

Implementation of the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and other benefits

*Report of an informal consultation
New Delhi, 5–6 March 2012*



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Acronyms

AFRIMS	Armed Forces Research Institute of Medical Sciences, Thailand
AFRIMS	Armed Forces Research Institute of Medical Sciences, Thailand
ARI	acute respiratory infection
ASEAN	Association of Southeast Asian Nations
GISN	Global Influenza Surveillance Network
GISRS	Global Influenza Surveillance and Response System
HCW	healthcare worker
ICMR	Indian Council of Medical Research
IHR (2005)	International Health Regulations (2005)
ILI	influenza-like illness
MoAF	Ministry of Agriculture and Forest
MoH	Ministry of Health
NIID	National Institute of Infectious Diseases, Japan
PCR	polymerase chain reaction
PIP Framework	Pandemic Influenza Preparedness Framework
RT-PCR	realtime polymerase chain reaction
SARI	severe acute respiratory infection
SMTA	Standard Material Transfer Agreement

1. Background and objectives

A regional consultation was held at the World Health Organization (WHO) Regional Office for South-East Asia on 5-6 March 2012. The overall objective of the consultation was to provide a forum to develop consensus on regional priorities for implementation of the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and other benefits (hereafter referred to as the PIP Framework).

The background to the PIP Framework was provided in the context of issues related to virus-sharing and access to vaccines, including the epizootic nature of the highly pathogenic avian influenza A(H5N1), the interministerial discussions on virus-sharing, the formation of the global Open-Ended Working Group and the development of the PIP Framework, which was adopted by the Sixty-fourth World Health Assembly and became effective on 24 May 2011. The “Governance and Review” mechanism, established by the WHO Director-General to monitor implementation of the PIP Framework by means of an 18-member Advisory Group, was also described.

The overall objective of the consultation was to provide a forum to develop consensus on regional priorities for implementation of the PIP Framework.

The specific objectives were to:

- review the content of the PIP Framework;
- develop consensus on regional implementation priorities;
- consider necessary steps to implement the Framework at national and regional levels.

2. Overview of the global and regional influenza situation

The burden of seasonal influenza is not well described in most countries of the South-East Asia Region, but is probably significant. Patterns of disease are different in temperate countries and subtropical/tropical countries. Outbreaks of avian influenza A(H5N1) in poultry have been reported in most Member States of the Region, including human cases of avian influenza H5N1 in four countries (Bangladesh, Indonesia, Myanmar and Thailand). There are also sporadic cases of other forms of zoonotic influenza reported in humans; for example, H9N2 in Bangladesh in 2011. The burden of pandemic influenza (H1N1)2009 in most countries of the Region was not well characterized.

The capacity for epidemiological surveillance varies between Member States in the South-East Asia Region. Eight countries have designated national influenza centres, and both India and Thailand have regional reference laboratories. Currently, only Thailand has a national programme for influenza vaccination. At present, no country in the Region is producing seasonal, or any other, influenza vaccine that is licensed for export. Production capacity in India, Indonesia and Thailand is at varying stages of development. Oseltamivir is produced under license in Bangladesh, India, Indonesia and Thailand.

Before the onset of pandemic influenza (H1N1)2009, all Member States had national influenza pandemic preparedness and response plans. Many countries have since updated their plans, taking into account the lessons learned.

The regional status on influenza research was considered in August 2010 in a meeting on “Public health research agenda for influenza in the South-East Asia Region: A review of current status and needs”. The meeting gave recommendations for: (1) development of regional and national influenza research agenda(s); (2) mapping research capacity for influenza and other infectious diseases; (3) advocating for and facilitating networking and partnerships among stakeholders, including government, academia and research institutions within the Region and beyond; and (4) facilitating coordination of intercountry support to conduct research in the Region,

including development of generic protocols/tools, and resource mobilization.

It was also highlighted that Member States in the South-East Asia Region require good quality data on the burden of seasonal influenza to build a justification for the introduction of vaccination programmes. Establishing local production of seasonal vaccine would also create a situation where a switch could be made to the production of pandemic vaccine when needed, thereby strengthening national and regional self-reliance.

3. Influenza in the South-East Asia Region

3.1 Bhutan

The first avian influenza outbreak in poultry in Bhutan was reported from a commercial farm in a town on the border with India in 2009. The second outbreak occurred in 2012, in backyard poultry at four sites including Thimphu. Active human surveillance was established and samples were collected and tested by real-time polymerase chain reaction (RT-PCR), but no human cases of avian influenza infection have been detected to date. Seasonal influenza surveillance was initiated with support from the Armed Force Research Institute of Medical Sciences (AFRIMS) in Bangkok, Thailand, starting with three sentinel sites in 2008 and expanding to 11 sites in May 2009. The central public health laboratory is responsible for coordination and analysis of the data, which is shared with WHO and AFRIMS. The laboratory uses a standardized case definition for sample collection. Nasal swabs for rapid test (influenza A and B) can also be performed at sentinel sites and two throat swabs are normally collected, with one sent to the public health laboratory for RT-PCR and the other to AFRIMS. Quality assurance and supply of reagents and consumables are supported primarily by AFRIMS and the WHO reference laboratory in China, Hong Kong Special Administrative Region (Hong Kong SAR). An integrated pandemic preparedness plan has been jointly developed by the Ministry of Agriculture and Forests and the Ministry of Health, which has since been revised and updated through a tabletop exercise and a field simulation exercise.

3.2 India

The burden of seasonal influenza in India is not known. Outbreaks of avian influenza among poultry were first reported in 2006, with major outbreaks reported from West Bengal and Assam in 2008 and 2009. More recently, outbreaks among poultry have been reported from three epicentres in Odisha, from one epicentre in Meghalaya, and one in Tripura (November 2011 to February 2012). Outbreaks among wild birds (crows) have been reported in the states of Jharkhand and Odisha (from September 2011 onwards). These outbreaks have been contained, and no human case of avian influenza has been reported.

Influenza surveillance has been undertaken through a multi-site laboratory-based system. The network was established by the Indian Council of Medical Research in 2004 to identify emerging influenza virus strains. Published data are available for 2004 to 2008. A total of 45 laboratories (11 under the Integrated Disease Surveillance Project) supported laboratory testing during the 2009 to 2011 influenza pandemic. Multi-site sentinel surveillance for seasonal influenza was started by the National Centre for Disease Control in 2011, and consideration has been given to expanding this initiative during 2012 to 2017 into a national influenza surveillance programme. There are five manufacturers of the generic drug oseltamivir in India, which collectively provide sufficient capacity to maintain a national stockpile. A taskforce in the Department of Pharmaceuticals, Government of India, has responsibility for monitoring the availability of raw material and the formulation of these drugs. There are four manufacturers with established capacity to produce influenza H1N1 vaccine. This could also provide a platform to support the manufacture of seasonal influenza vaccine. There is currently no influenza vaccination programme in India.

The national influenza pandemic preparedness plan was first developed in 2007 and subsequently revised in 2009. The existing national plan was used to guide the response to the H1N1 2009 pandemic. It will be revised in the light of experience gained and gaps will be identified. Influenza research being conducted includes: molecular characterization of circulating strains; development of diagnostics (indigenous multiplex PCR and bedside RT-PCR); identification of pathogenic markers; disease burden (in Vadu, Pune, and Ballabgarh, Delhi); and, vaccine development including H5N1, non-pathogenic pandemic strains and recombinant vaccines.

3.3 Indonesia

Influenza surveillance in Indonesia operates through a number of sentinel sites. The three components of the system are: (1) laboratory-based virological surveillance; (2) syndromic surveillance for patients with influenza-like illness (ILI); and, (3) nationwide surveillance for pneumonia.

The laboratory-based system received ILI samples from 24 sentinel health centres in 2011 (to be expanded to 30 sites in 2012), and severe acute respiratory infection (SARI) samples from patients in 10 sentinel hospitals (all from the same provinces that have ILI surveillance sites).

Syndromic surveillance collects epidemiological data (without laboratory testing) in patients with ILI from 20 health centres in 20 provinces, geographically representative of the main provinces in Indonesia together with four provinces that are included in the early warning alert and response system.

The pneumonia sentinel surveillance system has 80 sites, including 40 hospitals and 40 health centres. There is currently no programme for seasonal influenza vaccination. The company Bio Farma has been producing seasonal influenza vaccines for high-risk groups such as people going on the Hajj pilgrimage, and to laboratory workers in the National Influenza Centre. The local pharmaceutical industry has the capacity to produce generic oseltamivir. At present, government research institutions and academia have formed a consortium to develop vaccine “seed virus” and Bio Farma is developing infrastructure to support the production of both influenza H5N1 and A(H1N1)pdm09 vaccines. Indonesia has developed and implemented a national influenza pandemic preparedness plan. Plans are in place to strengthen early warning surveillance and the epidemiological investigation of clusters of human influenza cases.

Current areas of influenza research in Indonesia include: (1) disease ecology and transmission; (2) clinical spectrum and case management; and (3) molecular, genetic and antigenic features of influenza viruses.

3.4 Maldives

The Centre for Community Health and Disease Control in the Ministry of Health is responsible for influenza vaccination programmes as well as the integrated disease surveillance system, which includes reporting from island to atoll level, and then to the central level. The laboratory at Indira Gandhi Memorial Hospital in Malé has been identified as the national influenza reference laboratory, and has capacity to perform influenza rapid tests as well as PCR. No case of avian influenza has ever been reported in the country. Confirmed cases of pandemic influenza A(H1N1)pdm09 totalled 12. Influenza vaccines and antiviral drugs are imported. The national influenza pandemic preparedness plan was last updated in November 2009. No research is currently being conducted on influenza in the Maldives.

3.5 Myanmar

No formal study on the burden of seasonal influenza in Myanmar has been conducted; however, annual rates of morbidity due to acute respiratory infection (ARI) are estimated at 537 per 100 000 population and mortality rates at 1.18 per 100 000 population. A total of 138 cases of laboratory-confirmed pandemic A(H1N1)pdm09 cases were reported in 2009. Outbreaks of avian influenza in poultry have been reported between 2006 and 2012. Only one human case of avian influenza infection has been reported, which was in 2007.

The national epidemiological surveillance system includes immediate reporting (event-based surveillance). Through this system, three outbreaks of influenza including a total of 240 cases were reported in 2011. Other types of reporting include the weekly integrated disease surveillance system (which includes ARI/pneumonia, bird fall/chicken fall) and monthly reporting of 17 priority diseases under national surveillance (including ARI).

The national influenza centre was accredited by WHO in February 2008. The laboratory has one RT-PCR machine and one automated nucleic acid extraction machine. In this way, support is provided for routine seasonal influenza surveillance, including testing of approximately 600 ILI and SARI specimens per year. Untypable isolates are sent to the National Institute of Infectious Diseases, Japan, which is a WHO collaborating centre

for influenza. The laboratory shares data and viral isolates and receives support and information on vaccine strain selection and antiviral resistance testing. Some studies on influenza virus strains and ILI surveillance are being conducted at hospitals and private clinics.

The national influenza preparedness plan was updated in July 2012, through conducting tabletop exercises and simulation exercises. The development of a multisectoral business continuity plan is in process. A pandemic vaccine deployment plan was endorsed in October 2009 and updated in October 2011. Stockpiling of antiviral drugs has been supported by WHO and the Association of Southeast Asian Nations (ASEAN). Capacity-building activities include training of epidemiologists, rapid response teams and laboratory technicians. Pandemic influenza preparedness and response is supported by several legal instruments; for example, a prevention and control of communicable diseases law passed in 1995 and amended in 2011, and a disaster management law, which has not been ratified.

3.6 Nepal

The burden of influenza in Nepal is not well known, although a large outbreak due to influenza A virus was reported in north-western districts during the late 1990s. In July 2004, an outbreak of influenza A(H3N2) was detected at three Bhutanese refugee camps in south-eastern Nepal. In 2008, an outbreak of avian influenza A(H5N1) was reported in poultry in eastern Nepal and it has been reported more recently from western and far-western regions. Pandemic influenza A(H1N1)pdm09 was also reported throughout Nepal, commencing in June 2009. Between 2010 and 2011, influenza outbreaks were also reported in Chitwan district.

The National Public Health Laboratory was designated as a national influenza centre by the Ministry of Health and Population, and recognized as such by WHO on 19 April 2010. The national influenza surveillance network is managed by a coordinating committee and comprises 10 geographically representative sentinel hospitals/laboratories, all of which provide influenza samples. Influenza surveillance in Nepal commenced in 2004, when rapid diagnostic tests were used. PCR became available in 2007. Both influenza A and B have been responsible for outbreaks during 2004 to 2008. In 2009 to 2010, influenza A(H1N1)pdm09 was prominent.

Influenza A(H5N1) (clades 2.2 and 2.3.2) was detected in a poultry outbreak in 2010. On 1 September 2011, the National Public Health Laboratory started virus culture, and 28 virus isolates have since been sent to the National Institute of Infectious Diseases, Japan. Identification of viruses is based on haemagglutination, haemagglutination inhibition and immunofluorescent tests. There are plans to expand laboratory capacity to enable diagnosis of other respiratory viruses.

3.7 Thailand

During 2001 to 2009, approximately 20 000–50 000 influenza cases have been reported per year in Thailand. More than 30 000 cases and over 200 deaths were reported in 2009 due to pandemic influenza (H1N1) and an additional 115 183 cases were reported in 2010 (181 per 100 000 population). Based on prospective surveillance, it has been estimated that over 900 000 outpatient department visits and 10% of hospitalized pneumonia cases are caused by influenza. There were 25 human cases and 17 deaths caused by avian influenza A(H5N1) between 2004 and 2006. No human case has been reported since 2006, and no outbreaks in poultry since 2008. However, studies have shown that avian influenza virus A(H5N1) is still found at low rates in wild birds.

Epidemiological surveillance for influenza is conducted through influenza reporting from all public hospitals, and supported by sentinel ILI surveillance as well as ILI cluster and pneumonia death investigation. Surveillance is also supported by selected laboratory testing. Before the emergence of avian influenza, surveillance for emerging infectious diseases (including influenza) – undertaken by the Department of Medical Sciences in the Ministry of Public Health – was limited to active surveillance at 4 sentinel hospitals. After avian influenza emerged, the number of sentinel sites was increased to 11 sites with 5 samples per week per site during 2004 to 2009, and to 15 sites with 10 samples per site per week to date. Laboratory capacity exists for PCR, virus isolation, genome sequencing, phenotyping and antiviral sensitivity testing. Viruses are routinely shared with WHO collaborating centres.

With the aim of establishing self-reliance in the production of both live attenuated and inactivated influenza vaccines, the Ministry of Public Health has received government support for the construction of an

industrial plant with production capacity of 2–10 million doses of trivalent inactivated influenza vaccine per year. Support has also been received through WHO for the development of egg-based technology.

A seasonal influenza vaccination programme was initiated in 2005. Approximately 400 000 health-care workers and 2 million people “at risk” (i.e. those with chronic diseases, the elderly, and children aged under 5 years) are vaccinated each year. Early in 2010, 2 million doses of influenza H1N1 vaccine was offered to at-risk groups including people with chronic diseases, pregnant women, obese persons and health-care workers. There is ongoing research to assess the impact of the seasonal vaccination programme. The Government Pharmaceutical Organization of Thailand started production of oseltamivir in 2008, with capacity of 1 million capsules per week. The Government Pharmaceutical Organization is also undertaking research for alternative manufacture processes.

The first pandemic influenza preparedness and response plan covered 2005–2007, and was followed by a second plan covering 2008–2010. Both plans were implemented with an emphasis on multisectoral partnership, and tested through the use of simulation exercises. It is believed that the plan made a significant contribution to the response to pandemic H1N1 2009. A third plan for 2012–2016 is being developed.

4. Background to the development of the PIP Framework

Since the 1940s, WHO has coordinated a network of influenza public health laboratories recently renamed as the Global Influenza Surveillance and Response System (GISRS). In the past, interest in GISRS was limited to industrialized countries using seasonal vaccine, for which the seed strains for production were provided by GISRS. The emergence of H5N1 – and its potential to trigger an influenza pandemic – has led to a change in the level of interest in GISRS. In May 2007, the Sixtieth World Health Assembly adopted resolution WHA60.28, and convened an intergovernmental meeting to reform the practices and processes of GISRS, which culminated in the adoption of the PIP Framework in May 2011.

Among the findings of the Report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009 was the delay in the deployment of vaccines during the pandemic (for reasons that were complex and multifactorial). The Committee urged Member States and WHO to reach an agreement on virus-sharing and access to vaccines and other benefits.

The fundamental purpose of the PIP Framework is to increase access to pandemic influenza vaccines and related benefits for countries in need in the event of an influenza pandemic, and to ensure the continued sharing of viruses necessary for continuous global monitoring and assessment of risks as well as for the development of safe and effective influenza vaccines.

A background on the development of the PIP Framework including the fundamental purpose of the Framework, six important outcomes expected, partnership contribution and proportional allocation of benefit was presented.

5. Implementation of the PIP Framework: update on the work of the Advisory Group and the future agenda

The PIP Framework Advisory Group was formulated as a result of World Health Assembly resolution WHA64.5. This states that the WHO Director-General, in consultation with the Advisory Group, will be responsible for implementation of the Framework. The Advisory Group comprises 18 members, three from each WHO region. However, each member is appointed and works in his/her individual capacity, rather than as a representative of their country. The group includes individuals with expertise in public health, intellectual property and health policy. The first Advisory Group Meeting was held in November 2011, and the second in February 2012. Meetings have included interactive sessions with GISRS, civil society and pharmaceutical associations and manufacturers.

6. Implications of the PIP Framework on GISRS

Following the signing of the WHO constitution on 22 July 1946, the establishment of a committee on influenza was proposed. The Third World Health Assembly in May 1950 approved an influenza programme and, in September 1952, the first session of the Expert Committee on Influenza was convened in Geneva, which recommended WHO to establish a network of influenza laboratories. The network, officially named the Global Influenza Surveillance Network (GISN), then started its work on monitoring viruses, guiding vaccine composition and characterizing the epidemiology of influenza. It subsequently expanded the scope of work to cover risk assessment, laboratory diagnostics, and monitoring antiviral susceptibility. In February 2012, the network included six WHO collaborating centres and 136 national influenza centres in 106 countries. After the adoption of resolution World Health Assembly WHA64.5 on 24 May 2011, the network was renamed the Global Influenza Surveillance and Response System (GISRS). It serves an important function as a global alert mechanism for the emergence of new influenza strains. The network is run on a self-sustaining and voluntary basis, with all laboratories adopting standard terms of reference and WHO playing a coordinating role. The formal review of the response to the 2009 pandemic by the IHR Review Committee considered the services provided by GISRS to be substantial and timely.

7. Proposed arrangements for virus-sharing

The tools to facilitate virus-sharing include the influenza virus traceability mechanism, and the adoption of standard material transfer agreements (SMTAs) type I and type II.

8. Research issues in influenza preparedness

Some insight was given into research areas and topics in support of the PIP Framework, and some issues of concern in conducting research were highlighted. Analysing previous studies on influenza A(H5N1) and other viruses with pandemic potential, and reviewing the relevant recommendations, could provide a direction for further studies.

The possible areas for research include: (1) laboratory and surveillance capacity-building; (2) expansion of global vaccine production capacity; (3) access, affordability and effective deployment of pandemic vaccine and antiviral medicines; and (4) sustainable financing, solidarity mechanisms and other approaches. The specific areas that have been elaborated in detail are: (1) vaccine production; (2) sharing of tissue samples for research and disease surveillance purposes; (3) transfer of human samples; (4) strengthening of health system capacity; and (5) ethical issues in planning for implementation of the PIP Framework.

9. Proposed arrangements for sharing of benefits

The PIP benefit-sharing system will be overseen by the Advisory Group, Member States and WHO. Other concerned parties – who might derive benefit from receiving viruses – include influenza vaccine, diagnostics and pharmaceutical manufacturers, and public health researchers.

The PIP benefit-sharing system will operate to: (1) strengthen pandemic surveillance, risk assessment and early warning to all countries; (2) support national, regional and global capacity-building in influenza surveillance and burden of disease studies; (3) facilitate provision of antiviral medicines and vaccines against H5N1 and other influenza viruses to Member States; and (4) build capacity in receiving countries through technical assistance and transfer of technology over time.

Through the PIP Framework, GISRS laboratories will make available summary reports of laboratory analyses and other available information on PIP biological materials, as well as ensure supply of PIP candidate vaccine viruses to laboratories and influenza vaccine manufacturers. They will provide diagnostic reagents and test kits, free of cost. Funds made available to countries through the Framework will support laboratory and influenza surveillance capacity-building for developing countries, as well as regulatory capacity-building. The PIP Framework will also support establishment of stockpiles of antivirals and pandemic vaccine. Influenza vaccine manufacturers who receive PIP biological materials may also grant a non-exclusive, royalty-free licence to any influenza vaccine manufacturer from a developing country, to use its intellectual property.

The proposed annual contribution to WHO by influenza vaccine, diagnostic and pharmaceutical manufacturers is US\$ 28 million. The first contribution is to be received in 2012. The WHO Director-General, in consultation with the Advisory Group, will establish a dialogue with industry to negotiate further contributions by each company and propose to the Executive Board the proportional split for the allocation of partnership contribution funds between “inter-pandemic” preparedness versus a contingency fund for pandemic response.

Access to and use of partnership contribution resources will be based on fairness and equity, with preferential support to regions, subregions and Member States with low-level capacity, and where public health risk and need are the greatest.

The proposed proportional split of the partnership contribution fund for the initial 5 years is as follows: surveillance and laboratory capacity-building, 70%; disease-burden studies, 10%; risk communication, 10%; and, activities for future access and effective deployment of pandemic vaccines and antiviral medicines, 10%.

The vision for global pandemic preparedness and response in the next 10 years will be that all countries have capacity for surveillance, risk assessment and response; access to a national influenza centre laboratory; pandemic vaccines and antiviral medicines; improved capacities in risk communication; and, a better understanding of the burden of influenza in their country.

10. Industry preparedness and response to the PIP Framework

The recent meeting of the PIP Advisory Group included an interactive session with representatives from the International Federation of Pharmaceutical Manufacturers and Associations (www.ifpma.org/), Biotechnology Industry Organization (www.bio.org/), the Developing Countries Vaccine Manufacturers Network (www.dcvmn.org/), and the Advanced Medical Technology Association (www.advameddx.org/), and was followed by a meeting with 35 representatives from various industry stakeholders. Senior management from WHO headquarters and members

of the Advisory Group were also present, and participated in the discussion. Representatives from the International Federation of Pharmaceutical Manufacturers and Associations shared their assessment of industry preparedness during pandemic (H1N1) 2009. They described how the seasonal influenza vaccine market is increasing, and therefore manufacturers are scaling up production capacity. The interaction between industry and GISRS seems to be satisfactory and effective in some countries, and has the potential to result in better and more cost-effective technology and production techniques. Collaborative efforts need to be strengthened to shorten the period of development and manufacture of vaccines in case of a pandemic, and new and innovative partnership models need to be evolved.

11. Conclusion and next steps

The meeting discussed key issues raised, and provided perspectives from the country and regional viewpoints. Issues raised and discussed extensively included; (1) implementation of SMTA type 1 in the context that some countries in the Region do not have a National Influenza Centre (NIC), (2) implementation of the influenza virus tracking mechanism by NIC, (3) further development and implementation of SMTA type 2 by WHO, (4) potential priority areas that could be considered for support by the PC fund; i.e. development of Regional capacity for vaccine and antiviral production; technology transfer, (5) criteria for selecting countries for PC fund support (6) liability issues under the PIP Framework; i.e. safety of vaccines developed under SMTA type 2, and (7) the role of Member States and the Region in supporting the development and implementation of the PIP Framework.

The meeting recognized and appreciated the work undertaken by WHO in relation to the development of the PIP Framework. It also commended the role of the Regional Office in organizing the first informal consultation to consider implementation of the framework. Consensus reached by the participants from Member States is as following:

- The contents and approach of the PIP Framework are supported
- Implementation of the PIP Framework would constitute a global, regional and national 'public health good' and is expected to

promote equity in the sharing of influenza viruses and associated benefits

- Advocacy with policy / decision makers on the contents of the PIP Framework may be needed to harmonize the requirements of the framework with national arrangements and national regulatory frameworks
- Advocacy should be undertaken for laboratories that are part of GISRS, in consultation with policy / decision makers to adopt the Terms of reference (ToRs) defined by the Framework, including, if required, additions to SMTA type 1 to ensure alignment with existing arrangements
- Advocacy should also be undertaken with other concerned laboratories, including those with responsibility for influenza in countries that currently have no NIC and those working on animal and zoonotic influenza, to consider adopting similar ToRs / SMTA type 1
- Concerned laboratories should continue to share influenza viruses in a timely manner, including those with pandemic potential
- WHO, including the Regional Offices should work with national laboratories and other concerned parties to provide sensitization and orientation on the process and use of the influenza virus tracking mechanism (IVTM)
- The proposed approach to prioritizing the distribution of benefit to countries according to levels of economic development, current capacity and burden of AI is supported
- In order to reflect national / regional priorities, consideration should be given to reviewing the process for prioritization of benefits for different technical areas through the Partnership Contribution to allow input from Member States; for example
 - Inclusion of additional technical areas such as healthcare facility preparedness, influenza research

- Support to the establishment of NICs in countries that do not currently have such facilities, including harnessing the technical support of other laboratories in the Region
- Upgrading the level of lab facilities available for PIP Framework implementation, e.g. supporting development of CCs/ labs with ability to study human-animal interface issues
- The process for negotiation of SMTA type 2 should be accelerated
- Consideration should be given to developing a mechanism to allow Member States to provide input into the process of negotiation of SMTA type 2 arrangements for non-financial contributions, e.g. 'in kind' benefits / technology transfer
- Consider in advance the mechanism for distribution of funds from the Partnership Contribution and for monitoring the implementation of associated activities
- Consideration should be given to developing a 'Road Map' to guide development of implementation plans.
- Consideration should be given by Member States to harmonizing any plans to strengthen capacity for influenza pandemic preparedness and response in relation to the PIP Framework with plans to implement IHR core capacities
- Adequate consideration should be given to the issue of liability of all concerned parties with regard to SMTA type 2

The meeting also agreed on the next steps:

- The meeting report of the informal consultation should be shared with Member States and the WHO Secretariat/Advisory Group.
- Opportunities should be taken to raise awareness on the PIP Framework at other regional/national meetings
- Consideration should be given by Member States to undertaking formal/informal national consultations to consolidate/refine PIP Framework implementation priorities (which may then be

presented through the Regional Office to the Secretariat and Advisory Group)

- Consideration should be given to convening a regional meeting with manufacturers of vaccines and antivirals
- Consideration should be given to a discussion on implementation of the PIP Framework at a higher level and a more inclusive regional forum

Annex 1

Agenda

- (1) Opening
- (2) Background to the development of the PIP Framework
- (3) Proposed arrangements for virus-sharing
- (4) Proposed arrangements for sharing of benefits
- (5) Governance and review (role of PIP Secretariat and Advisory Committee)
- (6) Perspectives from the Region
- (7) Implementation of the PIP Framework: next steps at regional and national levels
- (8) Recommendations from the South-East Asia Region (for feedback to the next Advisory Committee Meeting)
- (9) Closing

Annex 2

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Since 1957, influenza viruses have been shared by Member States through the WHO global influenza surveillance and response network (GISRS); however, in 2007 issues were raised about how this might be linked to access to vaccines and other benefits. To address these issues, resolution WHA60.28 recommended the Director-General to:

- develop a framework and mechanism for the sharing of benefits;
- establish an international stockpile of influenza A(H5N1) vaccine;
- prepare guidance on vaccine distribution.

The resulting “Pandemic Influenza Preparedness Framework” (PIP Framework) is expected to enhance capacity for surveillance, risk assessment and early warning.

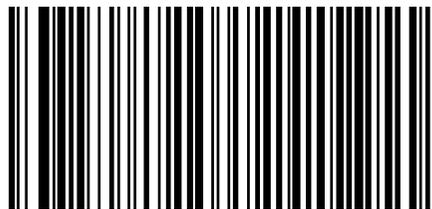
The objectives of this informal consultation were to review the content of the PIP Framework, develop a consensus on regional implementation priorities, and consider necessary steps to implement the Framework at national and regional levels. Accordingly, a number of key steps were elaborated to take this important work forward.



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