



**Vaccination is an integral component of many countries' pandemic preparedness plans. A number of recent studies suggest seasonal immunization can provide an important foundation for pandemic vaccination capabilities, while also helping protect against annual epidemics.**

### Executive Summary

- **Pandemic vaccines rely on seasonal vaccination.** Seasonal and pandemic vaccines are produced in the same specialist plants. These cannot simply be 'switched on' during a pandemic, and therefore demand for seasonal vaccines can provide the long-term sustainability they require.
- **Seasonal demand drives pandemic capacity.** Seasonal vaccine provision has grown in recent years. However, this continues to fall behind manufacturing capacity, which may increase further to 1.8 billion doses per year by 2015. This could result in a pandemic capacity of up to 17.7 billion doses (in one year), but also a potentially unsustainable excess seasonal capability. Therefore, increased seasonal demand could help sustain capacity and reduce the ongoing burden of influenza.
- **Seasonal demand supports technology transfer.** The research-based vaccine industry is supporting production initiatives in a number of countries (Brazil, China, Mexico, India, Indonesia and Thailand), and many of these have achieved notable growth in vaccine provision in recent years.
- **Seasonal vaccination can support pandemic infrastructure.** A WHO Review Committee found seasonal programs can provide vaccine deployment experience and assist pandemic preparations.
- **Regulatory co-operation can accelerate pandemic vaccine supply.** International regulatory co-operation and mutual recognition of required approvals could speed up pandemic vaccine deployment.
- **Robust influenza surveillance boosts seasonal and pandemic preparedness.** The WHO global system was commended for its rapid identification of the 2009 (H1N1) pandemic virus. However, surveillance and laboratory capacity is still low in many countries and could be strengthened.

# 5

## Improving Pandemic Preparedness

### Seasonal Influenza Vaccination Series: Paper 5



**IFPMA**

**Influenza Vaccine Supply  
International Task Force**

Pandemic influenza poses an ongoing threat to global public health, and as a result many countries have developed pandemic preparedness plans. Many of these plans include vaccines as an integral component<sup>1</sup>. However, the immunization of large numbers of people within a short period of time is highly challenging, and requires robust vaccine production, logistics and administration capabilities. Seasonal influenza vaccination can provide an important foundation for this capacity while also helping reduce the burden of annual epidemics.

### **Pandemic vaccines rely on seasonal vaccination**

Pandemic and seasonal influenza vaccines are inextricably linked as they share the same technology platforms and are produced in the same manufacturing facilities<sup>2,3</sup>. Production of these vaccines is complex and requires a highly-trained and experienced workforce, and it is not possible to simply 'switch on' manufacturing plants during a pandemic<sup>3</sup>. Rather, regular demand for seasonal influenza vaccines can provide the long-term sustainability manufacturing facilities and their workforces require<sup>3</sup>.

### **Seasonal demand drives pandemic vaccine production capacity**

The World Health Assembly (WHA) noted in 2003 'that better use of vaccines for seasonal epidemics will help to ensure that manufacturing capacity meets demand in a future pandemic'. In recent years, a growing number of health authorities have included seasonal vaccines in their national immunization schedules, global production capacity has increased and vaccine provision has grown substantially<sup>5,6,7,8</sup>. World Health Organization (WHO) technical studies suggest seasonal production capacity could grow further, from 876 million doses per year to approximately 1.8 billion by 2015<sup>2</sup>. In a 'high case' scenario this expansion could result in a pandemic vaccine production capacity of approximately 17.7 billion doses in one year<sup>2</sup>.

However, despite the growth in vaccine usage, it remains substantially below the level of existing manufacturing capacity, and coverage is low in many countries (a recent study of 157 nations found more than two-thirds distributed insufficient doses for 10% of their populations and over one-third distributed too few doses for 1% of inhabitants)<sup>9</sup>. This imbalance may become unsustainable if demand continues to fall behind capacity growth. The WHO studies found the

potential increase in seasonal capacity could result in an excess of 560–900 million doses above current demand, which could hinder expansion plans or impact existing capabilities<sup>2</sup>. This situation presents policy makers with an opportunity: increasing seasonal vaccine uptake can help to protect against annual epidemics while also sustaining pandemic production capacity<sup>8</sup>.

### **Seasonal demand supports local vaccine production and technology transfer**

Robust demand for seasonal influenza vaccines is an important factor in sustaining manufacturing capacity, and supporting technology transfer and local production<sup>3,8</sup>. The research-based vaccine industry is undertaking these initiatives in a number of countries, including Brazil, China, Mexico and Indonesia (and providing technology via WHO to China, India and Thailand), and a recent study found many of these achieved notable growth in seasonal vaccine provision over a number of years<sup>3,8,9</sup>.

### **Seasonal vaccination can support pandemic infrastructure**

Undertaking wide-scale immunization during a pandemic is highly challenging, and experience from the 2009 (H1N1) outbreak shows the necessary vaccine logistics and administration capabilities are not universally available<sup>2,10</sup>. A WHO Review Committee found strengthening healthcare delivery systems can advance preparedness, and seasonal vaccination of high risk groups can 'increase experience with local production, distribution and delivery and encourage more global capacity for vaccine production'<sup>10</sup>. The Committee also found experience with comprehensive seasonal programs 'provides valuable preparation in advance of a major pandemic'<sup>10</sup>.

### **Efficient regulatory systems can assist rapid pandemic vaccine deployment**

Influenza vaccine production is complex, and requires a robust regulatory and quality environment<sup>3</sup>. However, a WHO report identifies several regulatory obstacles to pandemic vaccine deployment, such as the limited or lack of recognition of national approvals by other countries or harmonization of manufacturing data requirements<sup>2</sup>. Experience gained during the 2009 (H1N1) pandemic shows enhanced international regulatory co-operation could help accelerate vaccine supply, while continuing to ensure robust safety standards<sup>7</sup>.

### Robust global surveillance boosts seasonal and pandemic preparedness

The WHO Global Influenza Surveillance and Response System monitors the evolution of influenza viruses, provides recommendations for vaccines and acts as an alert mechanism for potential pandemics<sup>11</sup>. In 2003, the WHA recognized the importance of strengthening local surveillance and laboratory capabilities to increase preparedness for both seasonal epidemics and future pandemics<sup>4</sup>. Although the global system was commended for its timely identification of the 2009 (H1N1) pandemic virus, a recent report suggests further local progress is needed as laboratory and surveillance capacity is low in many countries<sup>2,10</sup>.

### Conclusions

**Pandemic influenza poses an ongoing threat to global public health, and many countries include vaccination in their preparedness plans. However, immunizing large populations during a pandemic is highly challenging and requires robust vaccine production, distribution and administration capabilities. Seasonal vaccination can provide an important foundation for this infrastructure, while also helping protect against annual epidemics. Seasonal and pandemic vaccines are intrinsically linked, and as production plants cannot simply be 'switched on' during a pandemic, ongoing seasonal demand is an important factor in sustaining manufacturing capacity (and technology transfer). Seasonal vaccination can also increase vaccine deployment experience and provide valuable pandemic preparation. However, seasonal vaccine uptake is low in many countries, and remains substantially below manufacturing capacity. With capacity expected to grow further this imbalance may become unsustainable. Therefore, policy makers have an opportunity to boost pandemic capacity, and help reduce the burden of annual epidemics, by increasing the use of seasonal vaccines.**

### References

- <sup>1</sup> WHO. Comparative analysis of national pandemic influenza preparedness plans. January 2011.
- <sup>2</sup> WHO. Technical studies under resolution WHA63.1. Final document. A/PIP/OEWG/3/2, 4 April 2011.
- <sup>3</sup> IFPMA. Influenza vaccine manufacturers transfer production technology around the world. May 2009. Hyperlink accessed December 2011.
- <sup>4</sup> World Health Assembly. Resolution of the World Health Assembly. Prevention and control of influenza pandemics and annual epidemics. WHA 56.19, 28 May 2003.
- <sup>5</sup> Duclos P. Seasonal influenza vaccination: plan to update the WHO position paper. WHO SAGE meeting April 2010. Hyperlink accessed November 2011.
- <sup>6</sup> Miller E. Report from the SAGE Working Group on Influenza Vaccines and Immunizations. WHO SAGE meeting November 2010. Hyperlink accessed November 2011.
- <sup>7</sup> Abelin A, Colegate T, Gardner S et al. Lessons from pandemic influenza A(H1N1): The research-based vaccine industry's perspective. *Vaccine* 2011;29:1135-38.
- <sup>8</sup> Palache A. Seasonal influenza vaccine provision in 157 countries (2004 to 2009) and the potential influence of national public health policies. *Vaccine* 2011;29(51):9459-9466.
- <sup>9</sup> Rudenko L, van den Bosch H, Kiseleva I et al. Live attenuated pandemic influenza vaccine: Clinical studies on A/17/California/2009/38(H1N1) and licensing of the Russian-developed technology to WHO for pandemic influenza preparedness in developing countries. *Vaccine* 2011;29S:A40-A44.
- <sup>10</sup> WHO. Implementation of the International Health Regulations (2005). Report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009. A64/10, 5 May 2011.
- <sup>11</sup> WHO. Global Influenza Surveillance and Response System (GISRS). Hyperlink accessed December 2011.

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**About the IFPMA**

IFPMA represents the research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry's 1.3 million employees research, develop and provide medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.

IFPMA manages global initiatives including: IFPMA Developing World Health Partnerships Directory studies and identifies trends for the research-based pharmaceutical industry's long-term partnership programs to improve health in developing countries, IFPMA Code of Practice sets standards for ethical promotion of medicines, IFPMA Clinical Trials Portal helps patients and health professionals find out about on-going clinical trials and trial results.

**About the Influenza Vaccine Supply (IVS) Task Force**

The IVS Task Force includes 16 vaccine manufacturing companies that are involved in research, development and production of influenza vaccines, representing more than 95% of world production. The IVS member companies are, Abbott, Adimmune Corporation, Baxter, Biken, CSL Limited, Crucell, Denka Seiken, GlaxoSmithKline Biologicals, Green Cross Corporation, Hualan Biologicals, Kaketsuken, Kitasato Institute, MedImmune, Novartis Vaccines & Diagnostics, Sanofi Pasteur, Sanofi Pasteur MSD, and Sinovac.



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