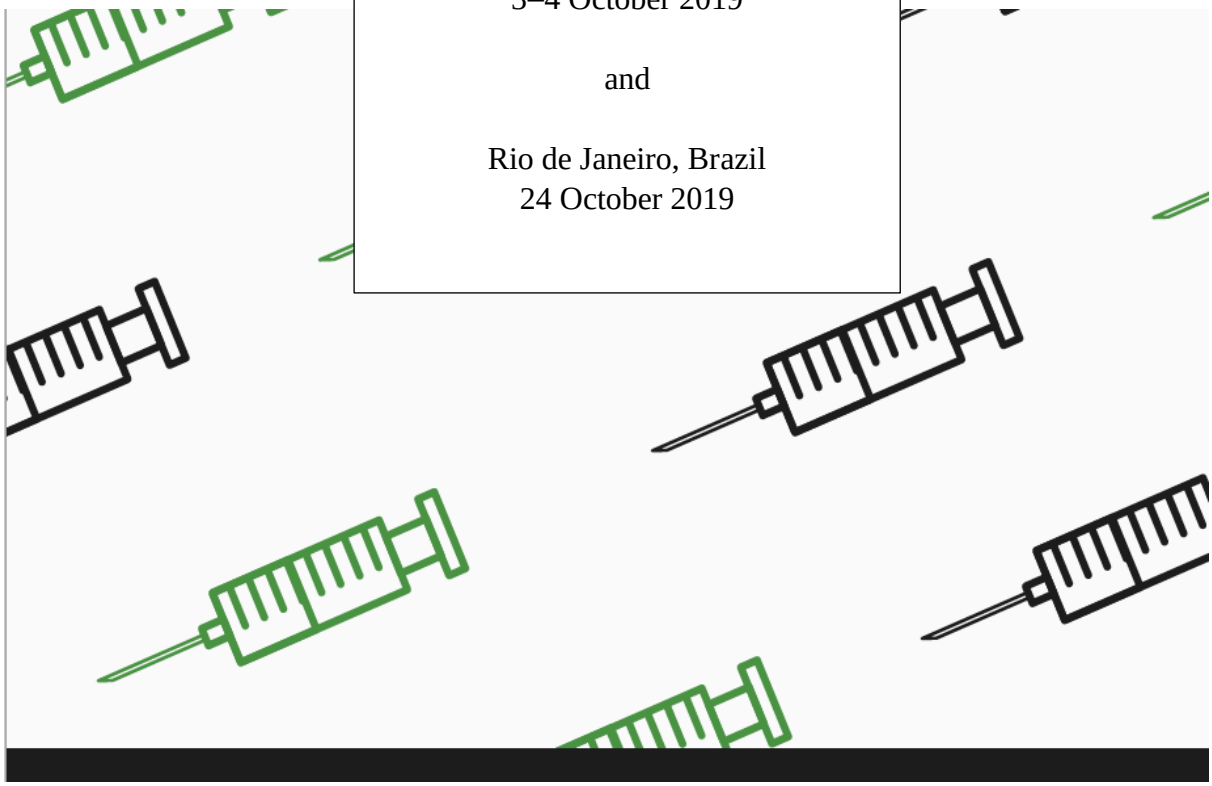
World Health Organization

REPORT OF THE MEETING WITH INDUSTRY TO DISCUSS COMMON ACTIVITIES FOR DEPLOYMENT OF PANDEMIC INFLUENZA RESPONSE PRODUCTS

Geneva, Switzerland
3–4 October 2019

and

Rio de Janeiro, Brazil
24 October 2019



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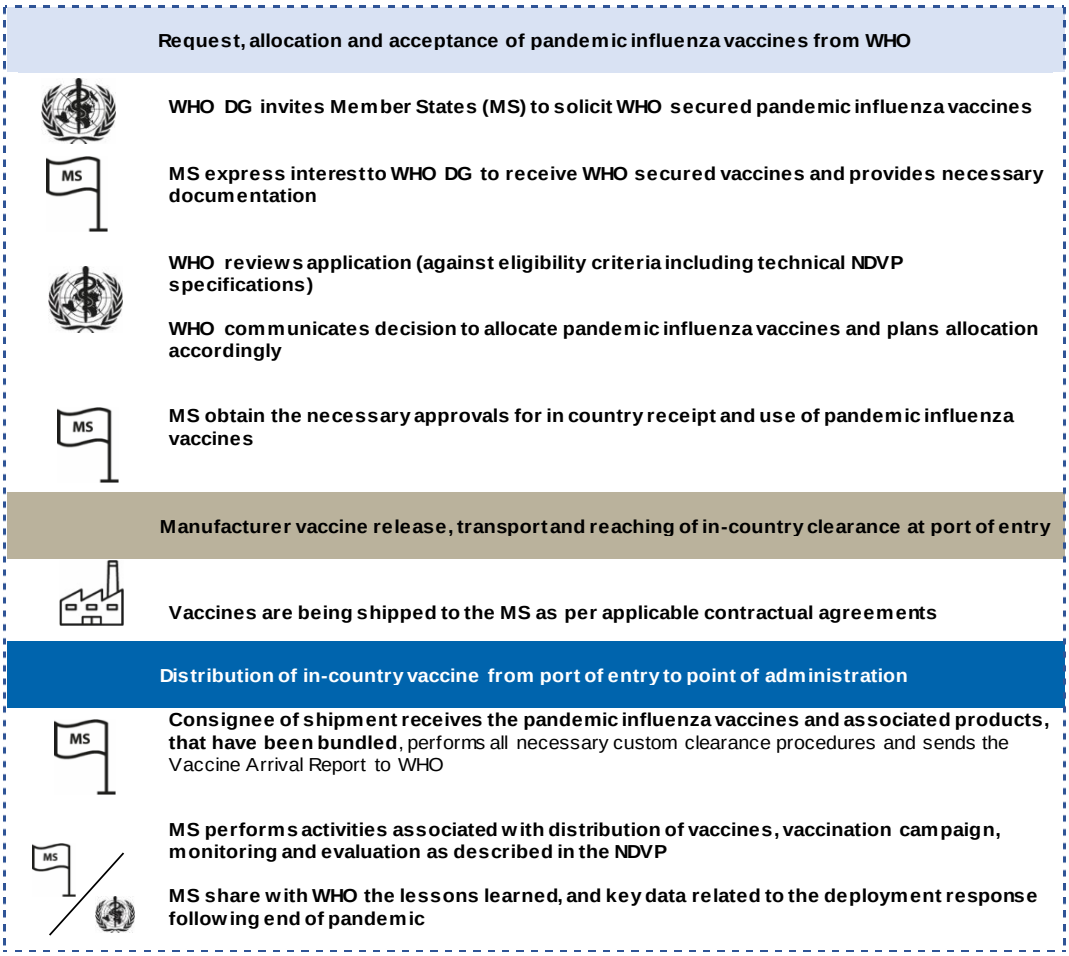
Executive summary

Preparedness and readiness for responding to a global pandemic influenza requires the engagement of many stakeholders. To ensure the effective and efficient allocation and deployment of pandemic influenza products to the populations most in need, manufacturers of such products play a critical role in the entire supply chain. Under the auspices of the Pandemic Influenza Preparedness Framework, the World Health Organization (WHO) organized two consultations with relevant industry representatives. The meetings provided an opportunity to exchange information on existing preparedness activities, to review challenges for pandemic vaccine production and deployment pathways and to identify areas where WHO and industry partners need to work together, including in the planning of future simulation exercises involving industry.



During the pandemic the main processes associated with the access, allocation and deployment of pandemic influenza vaccines are divided into three main categories (see also figure above):

Category 1) **Request, allocation and acceptance** of pandemic influenza vaccines from WHO;

Category 2) **Manufacturer vaccine release, transport and reaching of in-country clearance at port of entry**; and

Category 3) **Distribution of in-country vaccine** from port of entry to point of administration.

During the meetings, participants reviewed the three main categories, discusses and agreed on a list of actions to address gaps and improving these processes.

The key areas of activity resulting from these initial discussions are summarized below:

- Share, review and support the WHO Operational Framework for Access, Allocation and Deployment of Pandemic Influenza Vaccine.
- Engage in table-top simulation exercises relating to specific technical domains.
- Map countries' regulatory status and existing pathways that could be applicable to pandemic vaccine use.
- Sensitize various manufacturers regarding the prequalification process – including clarifications on prequalification fast-track processes and the languages that should be present on labels and package inserts.
- Collect data relevant to logistics to support WHO with planning activities in this area.
- Clarify how SMTA2 Standard Material Transfer Agreements would come into effect in the event of a pandemic being declared.

Highlighting the importance of global partnerships for effective pandemic influenza vaccine deployment

The workshop highlighted the complexity of pandemic influenza deployment operations and the importance of collective work involving industry partners, including vaccine and antiviral manufacturers as well as freight forwarders, under the auspices of the Pandemic Influenza Preparedness (PIP) Framework adopted by WHO Member States in 2011.

Challenges observed in the 2009 pandemic influenza vaccine deployment response were stressed, including the fact that vaccine access and availability was considered "too little and too late" for low-resource countries. A key achievement of the PIP Framework has been the signing of 13 Standard Material Transfer Agreements 2 (SMTA2), which are legally binding contracts between WHO and influenza vaccine manufacturers, to secure approximately 10% of their future real-time pandemic vaccine production for the next pandemic. This, together with mechanisms to assist the allocation of vaccines, will ensure wider access and more equitable distribution of pandemic vaccines to countries in need. The need for closer collaboration between pandemic influenza responders was emphasized as one of the critical elements for a robust and efficient global pandemic response.

The meeting on 3–4 October 2019 in Geneva, Switzerland, brought together several stakeholders: 1) industry – represented by seven companies which are part of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA); 2) representatives of the IFPMA Secretariat and of BIO; 3) representatives of two freight forwarding companies; and 4) WHO staff from different units across the Organization, notably Influenza Preparedness and Response, Global Influenza Programme, Pandemic Influenza Preparedness Framework, Support for Response, Regulatory Systems Strengthening, Prequalification, and Operations and Support for Logistics.[1]

A smaller-scale meeting took place with participants from four vaccine manufacturers that are members of the Developing Countries Vaccine Manufacturers Network (DCVMN) on 24 October 2019 in Rio de Janeiro, Brazil. WHO provided an overview of the main conclusions of the meeting held in Geneva. The participants offered positive feedback on the areas of work identified and expressed willingness to be engaged in future meetings on the subject.

Setting the scene: 10 years after the H1N1 pandemic, where are we now?

This session was divided into two parts, with presentations from both WHO and manufacturers. Both presentations highlighted the achievements in strengthening pandemic preparedness capacities since the last (2009) H1N1 influenza pandemic, and stressed ways to foster global collaboration towards a more effective deployment process.

WHO underlined that pandemic influenza is one of the 10 main threats to global health, and introduced participants to the *Global Influenza Strategy 2019–2030*. The strategy has two main outcomes: 1) better global tools through coordination of research and innovation, and 2) stronger country capacities. The presentation also introduced the guidance and tools available to support countries in strengthening their pandemic preparedness and highlighted achievements from the deployment and regulatory outputs of the PIP Framework. Areas of

[1] See Annex 3 for the list of participants.

additional work to improve the pandemic response were identified, including: 1) early detection of the pandemic; 2) timely sharing of the pandemic virus strain for vaccine production; 3) candidate vaccine virus (CVV) development; and 4) regulatory readiness.

Industry stressed the need for stronger collaboration with WHO and the importance of well-established systems for seasonal vaccination to increase the capacity and efficiency for pandemic influenza vaccine production. The imbalance between supply and demand for seasonal and pandemic influenza production capacity was highlighted. One method of increasing production capacity for pandemic influenza vaccine is to foster demand for sustainable seasonal influenza programmes.

Manufacturers stated that there is a critical need for clearly defined triggers and communication to support manufacturers' decisions regarding the switch from seasonal to pandemic vaccine production; this is because the switch to pandemic vaccine production will have an impact on seasonal vaccine commitments to countries. Industry signaled a potential concern that the Nagoya Protocol may result in delayed access to seasonal viruses.

WHO and the industry discussed the importance of conducting simulation exercises (SimEX) to test the different aspects of a pandemic response. Additionally, it was highlighted that countries should be prepared to detect and assess Adverse Events Following Immunization (AEFI).

The point was raised that although the focus of this meeting was on the deployment of vaccine in a pandemic, strong mechanisms and close collaboration regarding antivirals and diagnostics are also needed.

Overview of WHO's operational framework for deployment of pandemic influenza vaccines

Participants were introduced to a draft operational framework for access, allocation and deployment of pandemic vaccines, which was based on the lessons learned from the 2009 WHO deployment initiative.[2] The framework, which will be shared with industry partners for comments and feedback, aims to establish a common understanding of roles, responsibilities and standard operating procedures for all the stakeholders involved in the pandemic vaccine allocation and deployment cascade.