

**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\(12\)](http://www.who.int/initiatives/pandemic-influenza-preparedness-framework/governance/implementation-of-decision-wha72(12)))

**Submitted by:** International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and Biotechnology Innovation Organization (BIO)

IFPMA-BIO feedback on **Decision WHA72(12) OP 1(a)**  
***Report on Influenza Virus Sharing***

*General comments:*

The International Federation of Pharmaceutical Manufacturers & Associations ([IFPMA](#)) and the Biotechnology Innovation Organization ([BIO](#)) welcomes this excellent report on influenza virus sharing; its concise, factual, evidence-based content, provided by all relevant stakeholders, offers an accurate depiction of the current issues with both seasonal and pandemic influenza virus sharing, and the proposed solutions (albeit of differing levels of difficulty to implement and probabilities of success) are actionable and realistic overall.

IFPMA and BIO are extremely concerned about the average length of time it takes to address virus sharing issues, particularly those due to ABS/NP legislation. As more countries implement the Nagoya Protocol and/or draft national ABS legislation, we expect such delays to increase.

We hope that the content and findings of this Report are fully acknowledged by WHO and Member-States so the global influenza community can move towards improving seasonal influenza processes and influenza pandemic preparedness and response.

## Sharing of seasonal viruses and associated CVVs

IFPMA and BIO are extremely concerned about the average length of time it takes to address virus sharing issues, particularly those due to ABS/NP legislation. As more countries implement the Nagoya Protocol and/or draft national ABS legislation, we expect such delays to increase.

As manufacturers, we would like to bring attention to an additional barrier to timely virus sharing caused by NP/ABS: not only must access to an influenza virus sample be compliant with the *provider's* country ABS legislation, but also some manufacturers (particularly those with R&D/manufacturing sites in the European Union) must ensure compliance with the *receiver's* country ABS legislation. For instance, in France, failure to comply with a provider's country ABS legislation carries up to a 1 million EUR criminal fine and one year of imprisonment, with the obligation of submitting a due diligence declaration (to ensure observance of the provider's country ABS legislation has been addressed) also to the French patent office. As such, if a provider country does not provide sufficient evidence that it has shared an influenza strain with GISRS in a way that is deemed as being compliant with French legislation, it will be impossible for a manufacturer to bring that strain to a site based in France, even if for research purposes only, due to the risk of incurring penalties including biopiracy charges<sup>1</sup>.

Moreover, we are concerned that, even if access to an influenza virus sample by a National Influenza Centre is deemed as being compliant with ABS legislation by a provider country and free for sharing with the GISRS network, it still often entails ABS obligations for manufacturers should a product be manufactured and commercialized from the use of that particular influenza virus sample. The well-established GISRS system has been supplying manufacturers with candidate vaccine viruses (CVV's) for decades; however, manufacturers can no longer assume that because they have received viruses through this route that no further action is required. They must now also check the ABS legislation of each particular provider country, and ensure that they are compliant with the legal requirements of the receiver country, if any. End-to-end understanding of, and compliance with, ABS obligations, from collection of the sample to CVV production and product commercialization across the world, is essential in addressing the issues with ABS/NP for seasonal influenza virus sharing. Industry wholeheartedly agrees that *"The need to navigate a system where each country has different ABS terms that must be negotiated on a bi-lateral basis is extremely burdensome and inefficient and could cause inequities in benefit sharing and limit virus access for research and development of improved influenza vaccines"*.

On the *"Proposed Solutions to Mitigate Hindrances to Seasonal Virus Sharing"*, IFPMA-BIO would like to comment on the following:

- a) *WHO and CCs should provide enhanced guidance to individual NICs/OALs as needed to clarify the specific numbers of viruses and optimal timing of shipments:*

IFPMA-BIO are supportive of this solution.

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<sup>1</sup> France was used as example only due to the heavy penalties incurred shall compliance not be observed; IFPMA-BIO have no intention of singling out the country for any other reason.

- b) GISRS laboratories should improve communications with vaccine producers about the availability of CVVs:**

IFPMA-BIO are extremely supportive of this solution, as not all the manufacturers receive the information at the same time, and some face extra challenges with shipping and import permits which will be eased by letting all manufacturers know of CVV availability as soon as possible.

- c) GISRS laboratories within each country should work with regulatory authorities to establish requirements for timely import/export approvals:**

IFPMA-BIO support this and would like to also suggest that NICs are requested to contact their national ABS Focal Points (listed in the [ABS Clearing House](#)) to clarify the requirements of the national ABS/NP legislation and to determine the procedure to be followed as soon as possible.

- d) WHO should raise awareness among Member States of the critical need for rapid, streamlined virus sharing, including the need for sharing of human clinical samples, to support global public health security. Ministries of Health should raise awareness of this need with their national ABS/NP authorities:**

IFPMA-BIO are fully supportive of this solution. Also, although the Nagoya Protocol provisions have focused attention on virus and sequence sharing, rapid and open sharing of human serum samples has not received as much attention. In the COVID-19 pandemic and in the Zika outbreak, limited access to human convalescent serum samples impeded development of diagnostic serological assays, which is vital in the early public health response. Serum samples also will be needed at the earliest stage of an influenza pandemic to evaluate the performance of available serological assays.

- e) WHO should encourage countries that have not yet implemented national ABS/NP legislation to give special consideration to processes that facilitate the rapid sharing of influenza viruses (and other pathogens) and ideally exclude seasonal influenza viruses from ABS requirements:**

IFPMA-BIO are fully supportive of this solution, and would like to highlight that, at least for one country which has formally included pathogens in the scope of their ABS legislation but has allowed for exceptions on the grounds of global public health (Article 8b of the Nagoya Protocol), applying for that exception involves paperwork and formalities which end up being more complex and time-consuming than applying the regular ABS legislation. As such, exemption is, in our opinion, the simplest procedure.

- f) Countries not requiring benefit sharing should provide documentation of this as legal certainty for vaccine producers:**

IFPMA-BIO would like it be noted that although some EU countries do not require benefit sharing, they are quite strict with regards to compliance with ABS/Nagoya legislation. This means that evidence must still be provided as proof that no benefit sharing is required

- g) WHO and GISRS should implement a standardized WHO MTA between CCs and NICs to provide harmonized and timely sharing of viruses, outlining GISRS benefits and providing transparency as to how viruses may be shared and used:**

IFPMA and BIO, while mindful of the challenges behind such a MTA, are fully supportive of it, and would like to ask for the terms of such a MTA to be as comprehensive as possible, and covering the full “journey” of a strain. This would include the isolation of the virus from a patient, use by WHO laboratories for routine surveillance activities and isolation of CVV’s, reassortant laboratory activities as well as vaccine development and commercialization.

- h) WHO and Member States should work together to gain international recognition of GISRS as a specialized international ABS instrument:**

IFPMA and BIO would like to recommend some caution with regards to this approach, as the official CBD process for defining the criteria for and establishing a specialized international instrument (SII) is still unclear and have not been agreed. Even when this is established, countries would still need to recognise such instruments in their national legislation. Feedback from the CBD Secretariat suggested that this would likely take a decade to achieve. Moreover, several countries believe it is not up to the CBD to determine which genetic resources should be exempted from their ABS obligations on the grounds of national sovereignty over those resources, so establishing GISRS as a SII does not guarantee that it will have international, legally-binding recognition and therefore solve the issue of delays and disruption to the timely sharing of influenza viruses.

### Sharing of IVPP and associated CVVs

IFPMA and BIO are greatly concerned about the extent and impact of the issues around sharing of influenza viruses of pandemic potential (IVPPs), as well as the acknowledgement that GISRS laboratories are under-resourced to address those issues. Considering that delays in sharing all IVPP upon request ranged from two months to greater than 3 years, with one biotechnology company reporting that it has given up on receiving H7N9 CVV due to the paperwork required for the process, it is imperative that this is addressed with great urgency. Any delay in sharing IVPP’s has a direct impact on industry’s ability to supply medical countermeasures, including vaccines, within the timelines required to respond to a pandemic.

IFPMA and BIO support all of the “*Proposed Solutions to Mitigate Hindrances to Sharing of IVPP*”, In addition, considering that the objective of the PIP Framework is “*to improve pandemic influenza preparedness and response, and strengthen protection against pandemic influenza by improving and strengthening the WHO global influenza surveillance and response system (“WHO GISRS”), with the objective of a fair, transparent, equitable, efficient, effective system for, on an equal footing: the sharing of H5N1 and other influenza viruses with human pandemic potential, and; access to vaccines and sharing of other benefits*” we strongly believe that the proposed solutions should be urgently implemented and fully supported by the PIP Secretariat. This could be achieved by including the proposed

activities in the relevant work areas of the PIP Framework high level implementation plan II (HLIP II) and working in collaboration with GISRS

**Question to WHO on OP1(a) report**

- For the sharing of seasonal influenza viruses, and establishing a WHO MTA between CCs and NICs to provide harmonized and timely sharing of viruses: what specific aspects would WHO aim to cover in that MTA?
  - While mindful of FENSA, industry offers to provide input to WHO on any parts of the MTA concerning manufacturers.

DRAFT

## IFPMA-BIO feedback on *Decision WHA72(12) OP 1(b)*

### *Report on Legislative and Regulatory Measures*

The legal mapping undertaken for the report is relatively superficial and should not be relied upon as a source of understanding of ABS legislation for the following reasons:

1. The report relies on the 'law and policy documents' uploaded by Member States to the ABSCH; whether the laws are in force or whether the policy documents have any legal weight have not been analysed. The WHO acknowledges that many of the documents analysed were 'policy documents' rather than laws. Although those limitations are acknowledged in the report, at the same time they raise relevant concerns about the usefulness of the report or what would be its added value versus a research of the ABS Clearing House website.
2. Of the 194 WHO Member States only 62 have uploaded documents to the ABSCH, meaning that 132 countries' national legislative measures have not been analysed under the report. (*see below for a map outlining this*).
3. Only the documents with an English or French translation were analysed.<sup>2</sup>
4. Legislation which relates to ABS and pathogens which was not translated into French/English and is not uploaded to the ABSCH is not covered by the study (e.g. Indonesia's laws relating to ABS).
5. There appears to be no legal analysis of the documents reviewed. For example:
  - a. Malta is listed as a country which includes reference to *influenza* under its implementing legislation. However, Malta appears to have included the word *influenza* only to the extent that it is within the name of the PIP FW rather than as a stand-alone provision. It is unclear why the WHO have referenced the same provision twice, once as a reference to influenza and once as a reference to the PIP FW.

#### Exception of prior informed consent (PIC) and mutually agreed terms (MAT) for pathogens:

The report states that Malta expressly excludes "pathogens from the operation of prior informed consent obligations under certain circumstances."<sup>3</sup> This appears to only be partially true, as on closer reading, the legislation in question this appears to altogether exempt pathogens from the ABS regulation in question: the Environment Protection Act (CAP. 549)

<sup>2</sup> Of the 206 documents uploaded to the ABSCH, 146 were analysed for the report.

<sup>3</sup> Page 7 of the WHO report.



Article 25 states that accessing pathogens originating in Malta are not subject to the requirement of PIC.<sup>4</sup> Following on from this Article 2(2)(e) states that the ABS regulation does not apply to “genetic resources that Malta determines do not require prior informed consent,” i.e. Malta does not require PIC or MAT for accessing pathogens originating on its territory.

The statistics given by the report:

WHO Member States which expressly refer to:

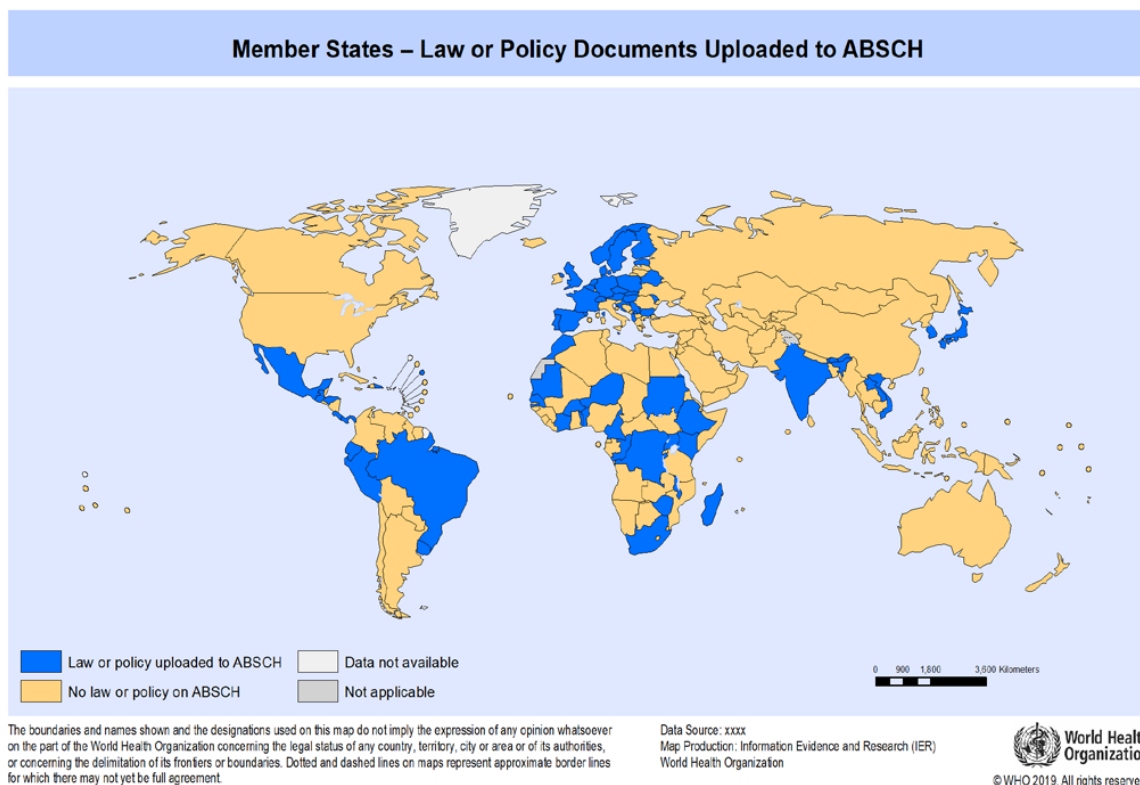
- a. Pathogens:
  - i. 4 (Bulgaria, Germany, Malta and Mauritania) + the EU expressly include pathogens under ABS regulations
  - ii. 31<sup>5</sup> + the EU “impliedly include pathogens [through] a broad definition of genetic resources” using terms such as microorganisms, microbes or the CBD definition of genetic resources.
  - iii. 1 expressly excludes pathogens (in specific circumstances)
- b. The PIP FW as a specialised instrument for the purposes of the Nagoya Protocol: 2 countries + the EU.
- c. Influenza: Malta + the EU.
- d. The International Health Regulations (2005): 2 countries + the EU.
- e. Genetic Sequence Data/Digital Sequence Information: 4 countries.

In relation to the implicit inclusion of pathogens under national ABS regulations, the WHO acknowledges that their classification does not take into account the Member State interpretation of terms such as ‘genetic resources’, ‘microbes’ and ‘microorganisms’. In practice Member States could interpret these as excluding pathogens on the basis that they harm human health, or include them otherwise.

<sup>4</sup> This is the provision included in the WHO report.

<sup>5</sup> Antigua and Barbuda, Brazil, Burkina Faso, Burundi, Cameroon, Congo, Côte d'Ivoire, Czechia, Democratic Republic of the Congo, Denmark, Ethiopia, Finland, France, Germany, India, Japan, Kenya, Lao People's Democratic Republic, Madagascar, Malawi, Morocco, Niger, Norway Republic of Korea, Senegal, Serbia, Switzerland, Togo, Uganda, UK, Viet Nam.





IFPMA-BIO believes that the extent of the report limitations and associated consequences should have been made clearer, as the report in its current form could be easily perceived as providing suitable guidance on national ABS legislation for those who are not fully acquainted with the Protocol and its legal implications (e.g. biopiracy).

IFPMA-BIO feedback on ***Decision WHA72(12) OP 1(c)(d)(e)***  
***Report on search engine, raising awareness & new technologies***

**General comments:**

1. We strongly believe that there is not enough information to justify a continuation of the efforts towards a prototype search engine; the limitations outlined in this report are significant enough to question its usefulness.
2. We believe PIP PC funds should not be used for the prototype search engine and the assessment of its usefulness, or to expand its functions; we feel this activity falls outside of the mandate of the PIP Framework and the agreed objectives for the use of PIP PC funds.
3. We urge the PIP Secretariat to focus resources in activities with demonstrable impact on pandemic preparedness and response and which fall within its mandate, e.g. by addressing the issues with IVPP sharing identified in *Decision WHA72(12) OP 1(a) Report on Influenza Virus Sharing*.

## Part I – Information on the functioning, usefulness and limitations of the prototype search engine

From industry's perspective, the World Data Centre for Microorganisms (WDCM) is merely a compiled list of holdings of culture collections: algae, cyanobacteria, bacteria, fungi, yeasts, lichens, protozoa, tissue cultures and viruses, helping culture collections to manage, disseminate and share the information related to their holdings (species, strains, originator collection, place of origin, temperature). As such, their credentials with regards developing a search engine for human pandemic influenza GSD are not clear. Moreover, none of those microorganisms are human pathogens, with any access to influenza virus information by the WDCM being done via GenBank only.

As per **Paragraphs 17 and 18**, it is confirmed that the prototype search engine is just a collation of already publicly available data, which on top rely on manual searches.

**Paragraphs 18 and 19** raise an important concern of which entity owns the prototype search engine, which would be the WDCM. However, the WDCM is hosted by a rotation of countries, being hosted by the Institute of Microbiology, Chinese Academy of Sciences in China since 2011 and after being hosted by Australia and Japan in the past. Moreover, it is not made clear the number of FTEs needed to update the data manually.

1. **Question to WHO:** is data collection being set up independently of any national legislation on data sharing protections? Is China the owner of the prototype search engine and its information? How would a change in the hosting country affect the handling of data collected by the prototype search engine?
2. **Question to WHO:** who would be an "authorized user" of the prototype search engine? What would be the criteria behind identifying an "authorized user"? Why is there a need to make the prototype search engine closed to just some parties? Will the information collected be made available to all stakeholders of the PIP Framework?

On **Paragraph 21**, different fields are mentioned as potential areas of interest for a search aimed at looking for use of IVPP GSD, although it is not clear what is the value of e.g. identifying a publication mentioning a pandemic influenza virus, as it doesn't necessarily mean sequences were even used. The value of each search field is unclear and it seems that a significant amount of useless, redundant or repetitive data will be found, as well as that most data will unlikely change significantly over time, and they will likely imply a significant workload for little return.

3. **Question to WHO:** what is the objective of including each of the search fields mentioned (nucleotide sequences, publications, patents, clinical trials files, regulatory approvals files)? How and why were those particular search fields selected?

Moreover, it seems that reports are not generated automatically and must be developed manually (**Paragraph 25**), which raises more questions about the workload involved to collect and curate the information, and on top develop a report that should add value compared to previous editions. For instance, in Annex 2, Page 16, it shows that the prototype search engine retrieved 12.964 publications for H5N1, which would seemingly

have to be read and analyzed in order to assess the value of their content, which is just not realistic.

On **Paragraphs 27 and 28**, under “*Usefulness of the search engine*” it is mentioned that the objective is to monitor the use of IVPP GSD in the development of influenza-related end-products and identify entities that have used IVPP GSD to develop such products. Also, a pilot test of the prototype search engine nearly 4 years ago identified 10 of such end products by 8 companies which did not receive PIP BM. First, it seems contradictory that the PIP Secretariat is still assessing the usefulness of the prototype search engine, and urging Member States to do so via the Executive Bodies, when the engine was allegedly already able to identify 10 products developed using IVPP GSD without ever using PIP BM four years ago. Second, it seems those products are already final (“*end-product*”), so it is not clear how influenza pandemic products were developed and approved by regulatory authorities without WHO being aware of it. Third, PIP BM will, for the time being, be needed for testing purposes even if the product will be developed based on GSD only, so the footnote amendment for the SMTA-2, which aims at addressing the indirect use of PIP BM, should already cover those instances for the foreseeable future. Fourth, it is not clear what products were developed using IVPP GSD and whether the manufacturers fall in the categories of influenza vaccines, antiviral and diagnostics manufacturers, which would be the ones eligible to sign a SMTA-2.

4. **Question to WHO:** why is WHO assessing the usefulness of the prototype search engine, via a Decision triggered in 2018 at the World Health Assembly, when in 2016 there was already evidence the prototype search engine could be useful? Why hasn't that information been widely shared before?
5. **Question to WHO:** which are the 8 companies which develop 10 pandemic influenza end-products by using GSD IVPP only? What feature of the prototype search engine allowed for their identification (e.g. Publications? Regulatory approval)?
6. **Question to WHO:** What was the process that allowed those 8 companies to develop a product without using PIP BM, either directly or indirectly? Would the footnote amendment allow for the identification of those 8 companies as of today?

In **Paragraph 31** (points a., b. and c.), it is mentioned that the current IVTM could be somehow integrated in the search engine. However, monitoring IVPP GSD in the IVTM has already been discussed before and the increased workload for CCs and NICs, as well as the technical feasibility of doing so, have been mentioned as rather significant concerns by those working day-to-day with the IVTM. The PIP Secretariat has not provided so far any evidence that tracking GSD IVPP would be feasible nor what the human, technical and financial implications would be like. As such, and on top of the fact that WHO has no mandate to track GSD (be of influenza or any other pathogens), we believe it is somewhat misleading to suggest that the IVTM could somehow support GSD IVPP tracking, or GSD for any other pathogens in the absence of any evidence supporting it. Also, the alleged objective of the search engine is to identify “*end-products*”, so the need to link it with the IVTM is unclear.

Also, in terms of collaboration amongst the scientific community and sharing of information, it is not clear what advantages would arise from the prototype search engine that e.g. are not already covered by GISAID, a platform widely used by the scientific community and with an excellent track record of sharing influenza GSD. GISAID has also shared the sequences of SARS-CoV-2 with incredible speed, showing that its sharing mechanism works beyond influenza. We believe WHO should not try to replicate what already exists and has already shown to work with efficiency.

From **Paragraph 32 to Paragraph 38**, the report outlines a series of limitations of the prototype search engine which seem strong enough to question the actual usefulness of the prototype search engine at this stage and the interest in proceeding with further efforts at assessing the possibility of its use, particularly considering that such efforts would entail a financial cost (**Paragraph 39**). Also, no information is provided so an informed assessment can be made, e.g. in **Paragraph 35** it is mentioned that certain databases (we believe it is the case of GISAID) cannot be included in data mining; we believe WHO should have included a mention of how significant is the impact of this technical limitation and what its importance is.

**Industry would also like to reemphasize that we strongly believe PIP PC funds should not be used for the prototype search engine and the assessment of its usefulness, or to expands its functions; we feel this activity falls outside of the mandate of the PIP Framework and the objectives for the use of PIP PC funds, and does not have a demonstrable link to improving pandemic influenza preparedness and response.**

In **Paragraphs 39 and 40**, the report outlines the two main conclusions so far; we strongly believe that there is not enough information to justify a continuation of the efforts towards a prototype search engine, which seems to be corroborated in some extent by WHO (*"It is clear that the search engine cannot be transformed into a tool to monitor all uses of IVPP GSD by companies"*). A clear link between the prototype search engine and pandemic influenza preparedness and response has not been established so far, and activities addressing the issues with IVPP sharing identified in *Decision WHA72(12) OP 1(a) Report on Influenza Virus Sharing* would arguably contribute more substantially towards addressing the overarching objectives of the PIP Framework.

#### **Perceived weaknesses of the prototype search engine - summary:**

- It is not made clear which organization and/or country would own the prototype search engine and its associated data;
- It seems to be rather time-consuming and largely reliant on manual work;
- It is unclear what is the added value of the prototype search engine versus performing the manual searches in each of the identified publicly accessible databases.
- A significant amount of the information collected will be useless, redundant or repetitive, and unlikely to change over significant periods of time; data curation will be needed and will likely be extremely time-consuming.
- It is not made clear who will be responsible for collecting and curating the information collected from the prototype search engine, nor for developing a report;
- The search engine can only search publicly accessible information that do not require a data access or similar user agreement, so the information collected will be incomplete to an extent which is not clear.
- The search engine only searches for information in English, so the information collected will be incomplete to an extent which is not clear. Expanding the prototype search engine to more languages would likely increase the workload associated with those searches, as well as the extent of the data curation needed.
- No perceived added value towards improving pandemic influenza preparedness and response.

## **Part II – Options to raise awareness of the PIP Framework among databases and initiatives, data providers and data users (Decision WHA72(12)(d))**

Industry questions how raising awareness amongst databases, initiatives, data providers and data users towards a greater understanding of the significant value of the GSD generated by GISRS laboratories will contribute towards improving pandemic influenza preparedness and response. It can be argued that anyone working in influenza knows already the value of both pandemic and seasonal influenza GSD, and that there is no apparent need to mention the PIP Framework in order to sensitize users to the critical work of GISRS to prevent and control influenza, when raising awareness of GISRS alone would be enough for that purpose.

Moreover, the GSD database most commonly used by the scientific community when it comes to influenza is GISAID, whose data user agreement already includes provisions in acknowledging the origin of the data in any publications. Also, we do not believe the PIP Secretariat should have any authority nor responsibility with regards promoting the contributions of GSD providers, and again we do not see how such an activity improves in any way towards an improved pandemic preparedness or response. We urge the PIP Secretariat to focus resources in activities with demonstrable impact on pandemic preparedness and response and which fall within its mandate, e.g. by addressing the issues with IVPP sharing identified in *Decision WHA72(12) OP 1(a) Report on Influenza Virus Sharing*.

- 7. Question to WHO:** What is the link between raising awareness amongst GSD databases, initiatives, data providers and data users, and improved pandemic influenza preparedness and response?

## **Part III – New challenges posed and opportunities provided by new technologies in the context of the PIP Framework and possible approaches**

No comments from industry on this section, other than that we are fully supportive of the Global influenza Strategy 2019-2030 and its objectives.