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:** African Union Continental Coordinating Committee on Matters Related to Biodiversity, Biosafety and ABS

African Group comments on the Report on WHA72(12) OP1(a)

The African Group recognizes that effective and timely influenza virus sharing, balanced by expeditious and affordable sharing of vaccines and treatments, is an important global public health imperative. As noted in paragraph 17(c) of the 2015 African Union Strategic Guidelines for the Coordinated Implementation of the Nagoya Protocol:

"Subject to national development strategies and in accordance with Article 8 of the Nagoya Protocol, African Union Member States shall strive to . . . Pay due regard to cases of present or imminent emergencies that threaten or damage human . . . health, as determined nationally or internationally, taking into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries "

Africa recognizes that there is an opportunity to work towards harmonizing administrative and ABS processes and procedures for sharing influenza viruses. Over 80% of African Union Member States are Parties to the Nagoya Protocol. Support should be provided to facilitate appropriate ways of implementing Article 8(b) of the Nagoya Protocol based on respect for the sovereign rights of countries over their genetic resources. Mobilising political support for expedited access depends on being able to demonstrate to decision makers that adequate benefit sharing measures are in place to make vaccines and treatments available and affordable to African countries.

As proposed in paragraph 22(g) of the Report, one approach could be the development of a standard material transfer agreement for seasonal influenza viruses and associated candidate vaccine viruses (CVVs). Such SMTA would need to include adequate measures covering use of digital sequence information/genetic sequence data (DSI/GSD) and would need to be clear about how countries that contribute viruses and genetic information would then obtain expedited affordable access to vaccines and treatments.

Although there are not yet clear guidelines on what constitutes a specialized international instrument under Article 4(4) of the Nagoya Protocol, it seems unlikely that GISRS would be considered such an instrument. A preferred approach would be to work with WHO Member States on ways to operationalize Article 8(b) of the Protocol, particularly its call for Parties to take into consideration the need for "expeditious access to genetic resources and expeditious fair and equitable sharing of benefits, including access to affordable treatments."

An additional, complementary, approach would be to provide support for regulatory capacity building on ABS and pathogen sharing. As clearly noted in this report (paras 21 & 35), timely access to pandemic influenza products, such as vaccines, cannot be assured without regulatory systems and processes that allow for timely access to influenza viruses and CVVs.

The African Group believes that the PIP Benefit Sharing System should support the development of Nagoya Protocol-compliant regulatory systems that enhance pandemic influenza preparedness and response. Partnership contribution funds could be used to carry out this work under the work area of "improving national regulatory systems to ensure timely access to pandemic products".

The African Group proposes that this be added to the proposed solutions listed in paragraph 32 of the report.

African Group comments on the Report on WHA72(12) OP1(b)

The WHA Resolution calls for the development of a report on the treatment of influenza virus sharing with inputs from Member States. The author of the study should work more closely with National Focal Points and Competent National Authorities in Member States that are Parties to the Nagoya Protocol in order to obtain further information on existing legislation and regulatory measures, as the ABS Clearing House is not yet a comprehensive source of information on these measures (as recognized in Section 2.2 of the report). The African Union would welcome further discussions about how it could facilitate such consultation with its Member States.

African Group comments on the Report on WHA72(12) OP1(c)(d)(e)

The African Group is pleased to note the work being done on the prototype search engine and supports its further development into a fully-functional traceability mechanism. Given the growing importance of digital sequence information/genetic sequence data (DSI/GSD) in pandemic response – as exemplified by the use of SARS-CoV-2 DSI/GSD to diagnose and develop treatments for COVID 19 – there is a need to monitor what is being done with DSI/GSD on influenza viruses with pandemic potential (IVPP) in order to support the implementation of the PIP Framework's benefit sharing objectives.

As noted in s 5.2.2 of the PIP Framework, greater transparency concerning influenza virus DSI/GSD is important to public health. The publication of DSI/GSD continues to be considered sensitive by countries providing genetic resources, as noted in s. 5.2.3. Despite its potential limitations, the African Group considers that the prototype search engine could help provide a more fulsome evidence base for the Advisory Group in its discussion and resolution of issues relating to the handling of DSI/GSD from IVPP as part of the PIP Framework.

The African Group also supports continued awareness raising on the PIP Framework and its objectives, including through outreach to databases and initiatives, journals, data providers and data users. It is also supportive of the goal of promoting the acknowledgement of data providers and originating laboratories, which would enable the identification of provenance and demonstrate the important role played by all WHO Member States in pandemic influenza preparedness and response.

Finally the African Group would like to reiterate its view that a comprehensive global multilateral solution for sharing benefits arising from the use of biological resources and associated knowledge, including traditional knowledge and DSI/GSD, would help to solve the problems around access to influenza viruses and pathogens more generally.