ANNEX 1

PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK ADVISORY GROUP MEETING (GENEVA, 7–9 OCTOBER 2013)
SUMMARY OF KEY POINTS OF DISCUSSION

Standard Material Transfer Agreement 2: Update on current negotiations

1. The PIP secretariat provided an update on the status of Standard Material Transfer Agreement 2 (SMTA 2) negotiations. An SMTA 2 was concluded on 1 October 2013 with the Serum Institute of India (SII), a developing country vaccine manufacturer and also a grantee under the WHO Global pandemic influenza action plan to increase vaccine supply. An SMTA 2 had previously been concluded with Glaxo Group Limited (GSK). Negotiations are under way with Sanofi, Baxter and China National Biotec Group, and pre-negotiation discussions are being held with MedImmune and Novartis. A SMTA 2 concluded in October 2012 with the University of Florida was also discussed and noted.

2. Discussions and negotiations are proving to be time consuming, and reaching agreement with vaccine manufacturers on the terms of benefit sharing is often a lengthy process. The Secretariat plans to initiate discussions with additional manufacturers with legal support from a consultant lawyer who will begin shortly.

3. The Advisory Group provided the following advice to the Director-General on SMTA 2 negotiations:

   The Advisory Group welcomed the second SMTA 2 that has been concluded with a vaccine manufacturer.

   The Advisory Group recognized, however, that there have been difficulties in concluding additional agreements:

   • The Advisory Group recommended that WHO showcase the successful conclusion of the SMTA 2s with GSK and SII as an incentive to conclude agreements with other vaccine manufacturers as quickly as is feasible.

   • In situations where discussions with manufacturers would benefit from high level exchanges between the Organization and the manufacturer, the Advisory Group strongly recommended that such exchanges be made.

Handling genetic sequence data in the context of the PIP Framework

4. The Secretariat provided an overview of synthetic biology with a view to initiating the Group’s discussion on the best process to handle the use of influenza virus genetic sequence data under the Framework.

5. The Advisory Group agreed that developments in synthetic biology raise complex issues with legal, technical, public health and biosecurity implications that require careful review and consideration.
6. To assist the Advisory Group in developing guidance for the Director-General on this matter, technical support from a technical expert working group would be beneficial. The Advisory Group developed Terms of Reference for such an expert group.

**Partnership Contribution: review of 2013 results**

7. The Secretariat provided an update on the process to collect the partnership contributions due for 2013. The Secretariat, through the “PIP PC 2013 Questionnaire”, identified 37 companies as contributors. Following an extensive process to receive Band Selection and Certification Forms from all 37 companies, four Band Selection and Certification Forms were outstanding as at 7 October 2013.

8. Using publicly available financial and other information, the Secretariat has placed the outstanding companies into bands. Invoices were sent to the 37 companies in mid-October to allow time for processing before the end of 2013.

9. The Advisory Group concurred with the Secretariat’s approach to generating invoices so that partnership contribution payments for 2013 would be received in a timely fashion. If the estimation of bands for the four companies subsequently needs revision, adjustments could be made in 2014.

**Partnership Contributions: gap analysis and implementation plans**

10. The Secretariat presented the draft Partnership Contribution implementation plan: 2013–2016, including the process for identifying and analysing gaps and needs. The Advisory Group discussed the plan as well as a document on the Regional Office Recommended Country Recipients.

11. The Advisory Group met representatives of industry associations, manufacturers and other stakeholders to discuss the draft plan.

12. The Advisory Group discussed the views and comments of industry and other stakeholders. The Secretariat will revise the implementation plan to take into account these discussions. The revised implementation plan and the results of the gap analyses will be shared with the Advisory Group, industry and other stakeholders.

13. The Advisory Group provided the following advice to the Director-General on implementation of activities under the Partnership Contribution.

> *To avoid the risk of perceived conflict of interest in selection of countries, the Advisory Group wished to clearly articulate the process to develop the draft Regional Office Recommended Country Recipients document. The following was noted:*

- The role of the Advisory Group was limited to providing criteria for country selection:
  - Country development status;
  - IHR core capacities;
  - Country needs for influenza epidemiological and laboratory surveillance; and
  - H5N1 vulnerability.
• These factors were compiled into a database by the PIP Secretariat and shared with Regional Offices for their use in identifying priority countries for strengthening laboratory and surveillance capacities.

• Regions further refined their gap analyses with additional elements including:
  – Political situation in countries, notably whether a country is in a complex emergency;
  – Ongoing donor funding and investments in a country;
  – Absorptive capacity of the country;
  – Country population size;
  – Geographical location of the country in the region/subregion (notably for island states);
  – Interest of the country/Ministry of Health to work in influenza; and
  – Ability of countries to build on existing capacities to produce influenza surveillance data which could be shared with neighbouring countries.

• Using all the factors above, Regional Offices recommended countries in priority order.

In their review of the list, the Advisory Group:

• Noted the work of selection which has been made among the numerous possible recipients by the WHO Regional Offices for this first phase of the implementation plan and acknowledged the need for supporting rationales.

• Noted the importance of providing PC resources to countries that need basic capacities as well as to countries that have existing capacities but where additional support can serve as a regional resource to other countries.

The Advisory Group recommended that implementation of activities under the PC begin in January 2014. They noted that the PIP implementation plan should be considered a “living document” that can be revised over time.

Annual report

14. The Advisory Group adopted its annual report to the Director-General (see Annex 2). It was agreed that future reports will cover the period beginning 1 October and ending 30 September of each year.

Election of the new Chair and Vice-Chair of the Advisory Group

15. After an informal consultation, the Advisory Group reached consensus that Dr William Kwabena Ampofo (Ghana) and Professor Rajae El Aouad (Morocco) would be its new Chair and Vice-Chair, respectively.

Next meeting of the Advisory Group

16. The next meeting of the Advisory Group will take place in Geneva on 9–11 April 2014.