Meeting with international partners on prospects for influenza vaccine technology transfer to developing countries

27–28 November 2008
Pune, Maharashtra, India
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Abbreviations and Acronyms

DTaP  diphtheria tetanus acellular pertussis
EPI  Expanded Programme on Immunization
FDA  Food and Drug Administration (Thailand)
GAP  Global pandemic influenza action plan
GMP  Good Manufacturing Practices
GPO  Government Pharmaceutical Organization (Thailand)
IPR  Intellectual Property Rights
ITPIV  international technology platform for pandemic influenza vaccines
IVAC  Institute of Vaccine and Biological Substances (Viet Nam)
IVR  Initiative for Vaccine Research
JE  Japanese encephalitis
LAIV  live attenuated influenza vaccines
MDCK  Madin Darby canine kidney cells
MPLA  monophosphoryl lipid A
NRA  National Regulatory Authority
NVI  Netherlands Vaccine Institute
PATH  Program for Appropriate Technology in Health
QC  quality control
SII  Serum Institute of India
SRID  single radial immunodiffusion assay
Td  tetanus diphtheria toxoid
WHO  World Health Organization
Day 1:
27 November 2008

1. Objectives of the meeting

The purpose of the meeting was to review progress on the WHO technology transfer projects and to facilitate networking between the grantees and development partners. The meeting was chaired by Dr Gary Grohmann, Director, Immunobiology, Therapeutic Goods Administration, Australia, and was attended by representatives of the six developing country vaccine manufacturers already receiving a grant from WHO, as well as other participants from public or private manufacturers in Argentina, Croatia, Egypt, Hungary, Kazakhstan, Republic of Korea, Serbia and Montenegro, South Africa and Venezuela. In addition, one donor countries (Japan), international partners, and the WHO secretariat participated in the meeting.

2. Progress in the implementation of the Global pandemic influenza action plan to increase supply of vaccines

The Global pandemic influenza action plan (GAP) to increase vaccine supply was formulated, in May 2006, to identify approaches and strategies to reduce the anticipated gap between potential vaccine demand and supply during an influenza pandemic. GAP recognized three distinct strategies: A) to promote seasonal vaccination programmes as a driver of increased market and production capacity; B) to expand manufacturing capabilities; C) to promote influenza vaccine research and development.

Directly relevant to strategy B (increasing manufacturing capabilities) of GAP, the Initiative for Vaccine Research (IVR) has completed several activities since 2006, including finalizing a review of production technologies for influenza vaccine, analysing production cell line availability, investigating Intellectual Property Rights (IPR) issues related to influenza vaccines, and providing seed-grants to six developing country manufacturers to help them acquire the technology to produce influenza vaccine. These manufacturers are located in Brazil (Instituto Butantan), India (Serum Institute of India, SII), Indonesia (BioFarma), Mexico (Birmex), Thailand Governmental Pharmaceutical Organization (GPO) and Viet Nam (IVAC). Manufacturers started their projects in June (Butantan, SII and GPO) and September (BioFarma, Birmex and IVAC) in 2007. In October 2007, WHO organized a meeting with international partners to review progress on the first technology grants. The following recommendations were made to WHO and international partners.
• Seed funding for the current grantees should be continued, with a possible extension of the grant programme to new applicants.
• Establishment of a manufacturing hub, as an available source of technology transfer, should be considered.
• There should be further examination of the advantages of converting inactivated influenza vaccine production to live attenuated influenza vaccines (LAIV) for mass-immunization campaigns in the event of a pandemic.

The 2008 Pune meeting also concentrated on objective B of the GAP. Its main objectives were as follows.
• To review the progress made by WHO grantees in developing capacity for production of influenza vaccines.
• To review the status of new developing country manufacturers potentially interested in influenza vaccine production.
• To update participants on the WHO initiative to establish a manufacturing hub for technology transfer of influenza vaccine manufacturing.
• To review international initiatives towards increasing the potential supply of pandemic influenza vaccines.
• To discuss and finalize the way forward including next steps for capacity building for influenza vaccine production.

3. Influenza vaccine production: progress made by WHO grantees

The Government Pharmaceutical Organization (Bangkok, Thailand)

GPO plans to establish production of egg-based inactivated trivalent seasonal (whole and subunit) vaccine and of egg-based live attenuated influenza vaccine for seasonal and pandemic use. Mr Sit presented the progress as follows: a) The basic and conceptual design of a new manufacturing facility has been completed and discussions with the Thai Food and Drug Administration (FDA) are in progress for approval of the plans. b) A process for inactivated trivalent seasonal (whole virus and subunit) vaccine was developed in accordance with WHO specifications for purity and yield. Upscaling to industrial scale-up will be undertaken. c) The single radial immunodiffusion assay (SRID) quality-control assay was validated. d) Development of a process for LAIV has been initiated using the same influenza virus strains as for inactivated vaccine. d) GPO is holding discussions with WHO for sourcing of LAIV strains.

Discussion

The Chair inquired about the inactivation process used for vaccine production. Mr Sit explained the process, and there were no further questions.
**Serum Institute of India (Pune, India)**

SII focuses on concrete evaluation and assessment of inactivated whole and subunit virus preparations with adjuvants, and explores the possibility of egg-based live attenuated influenza vaccine for intranasal applications. Dr Dhere presented the progress to date. For seasonal vaccine, protocols related to development and analytical characterization of inactivated preparations [A (H1N1), A (H3N2), type B] were established. Murine immunogenicity studies on seasonal subunit preparations suggest a moderate increase in antibody titres after two immunizations at three weeks apart. Concerning H5N1 vaccine development, protocols were established for production and analytical characterization of subunit and whole virus preparations using H5N1-NIBRG-14 strain. Immunogenicity studies of H5N1 vaccine in mice suggest higher titres with inactivated whole virus vaccines compared to subunit vaccine preparations. Furthermore, adjuvanted (alum hydroxide and alum phosphate) preparations showed higher immunogenicity with whole virus as compared to subunit vaccines. Interestingly, seroconversion was observed with adjuvants in mice using a 2-dose regime, even at very low doses (1.8 microgram HA antigen) of whole virus, or, to a lesser degree, subunit virus preparations. These preliminary results need further investigation.

**Discussion**

The Chairman asked Dr Dhere about usage of seasonal influenza vaccine in India and SII’s future plans for this. Dr Dhere responded that the Indian government does not have a clear policy on seasonal influenza vaccination at present, and so estimating Indian demand is difficult. However, SII production plans will depend on future market demand. There were some queries on immunogenicity data, to which Dr Dhere responded that trends shown here are preliminary and that more confirmatory experiments are underway to obtain conclusive results. Dr Sadrizadeh enquired about SII plans on LAIV and export to other countries. Dr Dhere explained that SII is currently exploring options for LAIV and is open to other markets.

**Instituto Butantan (São Paulo, Brazil)**

The Institute has production capability for egg-based split seasonal vaccine, from a prior technology transfer from Sanofi Aventis. Dr Miyaki presented the progress on activities, including establishment of a quality-control laboratory and testing of A/Vietnam/1194 derived split and whole virion inactivated vaccine. Furthermore, the new adjuvant MPLA demonstrated significant dose-sparing effect with the A/Vietnam/1194 strain. Future plans include formulation and stability studies with A/Vietnam/1194 and production of A/Indonesia experimental lots, as well as clinical trials to investigate new adjuvants and alternative routes of administration.

**Discussion**

Dr Hendriks enquired about the batch-wise capacity of the process at the Institute. Dr Miyaki responded that currently Instituto Butantan can produce 5000 egg batches.
**Birmex (Mexico City, Mexico)**

The grant from WHO was utilized for plant design and validation of design and equipment for quality-control laboratories. In addition, Birmex will invest US$ 31 million to complete the facility, including land purchase, construction, training of staff, and plant and process validation.

Dr Ponce de Leon presented the progress made during 2008. Land acquisition and agreements with Sanofi Pasteur have been completed, as has procurement of equipment for the quality-control laboratory. In addition, hiring of consultants for plant design and also quality assurance staff is also completed. Activities relating to plant construction, equipment specification and training, will be undertaken in 2009.

**Discussion**

No questions were raised.

**Institute of Vaccine and Biological Substances (IVAC, Nha Trang, Vietnam)**

The WHO grant aims to establish an egg-derived whole virion, alum adjuvanted influenza vaccine production facility. IVAC decided to create an initial capacity of 500 000 doses of H5N1 vaccine production, with expansion possibilities up to 3 million doses.

Professor Le Van Hiep presented the progress of the project. The first phase of project involving conceptual design by international experts has been completed. Construction activities are underway and are estimated to be completed by March 2009.

**Discussion**

No questions were raised.

**BioFarma Persero-BF (Bandung, Indonesia)**

The production technology being transferred with WHO funding is fill/finish of egg-based split influenza vaccine antigen produced by the Japanese manufacturer Biken. BioFarma aims to subsequently acquire capacity for bulk manufacturing of seasonal and pandemic influenza vaccine. Current expected capacity will be for 10 million doses of seasonal influenza vaccine. Dr Suhardono presented the progress and activities relating to acquiring downstream process capacity (QC, formulation, filling). Formulation and fill/finish for imported monovalent bulks A/Solomon Islands/3/2006 (H1N1), A/Hiroshima/52/205 (H3N2) and B/Malaysia/2506/2004 were completed. Batches were found to comply with local NRA and Biken specifications. Most of the equipment has been procured, and installation was expected to be completed by December 2008.
In addition, a clinical trial with locally fill/finished seasonal vaccine (A/Solomon Islands/3/2006 (H1N1), A/Hiroshima/52/205 (H3N2) and B/Malaysia/2506), was initiated in August 2008 in order to evaluate the safety and immunogenicity of the product in adults and adolescents. Vaccine was administered intramuscularly at a dose of 15 micrograms HA (0.5 ml). Serological responses at 28 days post immunization was conserved as a criterion of immunogenicity. The trial was completed in October 2008, and a report was expected early in 2009.

Discussion
No questions were raised.

4. WHO efforts in strengthening NRA from six countries with new influenza vaccine manufacturing

Dr Alfonso and Dr Pfeifer presented findings from the WHO initiative to assess regulatory capacity and preparedness needs in countries where NRA and manufacturers are new to influenza vaccines. The survey included six countries where WHO grantees are located, and focused on: a) pandemic influenza preparedness plans; b) national regulatory pathways; c) regulatory pathways used in emergency; d) policy on seasonal influenza vaccine; e) capacity for clinical trials evaluation and approval; f) post-marketing surveillance. The survey suggests country-wise variability in licensing requirements, clinical trial authorization, approval capacity and post-surveillance systems. Dr Pfeifer also introduced the challenges in post-marketing surveillance, and suggested targets for improvement, including increasing capacity to identify and report adverse events for Expanded Programme on Immunization (EPI) and non-EPI vaccines, data analysis and evidence-based decision making. The need for capacity strengthening was highlighted in areas of licensing, lot release, clinical trial evaluation and post-marketing surveillance. WHO efforts in overall strengthening of NRA 1,2 were also summarized.

Discussion
There was general discussion on the rating scales used for the survey, and on limitations in conducting such surveys in view of the current variability in regulations, policies, awareness and capacities.

5. **WHO influenza vaccine technology transfer “hub” at the Netherlands Vaccine Institute**

Dr Hendriks and Dr De Boer presented the Netherlands Vaccine Institute NVI-WHO initiative to establish a technology “hub” for technology transfer for the production of influenza vaccines. The international technology platform for pandemic influenza vaccines (ITPIV) project, whereby NVI will serve as a technology platform for the transfer of a pilot scale generic process, was signed between WHO and NVI in December 2007, initially for seasonal influenza vaccine production. NVI will establish, test and document the process for an egg-based influenza vaccine production process suitable for upscaling, training and technology transfer to developing countries. To date, the initiative has completed laboratory scale process starting from seed-lot production and up to virus concentration. Working towards development of expertise and technology-transfer activities, the Institute has undertaken several initiatives, such as organization of e-based learning (website) workshops (GMP and QA) for June 2009 and a generic training course for December 2009.

**Discussion**

Dr Pathom enquired whether NVI faced some IPR issues for the proposed generic process. Dr Hendriks answered that this was not the case. Dr Pathom further asked why the hub had decided to concentrate on monovalent seasonal vaccine, to which Dr Hendriks responded that the decision was based on timelines constraints and the funding available from WHO. Dr Kieny added that WHO’s first priority was to make this hub operational. Depending on funding, seasonal trivalent vaccine may be included. Dr Hehme then enquired about NVI plans on split and subunit antigens, to which the presenters responded that currently NVI and WHO have decided to focus on whole-virus approaches, but may consider the split or subunit vaccines at a later stage.
Dr Grohmann invited presentations from potential new manufacturers interested in technology transfer for influenza vaccine manufacturing.

6. Presentation from new manufacturers interested in influenza vaccine production

**Egypt (VACSERA)**

Dr Zedan presented a VACSERA profile, and its expectations from a potential WHO grant. VACSERA is a very old company in Egypt, with expertise in the production of bacterial and viral vaccines. VACSERA aims to develop production capacity for pandemic and seasonal vaccines, to the level of 500,000 to 2 million doses. The WHO grant would be used for buying equipment and staff training, and for conducting preclinical and clinical studies.

**South Africa (Biovac)**

Dr Tippoo presented Biovac’s profile and its expectations from the WHO grant. Biovac is a public-private partnership, and aims to develop technology platforms for cell-culture based influenza vaccines. It has plans for a production capacity of 1 to 2 million doses.

**Argentina (Asofarma)**

Dr Mammarella presented the company’s objectives and capabilities. Asofarma has experience in its own development of influenza vaccines, and is currently producing lots for preclinical and clinical studies. The vaccine is prepared to European specifications and has demonstrated moderate immunogenicity and stability in studies so far. The company expects funding to further enhance its production capabilities to deliver vaccines for local and other markets.

**Serbia and Montenegro (Torlak)**

Dr Dakic presented the company’s profile. Torlak is 80 years old and was established by the government of the Federal Republic of Yugoslavia. The company has been producing whole virion inactivated influenza vaccine in chicken eggs since 1960. Since 2006 Torlak has been the recipient of a grant for the construction of a new Good Manufacturing Practices (GMP) facility producing influenza vaccines. Work related to design, equipment procurement and water treatment plans has been completed. The company would like to use the WHO grant for further improvements, particularly on the plant’s filling line.
Discussion
There was general discussion on GMP practices implemented at Torlak.

Kazakhstan (National Centre of Biotechnology)
Ms Burkitbaeva presented the company’s prospects. The institute is currently engaged in an influenza vaccine research project which is funded and supported by a grant from the national government. The project aims at developing a trivalent live attenuated influenza vaccine (intranasal) from type A(A/H1N1, A/H3N2) and B strains using Madin Darby canine kidney (MDCK) cells as the substrate for production. Preliminary preclinical safety and efficacy evaluation is under way.

Croatia (Institute of Immunology)
Dr Vrdoljak gave an account of the Institute’s prior experience with influenza vaccine. He explained that it is currently engaged in self-financed development of production capability for Vero cell-based inactivated influenza vaccine. Development of master virus lots and cell banking is under way. A WHO grant would be used to upgrade fill/finish capacity and technology transfer.

Hungary (Omninvest)
Dr Nemeth described Omninvest’s expertise in influenza vaccine production. The company has currently two influenza-related products. FluvalABR, a whole virion adjuvanted trivalent vaccine (A/H1N1, A/H3N2 and B) has been registered in Hungary since 1997, and Omninvest provides 1 300 000 doses annually for distribution in Hungary. The other product, FluvalR H5N1, is a H5N1 influenza vaccine which has been registered in Hungary since 2006. Omninvest has completed three clinical trials (600 participants) on FluvalR H5N1, which included children, adults, adolescents and elderly people. Future plans include studies on the intradermal route of administration, and development of tetravalent influenza vaccine for the Hungarian population.

Discussion
Dr El Sayed inquired whether Omninvest supplies vaccines outside Hungary, and Dr Nemeth replied that it did not. Dr Pathom asked Dr Kieny whether WHO would be interested in supporting Omninvest as a knowledge hub. Dr Kieny responded that WHO is currently focused on the NVI as a technology-transfer platform, and has no plans for additional technology hubs for influenza vaccine.

Green Cross Corporation (Republic of Korea)
Dr Rhee presented the company’s experience in influenza vaccine production. Green Cross has various product lines, including: vaccines for Varicella Zoster; Japanese encephalitis (JE); Hantaan; seasonal and H5N1 influenza; anthrax, tetanus diphtheria toxoid (Td) and diphtheria tetanus acellular pertussis (DTaP). The company has already completed the construction of new facilities for the production of influenza vaccines. It has plans for Phase III clinical trials, with seasonal vaccine in 2009. Development of a whole viron alum-adjuvanted H5N1 influenza vaccine is in progress.
**Quimbiotec (Caracas, Venezuela)**

Dr Suarez presented the company’s profile. Quimbiotec already has a local government-funded project to establish production of seasonal influenza vaccine. The company has completed activities related to laboratory-scale development and is looking forward to WHO funding for capacity building, especially in the areas of plant design, training and quality control laboratory installation.

### 7. International initiatives to increase potential supply of pandemic influenza vaccines

Dr Bright presented a PATH initiative in the area of influenza vaccines. The initiative is based on collaboration with private- and public-sector partners to advance the development of new, safe, economic and effective influenza vaccines, in large quantities, to combat a global influenza pandemic. Funding of US$ 38.75 million for three years (from 2008 to 2011) was obtained from the Bill & Melinda Gates Foundation. The initiative will attempt to accelerate the development of new technologies, such as live attenuated influenza vaccines, adjuvants, recombinant DNA and HA peptide-based vaccines, as well as broadly reactive vaccines. The initiative was launched in the first quarter of 2008 since when it has received 72 letters of intent. Scientific review is currently in progress and the first partnership was expected to be concluded in December 2008. The presentation also covered challenges in influenza vaccine production.

**Discussion**

Dr Inoue enquired whether PATH could facilitate technology transfer. Dr Bright answered that PATH had this expertise from previous projects. Dr Bright also confirmed that PATH would be interested in entering into discussions with potential new manufacturers in the near future.

### 8. General discussion

The following topics were discussed.

- Tracking the key developments and progress achieved in capacity building (Dr Francis, Dr Kieny, Dr Nicoll). The importance and limitations of site visits and the peer-review process were discussed. Dr Kieny also briefed the group on WHO’s efforts in bringing regulatory convergence among different NRAs in grantees’ countries.
- Need for a technology hub to avoid delays in technology transfer, availability of strains, etc. (Dr Hendriks, Dr Kieny, Dr Wood).
- Role of adjuvants, such as MPLA, chitosan, MPL, etc., and observed significant antigen dose-sparing effects. There was general consensus among participants that adjuvant technologies are of the highest interest and must be pursued further.
9. **Recommendations and the way forward**

The Chairman thanked all the speakers and participants for their contribution to an informative meeting. Dr Kieny also thanked everyone for their participation. The following recommendations were made as a way forward.

- The WHO seed funding scheme should be continued for the current grantees and extended to new applicants.
- Hub activities should be supported.
- WHO should continue to explore LAIV opportunities for mass immunization campaigns in the event of a pandemic.
List of Participants

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Meeting with international partners on prospects for influenza vaccine technology transfer to developing countries
The World Health Organization has provided technical support to its Member States in the field of vaccine-preventable diseases since 1975. The office carrying out this function at WHO headquarters is the Department of Immunization, Vaccines and Biologicals (IVB).

IVB’s mission is the achievement of a world in which all people at risk are protected against vaccine-preventable diseases. The Department covers a range of activities including research and development, standard-setting, vaccine regulation and quality, vaccine supply and immunization financing, and immunization system strengthening.

These activities are carried out by three technical units: the Initiative for Vaccine Research; the Quality, Safety and Standards team; and the Expanded Programme on Immunization.

The Initiative for Vaccine Research guides, facilitates and provides a vision for worldwide vaccine and immunization technology research and development efforts. It focuses on current and emerging diseases of global public health importance, including pandemic influenza. Its main activities cover: i) research and development of key candidate vaccines; ii) implementation research to promote evidence-based decision-making on the early introduction of new vaccines; and iii) promotion of the development, evaluation and future availability of HIV, tuberculosis and malaria vaccines.

The Quality, Safety and Standards team focuses on supporting the use of vaccines, other biological products and immunization-related equipment that meet current international norms and standards of quality and safety. Activities cover: i) setting norms and standards and establishing reference preparation materials; ii) ensuring the use of quality vaccines and immunization equipment through prequalification activities and strengthening national regulatory authorities; and iii) monitoring, assessing and responding to immunization safety issues of global concern.

The Expanded Programme on Immunization focuses on maximizing access to high quality immunization services, accelerating disease control and linking to other health interventions that can be delivered during immunization contacts. Activities cover: i) immunization systems strengthening, including expansion of immunization services beyond the infant age group; ii) accelerated control of measles and maternal and neonatal tetanus; iii) introduction of new and underutilized vaccines; iv) vaccine supply and immunization financing; and v) disease surveillance and immunization coverage monitoring for tracking global progress.

The Director’s Office directs the work of these units through oversight of immunization programme policy, planning, coordination and management. It also mobilizes resources and carries out communication, advocacy and media-related work.