

**Submission on Implementation of Decision WHA70(10)(8)(b)**

<b>Reference No.</b>	001
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<b>Category</b>	GISRS laboratory
<b>Received via</b>	Online questionnaire on Scoping Paper

## WHO Consultation on Implementation of Decision WHA70(10), paragraph 8(b)

This questionnaire is designed to collect views on *Implementation of Decision WHA70(10)(8)(b): Scoping Paper on approaches to seasonal influenza and genetic sequence data under the PIP Framework*, which can be found at <http://www.who.int/influenza/pip/scopingpaper.pdf>.

Should you have any questions or experience any difficulty in completing this questionnaire, please contact [pipanalysis@who.int](mailto:pipanalysis@who.int).

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### Background

Having considered the Report of 2016 PIP Review, the Seventieth World Health Assembly adopted decision WHA70(10) paragraph 8(b), requesting the Director-General, inter alia, as follows:

"8.b) Regarding the Review Group's recommendations on 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 WHO Global Influenza Surveillance and Response System (GISRS)." See [http://apps.who.int/gb/ebwha/pdf\\_files/WHA70/A70\(10\)-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70(10)-en.pdf)

Information about the process to implement decision WHA70(10) paragraph 8(b) can be found at [http://www.who.int/influenza/pip/WHA70\\_10\\_8\\_b/en/](http://www.who.int/influenza/pip/WHA70_10_8_b/en/).

As an initial step in developing this Analysis, the Secretariat has developed a [Scoping Paper](#) and is seeking your views on the following questions in relation to this document.

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### Overarching Section

#### Overarching section (Scoping Paper, paras 1-19)

[The Scoping Paper can be found at <http://www.who.int/influenza/pip/scopingpaper.pdf>]

*Does the overarching section of the Scoping Paper cover all of the overarching issues that are relevant to the Analysis? If not, what other issues should be addressed?*

#### 7) Views on Overarching Section

Yes, the section covers all the overarching issues, although further clarification on SII is needed.

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## **Seasonal Influenza - Background**

### **Background to the seasonal influenza section (Scoping Paper, paras 20-25)**

[The Scoping Paper can be found at  
<http://www.who.int/influenza/pip/scopingpaper.pdf>]

*Does the Scoping Paper cover all the issues that are relevant to the analysis of pursuing or not pursuing possible approaches to include seasonal influenza in the Framework? If not, what issues should be addressed?*

### **8) Views on Seasonal Influenza - Background Section**

Yes, the scoping paper covers all the relevant issues.

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## **Seasonal Influenza - Approach 1**

### **Approach 1: Expand the PIP Framework to include seasonal influenza viruses (Scoping Paper, paras 26-27 and Table A)**

[The Scoping Paper can be found at  
<http://www.who.int/influenza/pip/scopingpaper.pdf>]

*What would be the implications of including seasonal influenza viruses in the PIP Framework for:*

- *Pandemic influenza preparedness and response?*
- *Seasonal influenza prevention and control?*
- *The work of GISRS?*
- *The development of influenza vaccines and other influenza products?*

*Are there other implications to consider?*

*How should the challenges identified under this approach be addressed?*

### **9) Views on Seasonal Influenza - Approach 1**

Sharing of seasonal influenza viruses in the context of GISRS is already under an international agreement and should not be under NP or PIPFM. These options would impact the timelessness and effectiveness of GISRS and thus the seasonal influenza prevention and control and

the development of vaccines.  
In addition, PIPFM should remain mainly focused on emergency and pandemic influenza preparedness and response.

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## **Seasonal Influenza - Approach 2**

**Approach 2: Do not expand the PIP Framework so that national access and benefit-sharing regimes under the Nagoya Protocol apply to the sharing of seasonal influenza viruses (Scoping Paper, paras 26-27 and Table A)**

[The Scoping Paper can be found at  
<http://www.who.int/influenza/pip/scopingpaper.pdf>]

*With reference to the findings contained in the [WHO Nagoya Study](#), are there other opportunities or challenges that might arise from seasonal influenza viruses being covered by the Nagoya Protocol?*

### **10) Views on Seasonal Influenza - Approach 2**

We strongly disagree with this option.

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## **Seasonal Influenza - Approach 3**

**Approach 3: Develop or adapt another instrument to cover seasonal influenza viruses, with a view to that instrument being recognized as an SII under the Nagoya Protocol (Scoping Paper, paras 26-27 and Table A)**

[The Scoping Paper can be found at  
<http://www.who.int/influenza/pip/scopingpaper.pdf>]

*What would be the implications of developing or adapting another instrument to cover seasonal influenza viruses for:*

- *Pandemic influenza preparedness and response?*
- *Seasonal influenza prevention and control?*
- *The work of GISRS?*
- *The development of influenza vaccines and other influenza products?*

*Are there other implications to consider?*

*How should the challenges identified under this approach be addressed?*

### **11) Views on Seasonal Influenza - Approach 3**

GISRS could be recognized as an SII to cover seasonal influenza viruses but with minimum legal requirements (i.e. existing international agreements) as compared to PIPFM, in order to avoid

any delay in seasonal prevention and control activities and thus development of vaccines.
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## **Genetic Sequence Data - Background**

### **Background to the GSD section (Scoping Paper, paras 28-40)**

[The Scoping Paper can be found at  
<http://www.who.int/influenza/pip/scopingpaper.pdf>]

*Does the Scoping Paper cover all the issues that are relevant to the analysis of pursuing or not pursuing possible approaches to GSD under the PIP Framework? If not, what issues should be addressed?*

### **12) Views on GSD - Background**

Yes, the scoping paper covers all relevant issues.
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## **Genetic Sequence Data**

### **Considerations in relation to GSD under the PIP Framework (Scoping Paper, paras 40-42 and Table B)**

[The Scoping Paper can be found at  
<http://www.who.int/influenza/pip/scopingpaper.pdf>]

*How would implementation of the Review Group recommendations on GSD affect:*

- *The work of GISRS?*
- *The development of influenza vaccines and other influenza products?*
- *The implementation of the PIP Framework?*

*If the definition of PIP biological materials is not amended to include GSD, are there implications for:*

- *Pandemic influenza preparedness and response?*
- *Implementation of the PIP Framework?*

*Are there additional considerations or implications?*

### **13) Views on genetic sequence data**

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| <ul style="list-style-type: none"><li>- Any change would affect the work of GISRS and thus the timely and effective development of influenza vaccines.</li><li>- If GSD are not included as PIP biological materials, this would undermine the PIPFM and pandemic influenza preparedness and</li></ul> |
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response. In case of production of vaccines or derivatives from GSD, industry regulations should be made to provide WHO access to pandemic vaccines and for sharing of the benefits.
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## ***Additional Comments***

*Do you have any additional comments?*

### **14) Additional comments**

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