16 October 2017

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Implementation of Decision WHA70(10) 8(b)

Evidence for *"Scoping Paper on approaches to seasonal influenza and genetic sequence data under the PIP Framework" ("Scoping Paper")*

Compilation I. Seasonal Analysis

This document compiles Member State and stakeholder input to the 2016 PIP Framework Review[1] and the WHO *Study on the public health implications of the implementation of the Nagoya Protocol*[2] ("Nagoya Study"), as follows:

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NB: Each transcript or submission found in this compilation is associated to a reference number. These reference numbers are used in Part A of the Scoping Paper.[3]

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Every effort has been made to be as inclusive, balanced and thorough as possible while recognizing the need to maintain a focus on the topics relevant to the Scoping Paper. Member States and stakeholders are encouraged to contact the Secretariat at pipanalysis@who.int regarding issues or comments on the content of this document which should be considered to be a living document.

[1] Information on the 2016 PIP Framework Review can be found at http://www.who.int/influenza/pip/2016-review/en/.
[2] Available at http://www.who.int/un-collaboration/partners/Nagoya_Full_Study_English.pdf?ua=1
[3] http://www.who.int/influenza/pip/scopingpaper.pdf

Table I.1 Excerpts from transcripts of interviews with the 2016 PIP Framework Review Group

This table contains excerpts from transcripts of interviews conducted by the 2016 PIP Framework Review Group with representatives from GISRS laboratories, and other stakeholders. The excerpts focus on two questions asked of each interviewee:

1) Should seasonal influenza viruses be included in the PIP Framework?
2) What are the advantages and disadvantages as well as the opportunities and challenges of expanding the scope in this way?[4]

Excerpts have been anonymized to preserve confidentiality.

Reference No.	Source	Excerpts from Interview Transcripts
S1.	Transcript of GISRS interview for 2016 PIP Review Group	Some very specific advantages with respect to the Nagoya Protocol that potentially would occur if seasonal viruses were to be included in the PIP Framework. From an operational point of view, from a [GISRS laboratory] perspective, the volume of data entry into IVTM would go up by several orders of magnitude and so if it were to happen that seasonal influenza would be included, then there'd be some technical issues that would absolutely have to be addressed. But because of the advantages of having seasonal and pandemic influenza viruses covered under the same framework, then I think you might regularise the understanding that if you used products of GISRS, if you used materials or information, as I'll come to in a moment, that came as a result of the member states putting all this effort into creating this laboratory network and having this as a global resource, then you would have a smoother way toward... because you've got then virus and benefit-sharing, it could be treated as a legal instrument that meant the terms of the Nagoya Protocol. I haven't used the right legal language there but I think you get the concept. So, I think that I see that there are more advantages than disadvantages but that's just from the perspective of keeping the system going and making sure that we have a way to provide candidate vaccine viruses to industry in time to get vaccines made, both for seasonal and pandemic situations.
S2.	Transcript of GISRS interview for 2016 PIP Review Group	Good surveillance of seasonal influenza is the based for good preparedness for the next pandemic. Disadvantages would be more work. Not simple to implement a system that would cover all these seasonal viruses.

[4] See Report of the 2016 PIP Review Group, "Method of work, pp. 28-29, and Appendix II: Detailed Methods of work, pp. 103-106, available at http://apps.who.int/gb/ebwha/pdf_files/EB140/B140_16-en.pdf?ua=1.

Reference No.	Source	Excerpts from Interview Transcripts
S3.	Transcript of GISRS interview for 2016 PIP Review	The next question is, again, a very broad and difficult one on seasons influenza viruses in the PIP Framework. Our view in the past was very much that they shouldn't be in the PIP Framework but with the advent of the Nagoya Protocol, our views have somehow changed a bit and the answer now is maybe a perhaps; not a yes, not a no but a maybe. But I think to include seasonal influenza viruses in the PIP Framework would only make sense if there could be a guarantee that this then exempts them from Nagoya. If Nagoya would still apply, then really there is no benefit in including seasonal flu viruses in the PIP Framework. if you were to include seasonal viruses in the PIP Framework, then I think the PIP Framework would have to adapt to that. For seasonal influenza viruses we ship so many viruses that the tracking would just not be feasible. That would be a fulltime job, to record every shipment we do. Last year we did, I think, over 400 shipments of seasonal viruses, just to give you an idea of how many shipments would have to be tracked. The other thing that, if you were to include seasonal viruses in the PIP Framework, I don't really see that that would really increase the benefit that would come out of the Framework because most of the major contributors, the major manufacturers, are signed up to the PIP Framework anyway because of the use of PIP biological materials. So, I think you wouldn't really capture a lot of extra players.
S4.	Transcript of GISRS interview for 2016 PIP Review Group	With respect to seasonal viruses, in PIP I see advantages and disadvantages. I don't think it's going to be possible to track every seasonal virus. I think that would just be a nightmare the way we have to track PIP biologicals, so that's one negative for being within the PIP framework if that same tracking of every virus we receive is required. To be entered into a system, we do track shipments and that information is sent to WHO on a regular basis. But in terms of addressing the issues of Nagoya I think we need to all pay attention that this may be a huge problem for seasonal virus sharing in the future and that we need to come up with a solution. I don't know if it's including them under PIP or maybe the better solution would be to have GISRS identified as a benefit sharing program which it essentially is. But that's in a separate arena of political questions.
S5.	Transcript of GISRS interview for 2016 PIP Review Group	The only advantage, of course, is it brings more money into the season, but it will be an incredibly costly step to take, and it was not clear that any resources would be available to support the very dramatic increase in workload that that would place on Collaborating Centres and other laboratories which receive a lot of seasonal viruses. For our own [GISRS laboratory] in [country name] it would mean employing extra staff simply to do the paperwork, and that would have to be at the expense of doing the laboratory work, so there wouldn't be a source of funds to be able to cover the cost of doing that extra work. So it was not clear to me that that cost could possibly be justified by the advantages. I think if the inclusion of seasonal viruses includes tracking, it will be a disaster for both the CCs and ERLs, and it

Reference No.	Source	Excerpts from Interview Transcripts
		would need extra staff and a lot of extra work. There are many thousands of viruses shipped for seasonal influenza, and it would just a nightmare. But what concerns me is why would we want to include seasonal viruses within the PIP Framework? Naturally, seasonal flu viruses spread in nature from person to person, from region to region, from different parts of the world to different parts of the world without any help from GISRS. So it seems as though it's a kind of artificial way of tracking viruses, when the virus is spreading naturally. Yes, I think that's a really good point, a very good point that [name of person] makes. Why would...? If a company wants to make an influenza vaccine, they don't have to rely on GISRS to obtain a seasonal influenza virus. And so I think it would very rapidly lead to the breakdown of the WHO GISRS system because the companies would simply be able to work outside it. I think the other thing is that it would, apart from the workload on CCs and ERLs, it would simply be an impediment to NICs and other laboratories sharing viruses at all. So, again, I think that would just impede the functioning of the Framework, which has been working effectively for a very long time. Is this a real concern that seasonal influenza viruses will be included within the Nagoya Protocol? Is it realistic? In that case, it would be critical that the PIP Framework was modified to ensure that the laboratories don't drown in paperwork.
S6.	Transcript of GISRS interview for 2016 PIP Review Group	The PIP Framework for monitoring the sharing of seasonal influenza viruses is extremely cumbersome and if we look at where that information would come from, it would be for the people who are sending viruses to us and the viruses that we receive or the samples we receive. The point would be that should there be quite a workload associated with sending viruses, then that might well be seen to compromise the sharing of viruses and so that would be a real negative within sharing of seasonal influenza viruses. To put in any onus of activity, any increased demands to a national influenza centre would be really counterproductive. Then at the collaborating centre could receipts be recorded and shared as within the PIP Framework? Yes, but the problem with that is what do you want? Do you want all receipts which might well be samples that don't contain virus or have no recoverable virus or only those that are recovered? And so one would need to think about precisely what would be covered by having seasonal influenza viruses within the PIP Framework. One could certainly share information about isolates at the collaborating centre level but I don't think that samples would be... part sample receipt would be an appropriate thing.
S7.	Transcript of GISRS interview for 2016 PIP Review Group	It is important to involve all of these viruses in PIP because of the link between the seasonal influenza work and pandemic preparedness.

Reference No.	Source	Excerpts from Interview Transcripts
S8.	Transcript of GISRS interview for 2016 PIP Review Group	We need to take the advantage of the PIP mechanism to improve the virus sharing, including the seasonal influenza virus sharing.
S9.	Transcript of GISRS interview for 2016 PIP Review Group	Basically would justify why we are doing surveillance [for pandemic preparedness]. Countries should have some budget to procure vaccines annually. If we then include as part of budget our seasonal activities, then you would have more money available for seasonal activities.
S10.	Transcript of stakeholder interview for 2016 PIP Review Group	So, for me my perspective is that indeed we are struggling with the Nagoya Protocol and the fact that we are based in Europe and that part of our production is based in Europe, and because the European Union had implemented the Nagoya Protocol in the European legislation for us it's really, really a must to have a solution for the Nagoya Protocol because each time since the implementation, each time we have the strain selection we don't know if we have the strain coming from countries who have implemented Nagoya Protocol, how we are going to manage that because it will create some problem in terms of the availability of the vaccine because if we have to negotiate by each country who is providing the virus for seasonal flu it will take time to have the informed consent, to agree on mechanisms beneath each strain. So, I think really the best option that could be envisaged is to elevate the GISRS at the level of international instrument and by doing that I think we will really avoid the complications due to the implementation of the Nagoya Protocol. What is important is that the GISRS and the WHO stays really at the central point of collecting the samples and collecting the viruses, and also for countries to continue to share for viruses, and for industry to use the viruses according to a specific framework and rules which are clear to everyone, because if not we may really be in trouble and we have been alerting WHO on the potential consequences for more than three years. We had a lot of discussion with the European Commission, because their first answer for the European manufacturers is the NIBIC in the UK, so I think there is a lot of sensitivity around that, there are compliance aspects, and really the best thing to do I think is really to elevate the GISRS, and I think the WHO legal adviser is also waiting to listen to the countries. As [stakeholder] we cannot make this proposal, we can suggest it, but the only ones who could act on it are the countries, other member states. But it will really create a very, very complex situation, and for companies like mine, because not all manufacturers are doing vaccine for southern hemisphere and northern hemisphere, we are. We are the major producer for southern hemisphere vaccine, so really if we have an agreed option solution it will be really very, very helpful for public health and really it will avoid another level of complexity. […]

Reference No.	Source	Excerpts from Interview Transcripts
		if we open the scope of the PIP framework agreement I think we will be facing major problems, because I remember I was attending the discussion before the adoption of PIP so I am really afraid that we will answer still the same level of negotiation, other countries saying this, that for me it will really put at risk the PIP framework agreement and other institutions or interested parties will say, okay, we open for seasonal flu, why not other pathogens, so I think it will create more problems than come up with a solution. So, really for us, if you could avoid opening the scope to the flu, which is seasonal flu, which is excluded currently by the framework agreement, I think otherwise we will have to manage a very complex situation, and other countries will have to do so as well.
S11.	Transcript of stakeholder interview for 2016 PIP Review Group	In that context we also would like to stress that this commitment has been developed and designed for a pandemic specific situation which is fundamentally different from the nature of a seasonal influenza programme which is much more similar to different types of vaccination programmes, so after careful consideration we see that this framework should maintain a focus on pandemic in order to bring efficient results and preparedness for pandemic response as possible. Potential disadvantages of including influenza as we see it, mostly less focus on influenza, lessening of the priorities, and as a consequence then fewer tangible pandemic preparedness outcome. We also have concerns that a potential extension would create further complexity, and complexity might mean that countries would not prioritise the pandemic focus of the activities. We also have concerns that complexity related to the potential expansion might also create challenges around the review of the framework itself that might require much more negotiations and recommitment from different stakeholders, including industry. We also would like in that case to stress that the economic reality of seasonal business is very different from the pandemic preparedness, and of course the pandemic preparedness is depending on the seasonal business, but we strongly feel that these two areas should be separate for the predictability simplicity. At the same time we strongly support WHO or any other type of activities in the area of seasonal vaccination programmes, such as the ongoing [unclear] studies, and we also recognise that different countries, like the US CDC, have partnerships and are donating certain seasonal vaccines to the developing countries. As industry we strongly support those activities, but believe that they should be separate from the framework of the pandemic influenza as such. When it comes to the concern that we have raised concerning the Nagoya protocol implementation, we also feel that any potential response for seasonal should have a tailored approach and should not be connected to the PIP framework. I think that's in a nutshell our position. I of course ask any colleagues if they have any additional

Reference No.	Source	Excerpts from Interview Transcripts
		comments on that topic.
S12.	Transcript of stakeholder interview for 2016 PIP Review Group	So I guess, yes, but, and the but is I think on the things that I focused before with the goal of burden of illness studies and vaccine introduction and evaluating the impact that that introduction has as the basis for sustainable markets by these manufacturers. That's separate from, do I think that seasonal viruses need to be in this PIP framework. That's a much more complicated question and so I guess I'll leave it on the former side that the rationale is building onto the burden of illness studies which you support into the, okay, if you're going to have burden of illness and it's there, then how do you then help to support the introduction of seasonal influenza in a sustainable way with the goal being that without a sustainable programme, I've said it before, without the sustainable programmes the manufacturing capacity that's been built may dry up.

Table I.2 Excerpts from Member State and stakeholder written submissions to the 2016 PIP Framework Review

This table contains excerpts from Member State and stakeholder written submissions to the 2016 PIP Review.[5] All submissions were reviewed and content relevant to Part A of the Scoping Paper was excerpted. In some cases, the excerpts have been anonymized to maintain confidentiality.

Reference No.	Source	Excerpts from written submission
S13.	Australia submission for the 2016 PIP Review	Further details of the Review Group's deliberations regarding expanding the Framework to include seasonal influenza would be welcomed, noting the associated complexities with this proposal. While this option presents a solution to the implications associated with the Nagoya Protocol (If the Framework is recognized as a "specialized international access and benefit-sharing instrument for all human influenza viruses"), the increased workload and associated burden on the Framework's infrastructure, including the Global influenza surveillance and response system and the Influenza Virus Traceability Mechanism is concerning. It is expected that the inclusion of seasonal influenza viruses under the Framework would be resource intensive and has the potential to overwhelm GISRS and impact the timeliness and effectiveness of GISRS members' essential "business as usual" work.
S14.	Norway submission for the 2016 PIP Review	Norway believes that integrating other pathogens into the existing PIP Framework is not an option. Focus should instead be on strengthening the implementation of the Framework as it stands in order to make it work as intended. Adding other pathogens to the Framework would significantly add to the implementation challenges, not to mention what it would take for Member States to renegotiate an expanded framework for this purpose. We would not want to go down this road.
S15.	Member State submission for the 2016 PIP Review	Missing this questionnaire is the obvious link to the broader context of the CBD/Nagoya Protocol. It seems, that at least under the European interpretation, we are working now under 2 ABS-frameworks: the PIP Framework for the sharing of pandemic flu strains, and the Nagoya Framework for seasonal flu strains. This situation has already led to confusion in the scientific and public health community and should be clarified to ensure relevance and sustainability of Framework in the long run
S16.	United States submission for the 2016 PIP Review - Sept 2016	We support continued recognition of the linkage between seasonal and pandemic influenza efforts/programs (see, e.g., Overarching Finding 3). While we note the Review Group's finding regarding expanding the Framework to seasonal influenza, we recommend and encourage that any decision on such an expansion should be done so through a comprehensive consultative and analytical process sooner rather than later. In particular, any expansion of the Framework should not place undue burden on the Global Influenza Surveillance and Response System (GISRS) and its process for timely sharing of seasonal viruses. The potential expansion should also be driven by sound public health policy rather than a perceived need to situate the Framework within separate international regimes (e.g., the

[5] See Report of the 2016 PIP Review Group, "Method of work, pp. 28-29, and Appendix II: Detailed Methods of work, pp. 103-106, available at http://apps.who.int/gb/ebwha/pdf_files/EB140/B140_16-en.pdf?ua=1.

Reference No.	Source	Excerpts from written submission
		Nagoya Protocol as stated in the Overarching Finding).
S17.	Stakeholder submission for the 2016 PIP Review	• Road for Pandemic preparedness goes thru preparedness for seasonal influenza ▪ For influenza, pandemic and seasonal influenza categorization is artificial. ▪ PIP BM focuses on pandemic viruses, where the "pandemic" potential is assessed post-hoc, after sharing the viruses with GISRS, ▪ Nagoya protocol on use of genetic resources endorses comprehensive provisions, and thus has implication on PIP framework. If we expand to include seasonal flu viruses, these provisions might be complied to. (Take measures to monitor the utilization of genetic resources after they leave a country including by designating effective checkpoints) ▪ If systems are ready for seasonal influenza, better preparedness for pandemic. • Currently there is no global sustainable finance mechanism to support seasonal flu introductions in developing countries. o GAVI VIS evaluated influenza vaccine portfolio for support. o GAVI analytics highlighted gaps in evidence generation, vaccine introduction logistics etc. **PIP implementation should address these gaps as a part of pandemic preparedness**
S18.	Stakeholder submission for the 2016 PIP Review - April 2016	In addition, the Review Committee may wish to discuss possible recommendations to ensure legal clarity for the WHO PIP Framework: (e.g. for MS or WHO support for the elevation of the GISRS network and the WHO PIP Framework to the status of "specialized international instrument" under Article 4.4. of the Nagoya Protocol (to be decided by the Convention on Biological Diversity Conference of Parties, Nagoya Protocol Members of Protocol (COP-MOP)). Without legal clarity and certainty on the linkage between the Nagoya Protocol and the WHO PIP Framework, it is possible to envision a situation in which PIP biological materials are not made available by Nagoya Protocol Party strain source countries to the WHO or vaccine and medicine manufacturers in a timely way (or possibly at all). It is also possible manufacturers could perceive greater risk in conducting R&D on, or produce vaccines with, such materials for fear of violating Nagoya Protocol Party country access and benefit sharing legislation stipulating administrative or criminal penalties for unauthorized use of such materials. In either case, the implications for pandemic influenza-related preparedness and response may be grave. [Stakeholder] strongly advise that the scope of WHO PIP Framework should remain on pandemic influenza.

Reference No.	Source	Excerpts from written submission
		The PIPFW is still a young international instrument, it should remain focused to ensure the most efficient global pandemic influenza preparedness and response which is the aim of the Framework.
S19.	Stakeholder submission for the 2016 PIP Review	A potential expansion might result in diluted pandemic preparedness outcomes, more complexity, a lack of prioritization, unsatisfactory implementation of pandemic-related commitments at Member State level, and might also require revisiting negotiations for the WHO PIP rather than what is envisioned by the current PIP review. The WHO PIP Framework has been developed and designed for the "pandemic – global public health emergency-preparedness" context which is fundamentally different from the nature of seasonal influenza programs. We strongly believe that the WHO PIP Framework should not be extended to seasonal influenza. We recognize the importance of sharing influenza viruses of human pandemic potential and the benefits, considering these as important parts of the collective action for global public health. This commitment has been made in the pandemic context and should be maintained in this form. Lessening the focus on pandemic preparedness might result in fewer tangible pandemic preparedness outcomes with possible indirect impacts on a future pandemic situation. Furthermore, this might result in more complexity, a lack of prioritization and unsatisfactory implementation of pandemic related commitments at the Member State level. Pandemic response is inherently linked to the sustainability of seasonal influenza vaccine and medicines businesses. The seasonal influenza vaccine industry, in particular, has been consolidating and as a result, several manufacturers have left this space or combined efforts with other manufacturers. Low demand for seasonal influenza vaccine and global over-capacity have further complicated the economic reality seasonal vaccine manufacturers face and may lower capacity for pandemic response. The possible expansion of the Framework to include seasonal influenza would create more complexity for all stakeholders and would require revisiting negotiations for the WHO PIP rather than envisioned by the current PIP review. From an industry perspective, this may lead to a need to re-consider possible commitments on an individual basis.
S20.	Stakeholder submission for the 2016 PIP Review	While we recognize the desirability of clear rules governing access and benefit sharing for seasonal influenza viruses, expansion of the PIP Framework to include seasonal viruses is impractical and could have consequences for the viability of PIP Framework. The PIP Framework was developed taking into account the specificities of influenza viruses of pandemic potential.

Reference No.	Source	Excerpts from written submission
		The objectives, scope, SMTAs, the ToRs of the GISRS labs are all specific to IVPP. To expand the Framework would mean unraveling the Framework. This is not advisable given that the Framework is at relatively early stages of implementation and appears to be functioning. In addition, the commercial benefit derived from seasonal viruses is much larger than that for pandemic ones and thus there would be a need for a serious discussion on new benefit sharing obligations. It is noteworthy that during the negotiation of the PIP Framework, proposals suggesting the inclusion of influenza biological materials were not accepted, thus the scope was limited to influenza viruses of pandemic potential. And Article 3.2 of the PIP Framework specifically states "This Framework does not apply to seasonal influenza viruses or other non-influenza pathogens or biological substances that may be contained in clinical specimens shared under this Framework." It would also seem that the driving rationale for expanding the Framework - rather than extending the Framework's approach (in another instrument for seasonal influenza viruses) - is to label the Framework a specialized instrument under the Nagoya Protocol. This logic is flawed as explained below as the focus should be on having an effective instrument rather than a particular label. We are of the view that the finding should be replaced in its entirety with text that stresses that given the global public health benefits derived from the PIP Framework, WHO Members should consider developing another instrument applying a similar approach to seasonal influenza viruses, applying the principles of treating virus sharing and benefit sharing on an equal footing, and of the CBD and the Nagoya Protocol. Of particular importance is ensuring fair and equitable benefit sharing in relation to utilization of seasonal influenza viruses.

Table I.3 Excerpts from Member State intervention at the Seventieth World Health Assembly

This table contains an excerpt from the provisional summary record of the sixth meeting of Committee A at the Seventieth World Health Assembly. All interventions at the sixth meeting of Committee A were reviewed and content relevant to Part A of the Scoping paper was excerpted.

Reference No.	Source	Excerpt
S21.	Malaysia intervention at WHA70	The representative of MALAYSIA said that he was in favour of extending the definition of biological materials to include genetic sequence data and agreed that the use of such data should trigger benefit sharing under the PIP Framework. However, stakeholders should seek further clarity before making a decision in that regard. He could not yet support the inclusion of seasonal influenza within the PIP Framework because there was a risk that such inclusion would divert resources and increase the workload for laboratories in the Global Influenza Surveillance and Response System. The Secretariat should evaluate the implications and desirability of such a decision. He welcomed the recommendation to consider the PIP Framework as a specialized international instrument under the Nagoya Protocol and supported the draft decision.

Table I.4 Excerpts from Member State and stakeholder written submissions to the Nagoya Study

This table contains excerpts from Member State and stakeholder written submissions to the WHO study on the public health implications of the implementation of the Nagoya Protocol ("Nagoya Study"). As part of the Nagoya Study, WHO Member States, Parties to the Convention on Biological Diversity and GISRS laboratories were asked the following two questions[6]:

1) What are the implications of implementing the Nagoya Protocol with respect to accessing seasonal influenza viruses?
2) What actions do you think could be taken to ensure that, in countries, where the Nagoya Protocol is being implemented, public health entities continue to have access to seasonal influenza viruses?

Excerpts have been anonymized to preserve confidentiality.

Reference No.	Source	Excerpts from written submission
S22.	Nagoya Study – CBD Party submission to CBD notification 2016-087	[MS name] is concerned about the potential implications of the Nagoya Protocol on the production of seasonal influenza vaccines, noting that uncertainty over legal obligations under the Nagoya Protocol may lead to delays in sharing materials. In our view, if seasonal influenza is not made exempt to the legal requirements under the Nagoya Protocol, there is potential for sub-optimal virus(s) to be used in the production of seasonal influenza vaccines or for there to be delays in the manufacturing of these vaccines. Both of these outcomes have the potential to result in a significant global public health threat. Under the Nagoya Protocol, there is uncertainty on the conditions a country may place on viruses originating from their country. However there are provisions under Articles 4 and 8 of the Nagoya Protocol which require Parties to facilitate access and expedite benefit-sharing agreements. Specifically in relation to present or imminent emergency situations that threaten human life, which seasonal influenza has the potential to do, Article 8(b) of the Nagoya Protocol requires Parties to "take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits", when implementing their access and benefit-sharing legislation or regulation. Although these clauses may be applied to facilitate access to seasonal influenza viruses, there is the potential that without further clarification of countries obligations the Nagoya Protocol is open to individual interpretation and may prevent virus sharing.
S23.	Nagoya Study – CBD Party submission to CBD notification 2016-087	As no relevant specialized instrument applies to seasonal flu viruses, their access may be covered by the Nagoya Protocol whenever the provider country is a party to the Protocol. The conditions for accessing seasonal influenza viruses and for sharing benefits arising from their utilisation may therefore differ widely within parties to the

[6] See Nagoya Study, Annex 1 – Methodology at http://www.who.int/un-collaboration/partners/Nagoya_Full_Study_English.pdf?ua=1

Reference No.	Source	Excerpts from written submission
		Protocol. Depending on the access requirements, the time period necessary for obtaining the access permit may be problematic and jeopardize the development of the seasonal vaccine. […It could be suggested that the principles and working of the PIP framework be extended to any utilisation of a genetic resource (seasonal influenza or other pathogen) supplied by the WHO and its network. All utilisation of samples for the purpose for which they were supplied to WHO could in that case be deemed compliant with the Regulation.
S24.	Nagoya Study – CBD Party submission to CBD notification 2016-087	The PIP Framework applies only to influenza viruses with human pandemic potential and specifically does not apply to seasonal influenza viruses. Although these influenza viruses are not generally considered to be public health emergencies, similar rules should apply in their case. Taking measures in global influenza prevention and surveillance should be continuous and the data should be kept available, otherwise international public health threats might be triggered. In broad terms, this applies also to other pathogens that affect human health.
S25.	Nagoya Study – CBD Party submission to CBD notification 2016-087	Vu que la grippe saisonnière pose également un problème de santé publique qui provoque des maladies graves et des décès dans les populations vulnérable, il y a nécessité d'appliquer les mêmes mesures que pour les virus à grippe pandémique. [TR: Since seasonal influenza is also a public health threat that cause severe disease and death in vulnerable populations, it is necessary to apply the same measures as for pandemic influenza.]
S26.	GISRS submission to Nagoya Study	2. What actions do you think could be taken to ensure that, in countries where the Nagoya Protocol is being implemented, public health entities continue to have access to: b. Seasonal influenza viruses? [To have available a standard mutually-agreed Material Transfer Agreement that is ratified by all parties to facilitate access/sharing.]
S27.	GISRS submission to Nagoya Study	Implementation of the Nagoya protocol could have serious and important implications for access to seasonal influenza viruses by the GISRS and the wider influenza public health community (including vaccine manufacturers). The GISRS would lose nimbleness and the ability to respond quickly to newly emerging antigenic variants of seasonal viruses. This in turn would affect the quality of the WHO recommendations on the composition of influenza vaccines. […] The PIP Framework could be extended to include seasonal influenza viruses; however, this would only work if changes to the PIP Framework were made. In particular, the requirement to track all shipments of materials would be impractical and this requirement should not apply to any seasonal viruses. Also, there would have to be a transition period, similar to what was enacted following the coming into force of the PIP Framework in 2011, during which current procedures can be continued while new requirements, for instance conclusion of SMTA2s with sample

Reference No.	Source	Excerpts from written submission
		recipients, were phased in and processed.
S28.	GISRS submission to Nagoya Study	1.b. The current system for the development of seasonal influenza vaccines is very time-sensitive and involves sharing of tens of thousands of viruses within the WHO Global Influenza Surveillance and Response System (GISRS), an extensive network of over 140 laboratories performing influenza surveillance activities. A small number of viruses that are characterized to represent newly circulating variant viruses are also shared with seasonal influenza vaccine manufacturers for vaccine production. Surveillance for new seasonal influenza viruses occurs year round and the Nagoya Protocol has the potential to significantly delay or prevent the sharing of viruses needed to make seasonal influenza vaccine composition decisions if benefit sharing agreements are not in place. It is quite possible that implementation of the Protocol could lead to decreased global influenza surveillance resulting in selection of sub-optimal vaccine strains. A possible strategy for mitigation of these effects is presented in the answer to 2b. below. 2.b.Global sharing of influenza viruses could certainly be adversely impacted by the Nagoya Protocol unless a benefit-sharing mechanism for seasonal influenza virus sharing can be recognized or seasonal viruses are excluded from the Nagoya Protocol. In return for participating in GISRS, laboratories receive multiple benefits including, technical training and support, the latest laboratory protocols and guidance documents, reagents and kits for molecular and antigenic testing, virus characterization reports on viruses submitted and access to associated genetic sequence data, as well as candidate vaccine viruses. Thus, GISRS can fulfill the requirements under Article 4.4 as being a specialized instrument for access and benefit-sharing for seasonal influenza. Recognition of GISRS as an instrument of benefit-sharing is needed so that National Influenza Centers in countries where the Nagoya Protocol will be implemented, can continue to share seasonal viruses and/or their genetic sequences within this critical network and WHO Collaborating Centers can share vaccine viruses with manufacturers.
S29.	WHO Member State submission to Nagoya Study	As seasonal influenza viruses and other pathogens are not exempt from the Nagoya Protocol, it may be prudent for Member states to ensure that delays or problems related to access have been identified and are avoided. WHO Member States could consider developing, under the auspices of the WHO, a specialized access and benefit-sharing instrument for seasonal influenza viruses, or consider expanding the scope of the Pandemic Influenza Preparedness Framework to include seasonal influenza viruses.
S30.	WHO Member State submission to Nagoya Study	As mentioned earlier and also proposed by the PIP Secretariat, it might be an advantage to put all human influenza viruses under a "special entity". Now, the PIP Secretariat can legally handle such issues, but the people staffing the Secretariat have no expertise about viruses. It would be better to use the GISRS as this "special entity" because the GISRS has the understanding of viruses, is coordinating the laboratory network, and has the required instruments. Should such an approach be taken, it should be ensured that the administrative processes when shipping seasonal

Reference No.	Source	Excerpts from written submission
		influenza viruses within the GISRS are handled in an easy, straightforward way, without registration of each shipment in the IVTM. […] What actions do you think could be taken to ensure that, in countries where the Nagoya Protocol is being implemented, public health entities continue to have access to seasonal influenza viruses? 1. Negotiating special terms in NP for human pathogens to be used for diagnostic purposes or vaccine development for ensuring their speedy transfer in epidemic situations; 2. Identifying the GISRS as a "special entity" for dealing with seasonal human influenza viruses and with influenza viruses with pandemic potential; 3. The PIP Framework is not established for seasonal influenza viruses and therefore the GISRS network should be regarded as the "special entity"; 4. Administrative work for sharing influenza viruses within the GISRS network must be simple in order not to overwhelm people working in the GISRS network; 5. Sharing of seasonal influenza viruses within the GISRS to entities outside of GISRS is a continuous public health action and therefore the recipient must not be obligated to contribute to benefit sharing.
S31.	WHO Member State submission to Nagoya Study	2. What actions do you think could be taken to ensure that, in countries where the Nagoya Protocol is being implemented, public health entities continue to have access to: b. Seasonal influenza viruses? Extend the scope of PIP Framework to all viruses with potential impacts for public health.
S32.	WHO Member State submission to Nagoya Study	[…] implementation of the Nagoya Protocol and negotiation of a benefit sharing system may delay access to the influenza viruses for seasonal influenza vaccine production recommended by WHO ad thus delay timely access to vaccine for national immunization programs. Legal uncertainty may also play a role as national legislation and ratification procedures are still not finalized in many countries. Additional administrative burden whole amount cannot be estimated at the given time might play a role as well.
S33.	WHO Member State submission to Nagoya Study	Unlike IVPP, there is no framework in WHO governing the use of seasonal influenza viruses. In the absence of any special instrument for sharing of seasonal influenza and other pathogens, the provisions of the CBD and the Nagoya Protocol would automatically apply to sharing of such specimens/materials. Consideration should be given to the idea of developing a multilateral access and benefit-sharing arrangement, in harmony with the Nagoya Protocol, for

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		sharing of seasonal influenza viruses. However as mentioned above, the absence of rules consistent with the CBD and the Nagoya Protocol, on use of the pathogens that have been shared and the resulting misappropriation (e.g. by claiming patents, utilizing the pathogens for commercial use without the consent of the originating country, the lack of equitable benefit sharing does dis-incentivize sharing of pathogens.
S34.	WHO Member State submission to Nagoya Study	On the other hand with regard to seasonal influenza viruses, in the absence of a framework similar to the PIP Framework the legal principles established by the CBD would apply. Given WHO's role in influenza, consideration may perhaps be given to the development of a framework applicable to seasonal influenza viruses, with concrete benefit sharing obligations.
S35.	WHO Member State submission to Nagoya Study	Although coping with seasonal influenza is more routine and less urgent, the Nagoya Protocol may also impede vaccine development against the seasonal influenza due to the added bureaucracies. It would make it more difficult to transfer virus samples from counties that have implemented the Nagoya Protocol.
S36.	WHO Member State submission to Nagoya Study	2b. A recommendation would be for member states and the WHO to support the elevation of the GISRS network to the status of a specialized international instrument under Article 4 of the Nagoya Protocol. Since it is hard in reality to exclude seasonal flu viruses from the Nagoya Protocol in the discussion with the providing countries, it would be beneficial to ask WHO to lead to form the international concept that seasonal flu viruses is out of scope of the Nagoya Protocol in respect to the public health (the production and supply of flu vaccine).
S37.	WHO Member State submission to Nagoya Study	[MS name] has significant concerns about the increased risk to health security from any legal uncertainties and potential delays in sharing biological material and genetic information for Influenza viruses with pandemic potential (IVPP), seasonal influenza viruses and other human pathogens (particularly those with pandemic potential or emerging pathogens). Our concerns relate to any impediment to the timely sharing of genetic material and other information, including for development of reagents such as genomic RNAs, cDNAs, plasmid containing individual gene segments, anti sera, antibodies and pertinent information related to the IVPP and seasonal influenza viruses (past, present and future) for research purposes, as well as for the development of new (and updating of existing) vaccines and antivirals. The same applies to other existing, new and emerging human pathogens, including the sharing of drug-resistant bacteria and fungi, for example Mycobacterium tuberculosis.

Reference No.	Source	Excerpts from written submission
		Seasonal influenza virus information (including viral material) is currently shared by laboratories around the world through the Global Influenza Surveillance and Response System (GISRS) and other mechanisms. However, it remains unclear whether GISRS and other seasonal influenza virus and information-sharing mechanisms can be regarded as specialized international instruments under the Nagoya Protocol, and this raises legal uncertainty about the sharing of such genetic material and information.
S38.	WHO Member State submission to Nagoya Study	Seasonal influenza virus information (including viral material) is currently shared by laboratories around the world through the Global Influenza Surveillance and Response System (GISRS) and other mechanisms. However, it remains unclear whether GISRS and other seasonal influenza virus and information-sharing mechanisms can be regarded as specialized international instruments under the Nagoya Protocol, and this raises legal uncertainty about the sharing of such genetic material and information. If uncertainty over compliance with Nagoya leads to any delays in sharing materials, or if NICs restrict sharing of viruses to those countries in which benefit-sharing agreements are in place, this could significantly impact on the number and representativeness of the strains available for the analysis and lead to the selection of a sub-optimal vaccine strain. This is because, as noted above, every day matters: vaccines can only prevent influenza infections and their consequences before people are exposed to flu in their communities, and vaccines have to be properly matched to protect against the viruses that are circulating. If the system moves more slowly and is less comprehensive seasonal vaccines would be less effective, as they would not be as well matched to the circulating strains. There is a global benefit in being able to gather samples quickly and use them to produce vaccines. […] It is important to understand the potential impact of this. As noted above, seasonal (non-pandemic) influenza kills many thousands of people world-wide every year, many in developing countries. A sub-optimal vaccine and/or a vaccine that is not available prior to the start of the flu season is therefore a significant global public health threat. […] As some parties may consider it appropriate to apply access requirements, it would be possible to develop standard templates which would indicate whether there are any access obligations attached to particular samples – the Global Health Security Action Group (GHSAG)) Sample-Sharing Group is working on this model. GHSAG comprises the G7 countries plus Mexico, the European Commission and WHO. Wide use of these templates would enable issues around access to be resolved more quickly which is very important in this context. The alternative would be to seek to agree a PIP-style framework addressing seasonal flu, or to embark up on a

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		renegotiation of the Nagoya Protocol to create an exemption from the Protocol of pathogens of concerns, including seasonal influenza viruses. However, we are well aware that either option would be complex and difficult to negotiate, and a PIP-style framework highly challenging to administer.
S39.	WHO Member State submission to Nagoya Study	If Parties to the Nagoya Protocol, in their domestic legislation, were to require prior informed consent and mutually agreed terms for exchange of the seasonal influenza virus samples necessary for the development of diagnostics, vaccines, or therapeutic responses, the necessary international response to seasonal influenza could be delayed. As with pandemic influenza, the current system for the development of seasonal influenza vaccines is very time-sensitive. Late emergence of antigenically distinct variants of A(H3N2) influenza viruses in the 2013-14 flu season contributed to record low vaccine effectiveness during the 2014-15 influenza season. The mismatched seasonal influenza vaccine and the high hospitalization rate among the elderly highlight the need to make well-matched seasonal influenza vaccines faster and better. The WHO Global Influenza Surveillance and Response System is currently expanding influenza surveillance and implementing rapid, virus sequence characterization to support prediction models using 'real-time' data to improve vaccine virus composition decision making. If Parties to the Nagoya Protocol require prior informed consent and mutually agreed terms for exchange of samples this process may be significantly delayed, resulting in decreased influenza surveillance and selection of sub-optimal vaccine strains.