Regional Production of Pandemic Influenza Vaccine

Report of a Meeting

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

World Health Organization
Regional Office for South-East Asia

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Contents

1. Background and opening remarks

On 29-30 October 2009, a regional meeting was organized with the following objectives:

- To review and document regional pandemic influenza vaccine production capacity;
- to discuss the role of regulatory agencies; and
- to discuss next steps for pandemic vaccine production in the Region.

While opening the meeting, Dr Samlee Plianbangchang, WHO Regional Director for South-East Asia, stated that since the current pandemic (H1N1) 2009 was declared on June 11, 2009, more than 400 000 laboratory confirmed cases and at least 4735 deaths have been reported globally. This meeting had been called to discuss how to expedite the process of regional vaccine production, licensing and distribution while striving for maximum cost-effectiveness and safety. This issue had been raised at global and regional high-level meetings earlier in 2009 such as the sixty-second World Health Assembly (WHA) and the Regional H1N1 consultation held in July 2009 in Bangkok, Thailand.

The Regional Director emphasized that this Region requires much vaccine and he hoped the meeting would stimulate discussion on strengthening public–private partnerships (Annex 1).

The details of the meeting agenda are in Annex 2.

The meeting was attended by delegates from ministries of health and national regulatory authorities (NRAs) from Bangladesh, India, Indonesia and Thailand. There were representatives from seven vaccine companies in the Region in addition to experts on the subject (see Annex 3 for the list of participants).

Professor Ranjit Roy Chaudhury was nominated as chairperson and Dr Khondoker Mahbuba Jamil was nominated as rapporteur.

2. Pandemic (H1N1) 2009 – overview of the global and regional situations

An overview of the H1N1 global and regional situation was provided. Reference was made to past pandemics of 1918, 1957 and 1968. The WHO phases were discussed and it was noted that the classification is linked to interventions. One of the main issues arising was that the number of cases currently reported is an underestimate as many countries have stopped reporting individual case numbers to WHO. In the Region Bangladesh, India, Indonesia and Thailand have reported the highest number of cases to date, while DPR Korea had not reported any cases at that time. Maharashtra state in India is the hardest hit. Member States were providing data on a weekly basis to the Regional Office.

The epidemiological situation was summarized as follows: the most affected age group was 5-45 years; hospitalizations and case fatality rates were higher for pandemic influenza than for seasonal influenza; at-risk groups include pregnant women, those with chronic disease, and the immunosuppressed, with obesity appearing to be an associated factor. Pandemic influenza demonstrates rapid and efficient person-to-person transmission.

It was highlighted that the surveillance recommendation to countries at this stage of the pandemic is not to count individual cases but to monitor unusual events, i.e. clusters of severe and fatal virus infection and clusters of respiratory illness. There was discussion on the various circulating viruses and the need to monitor regional strains. It was also noted that decisions regarding key pharmaceutical interventions include the need to consider at-risk groups and certain target groups, treatment of which would have the greatest impact on transmission.

As the Region will be in short supply of the vaccine, there is a critical need to enhance regional production. Added to this, countries need to have in place proper plans for introducing the vaccine, and currently it appears that only Thailand has made progress in this area. Vaccine manufacturers stated that it was in their interest to know how much vaccine would be required, but countries noted that predicting demand was challenging.

3. Responding to the influenza pandemic– the role of pharmaceutical interventions

The use of antivirals was summarized and it was noted that these were best administered early. Prevention is the best form of treatment, and it is expected that the pandemic vaccine will be effective. Some considerations were highlighted – that not enough vaccine was being produced for global consumption and that strategic planning will be important; to assist countries there has already been a regional workshop on planning for vaccine deployment; the use of adjuvants could increase the quantity of available vaccine by reducing the antigen amount required per dose; in an established plant, production time lag is about six months; and that South-East Asia Region countries will not have adequate supplies of vaccine for their populations. The potential for contamination with the use of multi-dose vials was raised and Guillain Barré Syndrome was highlighted as a concern that has come up repeatedly in discussions and must be included in monitoring adverse events following immunization (AEFI).

Upcoming challenges include regulatory and licensing hurdles; gaps in pandemic preparedness plans (five Member States have WHO-supported polio networks, which are trained in undertaking influenza-like illness surveillance); limited financial resources; having systems in place for effective and timely deployment; and establishing systems to monitor and respond to adverse events. There has been training for national AEFI committees in India, Indonesia, Nepal and Sri Lanka, with one planned for Bangladesh in December 2009.

4. Pandemic influenza vaccination in the South-East Asia Region: setting the stage

The global vaccine situation was summarized. The pandemic vaccine is currently available in many countries and clinical trials are ongoing. However, in this Region, there is no locally available vaccine to date. In October 2009 vaccine became available for use in many countries. These countries are prioritizing certain groups for the vaccine such as pregnant women, children and health-care workers.

This presentation highlighted that three countries in the Region have the capacity to produce H1N1 vaccine – India, Indonesia and Thailand.

India has five companies able to produce the vaccine, while Indonesia and Thailand have one each. India will not depend on local vaccine production but will obtain vaccine from one of the four companies currently producing the vaccine (i.e. Baxter, GSK Biologicals, Novartis and Sanofi). India will do bridging studies to bridge the information that is already known to information that is required. Phase II and Phase III studies and post-marketing surveillance will be done for tolerance and safety for the vaccines obtained from these companies.

A clear account of the processes involved in obtaining regulatory approval was provided: when the vaccine is ready for use, Phase I studies must be undertaken and these results must be presented to the regulatory authority for approval for Phase II and Phase III studies. The process also involves obtaining clearance from the ethics committee. Once approval is obtained for Phase II and Phase III studies, these can be carried out in six weeks' time. The results of Phase II and Phase III studies need to be reported to the regulatory authority when a request for marketing authorization will be made.

A key issue was how to expedite the regulatory process and whether there is really a need to repeat studies if the vaccine is already in use. It was noted that there is a need to shorten the process without increasing risks to consumers. Several suggestions were put forward; it was noted that it should be possible to harmonize the requirements for approval by different regulatory agencies to fast-track the clearance process for H1N1 vaccine. A suggestion was to establish an intercountry technical expert committee to clinically evaluate and market vaccines in all countries. A further suggestion was to establish a common process for ethical approval. It was suggested that WHO should explore the development of a multicountry regulatory committee similar to the European Medicines Evaluation Agency (EMEA) for countries of the European Union. A further suggestion was to establish a multicountry committee on toxicology.

There was much discussion about speeding up the regulatory processes to advance availability of the vaccine. The group was reminded that responsibility for safety and efficacy lie with the regulatory agency and that care should be taken not to cut corners regarding safety and efficacy. It was mentioned that the US Food and Drug Administration has a fast-track process which could be studied and elements adopted in this Region. The government of Bangladesh has accepted to use a fast-track mechanism for pandemic vaccine that has been pre-qualified by WHO.

5. Vaccine production capacity in the South-East Asia Region: statements from manufacturers

All seven manufacturers made presentations on their production capacity (see Table Annex 4).

Bharat Biotech

The company's plans for producing vaccine were as follows: the seed virus was obtained from CDC Atlanta, USA and the strain proposed for use is Influenza A/California/7/2009 (H1N1)v. The company has the expertise and facilities available and are able to manufacture approximately 12 million doses using vero cells and the Madin-Darby canine kidney (MDCK) cell line annually. Bharat Biotech has obtained standard reagents from the National Institute of Biological Standards and Control (NIBSC), United Kingdom. Their quality control methodologies are almost optimized and scaling up is in progress. The advantages of cell culture include less lead time, no need to rely on high-quality eggs, scale up is easy, there are no allergy issues and the adapted virus is similar to the parental virus. The production capacity is one million doses a month. The firm currently produces rabies, rotavirus, Japanese encephalitis and chikungunya vaccine.

Cadila Pharmaceuticals Ltd.

The group was informed that the same concept for producing the human papilloma virus (HPV) vaccine can be adopted for H1N1 vaccine. The company plans to use a recombinant cell-based vaccine. The virus-like particles mimic the influenza virus but lack the genome for replication. There is no pathogenic virus involved in the process, so only a Biosafety Level 1 facility is required. Toxicology studies have shown no adverse effects and there are no eggs involved in the vaccine production. The process from strain selection to product release takes about 10–12 weeks. This company is part of a U.S.-based company with a pilot plant and commercial launch facility in the United States. This U.S. based facility is already producing vaccine that can be used for commercial supply. The facility in India will be operational in four months' time, with an anticipated annual vaccine capacity of 60 million doses. The speed of recombinant technology is about 20 times that of egg-based technology. In Mexico,

subjects have been recruited for a clinical study to evaluate the H1N1 virus-like particle vaccine for safety, immunogenicity and efficacy. The same procedure is planned for India but is awaiting approval.

Panacea Biotec Ltd.

The worldwide production of the vaccine will not be sufficient to cover the 6.8 billion susceptible population. The advantages of egg-based technology include it has been a time-tested and widely-used technology for over 40 years; the analytic assays and the regulatory pathways are well established. Cell culture-based technology has an unclear regulatory pathway and there is a high safety risk as cell lines need to be free of tumorigenic and oncogenic potential. The characterization and approval of cell lines is a long process which is not practical in emergency situations. In addition, these vaccines are generally regarded as more expensive.

The objective of this company is to use technology that will deliver H1N1 vaccine by March/April 2010. The vaccine strain is the classical reassortant H1N1 virus NYMCX – 179A procured from CDC Atlanta. The technology is egg-based whereby one egg will yield three doses of vaccine. Immunogenicity studies have been conducted successfully. The plant is under construction and will have a capacity of 45 million doses annually. Technology scale-up is due to commence in October 2009 and pre-clinical toxicology should start in November 2009. Phase I/II studies should begin in January 2010 and be completed by March 2010, with licensing for emergency use obtained in April 2010.

Serum Institute of India

This company plans to use an egg-based live attenuated influenza vaccine (LAIV), which will be delivered nasally. This route of administration mimics the natural route of infection. Russia has been using this type of vaccine for the past 50 years and there is proven safety and efficacy. The vaccine is capable of being produced in either eggs or mammalian cell culture; Serum Institute plans to grow it in eggs. There is a dedicated setup for bulk production and it is estimated that 50 million doses can be generated in six months from the date of registration. The candidate vaccine should be ready for commercial use by May 2010.

Zydus Cadila Healthcare

This company plans to manufacture classical egg-based vaccine in their new facility in Ahmedabad, India. They have been processing 21 000 eggs per week, which will increase to 50 000 eggs from December 2009. Capacity could be 12 million doses annually. The seed virus is A/California/7/2009 (H1N1) NIBRG-121 xp.

In terms of the regulatory approvals, pilot plant scale production commenced in August 2009, with completion of quality control testing by the end of October 2009. Pre-clinical testing was scheduled to begin during October/November and application to the regulatory agency for clinical trials planned for mid-November 2009. Clinical trials were to start in December 2009, with marketing authorization approval to be obtained early in 2010.

Bio Farma

The development of seasonal influenza vaccine will be used as a basis for production technology for pandemic influenza vaccine. Egg-based technology would be used and the facility should be ready in 2009, with vaccine available by November 2010.

GPO Pilot Plant

There are two projects for influenza vaccine production: one is a pilot plant project and the second is an industrial plant project. The planned production capacity for pandemic influenza vaccine is up to 300 million doses every six months; however, it would take 1.5 years for construction, 6 months for validation and 1 year for process validation.

Discussion centred on the potential lack of adequate vaccine supply. There are just six major vaccine companies that are providing the total supply for the world. Forty-nine companies are going to produce H1N1 vaccine, and 21 of these are in the developing world. The issue of developing standard minimal regulatory requirements for H1N1 was raised.

6. Role of national regulatory authorities

An account of the functions of the national regulatory authorities (NRAs) such as marketing authorization and licensing activities, was provided. In this Region there are 11 NRAs but 3 (India, Indonesia, Thailand) comply with the six required functions of a national regulatory authority.

Whether a 'fast-track' approach or normal process the regulatory process must be followed. If the country does not have a functioning NRA, WHO would not purchase vaccine from that country. In the case of WHO-donated vaccine that has been licensed in the country of origin the question was raised whether Member States will require full registration or if they will accept a fast-track process for such vaccine.

Role of national regulatory authorities

Bangladesh

Bangladesh does not currently produce vaccine. There is a regulatory body and well-developed strategies for vaccine procurement, stockpiling and distribution. The Directorate of Drug Administration is the regulatory body and the licensing body for drugs. The government plans to buy vaccine from WHO-recommended sources guided by the regulatory authority. All the activities of the regulatory authority are governed by drug acts and drug rules.

India

The various steps were outlined from applying to importing the strain to manufacture the vaccine to approval of the license to manufacture the vaccine.

The NRA is holding regular meetings with manufacturers to be kept aware of the status of their development. Implementing a fast-track clearance process taking into account European Medicines Evaluation Agency (EMEA) and other agency pathways is being considered. Granting special permission to manufacture the bulk while the Phase III trials are under progress is being considered. However, marketing for use will only be allowed after successful completion of trials.

Indonesia

The NRA in Indonesia fulfils the six regulatory functions of a NRA:

(1) Marketing authorization

(2) Post marketing monitoring of Adverse Events Following Immunization (AEFI)

(3) Lot Release

(4) Laboratory Access

(5) Regulatory Inspection

(6) Authorization and Monitoring of Clinical Trials

There are two processes for registering a product: the normal registration with normal evaluation path and timeline and the fast-track authorization for drugs use in an emergency situation and vaccines in EPI programmes. For vaccines produced locally, the NRA ensures that the applicant meets quality and safety requirements, and the facility should meet good manufacturing practice requirements. For vaccines previously licensed, or if experience has been gained in the inter-pandemic period, manufacturers can conduct a small safety and immunogenicity study to support licensing. Indonesia has a special access scheme for importation of drugs not already registered in the country in limited quantity for special use, based on scientific justification.

Thailand

Thailand has in place the six critical functions of a national regulatory authority. The local manufacturer, The Government Pharmaceutical Organization (GPO), plans to manufacture the LAIV, which requires an appropriate containment facility. Thailand has a fast-track mechanism for H1N1 and for emergency use of any kind of vaccine.

Discussion focused on fast-tracking. A question was posed to the national authorities as to whether a vaccine from India or Indonesia would be fast-tracked. In Thailand, it needs to be registered again. Bangladesh needs WHO pre-qualification for use of any vaccine in their country. It was highlighted that there are international conventions and guidelines for emergency use of vaccines. There is, therefore, a need for regulatory bodies to reach consensus based on global norms.

7. Prioritization of vaccine: SAGE on immunization recommendations for pandemic vaccine

The speaker informed the group that the Strategic Advisory Group of Experts (SAGE) met twice in 2009, in July and October, to make recommendations on the use of H1N1 vaccine. The recommendations of the meeting in October would be available soon. In summary, WHO recommends that all countries should immunize health-care workers as a first priority, followed by other priority groups. They recommend a single dose of vaccine in persons over 10 years if this is consistent with NRA indications.

The issue of differing antigenicity among different populations was raised. It was noted that antigenicity does not vary but immunogenicity may vary due to nutritional status, and that zinc and vitamin A deficiencies may be factors in the immune response, as may soil-transmitted helminths.

8. Deployment of pandemic influenza vaccine: report of a regional workshop on planning for deployment

A recommendation of the SAGE meeting in July 2009 was for WHO to assist Member States to develop plans for vaccine deployment. Some manufacturers and governments committed to donate in excess of 200 million doses of pandemic vaccine and each eligible country will receive vaccine for up to 10% of their population, with health-care workers as a priority. The donation will be available between November 2009 and February 2010.

At the SEARO regional workshop, a training workshop where ten Member States were represented, countries agreed a standardized framework for planning for the deployment of the pandemic vaccine.

Countries will need the following documents before they can receive vaccine:

- Letter of intent
- National pandemic vaccine deployment plan
- Letter of agreement signed by MoH and WHO

In the Region, there are nine countries eligible for vaccine excluding India and Thailand. India, however, requested a supply. Timor-Leste may receive vaccine from Australia. Four countries have already responded with letters of intent: India, Maldives, Myanmar and Nepal. The Myanmar plan had been forwarded to WHO headquarters.

It was noted during the discussion that although the donation looks promising, in reality the quantity is insufficient for the needs of the Region. It was firmly stated that there is a critical need to have regional capacity for producing pandemic vaccines for regional populations.

9. Recommendations

The group agreed on the following recommendations for Member States and WHO through consensus.

For Member States

Member States should:

(1) Collaborate with vaccine manufacturers to synchronize demand with supply.

(2) Develop and implement fast-track pathways in the regulatory process without compromising safety and efficacy; national regulatory authorities should work closely with manufacturers to ensure awareness of the regulatory pathways, which would facilitate adherence to production timelines.

(3) Identify priority groups for vaccination and in collaboration with the manufacturers facilitate access to the vaccine for priority groups.

(4) Establish robust national vaccine deployment plans.

(5) Develop a financial plan for implementation of their vaccine production and deployment activities and seek cooperation from developmental partners including WHO in mobilizing resources.

(6) Continue surveillance of influenza-like illness and severe acute respiratory infection and monitor clusters of respiratory illness; and conduct influenza burden-of-disease studies (including molecular characterization) to support a seasonal influenza vaccination policy.

For WHO

WHO should:

(1) Explore the feasibility of establishing (i) a multicountry regulatory committee so that one approval allows licensing in all 11 countries of the Region; (ii) a regional expert committee in toxicology; and (iii) a regional ethics committee.

(2) Organize a meeting of national regulatory authorities from all Member States to define common minimum regulatory requirements for H1N1 vaccine for the Region.

(3) Organize periodic meetings bringing together partners and national authorities to increase collaboration in the public health area and to review progress made on the recommendations from this meeting, in a spirit of public–private partnership.

10. Closing Remarks

Dr Jai P Narain, Director CDS, in his closing remarks stated that the meeting had been extremely interesting, informative and productive. Delegates were thanked for their information-sharing and transparency in sharing the progress being made in their respective companies. The group was assured that the recommendations will be followed up. He also thanked the chairperson, the rapporteur and all the delegates for attending and for their valuable contributions.

It was noted this was a unique meeting to bring stakeholders together to discuss ways to develop pandemic vaccine in the Region. This was particularly topical, the second wave could be coming soon, and vaccine is critically important in the evolving waves. It was highlighted that although the pandemic was declared five to six months ago, there are still many uncertainties and we should try to anticipate what will happen next.

Because of the uncertainties about the impact of the pandemic in terms of transmissibility, severity and regional capacity to respond, surge capacity in pharmaceutical and non pharmaceutical interventions is required; antivirals are needed to decrease the case fatality rate and vaccines for preventing transmission.

It was emphasized that the issue is not one of production capacity alone, but also ensuring access to all those who need it. Dr Narain recalled that in 2002, Cipla, an Indian manufacturer was critical in providing anti retroviral therapy (ART) to Africa at an affordable price. Patients in Africa are now surviving because of this step. He stressed that access to ART is a global ethical issue – if someone is born in Europe or the United States they can live with HIV; however, in some poorer parts of the world people die from AIDS. A similar principle applies to the pandemic situation and access to the vaccine and antiviral drugs. He concluded by saying that our Region could make a huge difference to public health by enhancing production capacity, bringing costs down globally and reducing morbidity and mortality.

Annex 1

Opening Remarks by Dr Samlee Plianbangchang, Regional Director

It is my pleasure to welcome you to this meeting on pandemic influenza vaccine production in the WHO South-East Asia Region.

As you know, the current pandemic (H1N1) 2009 was declared on 11 June 2009. So far more than 399 232 cases and at least 4735 deaths have been attributed to the new pandemic virus worldwide, bearing in mind that these figures are conservative estimates. In the South-East Asia Region, India and Thailand report the highest number of cases. The Region has recorded 42 715 cases and 637 deaths to date.

The pandemic (H1N1) 2009 virus has never before circulated among humans. Most people, therefore, have no or little immunity to the pandemic virus.

The pandemic virus is highly contagious. The severity of the disease ranges from very mild symptoms to severe illness and death. More than half of all hospitalized people 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 vaccines in vulnerable populations. Existing influenza vaccines are ineffective against the pandemic strain and there is, therefore, a need to develop and produce a new vaccine that is both safe and effective.

While the Region awaits production of an adequate quantity of the vaccine, Member States need to rely upon other recognized public health strategies such as a sound mechanism for coordination, effective surveillance and monitoring of acute respiratory illnesses in the community and health facilities, ability to implement relevant non-pharmaceutical measures, and the judicious use of antiviral agents to control severe disease. WHO recommends adopting a ''whole-of-society" approach while implementing these strategies.

The issue of vaccination as a countermeasure raises issues of access and equity as the bulk of global vaccine production is contained within Europe and North America.

This meeting is about regional vaccine production: how to expedite the process of production, licensing and distribution while striving for maximum cost-effectiveness and safety.

We have learnt from past experience that influenza pandemics have a tendency to attack populations in periodic waves and that the second or third waves may cause much more severe morbidity and mortality than the first. We are approaching the time when we would expect to see a second wave. Some countries of the world have already licensed the vaccine for use in their countries and the United Kingdom commenced vaccinating its people the third week in October. There is therefore the need to accelerate the process while keeping a close eye on the safety issue.

Our Member States have large populations living under more difficult socioeconomic conditions which make them more vulnerable to the effects of the pandemic.

Vaccines need to be produced in large quantities. The meeting needs to discuss the capacity of the Region to produce the required amount within certain timeframes. We are fortunate that three of our Member States - India, Indonesia and Thailand, are capable of producing the vaccine. It is also encouraging that the fourth country, Bangladesh, has expressed a keen interest in producing the vaccine.

At the Sixty-second session of the World Health Assembly in May 2009, one of the main issues discussed was H1N1 preparedness and access to the vaccine. Indeed, at this meeting, the Health Ministers of this Region committed to foster collaboration within the Region and to increase vaccine production capacity. This issue 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. Results of clinical trials have shown the vaccine to be safe. NRAs may need to put in place processes to accelerate the approval process while ensuring that quality and safety are not compromised.

When the vaccine has received approval from the NRA the national authorities of that country then need to implement their distribution plan. Countries, therefore, need to have a vaccine prioritization and deployment strategy in place.

The Strategic Advisory Group of Experts (SAGE) on Immunization was established in 1999 by the WHO Director-General as the principal advisory group to WHO for vaccines and immunization.

SAGE noted that countries should employ a strategy that reflects their epidemiological situation, access to the vaccine, and the ability to deploy the vaccine alongside available non-vaccine measures. WHO still recommends that health-care workers should be vaccinated first to protect 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 10 Member countries. The need for countries to develop pandemic influenza vaccine deployment plans, train the workforce and explore the legal requirements for licensing the vaccine prior to deployment were highlighted at this workshop.

Ladies and gentlemen,

We have present at this meeting key persons who can inform us about the vaccine production capacity within the region, persons from NRAs who can advise on the processes countries need to employ and persons from ministries of health who will be involved in the prioritization and deployment of the vaccine. We also have present here experts whose advice and technical input will be invaluable.

At the end of this meeting we should have a clearer understanding of the regional vaccine production capacity and of the regulatory processes involved. We plan to share the information obtained at this meeting with all Member States to help them plan their procurement, prioritization and distribution strategies.

I wish you fruitful deliberations and every success in achieving the objectives of this important meeting and a pleasant stay in Delhi.

Annex 2

Programme

Day 1

09.00–09.15	Opening Remarks – *Regional Director Dr Samlee Plianbangchang*
09.15–09.30	Meeting objectives and introduction of participants – *Dr Khanchit Limpakarnjanarat* Nomination of office bearers – *Dr Samlee Plianbangchang*
09.30–09.40	Group Photograph
09.40–10.00	*Tea/Coffee*
10.00–11.00	Pandemic (H1N1) 2009 – overview of the global and regional situations – *Dr Khanchit Limpakarnjanarat* Responding to the influenza pandemic: role of pharmaceutical interventions – *Dr Arun Thapa* Pandemic influenza vaccination in the South-East Asia Region: setting the stage – *Prof Ranjit Roy Chaudhury*

Vaccine Production Capacity in the South-East Asia Region – perspectives from the manufacturers

11.00–12.30	➢ Bharat Biotech, *India* ➢ Cadila Pharmaceuticals Ltd., *India* ➢ Panacea Biotec Ltd., *India*
12.30–1.30	*Lunch*
1.30–3.30	➢ Serum Institute of India Ltd, *India* ➢ Zydus Cadila, Cadila Healthcare Ltd., *India* ➢ Bio Farma, *Indonesia* ➢ The Government Pharmaceutical Organization (GPO), *Thailand*

3.30–3.45	*Tea/Coffee*
3.45–4.00	Role of National Regulatory Authorities: an overview – *Dr Anil Chawla*
4.00–5.00	Role of the National Regulatory Authorities: ➢ in countries without production capacity – *Bangladesh* ➢ in countries with production capacity – *India, Indonesia, Thailand*

Day 2

9.00–9.20	Prioritization of vaccine: Strategic Advisory Group of Experts (SAGE) on Immunization recommendations for pandemic vaccine – *Dr Arun Thapa*
9.20–9.40	Deployment of Pandemic Influenza Vaccine – report of a regional workshop on planning for deployment – *Dr Arun Thapa*
9.40–10.00	*Tea/Coffee*
10.00–11.30	Discussion on follow up actions
11.30–12.00	Summary of recommendations/follow up actions
12.00–12.15	Closing
12.15	*Lunch*

Annex 3

List of participants

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Annex 4

Status of H1N1 vaccine production capacity in SEA Region (30 October 2009)

Company	Facility to manufacture H1N1 vaccine bulk	Facility to manufacture finished product	Current Manufacturing capacity	Are capacity enhancements planned - Timeframe - Capacity	Technique	Date vaccine available for commercial use	Ability to export
Bharat Biotech International Limited	Yes	Yes	1 million doses per month	Yes - 6 months - 2 million doses per month	Vero cells and MDCK	May 2010	Yes
Cadila Pharmaceuticals Ltd	Yes	Yes	5 million doses per month	Yes - 12 months - Unlimited	Virus-like particles	Ready now but waiting for GOI approval to do clinical trials	Yes
Panacea Biotec Ltd	Yes	Yes	45 million doses per yr	No	Egg-based	April 2010	Yes
Serum Institute of India	Yes	Yes	8 million doses per month	No	Egg-based live attenuated influenza vaccine (LAIV)	May 2010	Yes
Zydus Cadila, Cadila Healthcare Ltd	Yes	Yes	300 000 doses per month	Yes - 3 months - 800000 – 1 million doses per month	Egg-based	Submitting application for GOI approval to do clinical trials; Early 2010	Yes
PT Biofarma	Yes Ready in 2010	Yes	1.66 million doses per month	No	Egg-based	Nov 2010	No
GPO Thailand	Yes	Yes	~ 500 000 doses per month	Yes - 5-6 months - 3 million doses/month	Egg-based (LAIV)	May 2010	~ 10% of capacity

A meeting on the regional production of pandemic influenza vaccine was organized by the WHO Regional Office for South-East Asia in New Delhi on 29-30 October 2009. The purpose of the meeting was to review regional vaccine production capacity and discuss the role of regulatory agencies. Vaccine production capacity currently exists in India, Indonesia and Thailand while Bangladesh has expressed an interest in producing it. The meeting highlighted the need for augmenting vaccine production within the Region to overcome the current shortages and to meet the requirements of countries in this Region.

It was emphasized that the issue is not one of production capacity alone, but also ensuring access to all those who need it. This Region could make a huge difference to public health by enhancing production capacity, bringing costs down globally and reducing morbidity and mortality.

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