The Global Action Plan to increase supply of pandemic influenza vaccines

Report of the second meeting of the Advisory Group
Pune, Maharashtra, India
26 November 2008
The Global Action Plan to increase supply of pandemic influenza vaccines

Report of the second meeting of the Advisory Group
Pune, Maharashtra, India

Immunization, Vaccines and Biologicals
Contents

Abbreviations and Acronyms .............................................................................................................. v

1. Objectives ................................................................................................................................. 1
   Background: Global Action Plan .................................................................................................. 1

2. Progress in implementing GAP strategies since 2007 ............................................................ 3
   Summary on progress .................................................................................................................. 3

3. Epidemiology of H5N1 influenza virus: recent trends ............................................................. 5

4. H5N1 influenza vaccines: development status .......................................................................... 6

5. Supply and demand for influenza vaccines: mapping .............................................................. 7

6. Strengthening influenza vaccine production capacity in developing countries: GAP-inspired approach .................................................................................................................. 9

7. Newer technologies for vaccine development .......................................................................... 10

8. H5N1 vaccine stockpile development ...................................................................................... 12


10. Discussion on GAP priorities ............................................................................................... 15

11. Recommendations and way forward (closed session, only Advisory Group members and Secretariat) .............................................................................................................. 16
    Increase use of seasonal influenza vaccine ............................................................................ 16
    Production capacity for pandemic vaccines .......................................................................... 16
    Research and development of new technologies ................................................................. 17
    H5N1 vaccine stockpile .......................................................................................................... 17
    Progress review ..................................................................................................................... 17

List of participants ...................................................................................................................... 18
Abbreviations and Acronyms

AG  Advisory Group
CHMP  Committee for Medicinal Products for Human Use
GAP  Global Action Plan
GPO  Governmental Pharmaceutical Organization (Thailand)
GSK  GlaxoSmithKline
IPR  intellectual property rights
IVR  Initiative for Vaccine Research
LAIV  live attenuated influenza vaccines
NIBSC  National Institute for Biological Standards and Control
NRA  national regulatory authority
NVI  Netherlands Vaccine Institute
QC  quality control
R&D  research and development
SAGE  Strategic Advisory Group of Experts on Immunization
UNICEF  United Nations Children’s Fund
VLP  virus-like particle
WHA  World Health Assembly
WHO  World Health Organization
1. Objectives

In May 2006, a Global Action plan (GAP) was developed by WHO for increasing supply of influenza pandemic vaccines in order to reduce the anticipated gap between potential vaccine demand and supply during an influenza pandemic. To oversee the implementation of GAP, an Advisory Group (AG) was established, composed of representatives from countries — industrialized/developing, with/without manufacturing capacity. The GAP Advisory Group held its first meeting on 19 October 2007 at WHO headquarters in Geneva. The second meeting of the AG was held on 26 November 2008 in Pune, Maharashtra, India. The purpose of this meeting was to update the AG on progress made since the 2007 meeting, to report on the action taken by the WHO Secretariat following the previous year’s recommendations, and to seek guidance on priority activities for 2009. The present document summarizes the discussions at the second meeting of the GAP Advisory Group.

Background: Global Action Plan

Immunization is considered as an essential public-health intervention to control both seasonal and pandemic influenza. However, there are marked differences within countries related to vaccine production capacity and surveillance capability, as well as policy on seasonal vaccination programmes. Thus, in 2005, when demand for seasonal influenza vaccine was less than 400 million doses per year, potential pandemic vaccine supply was expected to be short of the global need by several billion doses, if pandemic vaccine production capacity increase is commensurate to seasonal vaccine demand. In response, the World Health Assembly (WHA) in resolution 58.5 in 2005 requested the WHO secretariat to seek solutions with international and national partners, including the private sector, to address the global shortage of influenza vaccines. In 2006, WHO, in consultations with key stakeholders from national immunization programmes, national regulatory authorities, vaccine manufacturers and the research community, formulated a Global Action Plan outlining strategies to increase supply of pandemic influenza vaccines.\(^1\)\(^2\) Since the conception of GAP, significant progress has been made within the three major approaches: a) an increase in seasonal vaccine use; b) increase in production capacity; c) research and development (R&D) to produce more immunogenic influenza vaccines.

\(^1\) Global pandemic influenza action plan to increase vaccine supply http://www.who.int/vaccines-documents/DocsPDF06/863.pdf.
The Advisory Group, at its first meeting on 19 October 2007, issued the following four major recommendations:

a) to develop marketing strategies for the GAP business and operational plan and to further define financial requirements and potential sources;
b) to address potential liability issues associated with the GAP business plan;
c) to maintain global commitment through information, education and communication activities;
d) to investigate seasonal influenza disease burden in developing countries and augment existing capabilities towards surveillance of emerging diseases.³

³ The Global Action Plan (GAP) to increase supply of pandemic influenza vaccines. First meeting of the Advisory Group (AG) http://whqlibdoc.who.int/hq/2008/WHO_IVB_08.10_eng.pdf.
2. Progress in implementing GAP strategies since 2007

Dr Bijan Sadrizadeh, Senior Adviser to the Minister, Ministry of Health & Medical Education, Tehran, Iran, chaired the meeting. The Chair began the meeting with the introduction of committee members and participants followed by adoption of the agenda with the following major objectives:

- to review activities contributing to the implementation of the October 2007 GAP Advisory Group recommendations;
- to revise and update GAP on science and technology and preparedness progresses;
- to identify key 2008 priorities among GAP strategies.

Summary on progress

Dr Kieny summarized the achievements since 2007. Major ones included:

- A striking increase in production capacity globally through investment of multinational vaccine producers and industrialized countries (especially from the United States of America). In addition, developing country vaccine manufacturers have shown significant progress towards developing influenza vaccine production capacity — details in the following sections.
- The business plan to evaluate the short to medium term (2007–2017) options available to pursue the GAP objective of immunizing 6.7 billion people in 6–9 months was finalized, costed and published.4
- Progress was made on the constitution and logistics of the WHO H5N1 vaccine stockpile — details in the following sections.
- Significant progress was achieved in gaining access to the live attenuated influenza vaccines (LAIV) technology for developing countries, since WHO had reached agreement with Nobilon, owner of rights outside the states of the former Soviet Union, on the St Petersburg technology. Finalization of the license agreement was expected within a few weeks.
- Virus and benefit sharing have taken forefront in the international arena.

---

• Information, education and communication activities were scaled up through WHO.
• Regarding the third approach of GAP that targets research and new technologies, the Bill & Melinda Gates Foundation and the Wellcome Trust have committed to support R&D for better vaccines.

Discussion: The Chairman summarized the achievements to date and commended WHO on the Secretariat’s follow-up activities on the 2007 recommendations.
3. Epidemiology of H5N1 influenza virus: recent trends

Dr Kieny presented the recent trends in H5N1 influenza virus with respect to disease burden in humans and poultry, and transmission rates. The data in humans suggests that 15 countries were affected in the African, Asian and European continents. In 2008, 36 cases, with 28 deaths, were reported from Bangladesh, China, Indonesia, Myanmar and Viet Nam. Up to August 2008, 61 countries had reported Highly Pathogenic Avian, H5N1 Influenza infections in wild birds or poultry. In human-to-human transmission, Dr Kieny presented a review of 367 cases (1 January 2003 to 31 October 2008), which suggests that disease is sporadic and also exists in small clusters. For instance, out of 367 cases, there were 48 clusters spread over 10 countries. Furthermore, the cluster size was from two to eight cases. Overall case-fatality rate was observed at 63%, with higher severity in females compared with males. In summary, the risk of pandemic has not decreased. Moreover, poultry disease burden remains a threat, especially in densely populated countries. Finally, other viruses like H2, H7 and H9 continue to have pandemic potential.

**Discussion:** The Chairman summarized the main facts in presentation, and there was active discussion on the trends in cluster size and human-to-human transmission, with specific reference to densely populated countries.
4. H5N1 influenza vaccines: development status

The development status of H5N1 influenza vaccines was presented by Dr Kieny. The presentation focused on the review of products (inactivated whole virion vaccines, inactivated split virion and inactivated subunit vaccines) either already licensed, or expected to be approved by a national regulatory authority (NRA) in the near future. For inactivated whole virion vaccines, Baxter, Biken, Denka Seiken, GlaxoSmithKline (GSK), Kaketsuken, Kitasato Omnivest and Sinovac are the major players. Most of the companies have a two-dose schedule of 15 micrograms each, except for Omnivest which uses a single dose (6 micrograms) to meet Committee for Medicinal Products for Human Use (CHMP) criteria. CSL, GSK and Sanofi Pasteur are the major players in the area of inactivated split virion vaccines. Newer adjuvants, such as AS and AF03, are used in GSK and Pasteur vaccines respectively. Microgen and Novartis have licensed inactivated subunit vaccines. MF-59 and alum are the preferred adjuvants for Novartis (Focetria®) and Microgen respectively. Overall, the vaccines so far tested showed good safety profiles with 0.15 % serious adverse events, which were all however unrelated to vaccination. Furthermore, adjuvants have an important role to play towards increased immunogenicity and cross-reactogenicity of vaccines.
5. Supply and demand for influenza vaccines: mapping

Figure 1 below represents a summary of the current estimates for seasonal trivalent vaccine production capacity 2008–2014. These figures were developed through a project conducted by Oliver Wyman, consulting under contract with the Bill & Melinda Gates Foundation. WHO usually uses a multiplication factor of 9 to estimate production capacity for monovalent H5N1 inactivated influenza vaccine.5

Figure 1: Expected seasonal influenza vaccine global capacity, 2007-2014.

Seasonal capacity - Updated projections
Influenza vaccine capacity is expected to more than double by 2013

Future inactivated vaccine production capacity (2008 - 2014)
Seasonal doses per year, assuming 10 months of operation

- Cell-culture
- Egg-based

If sufficient demand does not exist for this capacity, manufacturers have voiced that some will likely be rationalised

Source: Expert interviews; company statements; news articles; UB S Report: “Flu Vaccine Capacity Outstripping Demand” – Nov. 2006; Oliver Wyman analysis. 1 GSK, Novartis, and Sanofi.

---

5 Business plan for the Global pandemic influenza action plan to increase vaccine supply
Dr Kieny commented that, as it is likely there will be significant overcapacity for seasonal influenza vaccine in the coming years, strategies should be developed to encourage manufacturers not to rationalize/close down production plants, as this would have adverse effects on the maintenance of an appropriate capacity for pandemic vaccine.

**Discussion:** There was a full discussion on market demand for seasonal influenza vaccines. It was agreed that increasing market demand is a complex issue and needs concerted efforts at global and local levels to increase awareness, and hence policy, on use of influenza vaccines in specific countries. The Oliver Wyman study was also discussed. It was agreed that the study assumptions and results should be periodically reviewed in the light of technology advancements in the field.
6. Strengthening influenza vaccine production capacity in developing countries: GAP-inspired approach

A technology transfer project was launched by the Initiative for Vaccine Research (IVR) in February 2007 with donor support from the US Department of Health and Human Services, the Government of Japan (through UNICEF), and the Asian Development Bank. Dr Palkonyay presented its progress as of November 2008. Thirteen proposals had been received by WHO, and, based on an independent peer review process, six of them were selected for funding. BioFarma (Indonesia) and Birmex (Mexico) preferred a fill-finish approach, whereas Butantan (Brazil), Serum Institute of India (India), the Governmental Pharmaceutical Organization (GPO) Thailand, and IVAC (Viet Nam) were approved for a full production approach. The grantees have shown significant progress with respect to infrastructure development, pilot scale production and immunogenicity studies. There were challenges in facilitating technology transfer to the new manufacturers however. In response, WHO established a technology hub to serve as technology provider and platform for transferring optimized and documented production and quality control processes to grantees without intellectual property rights (IPR) hurdles. The hub was established at the Netherlands Vaccine Institute (NVI) and is supported by the Government of the Netherlands and WHO. It will become operational in 2009. WHO also facilitated human resources training on influenza vaccine quality control (QC) testing through various workshops (NIBSC/WHO).

Discussion: Meeting participants discussed potential market demand in countries where the new manufacturers are located, and also WHO plans for this. Dr Palkonyay explained that all six manufacturers’ countries are different with respect to national policy and government support, and therefore forecasting market demand is difficult at this stage. Dr Kiery added that manufacturers have yet to bring products to market. WHO is hoping to have some clarity with respect to government policies in the coming years and a clear forecast may then be possible. The Chairman further added that this issue is complex and that political will, awareness, and surveillance activities will be important for up-scaling demand. Further discussion was held on the possible roles of agencies such as UNICEF in facilitating sustainability of demand.
7. Newer technologies for vaccine development

Dr Bright presented the emerging technology landscape for newer influenza vaccines. The presentation gave an exhaustive overview of emerging technologies, such as live attenuated, recombinant (virus-like particles, subunit/fusion protein) and naked DNA, and universal technologies with respect to products, formulation, safety and stage of development. The major trends are as follows.

- **Live attenuated influenza vaccine**: three products were presented based on cold-adapted reassortant attenuated influenza virus strains (IEM, St Petersburg, Russian Federation, and MedImmune, USA), and on a NS1-deleted attenuated virus (Avigreen Hills, USA). These products are immunogenic by the nasal route and have fast developmental cycles. They are currently in Phase I-II trials for H5N1.

- **Recombinant virus-like particles (VLP)**: VLP produced from lentiviral vector transduced 293 cell lines (Lentigen); chimeric virus subunit particle (Baculovirus expression in insect/mammalian cells, Ligocyte); chimeric adjuvanted VLP (Baculovirus, Zeta Biologicals); plant-based VLP (plant-derived *N. benthamiana*, Medicago Ltd), and fungus-derived VLP (fungal expression system, Neugenesis Ltd). These products, and especially plant- and fungal-based VLP have the advantages of easy sourcing, low production cost and short development cycles.

- **Recombinant fusion proteins**: potential new vaccines include subunit HA products based on a plant or baculovirus expression system (Flublok® for seasonal vaccine, Panblock® for H5N1). Flublock® is likely to be licensed in 2009 and has shown improved immunogenicity, specifically relevant in elderly (age 75 and older) and immunocompromised individuals.

- **DNA vaccines**: monovalent and trivalent pandemic H5 DNA vaccines with Vaxfectin® adjuvant showed promising results in preclinical trials.

- **Universal vaccines**: the M2e/NP-ISS (ISS = CpG, chemically linked to M2e/NP) fusion protein (Dynavax) has shown universal cross protection against divergent strains. It was found to induce cytotoxic T-cells and good immunological memory. This product is undergoing advanced preclinical studies.

To summarize, current trends suggest that the technology landscape is rapidly evolving, with low-cost, rapid-response technologies in the pipeline. However, there is an urgent need for additional R&D to accelerate the successful transfer of innovative technologies to developing countries.
**Discussion:** There was discussion and questions about H5N1 and pandemic vaccine development. Dr Bright agreed that there are challenges in the development of broad spectrum vaccines; however he supported LAIV as the preferred approach to this. Dr Inoue enquired about the possible role of newer technological developments in reaching GAP production capacity goals. Dr Bright replied that the technologies may offer significant improvement in immunogenicity, yields, safety and shelf life etc., which in return will improve capacity. He added that such innovation cannot happen in isolation and will need funding, collaboration, incentives and regulatory considerations for speedy development. Indeed, such new technologies are facing many regulatory hurdles.
In November 2007, the Strategic Advisory Group of Experts on Immunization (SAGE) recommended that WHO should put in place an H5N1 vaccine stockpile, taking into consideration logistical needs and long-term sustainability, and drawing up associated procedures for procurement, management, governance, regulation and deployment. SAGE recommended specifically that the stockpile should hold 150 million doses of H5N1 vaccine with related ancillary equipment. It indicated that up to 50 million doses should be maintained for rapid-response activities to an outbreak in which there was sustained human-to-human transmission of H5N1 virus. An additional 100 million doses should be distributed to low-income and middle-income countries for use in nationally-defined essential populations as part of their response to an influenza pandemic caused by an H5N1 virus variant. Criteria for acceptance of H5N1 vaccines into the stockpile are under review, including those for licensure, as are issues related to liability. WHO is working with manufacturers to accelerate regulatory pathways for licensure and prequalification of H5N1 vaccines. Pledges of donations of H5N1 vaccine to the stockpile have been made by GlaxoSmithKline Biologicals (50 million doses), Sanofi Pasteur (60 million doses), and Omninest (100 000 doses). Other manufacturers are also considering making initial donations to the stockpile.

An in-depth study of logistical options was conducted by WHO and partners (supported by the Bill & Melinda Gates Foundation). This included rules and procedures for deployment, management, oversight and financing. Three options for the H5N1 vaccine stockpile were presented.

Option 1: WHO holds a long-term (10-year) physical stockpile of filled and finished vaccine at two or three locations selected for optimal logistics and lowest risk profiles. Vaccine doses would be stored in filled form, with the option of storing adjuvant and antigen separately, and the stockpile would be replenished as the vaccine reaches its expiration date.

Option 2: WHO holds a short-term (3-year+) physical stockpile, with no upfront provision for replenishment as vaccine reaches its expiration date.

Option 3: Manufacturers hold a stockpile of filled and finished vaccine. Industry would ensure that all products released from the stockpile have at least six months’ remaining shelf life.

The costs of each of the three options above vary considerably, and may require use of one or more innovative financing mechanisms.
Discussion: The GAP Advisory Group enquired about SAGE-recommended figures for vaccine dose requirements. Dr Kieny explained that the figures are based on general assumptions that “essential populations” represent about 1% of global populations. There were further discussions on shelf life of vaccines and on the cost implications of replenishment of the stockpile.

In order to improve access to and use of H5N1 vaccines, WHO is following a SAGE review process to develop policy guidance on the potential use of H5N1 influenza vaccine in the interpandemic period. The SAGE Working Group is currently analyzing the status of evidence which might lead to a recommendation by WHO to use licensed human H5N1 influenza vaccines to immunize populations with different risks of exposure in the interpandemic period. The different immunization target groups include:

- people at higher risk of infection (e.g. laboratory workers exposed to H5N1 virus, cullers/handlers of infected poultry, farmers, personnel involved in surveillance and investigation activities, etc.);
- essential personnel (as defined by Member States);
- larger general population groups.

Elements taken into consideration by the SAGE Working Group include: immunogenicity; safety and shelf life of H5N1 licensed vaccines; correlates of protection for new or existing vaccines; pathogenesis and transmission of H5N1 viruses, and global production capacity for H5N1 vaccines, as well as risk/benefit ratios for different populations, epidemiology, cost of vaccination and ethical issues.

Discussion: The size of populations, with specific reference to high risk, and essential or general populations was discussed. Dr Kieny clarified that these population percentages will depend on particular country situations and policies.
10. Discussion on GAP priorities

Discussion opened with remarks on the importance of surveillance, seasonal vaccine market, sustainability and political will in generating enough demand for influenza vaccines.

Dr Inoue said that major GAP priorities should be to increase usage of seasonal vaccine, to continue efforts in increasing production capacity, and to promote more R&D on newer innovative solutions.

The Chairman stressed the need for more surveillance and awareness-promoting activities in the global context.

Dr Pathom Sawanpanyalert commented that the GAP priority on stockpiling should be updated with time as the technology landscape changes. Furthermore, as new promising technologies arise, initiatives must be taken to remove regulatory hurdles so as to quickly absorb them for increasing production capacities. Dr Grohmann commented that regulators do consider public-health importance, as in the case of influenza, when they review new technologies. However, safety, quality and traceability are some of the overarching parameters for licensing any new technology.

The following comments were made.

- Efforts should be made to improve surveillance and increase influenza disease burden awareness activities.
- In countries which do not have a policy on seasonal influenza vaccine, measures should be taken at country level to promote awareness of the need for routine seasonal vaccination.
- A potential role for newer technologies should be explored in improving access and coverage of vaccines. Live attenuated vaccines have shorter development cycles and so can improve access and availability of vaccines, while many challenges still face the development of broad spectrum vaccines.
- Stockpiling modelling should consider a potential role for newer technology developments on a regular basis.
- A comprehensive document should be produced to update the 2006 Global action plan to increase supply of pandemic influenza vaccines.

The Chairman and WHO thanked all the participants and speakers for the informative meeting.
11. Recommendations and way forward (closed session, only Advisory Group members and Secretariat)

In accordance with WHO procedures, a closed session of the Advisory Group was held for formulation of recommendations to WHO and the scientific community. The following provides a summary of the major recommendations for 2009.

Increase use of seasonal influenza vaccine

The AG agreed that seasonal vaccine usage must be promoted globally, and made the following points.

- More data should be gathered in developing countries on the burden of seasonal influenza, both in terms of disease and in terms of economic impact. This data would allow countries to review the cost-effectiveness of annual influenza vaccination, and would be likely to increase demand.
- WHO should conduct a new survey of country policies on seasonal vaccine usage (current and projected).
- High-level political awareness should be stimulated.
- The WHA resolution on seasonal influenza vaccination should be refreshed, and should include a mention on the link between pandemic vaccine availability and seasonal vaccine use. IVR should work with the WHO Global Influenza Programme to make this happen.

Production capacity for pandemic vaccines

The AG considered that great progress had been made in increasing production capacity globally, which will be important in meeting vaccine demand in case of a pandemic. However, the AG recommended that:

- the production capacity should be increased and sustained irrespective of seasonal vaccine use;
- transfer of technology to developing country vaccine manufacturers should continue to be promoted;
- the results of the Oliver Wyman study should be published in order to allow analysis of its assumptions and results.
Research and development of new technologies

The AG applauded the antigen-sparing effects observed with new adjuvants and technologies, and encouraged initiatives to study correlates of protection. There were discussions on challenges in epidemic (seasonal) influenza vaccination due to antigenic drift of the circulating viruses, and to the need for boosters to induce protective immunity. The AG considered the feasibility of better seasonal vaccines, and made the following recommendations.

- More research should be conducted for better seasonal vaccines as the lack of vaccines which can induce broad spectrum immunity is a barrier to large-scale increase of seasonal vaccination.
- Work should be undertaken with regulatory authorities to decrease hurdles for new technologies.
- WHO should facilitate discussions and benefit-sharing approaches to promote access to new technologies, and in particular to the LAIV technology.

H5N1 vaccine stockpile

- The group requested that any modelling exercise should be reviewed on a regular basis with a view to suggest modifications in the stockpile due to technology advancements.

Progress review

- The AG requested that the next GAP progress review meeting be organized by WHO during 2009.
List of participants

GAP Advisory Group Members

Dr Nasr Mohammed El Sayed, Deputy Minister for Preventive Medicine, Ministry of Health and Population, Cairo, 11467 Egypt  
Dr Nguyen Tran Hien*, Director, National Institute of Hygiene and Epidemiology, Hanoi, Viet Nam  
Dr Hajime Inoue, Director, International Cooperation Office, Ministry of Health, Labour and Welfare, Tokyo 100–8916, Japan  
Dr Arlene King*, Director, Public Health Agency of Canada, Ottawa, Ontario K1A OK9, Canada (unable to attend)  
Dr Shiv Lal*, Director, National Institute of Communicable Diseases, New Delhi - 110 054, India (unable to attend)  
Dr Abdulsalami Nasidi*, Director, Special Projects, Federal Ministry of Health, Garki, Abuja, Nigeria (unable to attend)  
Dr Bijan Sadrizadeh, Senior Adviser to the Minister, Ministry of Health & Medical Education, Tehran, 11365 Iran  
Dr Pathom Sawanpanyalert, Director, Centre for International Cooperation, National Institute of Health, Thailand  
Dr Roberto Tapia-Conyer*, Director General, Instituto CARSO de la Salud, 01050 Mexico, D.F., Mexico (unable to attend)  

Participants/Observers  

Ms Janis Bernat, Biologicals and Vaccines, International Federation of Pharmaceutical Manufacturers and Associations, 1202 Geneva, Switzerland  
Dr Rick Bright, Scientific Director, Influenza Vaccine Project, Vaccine Development Global Program, Program for Appropriate Technology in Health (PATH), Washington DC 20006, United States of America  
Ms Saule Burkitbaeva, Laboratory of Toxicology and Pharmacology, National Centre for Biotechnology, Astana, Kazakhstan  

* Unable to attend
Dr Tony Colegate, Influenza Technical Affairs Manager, Novartis Vaccines, Liverpool L24 9DJ, United Kingdom of Great Britain & Northern Ireland

Dr Nicolas Collin, Consultant for the World Health Organization, Geneva, Switzerland

Dr Gordana Dakic, Head, Influenza Production Department, Institute of Virology, Vaccines and Sera Torlak, 11152 Belgrade, Serbia and Montenegro

Dr Otto de Boer, The Netherlands Vaccine Institute, Antonie van Leeuwenhoeklaan 9–11, 3720 AL Bilthoven, Netherlands

Dr Rajeev M. Dhere, Director, Vaccine Production, Serum Institute of India Ltd., Pune, 411 028 Maharashtra, India

Dr Erik d'Hondt, Bazel, B-9150 Belgium

Dr Nagwa Fouad El Kholly, Head of WHO-NIC, Influenza Reference Laboratory, VACSERA, Dokki, Cairo, Egypt

Dr Donald P. Francis, Global Solutions for Infectious Diseases, South San Francisco, California 94080, United States of America

Dr Manish Gautam, Serum Institute of India Limited, Pune, 411 028 India

Dr Gary Grohmann, Therapeutic Goods Administration, Woden, ACT 2606, Australia

Dr Hamdallah Hafez Zedan, Chairman and CEO, The Egyptian Organization for Biological Products and Vaccines (VACSERA), Cairo, Egypt

Dr Norbet Hehme, Vice President Flu Manufacturing Strategy, GlaxoSmithKline Biologicals SA, 01069 Dresden, Germany

Dr Jan T. Hendriks, Account Manager International Support, International Support, The Netherlands Vaccine Institute, 3720 AL Bilthoven, Netherlands

Dr Suresh S. Jadhav, Executive Director, President DCVMN, Quality Assurance & Regulatory Affairs, Serum Institute of India Limited, Pune, 411 028 India

Mr Alain Kupferman, 67000 Strasbourg, France

Professor Le Van Hiep, Vice Director, Institute of Vaccine and Biological Substances, Viet Nam

Dr Carlos Mammarella, Gerente Desarrollos Especiales, ASOFARMA S.A., Buenos Aires, Argentina

Dr Cosue Miyaki, Production Department, Fundação Butantan, 05503-900 São Paulo, Brazil

Dr Zsolt Nemeth, Chief Executive Officer, Omnivest Development Ltd., H-1056 Budapest, Hungary

Professor Angus Nicoll, Influenza Coordination, European Centre for Disease Prevention and Control, 171 83 Stockholm, Sweden

Dr Yuri Pervikov, Consultant for the World Health Organization, Geneva, Switzerland

Dr Samuel Ponce de Leon, General Director, Laboratorios de Biologicos y Reactivos de Mexico, S.A. de C.V., 06000 Mexico DF, Mexico
Dr Wagner Quintillio, Control Department, Butantan Foundation, Instituto Butantan, São Paulo, 05503-900 Brazil

Dr N. Ranjan, Director, Global Vaccines, Business Development & Commercialization, Baxter Healthcare (Asia) Pte Ltd., 189720 Singapore, Singapore

Dr Byung Geon Rhee, Executive Vice-President, Green Cross Corporate Development, Yongin 446-770, Republic of Korea

Dr Rosales C. Rocio Cervantes, Directora del Instituto Nacional de Virología, Laboratorios de Biológicos y Reactivos de Mexico, S.A. de C.V., 06000 Mexico DF, Mexico

Dr Carmen Sanoja, Quimbietec, Caracas 1010, Venezuela (Bolivarian Republic of)

Dr Jaspal Sokhey, New Delhi, 110048 India

Dr Monica Suarez, Quimbietec, Caracas 1010, Venezuela (Bolivarian Republic of)

Dr Mahendra Suhardono, Production Director, Bio Farma, Bandung, 40161 Indonesia

Dr Sit Thirapakpoomanunt, Director of the Viral Division, The Government Pharmaceutical Organization, Bangkok, 10400 Thailand

Mr Patrick Tippoo, R&D Manager, Biovac Institute, Wadeville 1422, South Africa

Ms Kanchala Utid, Viral Vaccine Division - The Biological Product Department, The Government Pharmaceutical Organization, Bangkok 10400, Thailand

Dr Han Van den Bosch, Director, Research and Development Director, Nobilon, Schering-Plough, 5830 AH Boxmeer, Netherlands

Dr Ruth Velazquez Fernandez, Manager of Research and Development, Birmex, Mexico D.F, 11340 Mexico, Mexico

Dr Anto Vrdoljak, Coordinator, Research and Development Department, Institute of Immunology, Croatia

Dr John Wood, Division of Virology, National Institute for Biological Standards & Control, United Kingdom of Great Britain & Northern Ireland

WHO Secretariat

Dr Claudia Alfonso, Scientist, QSS, World Health Organization, 1211 Geneva 27, Switzerland

Dr Marie-Paule Kieny, Director, Initiative for Vaccine Research, World Health Organization, 1211 Geneva 27, Switzerland

Dr Laszlo Palkonyay, Product Research and Development (RPD), Initiative for Vaccine Research, World Health Organization, 1211 Geneva 27, Switzerland

Dr Dina Pfeifer, Medical Officer, Quality Safety and Standards, WHO/HQ, 1211 Geneva 27, Switzerland
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.

Department of Immunization, Vaccines and Biologicals
Family and Community Health

World Health Organization
20, Avenue Appia
CH-1211 Geneva 27
Switzerland
E-mail: vaccines@who.int
Web site: http://www.who.int/immunization/en/