaceutical manufacturers. To be recognized as a specialized international ABS instrument, the instrument has to be "supportive of and do not run counter to the objectives of the Convention and this Protocol". Without concrete fair and equitable benefit sharing from non-GISRS laboratories, the GISRS system which is just a network of laboratories does not meet the objectives of the CBD and the Protocol.

This part of the report on seasonal flu viruses, fails to provide a sustainable and fair pathway to seasonal flu sharing. It would be reasonable to say that vested interests especially commercial interests may be guiding many of the responses received. The pharmaceutical companies' objection to fair and equitable benefit sharing is well-known. They demand rapid and open sharing of viruses but object to rapid sharing of knowledge, technology and intellectual property as well as any demands made to ensure timely and affordable access to vaccines, anti-virals and diagnostics.

We recall that the 2016 Expert Review Group found that "the PIP Framework is a bold and innovative tool for pandemic influenza preparedness, is being well implemented, and that the principle of the PIP Framework of placing virus sharing and benefit sharing on an equal footing remains relevant today. The

implementation of the PIP Framework has led to greater confidence and predictability in the global capacity to respond to an influenza pandemic".

It also recommended that the PIP Framework model "be used as a model for the sharing of other pathogens".

The PIP Framework ensures sharing of pathogens on an equal footing with sharing of benefits from GISRS laboratories as well as entities outside of GISRS laboratories such as manufacturers.

A similar framework should be developed for the sharing of seasonal flu viruses. And importantly WHO Secretariat must not take steps that undermine this effort and the obtaining of fair and equitable benefit sharing especially from manufacturers of vaccines, diagnostics and anti-virals.

Influenza Virus of Pandemic Potential

It is clear that the PIP Framework that treats virus sharing and benefit sharing on an equal footing is crucial to a sustainable and equitable mechanism for sharing pathogens.

In para 25, it is stated that "some institutions required lengthy negotiation of a bilateral MTA, including for CVVs that were developed using a patented genetic engineering process". But no solution has been given to address this problem. Given we are dealing with a pandemic situation, it should be recommended to countries and to IP holders that relevant IP should be suspended/waived to enable expeditious development of CVVs.

Conclusions

In the part on conclusions, the WHO Secretariat takes a very biased approach to the principles and rights under the CBD and the Nagoya Protocol. Para 1(a) of WHA72(12) requires the Secretariat to provide a "deeper understanding of the challenges, opportunities and implications for public health associated with virus sharing under GISRS". But Secretariat has decided to focus on very few instances of delay in sharing virus samples but not highlighting the opportunities presented by the ABS principles such as fair and equitable benefit sharing. It is important to note that it is meaningless to develop diagnostics, vaccines, anti-virals that are than inaccessible and unaffordable to most of the world population.

Important issues such as intellectual property barriers and freight embargoes that are delaying sharing of IVPP and CVVs are simply avoided in the concluding paragraph.

Report on the search engine, raising awareness of the PIP Framework, and new technologies (OP1(c), (d) and (e)

Comment on Part II. Options To Raise Awareness of the PIP Framework Among Representatives of Databases and Other Initiatives, Data Providers and Data Users (Decision WHA72(12), paragraph 1 (d)

The PIP Advisory Group Technical Working Group on the Sharing of Influenza Genetic Sequence Data in 2016 noted "In order to promote benefit-sharing under the PIP Framework, all data users would ideally

be asked to accept a data access and use agreement that would specify the obligations and expectations of the PIP Framework."[1]

Hence we maintain that the best way to raise awareness is to prepare a data access and use agreement specifying obligations and expectations of the PIP Framework and promoting the adoption of this type of an agreement with respect to access to IVPP genetic sequence data.

Part III. New Challenges posed and opportunities provided by new technologies in the context of the PIP Framework and possible approaches to them (Decision WHA72(12), paragraph 1(e)

It is very disappointing that this aspect has not been completed. We stress the importance of WHO Secretariat completing its analysis and reporting to WHO Member states.

[1] See https://www.who.int/influenza/pip/advisory_group/twg_doc.pdf?ua=1
, pg. 15