

# *Opening Remarks by*

*Dr Samlee Plianbangchang  
Regional Director, WHO South-East Asia*

*At the*

## *Informal Meeting on Regional Production of Pandemic Influenza Vaccine*

*29-30 October 2009  
WHO/SEARO, New Delhi*

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Prof. N.K. Ganguly, Prof. R.R. Chaudhury, distinguished advisers and partners, ladies and gentlemen,

It is my pleasure to welcome you to this meeting. This is an informal meeting to talk about pandemic influenza vaccine production in the WHO South-East Asia Region. As you know, the current pandemic A(H1N1) 2009 was announced on 11 June 2009.

So far more than 400 000 cases and, at least 4700 deaths, have been attributed to the new pandemic influenza virus worldwide. These figures are conservative estimates. In the South-East Asia Region, India and Thailand report the highest number of cases. The Region has recorded 43 000 cases and more than 600 deaths to date. The pandemic A(H1N1) 2009 virus has never before circulated among humans on a large scale. Most people, therefore, have little or no immunity to the infection.

The pandemic virus is highly contagious. However, the severity of the disease ranges from very mild symptoms to severe illness and death. More than half of all hospitalized people already had underlying health conditions or weak immune systems. One of the

strategies likely to be effective in combating the pandemic is the use of safe and efficacious vaccines in vulnerable populations. Existing seasonal influenza vaccines are not effective against the pandemic strain. And there is, therefore, a need to develop and produce a new vaccine that is both safe and effective for pandemic influenza.

While the Region awaits production of an adequate quantity of the pandemic influenza vaccine, Member States need to rely upon other public health interventions such as:

- an efficient mechanism for coordination;
- effective surveillance and monitoring of acute respiratory illnesses in community and at health facilities;
- to implement relevant non-pharmaceutical measures; and,
- the judicious use of antiviral agents to control the severe disease.

The vaccination as a countermeasure in cases such as this raises issues of “access” and “equity”; as the bulk of global production is within Europe and North America.

As said, this meeting is about regional production of pandemic influenza vaccine: how to expedite the process of production, licensing and distribution. While we are striving for maximum “cost-effectiveness” and “safety”, we have also learnt from past experience that:

- influenza pandemics have a tendency to attack populations in periodic waves;
- and,

- the second or third waves may cause more severe morbidity and mortality than the first.

We are approaching the time when we would expect to see a second wave. Some countries have already licensed the vaccine for use, and the United Kingdom commenced vaccinating its people from the third week of October. There is, therefore, the need to accelerate the process while keeping an eye on the safety issue. Member States in the SEA Region have large populations living under difficult socioeconomic conditions; which make them vulnerable to the effects of the pandemic. Vaccines for the SEA Region need to be produced in large quantities.

This meeting needs to discuss the capacity of the Region to produce the required amount of vaccine within certain timeframes. We are fortunate, however, that three Member States, India, Indonesia and Thailand, are capable of producing the vaccine. It is also encouraging to note that a fourth country, Bangladesh, has expressed a keen interest in producing the vaccine.

During the Sixty-second World Health Assembly in May 2009, one of the main issues discussed was pandemic influenza H1N1 preparedness and access to the vaccine. During the Health Assembly, the Health Ministers of this Region also committed to foster collaboration in pandemic influenza vaccine production within the Region. The issue of pandemic influenza vaccine was also raised at the Regional H1N1 consultation held in July 2009 in Bangkok, Thailand.

We are pleased to have with us today representatives from:

- vaccine-manufacturing companies;
- ministries of health; and,
- national regulatory authorities.

The vaccine production chain includes a number of steps. The average lead time for new vaccine production is about five months. Once the vaccine is made available, national regulatory authorities (NRAs) need to ensure its safety. The NRAs are responsible for examining the “risks” and “benefits” of any vaccine before granting its “license”. The results of clinical trials have to show the evidence that the vaccine is “safe”. NRAs may need to put in place the processes that can help accelerate the approval while ensuring that “quality” and “safety” are not compromised. When the vaccine has received approval from the NRA, the government of that country needs to implement their distribution plan.

Countries, therefore, need to have a “vaccine prioritization” and “deployment strategy” in place well in advance. The Strategic Advisory Group of Experts on Immunization or SAGE was established in 1999 as the principal advisory group to WHO for “vaccines” and “immunization”. SAGE noted that countries should employ a strategy that:

- reflects their epidemiological situation,
- takes into consideration the need to ensure access to the vaccine by those at risk; and the ability to deploy the vaccine alongside “non-vaccine measures”.

WHO recommends that health-care workers who are most vulnerable should be vaccinated first to protect the overall health-care infrastructure. Countries, therefore, need a

deployment strategy which should include “post-marketing surveillance” to detect any “adverse events” following immunization.

A regional workshop on vaccine deployment was held in SEARO in September 2009 with representatives from the countries. The workshop highlighted the need for countries to:

- develop pandemic influenza vaccine deployment plans;
- train the required workforce; and,
- explore the legal requirements for licensing the vaccine prior to deployment.

Ladies and gentlemen,

We have the presence at this meeting of:

- key persons who can inform us about the vaccine production capacity within the Region,
- persons from NRAs who can advise us on the processes that the countries need to follow; and,
- persons from ministries of health who will be involved in the prioritization and deployment of the vaccine.

We also have with us experts whose advice and technical inputs will be invaluable.

At the end of this meeting we should have a clear understanding of:

- the regional vaccine production capacity; and
- the regulatory processes involved.

We will share the information during this meeting with all Member States in order to help them plan their procurement, prioritization and distribution strategies. Furthermore, the SEA Region needs a considerable amount of vaccine for its large population. Combined efforts between the governments and the private sector are critical, indeed. I hope the meeting will also mull the issue of strengthening public-private partnerships in vaccine production.

I wish you fruitful deliberations, and every success in achieving the objectives of the meeting. I also wish all of you a pleasant stay in Delhi.