The Global Action Plan for Influenza Vaccines

Report of the tenth meeting of the Advisory Group of the WHO Global Action Plan for Influenza Vaccines

Saô Paulo, Brazil, 19 March 2015
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### Abbreviations and Acronyms

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<th>Full Form</th>
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<tr>
<td>AG</td>
<td>Advisory Group</td>
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<tr>
<td>ASPR</td>
<td>Office of the Assistant Secretary for Preparedness and Response, USA</td>
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<td>BoD</td>
<td>Burden of Disease</td>
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<td>BARDA</td>
<td>Biomedical Advanced Research and Development Authority</td>
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<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<td>ERL</td>
<td>Essential Regulatory Laboratory</td>
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<td>EPI</td>
<td>Expanded Programme on Immunization</td>
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<td>FDA</td>
<td>U.S. Food and Drug Administration</td>
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<td>GAP</td>
<td>Global Action Plan for Influenza Vaccines</td>
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<td>GAVI</td>
<td>Global Alliance for Vaccines and Immunization</td>
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<td>HHS</td>
<td>U.S. Department of Health and Human Services</td>
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<td>IFPMA-IVS</td>
<td>International Federation of Pharmaceutical Manufacturers &amp; Associations-Influenza Vaccine Supply</td>
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<td>IHR</td>
<td>International Health Regulations</td>
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<td>IP</td>
<td>Institut Pasteur</td>
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<td>IVR</td>
<td>WHO’s Initiative for Vaccine Research</td>
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<td>LAIV</td>
<td>Live Attenuated Influenza Vaccines</td>
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<td>NIBSC</td>
<td>National Institute for Biological Standards and Control</td>
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<td>NIH</td>
<td>National Institutes of Health</td>
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<td>NYMC</td>
<td>New York Medical Centre, USA</td>
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<td>PIP</td>
<td>Pandemic Influenza Preparedness Framework</td>
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<td>PIPPC</td>
<td>PIP Framework Partnership Contribution</td>
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<td>RCT</td>
<td>Randomized Control Trial</td>
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<td>R&amp;D</td>
<td>Research and Development</td>
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<td>SAGE</td>
<td>Strategic Advisory Group of Experts on Immunization</td>
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<td>SRID</td>
<td>Single Radial Immunodiffusion</td>
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<td>USA</td>
<td>United States of America</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Executive Summary

The Advisory Group (AG) reviewed progress and challenges based on information presented in the meeting with International Partners. Specific attention was paid to lessons learned from the Ebola epidemic that started in 2014.

The AG expressed concern about the lag in full implementation of the 2012 recommendations for seasonal vaccination and questioned whether the underlying assumption that pandemic preparedness is achievable through increase of seasonal influenza vaccine-uptake should be reconsidered. Evidence is limited on the severity and impact of seasonal influenza in high-risk groups, which contributes to the slow implementation of the policy recommendations.

Significant increases in global pandemic vaccine production capacity were reported from the United States of America (USA) and potentially from Japan through partnering of the USA licensed recombinant influenza vaccine manufacturer with a Japanese company and through the licensing of the first cell-based influenza vaccine production facility in the USA. Production capacity increases in GAP-supported countries have been modest and it is expected that several of the GAP-supported countries/companies will not reach the targets for a variety of reasons. The AG further noted that there is an ongoing consolidation process in the global influenza vaccine industry. It is currently unknown whether this will impact global pandemic production capacity.

A research update was provided which included advanced plans from the USA to stimulate development of more effective influenza vaccines that would lead towards universal influenza vaccines. Although much progress has been made under this objective, doubts were raised on the feasibility of a licensed “truly universal” vaccine. The most likely scenario seems to be incremental improvements. A radical change in thinking was mentioned as one of the potentially necessary actions for the next 10 years.

The Advisory Group recommends that the Secretariat:

- maps the influenza-related activities of the different Partnership Offices (BARDA, CDC, and the Institut Pasteur) with the objective of identifying synergies and areas for cooperation within country/regional implementation of these activities.
- continues to inform the Pandemic Influenza Preparedness (PIP) Framework Advisory Group on: the process to the closure of the GAP; the potential impact on pandemic vaccine production capacity in developing countries; and the areas (if any) for continued support to influenza manufacturers in developing countries.
- considers the main outcomes of the upcoming Ebola meetings in Q1-Q2 2015 to prepare for the 2016 GAP consultation.
- initiates in 2015 a web-based consultation in advance of the 2016 consultation in order to optimize the inclusion of stakeholder advice and interests in the pending closure and any follow-up of GAP.
1. Welcome and objectives

Dr Marie-Paule Kieny welcomed Professor Sylvie van der Werf from the Institut Pasteur, Paris and its International Network as a new GAP Partnership Office from Europe. She iterated that, as the GAP Initiative comes to a close, the Advisory Group must prepare for the GAP consultation in 2016, which will aim to answer the following questions: what were the objectives of the GAP Initiative, where are we now and where do we need to go from here? Another objective will be to review how lessons can be drawn from the current Ebola epidemic in West Africa to build more preparedness for influenza. Dr Kieny indicated that the Advisory Group will have a final face-to-face meeting immediately following the 2016 consultation to draft recommendations on vaccine matters in influenza pandemic preparedness.
2. Update by the Secretariat

The Secretariat provided an update on activities undertaken to achieve the increase of evidence-based seasonal vaccine uptake.

Dr Joachim Hombach indicated that the WHO’s Initiative for Vaccine Research (IVR) is working to understand the disease burden and the impact of vaccination in order to address obstacles to maternal influenza immunization programme implementation.

A WHO working group has recently analysed the risk of severe influenza in pregnancy and associated adverse fetal outcomes. Preliminary results indicate that while there is some evidence for increased risk of preterm birth and fetal death associated with pandemic H1N1 influenza A, the magnitude of it is very unclear. As it looks now, the influenza disease burden data do not seem to be sufficient to inform definite decisions regarding routine immunization of pregnant women in some locations. The preliminary impression is that there are not very solid data on the impact of influenza during pregnancy on the fetus.

IVR is also looking more specifically into methodological issues in a forthcoming WHO meeting on maternal influenza immunization that will discuss new data and implementation. One recent randomized control trial (RCT) in South Africa was designed to see if maternal influenza vaccination could affect fetal outcomes, infant and maternal disease. The study provided evidence of robust vaccine efficacy both in pregnant women and newborns, even in a HIV-positive (HIV+) cohort. Influenza attack rates were very high. However, this study could not demonstrate a beneficial effect on birth outcomes. Data analysis from other similar RCT’s from Mali and Nepal need to be completed before final conclusions can be drawn.

Finally, IVR has set up a group to look at data and parameters for impact modelling which will be of importance for another GAVI vaccine investment case analysis for maternal influenza immunization planned for 2018.

Dr Wenqing Zhang reported progress on burden of disease (BoD) studies, on studying seasonality in tropics and sub-tropics and on laboratory and surveillance capacity building activities. Ongoing studies in 19 countries from 6 regions are expected to yield regional and global estimates of BoD, mortality and economic burden of influenza by the end of 2016. Most (but not all) financial support comes from the PIP Framework Partnership Contribution (PIPPC). A Technical Expert Group on BoD has been established and associated training workshops are being organized.

Further, work has started to better understand which WHO vaccine formulation countries in the tropics and subtropics need to follow. Evidence is being analysed on seasonality, epidemiology as well as virological evolution over a 10 year period. This is expected to lead to “zone-specific”-recommendations on the best formulation to use and on the optimal timing to start seasonal vaccination. In April, an expert group will be convened to review evidence for the development of guidance, to be followed by a meeting in June in India to do pilot-test the draft guidance.

Finally, with respect to laboratory and surveillance capacity building, a lot of progress has been made under PIPPC funding. Surveillance capacities are being strengthened throughout the 6 regions (virus and event detection, sharing, reporting, and rapid response). WHO Regional Offices serve as focal points in these activities. A multitude of indicators have been developed to monitor activities and work has started to determine the optimal size of surveillance. An expert working group has reviewed in detail different surveillance components and corresponding public health objectives in order to develop guidance to countries on minimum and maximum sizes of surveillance.

Ms Claudia Nannei reported on communication training activities and workshops. In the WHO Western Pacific region, a training was held on communication for vaccination using influenza as a
case study. This was attended by country delegations of about 5 persons from different disciplines including health promotion and health care professionals from Cambodia, Republic of Korea, and Vietnam. The main objective was to train in methodologies of building communication systems into health systems to promote vaccination. In similar workshops in the Eastern Mediterranean and South-East Asian regions, training of trainers was also included. Finally, in China a national training was organized for national officials from the Centers for Disease Control and Prevention (CDC) and for managers of the Expanded Programmes on Immunization (EPI) from 6 different provinces. On-line training material is being developed that will be available by the end of 2015. A similar national training on communication is currently being considered by India.

Discussion
Dr John Watson stressed the fact that communication is now a major concern, at least in Europe. Vaccine hesitancy is aggravated this year by the current mismatch of the current dominant H3N2 virus clade that is causing severe disease and matches poorly with the H3N2 vaccine strain. Politicians ask: why are we spending all this money for something that is not working? What should be studied is how attitudes are shaped: what makes it that people want or not want the vaccine; if we don’t know that we cannot have a policy on vaccines. Dr Ziad Memish concurred and added as an illustration that Saudi Arabia had recently procured sufficient influenza vaccines for a campaign to vaccinate persons in Saudi Arabia with focus in areas surrounding the Hajj. People are still hesitant about benefit of influenza vaccine and they do not want to take the vaccine. Possibly a campaign should be designed first to establish in which group it is effective and then give it to that group.

The Secretariat, in response, clarified that while the GAP programme does not address these questions in depth (for vaccine hesitancy in general there is a specific SAGE working group), some attention is paid to communication capacity building in training activities. Further, it is increasingly recognised that vaccine hesitancy needs to be understood better.
3. GAP partnership offices: report on activities

3.1 Institut Pasteur

Professor Sylvie van der Werf gave an overview of the activities of the Institut Pasteur (IP) and its international network including capacity building activities and influenza vaccine projects in Europe.

Of relevance to GAP’s Pillar 1 is that the network includes 14 National Influenza Centres (NICs) and two H5 reference laboratories (Paris and the Institut Pasteur Cambodia), that are all members of WHO’s Global Influenza Surveillance and Response System (GISRS). The Institut Pasteur network is also strengthening core capacities in support of the IHR(2005) through an HHS/ASPR-supported project (InPRIS) to reinforce pandemic influenza preparedness and response. Another IP project, studies factors associated with severity of influenza virus in Cameroon, Madagascar and Cambodia. Within this project, a multicentre biobank of samples from influenza infected patients is set up and the genetic susceptibility to influenza infections is being studied.

As regards Pillar 3, Institut Pasteur is also working in vaccine development through different viral vector systems that may be used for future influenza vaccines, including a “Schwartz-measles based” vector system for the expression of various antigens.

Lastly, an overview was provided of ongoing influenza (vaccine) projects in Europe, several of which are on universal influenza vaccine. It also includes a recently started public private partnership with industry funded by the European Innovative Medicine Initiative (IMI) on standardization and development of assays of influenza vaccines correlates of protection (FLUCOP).

3.2 CDC

Dr Julie Villanueva, presented CDC activities in support of GAP objectives. CDC is building capacity for influenza prevention and control through several approaches: a) bilateral grants to Ministries’ of Health in over 40 countries; b) cooperative agreements to WHO Headquarters and each of the 6 WHO Regional Offices; and c) through research cooperative agreements and placements of about 20 staff overseas.

Studies are being done in many countries to develop the evidence base for seasonal influenza vaccination. Data gaps are being addressed to aid policy making on disease burden, risk factors, transmission, incidence data, seasonality, vaccine effectiveness and efficacy, vaccine programme optimization, antiviral effectiveness, non-pharmaceutical interventions and economic burden and cost effectiveness of vaccination.

With funding from the Bill and Melinda Gates Foundation several randomized control studies on vaccine performance have been executed: one in Senegal is looking at safety and immunogenicity of adjuvanted inactivated influenza vaccines and two others are taking place in India. Observational studies on vaccine effectiveness are taking place in 10 countries in Central and South America and a maternal vaccine immunization effectiveness study is pending in South Africa.

Finally, the Partnership for Influenza Vaccine Introduction Project (PIVI) that started with a deployment of 375 000 doses to Lao People’s Democratic Republic in 2012 has now expanded to about 980 000 doses to four countries in 2014 (Lao People’s Democratic Republic, Nicaragua, Morocco, Armenia). While an increasing number of countries are expressing interest in the programme and the number of partners who donate (vaccines, syringes, supplies, etc.) has increased, the programme still faces challenges: the contributions are unpredictable and vaccine supply can be limited. Optimal timing is a challenge as expired products cannot be used.
Dr Rick Bright presented BARDA's work, which falls under GAP objectives 2 and 3.

In addition to BARDA’s presentation in the preceding Partner’s meeting on the USA Government “more and better, sooner” pandemic influenza vaccine strategy, he highlighted the following advances.

Under Pillar 2 (production capacity increase), expansions were realized in the USA by licensing the cell-based Novartis facilities (200 million doses capacity increase) and by supporting the 50 million dose increase of Protein Sciences’ recombinant vaccine capacity in Pearl River, New York. Further, transfer was initiated from Novartis to Sanofi-Pasteur of MF59 adjuvant production technology. Sanofi establish a facility in the USA to make MF59, which will allow a further expansion of the number of available doses in a pandemic. Finally, one (of the three planned) centre to provide surge capacity in the USA within 4 months after the onset of a pandemic, has come on-line with a targeted 50 million dose excess capacity.

As regards Pillar 3 (research and development), BARDA is funding an initiative to improve influenza vaccine manufacturing (IVMI). Partners involved are HHS, CDC, FDA, NIH, NIBSC, NYMC and multiple global vaccine manufacturers. One goal is to develop high growth reassortants to increase the yields of influenza vaccines. Four lead candidates have been identified. Next year, scaling up will take place. These reassortants will be available to all manufacturers. BARDA is further supporting assay development of alternatives to the SRID potency test. An international collaborative screening evaluation study has started with participation of HHS, BARDA, NIBSC, CDC, NIH, FDA and IFPMA to compare various alternative in-vitro potency assays.

Discussion
The AG welcomed these presentations and suggested that it would be very helpful to have a systematic oversight of all these activities in one unified document. This would provide a worldwide view of what is going on and would help to to see how much synergy over addition can be achieved. This would avoid redundancy and therefore reduce costs.

Dr John Watson observed that there may be more institutions with an international footprint in influenza, for example the Wellcome Trust which has several centres in different regions of the world.
4. Lessons from Ebola for influenza pandemic preparedness

The Secretariat provided an overview of forthcoming events on the Ebola epidemic in West Africa, which may yield lessons for influenza pandemic preparedness.

The Executive Board resolution on Ebola in January 2015 called for continued work on research and development on health technologies for emerging and neglected tropical diseases. Building on this resolution, a WHO Ebola R&D Summit will be organized prior to the World Health Assembly on 11-12 May 2015. The overall objective will be to initiate the development of a blueprint for R&D preparedness in the context of global public health threats. Overviews will be made of pipelines of drugs and vaccines that target diseases with epidemic and pandemic potential. This will start with viral haemorrhagic fevers, but could be extended to respiratory diseases, including influenza.

Under WHO’s Global R&D Observatory, a special section will be created on vaccines, drugs, blood products, monoclonal antibodies and diagnostics.

Further, technical consultations are forthcoming on sample-sharing and on data-sharing. The sample-sharing consultation (immediately following the R&D summit of 11-12 May) will address the possibility of establishing a biobank in Senegal through the WHO Regional Office for Africa (AFRO). This is a desire expressed by the Ebola affected countries. Samples were not shared or if they were, it was in a random manner. The consultation on data-sharing will be planned in September and will include lessons learned from MERS, SARS and Ebola. Although data belong to countries according to International Health Regulations, there is an international risk of withholding data; for example during Ebola a diverging pattern of infections in health care workers in the 3 affected countries went unrecognized because data were not shared in time. An emerging lesson from the Ebola crisis seems to be that rapid, systematic and timely data-sharing was very weak. The challenge now is how to address this, especially during a Public Health Emergency of International Concern (PHEIC). Some ideas were discussed and the group agreed that in all cases, scientific journals will need to be brought into the discussions.

Discussion
Since various issues, challenges and potential collaborative solutions or mechanisms for Ebola will be of great value to influenza preparedness, the AG requested that the Secretariat take the main outcomes of these Ebola meetings on board in the preparation of the 2016 GAP consultation.
5. Interactions of PIP and GAP

Ms Anne Huvos gave a brief update on the implementation of PIP Partnership Contribution (PIPPC) and the Nagoya protocol. For the most part, relevant manufacturers are making their financial contributions. Most work in 2014 focused on establishing processes and procedures such as a financial systems for accountability. A web portal was created which shows the different areas of work and the countries where the work is done. The PIP Advisory Group will meet in Geneva 14-17 April 2015. It was re-iterated that the PIP Framework is a text adopted by a resolution of the WHA and that synergies are being built with IHR and GAP. One example of synergy is that the work under GAP on regulatory strengthening is financed through the PIPPC. Whether other elements from GAP should be brought in, needs to be decided by WHO in consultation with partners.

Discussion
GAP was created in response to the pandemic threat alongside with the PIP Framework and has contributed to benefit sharing by achieving a more equitable distribution of influenza vaccine manufacturing capacity in developing countries. PIP and GAP are complementary instruments which aim to increase global pandemic preparedness.

In the context of a pandemic, a key benefit will be access to vaccines. The impact of the end of GAP support to manufacturers in developing countries after 2016, should be anticipated.

The AG recommends therefore to inform the PIP AG on the current status of the GAP, its pending ending and any potential implications with a view to the upcoming 2016 Review of the PIP Framework.
6. Preparing the 2016 GAP consultation

The Secretariat introduced a concept note on preparing the 2016 GAP consultation, with a request for comments from the AG to allow the Secretariat to start the development of a roadmap and the commissioning of several background papers.

Several suggestions for continuation of GAP work, post-2016, were reviewed as follows:

On Objective 1 (increase of evidence-based seasonal vaccine uptake), much work has been done, but the implementation costs remain high and vaccine effectiveness is not very good. Global implementation of the 2012 recommendation for pregnant women is behind schedule, vaccine hesitancy is an increasing challenge, and BoD studies have so far failed to reverse this picture. While monitoring has to go on, it is clear that this objective shall not be reached by 2016. Other mechanisms for monitoring (evidence collection) may need to be considered, focusing less on pathogen monitoring, but more on severe disease monitoring by sentinel surveillance and impact measurement, for example through vaccine probe studies 1.

On Objective 2 (increase pandemic production capacity) there is agreement that, while global production capacity has significantly increased, it still falls short of needs in case of a pandemic, in particular if 2 doses would be needed to confer protection. GAP has contributed to a more equitable distribution of global pandemic production capacity and continuous support to at least some of these manufacturers should continue, but there is consensus that with the existing technologies we are not near to the targets as originally set. Experience over the past 10 years has confirmed that the challenges of establishing and maintaining a sustainable vaccine manufacturing facility in different regions are huge and require more than technical know-how, notably coherence in national policies on health, industrial development and science and technology.

On Objective 3 (R&D), the programme has seen considerable advances over the last 10 years - new vaccines and vaccine concepts have been developed and brought to market - but despite this, the world is still far from being protected against a pandemic threat with the current arsenal of available vaccines.

The 2016 consultation could serve as a moment to recognize that a new approach is needed. How can all stakeholders, partners and actors work together more effectively? What roads should be followed for the next (post-GAP) 10 years? New approaches might be explored, for example by creating a more enabling environment that allows novel and innovative approaches on new vaccines or entirely new vaccine concepts.

Through GAP, several developing countries have become players. How can these countries be sustained and what could they provide to other developing countries that are non-producing and have no intentions to produce? Should other stakeholders be involved to help address these issues, for instance, trade organizations, such as the World Trade Organization (WTO) or the Association of Southeast Asian Nations (ASEAN), or institutional development agencies like the World Bank or the United Nations Industrial Development Organization (UNIDO) for infrastructure development?

1 A standard vaccine efficacy trial measures disease to learn efficacy trial measures disease to learn about the vaccine efficacy; a vaccine probe study uses a vaccine of known efficacy to estimate disease incidence. A probe study determines vaccine-prevented incidence which is a pragmatic direct measure of the effect of the vaccine in the local setting, without concern for variable and often insensitive microbiological estimates.
**Discussion**

The Advisory Group made the following observations and suggestions.

The overall impression is that the current situation and strategy to improve pandemic preparedness through increasing evidence-based seasonal vaccination is not leading to the desired results.

Since a consultation is meant to collect input for further work, the Advisory Group proposes to include a re-assessment of the original objectives and assumptions as they were formulated in 2006. For example, the original target was to provide every person in the world with 2 doses of vaccine. Is this, in light of current knowledge and the experience gained, still an appropriate objective? Should more specific or more targeted objectives be made? A possible conclusion is that the goal of immunizing the entire world either 70% or 100% with 2 doses is unattainable. If so, what different scenarios could be developed? Another example is whether the underlying assumption of seasonal vaccination being the necessary pre-requisite for pandemic preparedness still holds in light of the current experiences. Finally, questions could be included on how to manage the deployment of vaccines in a pandemic. What GAP components need to be kept operational to maintain and consolidate results achieved?

One suggestion was to do a web-based open consultation among a wide range of stakeholders through a questionnaire that includes these and other questions. The feedback would then be summarized as input for the 2016 consultation with appropriate representation of all stakeholders.

The AG commented that as regards the burden of disease activities, the collection of evidence and the promotion of capacity building should focus more on severe disease surveillance and impact monitoring rather than pathogen/virus surveillance. Since it has proven challenging to show the public health impact of influenza by conventional studies, other ways such as vaccine probe studies and sentinel surveillance could be prioritized more through guidance documents from WHO.
7. Summary of Advisory Group recommendations

The Advisory Group recommends that the Secretariat:

- maps the influenza-related activities of the different Partnership Offices (BARDA, CDC, and the Institut Pasteur) with the objective of identifying synergies and areas for cooperation within country/regional implementation of these activities.

- continues to inform the PIP Advisory Group on: the process to the closure of the GAP; the potential impact on pandemic vaccine production capacity in developing countries; and the areas (if any) for continued support to influenza manufacturers in developing countries.

- considers the main outcomes of the upcoming Ebola meetings in Q1-Q2 2015 to prepare for the 2016 GAP consultation.

- initiates in 2015 a web-based consultation in advance of the 2016 consultation in order to optimize the inclusion of stakeholder advice and interests in the pending closure and any follow-up of GAP.
8. List of Participants

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