

## **Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits**

### **Intergovernmental Meeting: report of progress to date**

1. The Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and other Benefits was convened in response to resolution WHA60.28 (Annex 1). The Meeting elected Ms Jane Halton (Australia) as Chair. Five Vice-Chairs, nominated on a regional basis, were also elected: Mr A. Dick (Timor-Leste), Dr E. Palacios (Mexico), Mr K. Ahmadi (Islamic Republic of Iran), Dr A. Nasidi (Nigeria), and Mrs S.H. Steen (Norway). Participants included delegates from about 100 Member States, one regional economic integration organization, as well as representatives of the United Nations, specialized agencies, intergovernmental organizations and nongovernmental organizations (Annex 2).
2. The Director-General delivered opening remarks. After discussion, the Meeting adopted the agenda (Annex 3).
3. In the context of methods of work, it was agreed that the Developing Countries Vaccine Manufacturers Network would be represented on an exceptional basis. It was also agreed to work in plenary and a parallel working group.
4. The Chair outlined the mandate of the Meeting set out in resolution WHA60.28, namely to consider reports from the Director-General on paragraphs 2(1), 2(2), 2(3) and 2(8) and from the Interdisciplinary Working Group on paragraph 2(5). The Meeting decided on the scope of the discussions (Annex 4).
5. It was also agreed that an interim statement would be issued as part of the report on the work of the Intergovernmental Meeting to be submitted to the Executive Board (see Annex 5).
6. The consolidated outcome text is attached (Annex 6).
7. The Meeting decided that:
  - the Chair would convene an open-ended working group and will ensure its balanced representation in order to further advance the work of the IGM
  - the group will meet in Geneva, the schedule to be decided by the Chair and Vice-Chairs
  - the meeting will be resumed to consider the work of the group.



## ANNEX 1

**Resolution WHA60.28****WHA60.28      Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits**

The Sixtieth World Health Assembly,

Having considered the report on avian and pandemic influenza: developments, response and follow-up;<sup>1</sup>

Reaffirming obligations of States Parties under the International Health Regulations (2005);

Recalling resolutions WHA58.5 and WHA59.2, which expressed concern about the potential of the H5N1 strain of *Influenzavirus A* to cause a pandemic and urged Member States to disseminate to WHO collaborating centres information and relevant biological materials, including clinical specimens and viruses;

Recognizing the sovereign right of States over their biological resources, and the importance of collective action to mitigate public health risks;

Recognizing that intellectual property rights do not and should not prevent Member States from taking measures to protect public health;

Recalling the Jakarta Declaration on Responsible Practices for Sharing Avian Influenza Viruses and Resulting Benefits and the recommendations of the High-Level Meeting on Responsible Practices for Sharing Avian Influenza Viruses and Resulting Benefits (Jakarta, 26–28 March 2007);

Recognizing, in particular, the importance of international sharing, with WHO collaborating centres, of clinical specimens and viruses as a contribution to assessment of the pandemic risk, development of pandemic vaccines, updating of diagnostic reagents and test kits, and surveillance for resistance to antiviral medicines;

Stressing the need for effective and transparent international mechanisms aimed at ensuring fair and equitable sharing of benefits, including access to, and distribution of, affordable diagnostics and treatments, including vaccines, to those in need, especially in developing countries, in a timely manner;

Noting WHO's global pandemic influenza action plan to increase vaccine supply and its goal of reducing the gap between the potential vaccine demand and supply expected during an influenza pandemic by expanding over the medium- and long-term the supply of pandemic vaccine;<sup>2</sup>

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<sup>1</sup> Documents A60/7, A60/8 and A60/INF.DOC./1.

<sup>2</sup> Document WHO/IVB/06.13 – WHO/ODS/EPR/GIP/2006.1.

1. URGES Member States:

- (1) to continue to support, strengthen and improve the WHO Global Influenza Surveillance Network and its procedures through the timely sharing of viruses or specimens with WHO collaborating centres, as a foundation of public health, to ensure critical risk assessment and response, and to aim to ensure and promote transparent, fair and equitable sharing of benefits arising from the generation of information, diagnostics, medicines, vaccines and other technologies;
- (2) to support and promote research to improve the prevention, detection, diagnosis and management of influenza viral infection, with the goal of developing better tools for public health;
- (3) to support WHO as appropriate in order to identify and implement mechanisms referred to in paragraph 2, subparagraph (1);
- (4) to formulate as appropriate and to strengthen existing policies on influenza vaccines as an integral part of their national influenza-pandemic preparedness plans;
- (5) to strengthen where appropriate the capacity of national and regional regulatory authorities to carry out efficiently and effectively necessary measures for the rapid approval of safe and effective candidate influenza vaccines, especially those derived from new subtypes of influenza viruses, and in this respect to encourage international collaboration among regulatory authorities;

2. REQUESTS the Director-General:

- (1) to identify and propose, in close consultation with Member States, frameworks and mechanisms that aim to ensure fair and equitable sharing of benefits, in support of public health, among all Member States, taking strongly into consideration the specific needs of developing countries, such as, but not limited to:
  - (a) innovative financing mechanisms to facilitate timely and affordable procurement of pandemic vaccines for and by Member States in need;
  - (b) facilitation of acquisition by developing countries of capacity for manufacturing in-country influenza vaccine;
  - (c) access to influenza-vaccine viruses developed by WHO collaborating centres for the production of vaccines by all influenza-vaccine manufacturers, particularly in developing countries;
  - (d) in times of public health emergencies of international concern, full access of all influenza-vaccine manufacturers to pandemic influenza-vaccine viruses developed by WHO collaborating centres for the production of pandemic influenza vaccines;
  - (e) technical assistance to developing countries to enhance local research and surveillance capacity, including staff training, with the objective of assuring work on influenza viruses at national and regional levels;

- (f) upon request, provision of support to Member States, especially developing and affected countries, to improve their capacity to establish and strengthen testing capacity for H5 and other influenza viruses, including identification and characterization, and to establish and strengthen the capacity of those countries to meet WHO requirements for designating a reference laboratory or collaborating centre, if desired;
- (2) to establish, in close consultation with Member States, an international stockpile of vaccines for H5N1 or other influenza viruses of pandemic potential as appropriate, for use in countries in need in a timely manner and according to sound public-health principles, with transparent rules and procedures, informed by expert guidance and evidence, for operation, prioritization, release of stocks, management and oversight;
- (3) to formulate mechanisms and guidelines, in close consultation with Member States, aimed at ensuring fair and equitable distribution of pandemic-influenza vaccines at affordable prices in the event of a pandemic, in order to ensure timely availability of such vaccines to Member States in need;
- (4) to mobilize financial, technical and other appropriate support from Member States, vaccine manufacturers, development banks, charitable organizations, private donors and others, in order to implement mechanisms that increase the equitable sharing of benefits as described in paragraph 2, subparagraphs (1), (2) and (3);
- (5) to convene an interdisciplinary working group to revise the terms of reference of WHO collaborating centres, H5 Reference Laboratories, and national influenza centres, devise oversight mechanisms, formulate draft standard terms and conditions for sharing viruses between originating countries and WHO collaborating centres, and between the latter and third parties, and to review all relevant documents for sharing influenza viruses and sequencing data, based on mutual trust, transparency, and overriding principles such as:
- (a) timely sharing of viruses within the Global Influenza Surveillance Network;
  - (b) application of the same standard terms and conditions to all transactions, as appropriate;
  - (c) timely consultation and sharing of information with originating countries, especially on use outside the Network;
  - (d) for any use of influenza viruses outside the scope of the terms of reference of WHO collaborating centres, H5 Reference Laboratories, and national influenza centres, submission of a request directly to the relevant national influenza centre or other originating laboratory of the country where the virus was collected and obtention of an appropriate response from the national influenza centre; such requests would be bilateral activities not requiring the intervention of WHO;
  - (e) recognition and respect of the crucial and fundamental role and contribution of countries in providing viruses for the Global Influenza Surveillance Network;
  - (f) increased involvement, participation and recognition of contribution of scientists from originating country in research related to viruses and specimens;

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- (g) attribution of the work and increased co-authorship of scientists from originating countries in scientific publications;
- (h) due consideration of relevant national and international laws;
- (6) to assure a membership of the interdisciplinary working group consisting of four Member States from each of the six WHO regions, taking into account balanced representation between developed and developing countries and including both experts and policy makers;
- (7) to convene an intergovernmental meeting to consider the reports by the Director-General on paragraph 2, subparagraphs (1), (2), (3) and (8), and by the interdisciplinary working group on paragraph 2, subparagraph (5), that shall be open to all Member States and regional economic integration organizations;
- (8) to commission an expert report on the patent issues related to influenza viruses and their genes, and report to the intergovernmental meeting;
- (9) to continue to work with Member States on the potential for the conversion of existing biological facilities, such as those for the production of veterinary vaccines, so as to meet the standards for development and production of human vaccines, thereby increasing the availability of pandemic vaccines, and to enable them to receive vaccine seed strains;
- (10) to report on progress on implementation of this resolution, including the work of the intergovernmental meeting, to the Sixty-first World Health Assembly, through the Executive Board.

(Eleventh plenary meeting, 23 May 2007 –  
Committee A, fifth report)

## ANNEX 2



**WORLD HEALTH ORGANIZATION**  
**ORGANISATION MONDIALE DE LA SANTE**

**INTERGOVERNMENTAL MEETING ON  
 PANDEMIC INFLUENZA PREPAREDNESS:  
 SHARING OF INFLUENZA VIRUSES AND**

**A/PIP/IGM/DIV/2 Rev.1  
 22 November 2007**

**LIST OF PARTICIPANTS**  
**LISTE DES PARTICIPANTS**

**REPRESENTATIVES OF MEMBER STATES**

**REPRESENTANTS DES ETATS MEMBRES**

**ALBANIA - ALBANIE**

**Delegate(s) - Délégué(s)**

Mr G. Bejtja  
 Director, Department of Public Health, Ministry of Health

Ms S. Bino  
 Head, Department of Control of Infectious Diseases, Institute of  
 Public Health

**Alternate(s) - Suppléant(s)**

Ms M. Pistoli  
 Second Secretary, Permanent Mission, Geneva

**ALGERIA - ALGERIE**

**Chief delegate - Chef de délégation**

M. I. Jazairy  
 Ambassadeur, Représentant permanent, Genève

**Delegate(s) - Délégué(s)**

M. M. Bessedik  
 Ministre Conseiller, Mission permanente, Genève

M. E.-H. El Bey  
 Conseiller diplomatique, Mission permanente, Genève

**Alternate(s) - Suppléant(s)**

Dr S. Amrani  
 Chargée du Programme de Lutte contre la Grippe pandémique,  
 Ministère de la Santé publique, de la Population et de la  
 Réforme hospitalière

Dr F. Derrar  
 Chef de Service du Laboratoire de Surveillance de la Grippe,  
 Institute Pasteur d'Algérie

**ANGOLA - ANGOLA**

**Chief delegate - Chef de délégation**

M. A. do Nascimento  
 Ambassadeur, Représentant permanent, Genève

**Delegate(s) - Délégué(s)**

M. P. Vaz da Conceição  
 Conseiller, Mission permanente, Genève

**ARGENTINA - ARGENTINE**

**Chief delegate - Chef de délégation**

Sr. P. Cavaleri  
 Consejero, Misión Permanente, Ginebra

**Delegate(s) - Délégué(s)**

Srta. I. Fastame  
 Secretario de Embajada, Misión Permanente, Ginebra

Dra. C. Vizzoti  
 Ministerio de Salud

**ARMENIA - ARMENIE**

**Delegate(s) - Délégué(s)**

Ms L. Torosyan  
 Chief Specialist, Department of Infectious and Non-infectious  
 Diseases Epidemiology, State Sanitary Anti-epidemic  
 Inspectorate, Ministry of Health

**AUSTRALIA - AUSTRALIE****Chief delegate - Chef de délégation**

Ms J. Halton  
Secretary, Department of Health and Ageing

**Delegate(s) - Délégué(s)**

Ms M. Murnane  
Deputy Secretary, Department of Health and Ageing

Professor J. Horvath  
Chief Medical Officer, Department of Health and Ageing

**Alternate(s) - Suppléant(s)**

Mrs C. Patterson  
Minister Counsellor, Permanent Mission, Geneva

Mr Simon Cotterell  
Assitant Secretary, Department of Health and Ageing

Ms S. Ivatts  
Counsellor (Development), Permanent Mission, Geneva

Mr S. Thom  
First Secretary, Permanent Mission, Geneva

Ms T. Brink  
Second Secretary, Permanent Mission, Geneva

**AUSTRIA - AUTRICHE****Chief delegate - Chef de délégation**

Mrs C. Kokkinakis  
Minister, Permanent Mission, Geneva

**Delegate(s) - Délégué(s)**

Dr H. Friza  
Minister (Public Health), Permanent Mission, Geneva

Ms J. Valenta  
Permanent Mission, Geneva

**AZERBAIJAN - AZERBAIDJAN****Delegate(s) - Délégué(s)**

Dr F. Mammadzade  
Deputy Director, National Anti-plague Station, Ministry of Health

**BARBADOS - BARBADE****Delegate(s) - Délégué(s)**

Dr C. Babb-Schaefer  
Counsellor, Permanent Mission, Geneva

**BELGIUM - BELGIQUE****Chief delegate - Chef de délégation**

M. A. Van Meeuwen  
Ambassadeur, Représentant permanent, Genève

**Delegate(s) - Délégué(s)**

Mme B. Minart  
Représentant permanent adjoint, Genève

Mme L. Meulenbergs  
Chef de service, Service des Relations internationales, Service Public Fédéral Santé publique, Sécurité de la Chaîne alimentaire et Environnement

**Alternate(s) - Suppléant(s)**

Dr D. Reynders  
Direction générale Soins de Santé primaire et Gestion de Crises, Service Public Fédéral Santé publique, Sécurité de la Chaîne alimentaire et Environnement

M. J. De Preter  
Premier Secrétaire, Mission permanente, Genève

**Adviser(s) - Conseiller(s)**

Mme R. Baledda  
Délégation de la Communauté française de Belgique et de la Région wallonne, Genève

**BELIZE - BELIZE****Chief delegate - Chef de délégation**

Ms A. Hunt  
Chargé d'Affaires, Permanent Mission, Geneva

**Delegate(s) - Délégué(s)**

Mr M. Tamasko  
Permanent Mission, Geneva

**BHUTAN - BHOUTAN****Chief delegate - Chef de délégation**

Mr S.T. Rabgye  
Ambassador, Permanent Representative, Geneva

**Delegate(s) - Délégué(s)**

Dr U. Dophu  
Director, Department of Public Health, Ministry of Health

Ms D. Tshering  
Deputy Permanent Representative, Geneva

**Alternate(s) - Suppléant(s)**

Mr P. Norbu  
Second Secretary, Permanent Mission, Geneva

**BRAZIL - BRESIL****Chief delegate - Chef de délégation**

Mr C.A. Da Rocha Paranhos  
Ambassador, Alternate Permanent Representative, Geneva

**Delegate(s) - Délégué(s)**

Mr S. Alcazar  
Minister, Head, Department of International Affairs

Mr G. Patriota  
Minister, Permanent Mission, Geneva



**Alternate(s) - Suppléant(s)**

Mr J.R. Pio Marins  
Department of Communicable Diseases, Ministry of Health

Ms A.P.S.J. da Silveira E. Silva  
Department of International Sanitary Regulations, Agency of Sanitary Surveillance (ANVISA)

Ms J.V.B. Vallini  
National Programme of STD/AIDS, Ministry of Health

Mr R. Estrela de Carvalho  
Secretary, Permanent Mission, Geneva

**BRUNEI DARUSSALAM - BRUNEI DARUSSALAM****Delegate(s) - Délégué(s)**

Ms F.H. Hisham  
Second Secretary, Permanent Mission, Geneva

**BULGARIA - BULGARIE****Chief delegate - Chef de délégation**

Associate Professor R. Kotseva  
Head, National Reference Laboratory of Influenza and Acute Respiratory Diseases, National Centre of Infectious and Parasitic Diseases, Ministry of Health

**Delegate(s) - Délégué(s)**

Mrs D. Parusheva  
Second Secretary, Permanent Mission, Geneva

**BURKINA FASO - BURKINA FASO****Chief delegate - Chef de délégation**

M. M.B. Nebie  
Ministre Conseiller, Chargé d'Affaires a.i., Mission permanente, Genève

**Delegate(s) - Délégué(s)**

Mme E. Balima  
Attachée d'Ambassade, Mission permanente, Genève

**CAMBODIA - CAMBODGE****Delegate(s) - Délégué(s)**

Dr Sok Touch  
Director, Communicable Disease Control Department, Ministry of Health

**CAMEROON - CAMEROUN****Chief delegate - Chef de délégation**

M. A. Mama Fouda  
Ministre de la Santé publique

**Delegate(s) - Délégué(s)**

M. F. Ngantcha  
Chargé d'Affaires a.i., Mission permanente, Genève

Mme S. Ebelle  
Chargée de mission, Service du Premier Ministre

**Alternate(s) - Suppléant(s)**

Professeur L. Bella Assumpta  
Directeur de la Lutte contre la Maladie, Ministère de la Santé publique

**CANADA - CANADA****Chief delegate - Chef de délégation**

Dr A. King  
Director-General, Centre for Immunization and Respiratory Infectious Diseases, Public Health Agency

**Delegate(s) - Délégué(s)**

Ms B. Ephrem  
Director-General, International Affairs Directorate, Health Policy Branch, Health Canada

Mr P. Oldham  
Counsellor, Permanent Mission, Geneva

**Alternate(s) - Suppléant(s)**

Mr P. Blais  
Counsellor, Permanent Mission, Geneva

Ms S. LeBris  
Senior Policy Advisor, Pandemic Preparedness Secretariat, Public Health Agency

**CAPE VERDE - CAP-VERT****Delegate(s) - Délégué(s)**

Dr M.L. Monteiro  
Médecin épidémiologiste, responsable du Service de Surveillance épidémiologique, Ministère de la Santé

**CHILE - CHILI****Chief delegate - Chef de délégation**

Dra. X. Aguilera  
Jefa, División de Planificación Sanitaria, Ministerio de Salud

**Delegate(s) - Délégué(s)**

Sr. M. Santa Cruz  
Consejero, Misión Permanente ante la Organización Mundial de Comercio

Sr. B. del Picó  
Segundo Secretario, Misión Permanente, Ginebra

**CHINA - CHINE****Chief delegate - Chef de délégation**

Dr Liu Xia  
Deputy Division Director, Bureau of Disease Control, Ministry of Health

**Delegate(s) - Délégué(s)**

Mr Chen Wei  
Deputy Director-General, Pharmacy and Biotech Examination  
Department, Patent Office, State Intellectual Property Office

Mr Zhang Ze  
Third Secretary, Permanent Mission, Geneva

**Alternate(s) - Suppléant(s)**

Mr Jiang Deyuan  
Deputy Director-General, General Office, State Food and Drug  
Administration

Mr Xu Jing  
Project Officer, Department of Nature and Ecology  
Conservation, State Environmental Protection Administration

Ms Wang Dan  
Attaché, Permanent Mission, Geneva

**COSTA RICA - COSTA RICA****Chief delegate - Chef de délégation**

Sra. L. Thompson  
Embajador, Representante Permanente, Ginebra

**Delegate(s) - Délégué(s)**

Sr. C.F. Garbanzo Blanco  
Ministro Consejero, Misión Permanente, Ginebra

Sra. E. Sagot  
Misión Permanente, Ginebra

**COTE D'IVOIRE - COTE D'IVOIRE****Chief delegate - Chef de délégation**

M. G.A.E. Gauze  
Ambassadeur, Représentant permanent, Genève

**Delegate(s) - Délégué(s)**

M. F.K. Gleglaud  
Premier Conseiller, Mission permanente, Genève

M. N. Bamba  
Attaché, Mission permanente, Genève

**Alternate(s) - Suppléant(s)**

M. D. Guigui  
Attaché, Mission permanente, Genève

M. A. Traoré  
Attaché, Mission permanente, Genève

**CROATIA - CROATIE****Chief delegate - Chef de délégation**

Mr B. Socanac  
Chargé d'Affaires a.i., Permanent Mission, Geneva

**Delegate(s) - Délégué(s)**

Ms M. Adamic  
First Secretary, Permanent Mission, Geneva

**CUBA - CUBA****Chief delegate - Chef de délégation**

Sr. J.A. Fernández Palacios  
Embajador, Representante Permanente, Ginebra

**Delegate(s) - Délégué(s)**

Sra. G. Díaz Rodríguez  
Tercera Secretaria, Misión Permanente, Ginebra

**CZECH REPUBLIC - REPUBLIQUE  
TCHEQUE****Chief delegate - Chef de délégation**

Mr T. Husák  
Ambassador, Permanent Representative, Geneva

**Delegate(s) - Délégué(s)**

Mr P. Hrnčíř  
Deputy Permanent Representative, Geneva

Mr J. Kynel  
National Institute of Public Health

**Alternate(s) - Suppléant(s)**

Ms M. Havlicková  
National Institute of Public Health

Ms D. Beladová-Lupacová  
International Relations Department, Ministry of Health

**DEMOCRATIC PEOPLE'S REPUBLIC OF  
KOREA****REPUBLIQUE POPULAIRE  
DEMOCRATIQUE DE COREE****Chief delegate - Chef de délégation**

Mr Gye Chun Yong  
Deputy Permanent Representative, Geneva

**Delegate(s) - Délégué(s)**

Mr Sok Jong Myong  
Counsellor, Permanent Mission, Geneva

**DENMARK - DANEMARK****Chief delegate - Chef de délégation**

Dr L.P. Nielsen  
Consultant, WHO National Influenza Centre, Statens Serum  
Institute

**Delegate(s) - Délégué(s)**

Mr A. Berling-Rasmussen  
First Secretary, Permanent Mission, Geneva

**Adviser(s) - Conseiller(s)**

Ms I.W. Rasmussen  
Permanent Mission, Geneva

**DJIBOUTI - DJIBOUTI****Delegate(s) - Délégué(s)**

Dr S.B. Tourab  
Secrétaire général, Ministère de la Santé

**DOMINICAN REPUBLIC - REPUBLIQUE DOMINICAINE****Chief delegate - Chef de délégation**

Sr. C. Segura  
Ministro Consejero, Misión Permanente, Ginebra

**Delegate(s) - Délégué(s)**

Sra. M. Bello de Kemper  
Consejero, Misión Permanente, Ginebra

**ECUADOR - EQUATEUR****Chief delegate - Chef de délégation**

Sr. M. Montalvo  
Embajador, Representante Permanente, Ginebra

**Delegate(s) - Délégué(s)**

Srta. L. Baquerizo Guzmán  
Segundo Secretario, Misión Permanente, Ginebra

**EGYPT - EGYPTE****Chief delegate - Chef de délégation**

Mr S. Shoukry  
Ambassador, Permanent Representative, Geneva

**Delegate(s) - Délégué(s)**

Mr T. Khalaf  
Third Secretary, Permanent Mission, Geneva

**EL SALVADOR - EL SALVADOR****Delegate(s) - Délégué(s)**

Sra. L. Alvarado-Overdiek  
Consejero, Misión Permanente, Ginebra

**ESTONIA - ESTONIE****Delegate(s) - Délégué(s)**

Mrs K. Sibul  
Third Secretary, Permanent Mission, Geneva

**FINLAND - FINLANDE****Chief delegate - Chef de délégation**

Ms M. Saarinen  
Director, Ministry of Social Affairs and Health

**Deputy chief delegate - Chef adjoint de la délégation**

Ms A. Virolainen-Julkunen  
Ministerial Counsellor, Ministry of Social Affairs and Health

**Delegate(s) - Délégué(s)**

Ms O. Kuivasniemi  
Ministerial Adviser, Ministry of Social Affairs and Health

**Alternate(s) - Suppléant(s)**

Mr T. Ziegler  
Laboratory Director, National Public Health Institute

Ms S. Sammalkivi  
First Secretary, Permanent Mission, Geneva

**Adviser(s) - Conseiller(s)**

Ms M. Koivusalo  
Senior Expert, National Research and Development Centre for Welfare and Health

**FRANCE - FRANCE****Chief delegate - Chef de délégation**

M. J.-B. Mattei  
Ambassadeur, Représentant permanent, Genève

**Delegate(s) - Délégué(s)**

M. C. Guilhou  
Représentant permanent adjoint, Genève

Mme I. Virem  
Mission aux Affaires européennes et internationales, Direction générale de la Santé, Ministère de la Santé, de la Jeunesse et des Sports

**Alternate(s) - Suppléant(s)**

Dr B. Lina  
Virologie et Pathologie humaine, UCBL-CNRS FRE 3001, Faculté RTH, Laennec

Dr S. Henry  
Bureau des Risques infectieux et Politique vaccinale, Direction générale de la santé, Sous-direction prévention des risques infectieux, Ministère de la Santé, de la Jeunesse et des Sports

M. G. Saour  
Délégation interministérielle de Lutte contre la Grippe aviaire (DILGA), Direction générale de la Santé, Ministère de la Santé, de la Jeunesse et des Sports

Mme J. Tor-de Tarié  
Premier Secrétaire, Mission permanente, Genève

M. F. Million  
Premier Secrétaire, Mission permanente, Genève

**GEORGIA - GEORGIE****Chief delegate - Chef de délégation**

Dr E. Kipiani  
Senior Specialist, Department of Health and Management of Emergency Situations, Ministry of Labour, Health and Social Affairs

**Delegate(s) - Délégué(s)**

Mrs E. Kapanadze  
Senior Specialist, Department of Health and Management of  
Emergency Situations, Ministry of Labour, Health and Social  
Affairs

Mrs A. Archvadze  
Coordinator, Avian Influenza Control and Human Pandemic  
Preparedness and Response Project of the World Bank

**GERMANY - ALLEMAGNE****Chief delegate - Chef de délégation**

Mr R. Schweppe  
Ambassador, Permanent Representative, Geneva

**Delegate(s) - Délégué(s)**

Ms B. Siefker-Eberle  
Deputy Permanent Representative, Geneva

Ms D. Reitenbach  
Head of Unit, Federal Ministry of Health

**Alternate(s) - Suppléant(s)**

Dr L. Schaade  
Head of Unit, Federal Ministry of Health, Bonn

**Adviser(s) - Conseiller(s)**

Professor G. Pauli  
Head of Unit, Robert-Koch-Institut

Mr F. Oelschläger  
Adviser, Federal Ministry of Justice

Mr G. Berkemeier  
Attaché, Permanent Mission, Geneva

Mr B. Kümmel  
Adviser, Federal Ministry of Health

Mrs Y. Lindenlaub  
Federal Ministry of Health

Ms A. Zinecker  
Permanent Mission, Geneva

**GHANA - GHANA****Delegate(s) - Délégué(s)**

Mr K. Baah-Duodu  
Ambassador, Permanent Representative, Geneva

Mrs L. Asledu  
First Secretary, Permanent Mission, Geneva

**GREECE - GRECE****Chief delegate - Chef de délégation**

Mr F. Verros  
Ambassador, Permanent Representative, Geneva

**Deputy chief delegate - Chef adjoint de la  
délégation**

Ms A. Foteinea  
Director, Public Health Division, Ministry of Health and Social  
Solidarity

**Delegate(s) - Délégué(s)**

Mr A. Cambitsis  
Minister Counsellor, Permanent Mission, Geneva

**Alternate(s) - Suppléant(s)**

Mr T. Papadimitriou  
Director, Hellenic Centre for Diseases Control and Prevention,  
Ministry of Health and Social Solidarity

Ms A. Damigou  
Counsellor (Health Affairs), Permanent Mission, Geneva

Dr S. Tsiodras  
Hellenic Centre for Diseases Control and Prevention, Ministry of  
Health and Social Solidarity

Dr A. Karageorgiou  
National Health Operations Centre, Ministry of Health and Social  
Solidarity

**GUATEMALA - GUATEMALA****Chief delegate - Chef de délégation**

Sr. C.R. Martínez Alvarado  
Embajador, Representante Permanente, Ginebra

**Delegate(s) - Délégué(s)**

Sra. S. Hochstetter Skinner-Kléé  
Ministro Consejero, Misión Permanente, Ginebra

Srta. S. Urruela Arenales  
Segundo Secretario, Misión Permanente, Ginebra

**GUINEA - GUINEE****Delegate(s) - Délégué(s)**

M. P. Monlmou  
Conseiller chargé des Affaires humanitaires, Mission  
permanente, Genève

**HONDURAS - HONDURAS****Chief delegate - Chef de délégation**

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Embajador Plenipotenciario, Representante Permanente, Misión  
Permanente, Ginebra

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Embajadora Alterna, Misión Permanente, Ginebra

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Ambassador, Permanent Representative, Geneva

**Delegate(s) - Délégué(s)**

Mr G. Somogyi  
Attaché, Permanent Mission, Geneva

Mr A. Mészáros  
Deputy Head of Department, Ministry of Health

**Alternate(s) - Suppléant(s)**

Mr S. Kovács  
Counsellor, Embassy of the Republic of Hungary, Bern

Mrs M.S. Garainé  
Representative of the Hungarian Investment and Trade  
Development Agency (ITDH), Zürich

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**Alternate(s) - Suppléant(s)**

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Minister of Health

**Deputy chief delegate - Chef adjoint de la délégation**

Dr M. Wibisono  
Ambassador, Permanent Representative, Geneva

**Delegate(s) - Délégué(s)**

Dr W. Lukito  
Assistant to the Minister for Public Health, Ministry of Health

**Alternate(s) - Suppléant(s)**

Mr I.G.A.W. Puja  
Ambassador, Deputy Permanent Representative, Geneva

Dr I. Tantoro  
Adviser to the Minister for Health Protection, Ministry of Health

Dr. H.R. Thamrin  
Ministry of Health

Dr T. Subagyo  
Deputy for Intellectual property Rights, Intellectual property and  
Technology Transfer Office, Agency for Agricultural Research  
Development

Dr E.R. Sedyaningsih  
Director, Biomedical and Pharmaceutical Research Centre,  
Ministry of Health

Dr Budihardja  
Head, Planning Section, Ministry of Health

Mr S.M. Soemarno  
Director, Socio-cultural Affairs and International Organizations of  
Development Countries, Directorate General of Multilateral  
Affairs, Department of Foreign Affairs

Mr C. Herawan  
First Secretary, Permanent Mission, Geneva

Mr A. Somantri  
First Secretary, Permanent Mission, Geneva

Ms H.J. Parsomal  
Adviser of the Ministry of Health, Ministry of Health

Ms N.K. Naryatie  
Head, Section for Health Issues, Directorate General of  
Multilateral Affairs, Department of Foreign Affairs

Ms M. Utami  
Head of Section for Administration and Protocol, Ministry of  
Health

Mr B.S. Wibowo  
Official, Ministry of Health

**IRAN (ISLAMIC REPUBLIC OF)****IRAN (REPUBLIQUE ISLAMIQUE D')****Chief delegate - Chef de délégation**

Mr A. Moaiyeri  
Ambassador, Permanent Representative, Geneva

**Delegate(s) - Délégué(s)**

Mr A. Esteghamati  
Deputy Director-General, Communicable Diseases Department,  
Ministry of Health

Mr P. Sa'adat  
Deputy Director, Specialized International Agencies Department,  
Ministry of Foreign Affairs

**Alternate(s) - Suppléant(s)**

Mr K. Ahmadi  
Counsellor, Permanent Mission, Geneva

**IRAQ - IRAQ****Delegate(s) - Délégué(s)**

Dr H.M. Abdulhussein  
Deputy, General Directorate for Primary Health Care and Public  
Health, Ministry of Health

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Mr I. Levanon  
Ambassador, Permanent Mission, Geneva

**Delegate(s) - Délégué(s)**

Ms N. Furman  
Counsellor, Permanent Mission, Geneva

Ms D. Norris  
Adviser, Permanent Mission, Geneva



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Ministre Conseiller, Mission permanente, Genève

M. E. Vicenti  
Premier Conseiller, Mission permanente, Genève

**Alternate(s) - Suppléant(s)**

M. M.G. Pompa  
Prévention sanitaire, Ministère de la Santé

Mme E. Scolaro  
Mission permanente, Genève

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Dr M. Bullock DuCasse  
Director, Emergency Disaster Management and Special Services, Ministry of Health and Environment

**Delegate(s) - Délégué(s)**

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First Secretary, Permanent Mission, Geneva

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Mr H. Endo  
Director, Bureau of International Cooperation, International Medical Centre of Japan

**Delegate(s) - Délégué(s)**

Dr H. Inoue  
Director, International Cooperation Office, Minister's Secretariat, Ministry of Health, Labour and Welfare

Dr K. Miyake  
Deputy Director, Tuberculosis and Infectious Diseases Control Division, Health Service Bureau, Ministry of Health, Labour and Welfare

**Alternate(s) - Suppléant(s)**

Ms M. Toyota  
First Secretary, Permanent Mission, Geneva

Mr M. Okuma  
Official, Specialized Agencies Division, International Cooperation Bureau, Ministry of Foreign Affairs

**JORDAN - JORDANIE****Delegate(s) - Délégué(s)**

Mr N. Al-Faraj  
Third Secretary, Permanent Mission, Geneva

**KAZAKHSTAN - KAZAKHSTAN****Chief delegate - Chef de délégation**

Dr A. Zholshorinov  
Head, Department of Epidemiological Control, Committee of State Sanitary-Epidemiological Surveillance, Ministry of Health

**Delegate(s) - Délégué(s)**

Dr Z. Karagulova  
Counsellor, Permanent Mission, Geneva

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Dr T. Mboya Okeyo  
Ambassador, Deputy Permanent Representative, Geneva

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First Secretary (Legal), Permanent Mission, Geneva

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Mrs I. Dreimane  
First Secretary, Permanent Mission, Geneva

**LEBANON - LIBAN****Delegate(s) - Délégué(s)**

Dr Z. Tabarah  
Chief Medical Officer, Infectious Diseases Department, Rafik Hariri Governmental Hospital

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Dr M.A. Maruping  
Ambassador, Permanent Representative, Geneva

**Deputy chief delegate - Chef adjoint de la délégation**

Mrs S.S. Matsoele  
Deputy Tuberculosis and HIV Manager, Ministry of Health and Social Welfare

**Delegate(s) - Délégué(s)**

Mr L. Kopeli  
Minister Counsellor, Permanent Mission, Geneva

**Alternate(s) - Suppléant(s)**

Mr L. Moqhali  
Counsellor, Permanent Mission, Geneva

**LIBERIA - LIBERIA****Chief delegate - Chef de délégation**

Dr M.G.Y. Pewu  
Ministry of Health

**Delegate(s) - Délégué(s)**

Dr K.K. Koikoi  
Ministry of Agriculture

**LIBYAN ARAB JAMAHIRIYA - JAMAHIRIYA ARABE LIBYENNE****Chief delegate - Chef de délégation**

Dr M. Smeo  
Epidemiologist, National Centre for Infectious Diseases and Prevention

**Delegate(s) - Délégué(s)**

Dr O. Elahmer  
Virologist, National Centre for Infectious Diseases Prevention

Dr A. Smeo  
Surveillance Officer, National Centre for Infectious Diseases Prevention

**Alternate(s) - Suppléant(s)**

Dr H. Gashut  
Premier Conseiller, Mission permanente, Genève

**LITHUANIA - LITUANIE****Chief delegate - Chef de délégation**

Ms D. Sidiskiène  
Deputy Head, Safety Control Division, State Public Health Service, Ministry of Health

**Delegate(s) - Délégué(s)**

Ms A. Bankauskaite-Miliauskiene  
Chief Specialist, Emergency Situations Prevention Division, Health Emergency Situations Centre, Ministry of Health

Ms A. Bankauskaite-Miliauskiene  
Chief Specialist, Emergency Situations Prevention Division, Health Emergency Situations Centre, Ministry of Health

**LUXEMBOURG - LUXEMBOURG****Chief delegate - Chef de délégation**

M. J. Feyder  
Ambassadeur, Représentant permanent, Genève

**Delegate(s) - Délégué(s)**

Mme G. Goy  
Représentant permanent adjoint, Genève

M. J. Pundel  
Premier Secrétaire, Mission permanente, Genève

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Mr M. Limon  
Chargé d'affaires, Permanent Mission, Geneva

**Delegate(s) - Délégué(s)**

Ms S.A. Sattar  
First Secretary, Permanent Mission, Geneva

**MALI - MALI****Delegate(s) - Délégué(s)**

Dr N. Sylla  
Service à la Section Surveillance épidémiologique, Direction nationale de la Santé

**MAURITANIA - MAURITANIE****Chief delegate - Chef de délégation**

Mme M. Mint Abdellah  
Ambassadeur, Représentant permanent, Genève

**Delegate(s) - Délégué(s)**

M. M. Ould Ely Telmoudy  
Secrétaire général, Ministère de la Santé et Président, Commission nationale de riposte à la Grippe aviaire

M. A.O.M. Bousseif  
Deuxième Conseiller, Mission permanente, Genève

**MEXICO - MEXIQUE****Chief delegate - Chef de délégation**

Sra. D.M. Valle  
Consejero, Misión Permanente, Ginebra

**Delegate(s) - Délégué(s)**

Sra. E. Palacios  
Subdirectora de Emergencias Internacionales de Salud, Secretaría de Salud

Sra. G. Ramírez  
Asesor Técnico, Misión Permanente, Ginebra

**Alternate(s) - Suppléant(s)**

Sr. J.L. Amador  
Asesor Técnico, Misión Permanente, Ginebra

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M. A. Jahlan  
Troisième Secrétaire, Mission permanente, Genève

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M. M. Loulichki  
Ambassadeur, Représentant permanent, Genève

**Deputy chief delegate - Chef adjoint de la délégation**

M. J. Nouril  
Responsable du Laboratoire de Virologie, Institut Pasteur du Maroc

**Delegate(s) - Délégué(s)**

M. A. Benmamoun  
Chef, Division des Maladies transmissibles, Direction de l'Epidémiologie et de la Lutte contre les Maladies

M. M. Achgalou  
Premier Secrétaire, Mission permanente, Genève

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Mrs S. Shrestha  
State Minister for Health and Population

**Delegate(s) - Délégué(s)**

Mr B.R. Paudyal  
Chargé d'Affaires a.i., Minister Counsellor, Permanent Mission, Geneva

Dr M.K. Maskey  
Coordinator, Health Policy Advisory Committee

**Alternate(s) - Suppléant(s)**

Dr M.K. Banerjee  
Coordinator, Avian Influenza Control, Epidemiology and Disease Control Division, Department of Health Services

Mr D.R. Bhandari  
Attaché, Permanent Mission, Geneva

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Ms M. Kappeyne van de Coppello  
Deputy Permanent Representative, Geneva

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Ms G. Vrieling  
First Secretary, Permanent Mission, Geneva

Ms E. van Woersem  
Adviser, Permanent Mission, Geneva

**Alternate(s) - Suppléant(s)**

Mr R. Schers  
Adviser, Permanent Mission, Geneva

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Dr A. Nasidi  
Federal Ministry of Health

**Delegate(s) - Délégué(s)**

Mr M.S. Yakubu  
Minister, Permanent Mission, Geneva

Dr T. Fakeye  
Federal Ministry of Health

**Alternate(s) - Suppléant(s)**

Professor T. Harry  
Federal Ministry of Health

Dr S. Belgore  
Federal Ministry of Health

Mr M.I. Haidara  
Second Secretary, Permanent Mission, Geneva

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Dr H.J. Skorpen  
Minister Counsellor, Deputy Permanent Representative, Chargé d'Affaires, Geneva

**Delegate(s) - Délégué(s)**

Mr J. Fuglesang  
Senior Adviser, Norwegian Directorate of Health and Social Affairs

Dr O. Hugnes  
Norwegian Institute of Public Health

**Alternate(s) - Suppléant(s)**

Mr T.E. Lindgren  
Counsellor, Permanent Mission, Geneva

Mrs S.H. Steen  
Counsellor, Permanent Mission, Geneva

Mrs G.K. Waage  
First Secretary, Permanent Mission, Geneva

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Mr S.A.A. Gillani  
Second Secretary, Permanent Mission, Geneva



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Dra. G. Guerrero  
Jefa, Departamento de Epidemiología, Ministerio de Salud

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Tercer Secretario, Misión Permanente, Ginebra

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Minister, Permanent Mission, Geneva

**Delegate(s) - Délégué(s)**

Dr Y.E. Oliveros  
Director IV, National Centre for Disease Prevention and Control,  
Department of Health

Ms V.T. Abad  
Attaché, Permanent Mission, Geneva

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Ms A. Swiatecka  
Senior Expert, Department of Communicable Diseases Control,  
Chief Sanitary Inspectorate

**Delegate(s) - Délégué(s)**

Ms M. Romanowska  
National Centre for Influenza, National Institute of Hygiene

Mrs R. Lemieszewska  
Counsellor, Permanent Mission, Geneva

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Mme G. Freitas  
Direction général de la Santé

**Delegate(s) - Délégué(s)**

Mme F. Parra  
Direction général de la Santé

M. M. Soares  
Instituto Nacional da Farmacia e do Medicamento (INFARMED)

**Alternate(s) - Suppléant(s)**

Professeur H.R. de Andrade  
Institut national de la Santé (INSA)

M. J. Sousa Fialho  
Conseiller, Mission permanente, Genève

Mme B. Nogueira Martins  
Expert, Mission permanente, Genève

Mlle J. Canas  
Expert, Mission permanente, Genève

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Mr Park Hun-yul  
Counsellor, Permanent Mission, Geneva

**Delegate(s) - Délégué(s)**

Dr Park Hye Kyung  
Deputy Director, Infectious Disease Surveillance Team, Ministry  
of Health and Welfare

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Ambassadeur, Représentant permanent, Genève

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Dr M.P. Shevyriova  
Deputy Director, Department of Human Well-being, Science and  
Education, Ministry of Health

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Dr I.G. Drozdov  
Director-General, State Virology and Biotechnology Research  
Centre (VECTOR), Federal Service for Surveillance on  
Consumer Rights Protection and Human Well-being

Dr E.B. Ejlova  
Deputy Head, Federal Service for Surveillance on Consumer  
Rights Protection and Human Well-being

**Alternate(s) - Suppléant(s)**

Dr A.V. Pavlov  
Counsellor, Permanent Mission, Geneva

Mr L.V. Kulikov  
First Secretary, Permanent Mission, Geneva

Mr D.A. Khudov  
Attaché, Permanent Mission, Geneva

**Adviser(s) - Conseiller(s)**

Mr N.N. Sikachev  
Senior Adviser, Department of International Organizations,  
Ministry of Foreign Affairs

Mr V. Ryabenko  
Assistant to Director-General, State Virology and Biotechnology  
Research Centre (VECTOR), Novosibirsk

**SERBIA - SERBIE****Chief delegate - Chef de délégation**

Dr P. Kon  
Specialist in Epidemiology, Head, Expert Working Group for the Implementation of the Pandemic Preparedness Plan, Ministry of Health

**Delegate(s) - Délégué(s)**

Mr V. Lazovic  
Second Secretary, Permanent Mission, Geneva

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Mr D. Poiret  
Director, Environmental Health, Department of Health, Ministry of Health and Social Development

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Senior Minister of State for Foreign Affairs

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Associate Professor Chew Suok Kai  
Deputy Director, Medical Services, Ministry of Health

**Delegate(s) - Délégué(s)**

Mr S.N. Syed Hassim  
Counsellor and Chargé d'Affaires a.i., Permanent Mission, Geneva

**Alternate(s) - Suppléant(s)**

Dr J. Tey  
Assistant Director, Manpower Standards and Development Division, Ministry of Health

Mr C. Wong  
Assistant Director, International Cooperation Branch, Ministry of Health

Ms F. Gan  
First Secretary, Permanent Mission, Geneva

**SLOVAKIA - SLOVAQUIE****Delegate(s) - Délégué(s)**

Mr J. Mikas  
Head, Department of Epidemiology, Public Health Authority

Mr P. Šelepec  
Second Secretary, Permanent Mission, Geneva

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Ms G. Korze  
Counsellor, Permanent Mission, Geneva

**Delegate(s) - Délégué(s)**

Ms V.-K. Petric  
Head, Sector for Health Promotion and Healthy Lifestyles, Ministry of Health

Ms N. Prinat  
Assistant to Director, Institute of Public Health

**Alternate(s) - Suppléant(s)**

Mr B. Jerman  
Minister Counsellor, Permanent Mission, Geneva

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Mrs G. J. Mtshali  
Ambassador, Permanent Representative, Geneva

**Delegate(s) - Délégué(s)**

Ms C.C. Kotzenberg  
Department of Health

Mr J. van Wyk  
Counsellor (Economic Development), Permanent Mission, Geneva

**Alternate(s) - Suppléant(s)**

Ms S. Chung  
Second Secretary (Economic Development), Permanent Mission, Geneva

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Sr. J.A. March Pujol  
Embajador, Representante Permanente, Ginebra

**Delegate(s) - Délégué(s)**

Sr. G. López Mac-Lellan  
Consejero, Misión Permanente, Ginebra

Sra. M.J. Sierra Moros  
Jefe de Area, Centro de Coordinación de Alertas y Emergencias Sanitarias, Dirección General de Salud Pública, Ministerio de Sanidad y Consumo

**Alternate(s) - Suppléant(s)**

Dra. A. Limia Sánchez  
Jefe de Servicio, Centro de Coordinación de Alertas y Emergencias Sanitarias, Dirección General de Salud Pública, Ministerio de Sanidad y Consumo

**SRI LANKA - SRI LANKA****Delegate(s) - Délégué(s)**

Mrs M. Mallikaratchy  
Second Secretary, Permanent Mission, Geneva

**SUDAN - SOUDAN****Delegate(s) - Délégué(s)**

Dr M. Abdalla  
Director, Epidemiology Department, Federal Ministry of Health

**SWEDEN - SUEDE****Chief delegate - Chef de délégation**

Ms A. Janelm  
Senior Adviser, Division for Public Health, Ministry of Health and Social Affairs

**Delegate(s) - Délégué(s)**

Ms M. Möllgren  
Legal Adviser, Swedish National Board of Health and Welfare

**SWITZERLAND - SUISSE****Chief delegate - Chef de délégation**

M. G. Silberschmidt  
Vice directeur, Chef de la Division des Affaires Internationales, Office fédéral de la Santé publique, Département fédéral de l'Intérieur (OFSP/DFI)

**Delegate(s) - Délégué(s)**

Mme B. Schaefer Bourbeau  
Premier Secrétaire, Division multilatérale, Mission permanente, Genève

Mme B. Toti  
Collaboratrice scientifique, Division des Affaires internationales, Office fédérale de la Santé publique, Département fédérale de l'Intérieur (OFSP/DFI)

**Alternate(s) - Suppléant(s)**

M. M. Girsberger  
Co-chef, Service juridique Brevet et Design, Division Droit et Affaires internationales, Institut Fédérale de la Propriété Intellectuelle, Département fédéral de Justice et Police (DFJP/IPI)

**SYRIAN ARAB REPUBLIC - REPUBLIQUE ARABE SYRIENNE****Chief delegate - Chef de délégation**

Dr M.J. Al Owed  
Deputy Minister of Health

**Delegate(s) - Délégué(s)**

Dr H. Bakkour  
Deputy Director, Epidemiological Studies Department, Ministry of Health

**THAILAND - THAILANDE****Chief delegate - Chef de délégation**

Mr P. Sawanpanyalert  
Director, National Institute of Health, Department of Medical Sciences, Ministry of Public Health

**Delegate(s) - Délégué(s)**

Lt. T. Ekkayokkaya  
Senior Intellectual Property Officer, Department of Intellectual Property, Ministry of Commerce

Mr V. Srinetr  
Environmental Officer, Biological Diversity Division, Office of Natural Resources and Environmental Policy and Planning, Ministry of Natural Resources and Environment

**Alternate(s) - Suppléant(s)**

Miss S. Raviwan  
Deputy Secretary-General, Office of Natural Resources and Environment Policy and Planning, Ministry of Natural Resource and Environment

Mr V. Isarabhakdi  
Minister, Permanent Mission, Geneva

Mrs P. Kanchanahattakij  
First Secretary, Permanent Mission, Geneva

**THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA****EX-REPUBLIQUE YOUGOSLAVE DE MACEDOINE****Chief delegate - Chef de délégation**

Dr Z. Karadzovski  
President, National Commission for Monitoring Pandemic Influenza, Republic Institute for Health Protection

**Delegate(s) - Délégué(s)**

Dr E. Ramo  
Sector for Preventive Health Care, Ministry of Health

**TIMOR-LESTE - TIMOR-LESTE****Chief delegate - Chef de délégation**

Mr A. Dick  
Chargé d'Affaires a.i., Permanent Mission, Geneva

**Delegate(s) - Délégué(s)**

Mr I. P. Fay  
Permanent Mission, Geneva

Ms E. Feller  
Permanent Mission, Geneva

Ms M. Jocallaz  
Permanent Mission, Geneva

**Alternate(s) - Suppléant(s)**

Ms C. Helletzgruber  
Permanent Mission, Geneva

Ms D. Wenk  
Permanent Mission, Geneva

Ms K. Ranjbar  
Permanent Mission, Geneva

Ms M. Ben Ayed  
Permanent Mission, Geneva

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M. S. Labidi  
Ambassadeur, Représentant permanent, Genève

### Delegate(s) - Délégué(s)

Professeur A. Salim  
Professeur, Laboratoire national de référence à l'Hôpital Charles Nicole

Dr A. Ghram  
Chef de Service des Microbiologies vétérinaires, l'Institut Pasteur de Tunis

### Alternate(s) - Suppléant(s)

M. H. Landoulsi  
Conseiller, Mission permanente, Genève

## TURKEY - TURQUIE

### Chief delegate - Chef de délégation

Associate Professor A. Coskun  
Deputy Director-General, Directorate-General of Primary Health Care, Ministry of Health

### Delegate(s) - Délégué(s)

Mr E.S. Yüksel  
First Secretary, Permanent Mission, Geneva

## UKRAINE - UKRAINE

### Chief delegate - Chef de délégation

Dr L.M. Mukharskaia  
Deputy Chief Medical Officer, Ministry of Health

### Delegate(s) - Délégué(s)

Dr M.M. Aronova  
Chief Specialist, Epidemiological Well-being Unit, Department of Health and Epidemiological Surveillance, Ministry of Health

Dr I.S. Dush  
Chief Specialist, European Integration and International Relations Unit, Department for Legal Support and International Operations, Ministry of Health

### Alternate(s) - Suppléant(s)

Mrs S. Homanovska  
Counsellor, Permanent Mission, Geneva

## UNITED ARAB EMIRATES - EMIRATS ARABES UNIS

### Chief delegate - Chef de délégation

Dr M. Fikri  
Assistant Under-Secretary for Preventive Medicine, Ministry of Health

### Delegate(s) - Délégué(s)

Mr O.S.S. Al Zaabi  
Ambassador, Permanent Representative, Geneva

Miss N. Al Qassimi  
First Secretary, Permanent Mission, Geneva

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## ROYAUME-UNI DE GRANDE-BRETAGNE ET D'IRLANDE DU NORD

### Chief delegate - Chef de délégation

Professor D. Harper  
Chief Scientist/Director-General, Health Protection, International Health and Scientific Development, Department of Health

### Delegate(s) - Délégué(s)

Ms J. Newstead  
Head, International, Cross-Government and Secretariat Pandemic Influenza, Department of Health

Dr C. Presem  
Counsellor, Permanent Mission, Geneva

### Alternate(s) - Suppléant(s)

Dr S. Inglis  
Director, National Institute for Biological Standards and Control

Professor D. Salisbury

## UNITED STATES OF AMERICA - ETATS-UNIS D'AMERIQUE

### Chief delegate - Chef de délégation

The Honorable J.E. Lange  
Special Representative on Avian and Pandemic Influenza, Department of State

### Deputy chief delegate - Chef adjoint de la délégation

Mr D.E. Hohman  
Health Attaché, Permanent Mission, Geneva

### Alternate(s) - Suppléant(s)

Mr M. Abdo  
Director, Office of Multilateral Affairs, Office Global Health Affairs, Department of Health and Human Services

Mr J. House  
Patent Attorney, Office of International Relations, United States Patent and Trademark Office, Department of Commerce

Mr J. J. Kim  
Assistant Legal Adviser for Oceans, International Environmental and Scientific Affairs, Office of the Legal Adviser, Department of State

Mr D.A. Singer  
Senior Medical Policy Adviser, Avian Influenza Action Group, Department of State

**URUGUAY - URUGUAY****Delegate(s) - Délégué(s)**

Sra. L. Trucillo  
Ministerio de Salud Pública

**UZBEKISTAN - OUZBEKISTAN****Delegate(s) - Délégué(s)**

Mr H.B. Saparov  
Head, Especially-Dangerous Infection Department, Ministry of Health

**VENEZUELA (BOLIVARIAN REPUBLIC OF)****VENEZUELA (REPUBLIQUE BOLIVARIENNE DU)****Chief delegate - Chef de délégation**

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Embajador, Representante Permanente, Ginebra

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Embajador, Representante Permanente Alterno, Ginebra

Sr. E. Bitetto Gavilanes  
Primer Secretario, Misión Permanente, Ginebra

**VIET NAM - VIET NAM****Chief delegate - Chef de délégation**

Dr Pham Ngoc Dinh  
Deputy Director, National Institute of Hygiene and Epidemiology,  
Ministry of Health

**Delegate(s) - Délégué(s)**

Mr Pham Hong Nga  
Counsellor, Permanent Mission, Geneva

**YEMEN - YEMEN****Delegate(s) - Délégué(s)**

Dr A.H. Al Kohlani  
Director General for Surveillance and Disease Control, Ministry  
of Public Health and Population

Dr E. Al-Mahbashi  
Third Secretary, Permanent Mission, Geneva

**ZAMBIA - ZAMBIE****Chief delegate - Chef de délégation**

M. C. Banda  
Technical Liaison and Publicity, Ministry of Health

**Deputy chief delegate - Chef adjoint de la délégation**

M. E.M. Wamuwi  
Influenza Focal Point, Ministry of Health

**Delegate(s) - Délégué(s)**

Mr A. Zulu  
First Secretary, Permanent Mission, Geneva

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Mrs P. Nyagura  
Counsellor, Permanent Mission, Geneva

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Mrs F. Merico

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Mr A. Smith Serrano  
External and Inter-Agency Affairs Officer, Office of the Director-General, Geneva

Dr D. Nabarro  
UN System Senior Coordinator for Avian and Human Influenza

Dr J. Sfeir  
Economic and Social Commission for Western Africa (ESCWA)

---

**UNITED NATIONS RELIEF AND WORKS  
AGENCY FOR PALESTINE REFUGEES IN  
THE NEAR EAST**

**OFFICE DE SECOURS ET DE TRAVAUX  
DES NATIONS UNIES POUR LES REFUGIES  
DE PALESTINE DANS LE PROCHE-ORIENT**

---

Ms E.M. Materi  
Senior Liaison Officer

Ms Y. Burton

Ms M. Gilani

---

**OFFICE OF THE UNITED NATIONS HIGH  
COMMISSIONER FOR REFUGEES**

**HAUT COMMISSARIAT DES NATIONS  
UNIES POUR LES REFUGIES**

---

Mr R. Vivarie  
Senior Policy Officer, Emergency Preparedness and Response  
Section

---

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**INSTITUTIONS SPECIALISEES**

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**ORGANISATION INTERNATIONALE DU  
TRAVAIL**

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Mr D. Kiniger-Passigli  
Programme on Crisis Responses and Reconstruction

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**FOOD AND AGRICULTURE ORGANIZATION  
OF THE UNITED NATIONS**

**ORGANISATION DES NATIONS UNIES  
POUR L'ALIMENTATION ET  
L'AGRICULTURE**

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Mr S. Bhatti  
Secretary, International Treaty on Plant Genetic Resources for  
Food and Agriculture, Plant Production and Protection Division,  
Agriculture and Consumer Protection Department

---

**WORLD INTELLECTUAL PROPERTY  
ORGANIZATION**

**ORGANISATION MONDIALE DE LA  
PROPRIETE INTELLECTUELLE**

---

Mr A. Taubman  
Acting Director and Head, Global Intellectual Property Issues  
Division

Mr C. Mazal  
Senior Counsellor, Coordination Sector for External Relations  
Industries, Communication and Public Outreach

Mr H.G. Bartels  
Head, Life Sciences and Public Policy Section

Ms A. Von Der Ropp  
Associate Officer, Global Intellectual Property Issues Division

---

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DEVELOPMENT ORGANIZATION**

**ORGANISATION DES NATIONS UNIES  
POUR LE DEVELOPPEMENT INDUSTRIEL**

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M. B. Caizadilla-Sarmiento

M. J. Towara

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ORGANISATION MONDIALE DU  
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Dr C. Mazeyrac  
Medical Service

Mrs Xiaoping Wu  
Counsellor, Intellectual Property Division

---

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**REPRESENTANTS D'AUTRES  
ORGANISATIONS  
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**OFFICE INTERNATIONAL DES EPIZOOTIES**

**ORGANISATION MONDIALE DE LA SANTE  
ANIMALE**

Dr C. Bruschke

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Mme K. Masri  
Ambassador, Permanent Observer, Geneva

Mr Y. El Habib  
First Secretary, Permanent Observer, Geneva

Mlle B. Naidoo  
First Secretary, Permanent Observer, Geneva

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EUROPEENNE**

Mr M. Rajala  
Minister Counsellor, Permanent Delegation, Geneva

Mr F. Karcher  
Legislative Officer, Health and Consumer Protection Directorate  
General

Mr S. Balibrea  
Counsellor, Permanent Delegation, Geneva

Mr J. O Toole  
External Relations and Partnerships, European Centre for  
Disease Prevention and Control (ECDC)

Mr M. Schwarz  
Attaché, European Commission Delegation, Geneva

Ms A. Ricol  
Attachée, European Commission Delegation, Geneva

Mr F. Luccisano  
Attaché, European Commission Delegation, Geneva

---

**INTERNATIONAL ORGANIZATION FOR  
MIGRATION**

**ORGANISATION INTERNATIONALE POUR  
LES MIGRATIONS**

Dr A. Davies  
Public Health Specialist/AHI/HRH Coordinator, Migration Health  
Department

Dr S. Gunaratne  
Coordinator, Migration Health Emergencies, Migration Health  
Department

---

**ORGANIZATION OF THE ISLAMIC  
CONFERENCE**

**ORGANISATION DE LA CONFERENCE  
ISLAMIQUE**

Mr B. Ba  
Ambassador, Permanent Observer, Geneva

Mme A. Kane  
First Secretary, Permanent Observer Mission, Geneva

---

**REPRESENTATIVES OF  
NONGOVERNMENTAL  
ORGANIZATIONS IN OFFICIAL  
RELATIONS WITH WHO**

**REPRESENTANTS DES  
ORGANISATIONS NON  
GOUVERNEMENTALES EN  
RELATIONS OFFICIELLES AVEC  
L'OMS**

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**CMC - CHURCHES' ACTION FOR HEALTH**

**CMC - L'ACTION DES EGLISES POUR LA  
SANTÉ**

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Ms P. Boulet

Mr E. Hammond

Dr G. Jourdan

Mr M. Khor Kok Peng

Dr M. Kurian

Ms Lim Li Lin



Ms Y. Miller  
 Ms S. Shashikant  
 Mr R.K. Tayob  
 Ms G. Upham  
 Mr T. Balasubramaniam

---

**INTERNATIONAL ASSOCIATION FOR  
 BIOLOGICALS**

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**ASSOCIATION INTERNATIONALE POUR  
 LES PRODUITS BIOLOGIQUES**

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Dr L. Hessel

---

**INTERNATIONAL ASSOCIATION FOR  
 MATERNAL AND NEONATAL HEALTH**

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**ASSOCIATION INTERNATIONALE POUR LA  
 SANTÉ DE LA MÈRE ET DU NOUVEAU-NÉ**

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Dr R. Kulier

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**INTERNATIONAL CENTRE FOR TRADE AND  
 SUSTAINABLE DEVELOPMENT**

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**CENTRE INTERNATIONAL POUR LE  
 COMMERCE ET LE DÉVELOPPEMENT  
 DURABLE**

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 Mr A.A. Latif  
 Ms G. Vea  
 Mr M. McDermott

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**CONSEIL INTERNATIONAL DES  
 INFIRMIÈRES**

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Dr T. Ghebrehiwet

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**INTERNATIONAL FEDERATION OF  
 PHARMACEUTICAL MANUFACTURERS  
 AND ASSOCIATIONS**

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**FÉDÉRATION INTERNATIONALE DE  
 L'INDUSTRIE DU MÉDICAMENT**

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 Ms A. Abelin  
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 Mr R. Burden  
 Mr S. Gardner  
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 Ms S. Copt-Gregorio  
 Dr H.E. Bale  
 Mr R. Krause  
 Mr S. Pannatier  
 Ms J. Bernat  
 Mr C. Marshall

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**INTERNATIONAL PHARMACEUTICAL  
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**FÉDÉRATION INTERNATIONALE  
 PHARMACEUTIQUE**

---

Dr T. Hoek  
 Mr Xuan Hao Chan

---

**MEDICAL WOMEN'S INTERNATIONAL  
 ASSOCIATION**

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**ASSOCIATION INTERNATIONALE DES  
 FEMMES MÉDECINS**

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Dr C. Landerer  
 Dr E. Dulic  
 Dr E. Blöchlinger  
 Dr C. Bretscher-Dutoit



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**WORLD FEDERATION FOR MEDICAL  
EDUCATION**

**FÉDÉRATION MONDIALE POUR  
L'ENSEIGNEMENT DE LA MÉDECINE**

---

Dr H. Karle

Professor L. Christensen

---

**WORLD VISION INTERNATIONAL**

**VISION MONDIALE INTERNATIONALE**

---

Dr T. Getman

---

**INVITED NONGOVERNMENTAL  
ORGANIZATION**

**ORGANISATION NON  
GOUVERNEMENTALE INVITEE**

---

**DEVELOPING COUNTRIES VACCINE  
MANUFACTURERS NETWORK**

**DEVELOPING COUNTRIES VACCINE  
MANUFACTURERS NETWORK**

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Dr S. Jadhav

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ANNEX 3

## Agenda

**1. Opening of the session,<sup>1</sup> adoption of the agenda and method of work**

Document A/PIP/IGM/1

**2. Reports by the Director-General**

Document A/PIP/IGM/INF.DOC./1 and resolution WHA60.28

2.1 Summary progress reports:

Document A/PIP/IGM/2 Rev.1

- identification of frameworks and mechanisms for sharing benefits (resolution WHA60.28, paragraph 2(1))
- establishment of an international stockpile of vaccines (resolution WHA60.28, paragraph 2(2))
- formulation of mechanisms and guidelines for distribution of pandemic-influenza vaccines (resolution WHA60.28, paragraph 2(3))

2.2 Patent issues related to influenza viruses and their genes

Document A/PIP/IGM/3

**3. Sharing of influenza viruses and access to vaccines and other benefits:  
Interdisciplinary Working Group on Pandemic Influenza Preparedness**

Document A/PIP/IGM/4

**4. Preparation of draft outcome for consideration by the Sixty-first World Health Assembly**

Documents A/PIP/IGM/5 and A/PIP/IGM/6

**5. Closure of the session**

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<sup>1</sup> Including election of the Chairman and other officers.

## ANNEX 4

**Scope of discussions**

- *What kind of virus*
  - *H5N1 and other viruses from human sources which may cause influenza pandemic*
- *Purpose of the use of viruses*
  - *[Only for non-commercial risk assessment according to a certain agreed terms of reference(IGM5)]*
  - *Assessment of pandemic risk, development of pandemic vaccines, updating of diagnostic reagents and test kits and surveillance of anti-viral resistance (WHA60.28)*
- *What mechanism are we referring to*
  - *GISN (describing and evaluating current components) and*
  - *Proposing a strengthened, improved, more transparent and expanded GISN*
  - *Other processes and parties as outlined in WHA60.28 2(5)*
- *Number of parties identified in the STC*
  - *[Party 1: Originating Member States (NIC, Essential national regulatory labs or any entities that are designated and authorized by the MS)*
  - *Party 2: Current five WHO Collaborating Centres on Influenza, WHO H5 reference laboratories, Other entities designated by WHO, Essential national regulatory labs involved in specific WHO influenza projects and other labs involved in specific WHO influenza projects*
  - *Party 3: Other entities(institutions, organizations and companies) that are approved by WHO to receive biological materials]*

*Or*

- *Originating Member States*
- *Essential National Regulatory Laboratories*
  - *The influenza laboratories at the Food and Drug Administration of the United States of America, the National Institute for Biological Standards and Control (United Kingdom of Great Britain and Northern Ireland) and the Australian Therapeutic Goods Administration*
- *WHO Collaborating Centres on Influenza*
  - *Centres concerned with influenza generally are influenza laboratories designated by national authorities and recognized by WHO to perform certain roles within the Global Influenza Surveillance Network. In general, they differ from National Influenza Centres in having global responsibilities and greater technical capacities*
- *WHO H5 Reference Laboratories*
  - *a group of influenza laboratories that have been designated by WHO as having the capacity to reliably diagnose H5 infection in humans*
- *National Influenza Centres*
  - *influenza laboratories designated by national authorities and recognized by WHO to perform certain roles within the Global Influenza Surveillance Network*

- *Laboratories involved in specific WHO influenza projects*
- *Institutions, organizations and companies approved by WHO to receive biological materials*

## ANNEX 5

**Interim Statement of the Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of influenza viruses and access to vaccine and other benefits**

Reaffirming resolution WHA60.28;

Stressing the critical importance of global public health;

Reaffirming obligations of States Parties under the International Health Regulations (2005);

In view of the threat of an influenza pandemic;

Acknowledging the importance of the international collaboration and collective action in risk assessment, timely sharing of viruses and specimens, the development and production of preventive and curative measures such as vaccine and antivirals as well as other measures to protect public health globally and in each Member State;

Acknowledging the urgent need for fair, transparent, equitable and effective international mechanisms aimed at ensuring access to H5N1 vaccine and fair and equitable sharing of benefits, in support of public health amongst Member States taking into consideration the needs of developing countries (resolution WHA60.28);

Acknowledging the fact there has been a breakdown of trust in this essential system of the international collaboration and collective action;

Acknowledging that the current system does not deliver the desired level of fairness, transparency and equity;

Pending the agreement by the World Health Assembly on a detailed framework for virus sharing and benefit sharing and as a demonstration of good will;

We agree to take urgent action to develop fair, transparent and equitable international mechanisms on virus sharing and benefit sharing.

We also agree on the following two immediate measures for delivering transparency:

**Traceability mechanism**

The Director-General will establish a technical and feasible system as soon as possible within WHO to track all shared H5N1 and other potentially pandemic human viruses and the parts thereof. A report on the progress of the implementation of the system will be provided to the Sixty-first World Health Assembly. Pending the functioning of such traceability mechanism, an interim system providing full disclosure of information on transfer and movement of virus shall be made operational immediately.

**Advisory mechanism**

The Director-General will establish an advisory mechanism to monitor, provide guidance to strengthen the functioning of the system and undertake necessary assessment of the trust-based system needed to

protect public health. An advisory group will be appointed by the Director-General in consultation with Member States, based on equitable representation of the WHO regions and of affected countries.

Further, as a tangible demonstration of good will, we agree that viruses and samples are to be shared within the WHO system, consistent with national laws and regulations, while the detailed framework for virus sharing and benefit sharing continues to be developed.

The IGM decided that the Chair would convene an open-ended working group of the IGM and will ensure a balanced representation to further advance its work.

The group will meet in Geneva, the schedule to be decided by the Chair and Vice-Chairs.

The IGM will be re-convened to consider the work of the group.

We invite the Director-General within her existing mandates in particular with respect to resolution WHA60.28 to take forward the actions outlined in this Statement and we will support her in this endeavour.

ANNEX 6

## Consolidated outcome text: index

- Principles
  - Virus sharing
  - Benefit sharing
  - Financing
  - Collective action
  - Sovereign rights
  - Capacity building and technology transfer
  - Intellectual property
  - Oversight mechanisms
  
- Operational components
  - Virus sharing
  - Benefit sharing
  - Financing
  - Oversight mechanism
  - *Capacity building and technology transfer*
  - *Collective action*
  - Appendix (Standard Terms and Conditions for the transfer and use of influenza biological materials)
  
- Dictionary of terms

## PRINCIPLES

### 1. Virus sharing

1.1 *WHO has the leadership of the whole process of virus sharing [and benefit sharing] within the framework. Within this framework, WHO should aim to ensure [fairness, equitability,] transparency, efficiency, reliability and the inclusive nature of the process. The framework should be able to adapt to new threats*

1.2 *Timely, transparent, accountable, and [free] [mandatory] international sharing of clinical specimens and H5N1 and other viruses from human sources which may cause influenza pandemics [to (GISN members who are in good standing in the operation of the network) WHO mechanisms which have been in good standing in respect of practices and processes for assessment of pandemic risk,] is critical for the assessment of pandemic risk, development of pandemic vaccines, updating of diagnostic reagents and test kits, [and] surveillance for resistance to antiviral medicines [and other public health oriented research].*

1.3 *To accomplish this, continued support is required to strengthen, improve, expand and consolidate existing systems for global influenza surveillance. **Consensus***

*[1.4 [Access to benefits][Benefit sharing][for those in good standing of GISN] is [primary ] based on public health needs regardless of the source of the virus, [but those not in good standing of GISN are not eligible to share benefits except in an emergency.]]*

*[1.5 Without prejudice to Global Public health security and needs, Virus sharing and benefit sharing should be managed under the same [[mechanisms] and based on the same] basis [mandatory/voluntary] [principles].]*

*1.5a Virus sharing [and Benefits sharing] should be managed in a way [which aims] aimed to ensure mutual trust, [and] transparency and [Global Public Health],[ [takes] [ taking into consideration the specific needs of developing countries WHA 60.28 2 (1), and] consistent with the principles as stated in the WHA 60.28 ]*

*[1.5b Virus sharing should be managed in a way aimed to ensure mutual trust, transparency and Global Public Health, consistent with the principles as stated in the WHA 60.28 ]*

*[1.5c Benefits sharing should be managed in a way aimed to ensure mutual trust, transparency and Global Public Health, taking into consideration the specific needs of developing countries WHA 60.28 2 (1), ]*

1.6 *Roles and responsibilities of all parties and institutions involved in global influenza surveillance [Network], must be clearly defined.*

*[1.7 While Recognizing the sovereign rights of the States over their biological resources and the importance of a collective action to mitigate the risks for public health, no country, including the country of origin or any other entity, may [claim] [exercise] ownership rights over [samples and its derivatives] [clinical specimens] submitted to the global influenza surveillance system.] [5.7aAccess*



to specimen/virus must be done through an agreement in the form of a standard Material Transfer Agreement (MTA) agreed by Member States.]

[1.8 Prior informed consent of the originating countries is required for transfer of the virus and for placing sequence data in a database.]

[1.9 All influenza vaccine manufacturers must have full access to influenza vaccine viruses developed by the surveillance mechanism, for research and development of influenza vaccines.]

*[1.9a All influenza vaccine manufacturers must have full access to influenza vaccine viruses developed by the surveillance mechanism, for research and development of influenza vaccines with prior informed consent of the originating country and using Standard Material Transfer agreements agreed by MS.]*

[1.10 Influenza vaccine manufacturers can only obtain *[candidate influenza vaccine viruses]* [seed virus] from the system with prior informed consent of the originating country [and must commit to benefit sharing].]

## 2. Benefit sharing

2.1 The international benefit sharing mechanism must be transparent, and aimed at ensuring fair and equitable sharing of, access to, and distribution of benefits *based on public health need*, especially developing countries, in a timely manner, and particularly *but not limited to* during public health emergencies of international concern. **Consensus**

*2.1a [Access to benefits][Benefit sharing][for those in good standing of GISN] is [primary ] based on public health needs regardless of the source of the virus, [but those not in good standing of GISN are not eligible to share benefits except in an emergency.]*

[2.2 Benefits must be concrete, *and* specific and include but not be limited to:

*(a) innovative financing mechanisms to facilitate timely and affordable procurement of pandemic vaccines for and by Member States in need;*

*(b) facilitation of acquisition by developing countries of capacity for manufacturing in-country influenza vaccine;*

*(c) access to influenza-vaccine viruses developed by WHO Collaborating Centres for the production of vaccines by all influenza-vaccine manufacturers, particularly in developing countries;*

*(d) in times of public health emergencies of international concern, full access of all influenza-vaccine manufacturers to pandemic influenza-vaccine viruses developed by WHO Collaborating Centres for the production of pandemic influenza vaccines;*

*(e) technical assistance to developing countries to enhance local research and surveillance capacity, including staff training, with the objective of assuring work on influenza viruses at national and regional levels;*

(f) upon request, provision of support to Member States, especially developing and affected countries, to improve their capacity to establish and strengthen testing capacity for H5 and other influenza viruses, including identification and characterization, and to establish and strengthen their capacity to meet WHO requirements for becoming a reference laboratory or Collaborating Centre, if desired;

- affordable diagnostics, [and] treatments, [including] vaccines and ancillary supplies (e.g. syringes);
- strengthening the capacity of national laboratories and regulatory agencies;
- upgraded information systems to provide full, reliable and timely tracking of viruses and access to information on their use in the global influenza surveillance system;
- promoting, developing and strengthening the core capacity of Member States to participate in global risk assessment, conduct surveillance, develop pandemic preparedness and respond to influenza outbreaks.]

2.2a Benefits *should* [be concrete, specific and ] include but not be limited to *those in WHA60.28 2(1)*

2.3 [Benefits must be shared on the same principle as viruses are shared.]

2.3a [*Virus sharing and] Benefits sharing should be managed in a way [which aims] aimed to ensure mutual trust, [and] transparency and [Global Public Health.],[ [takes] [ taking into consideration the specific needs of developing countries WHA60.28 2(1), and] consistent with the principles as stated in the WHA60.28 ]*

[2.3b *Benefits sharing should be managed in a way aimed to ensure mutual trust, transparency and Global Public Health, taking into consideration the specific needs of developing countries WHA60.28 2(1), ]*

[2.4 *Recognition that developing countries have limited capacities and they face economic, financial and administrative constraints, means effort to empower and build capacity are urgently required.]*

[2.5 *Capacity building [must] [should] include increased involvement, participation and recognition of contribution of scientists from the originating country, in research and scientific journal publications related to viruses and specimens while recognizing the need to establish technically competent WHO CCs in developing countries. Capacity building should also include improvement of technical equipment available for research in developing countries.]*

### 3. Financing

3.1 There is a need to facilitate [*voluntary,*] timely, sustainable, innovative and equitable mechanisms to finance virus and benefit sharing.

3.2 There is a need to mobilize financial, technical and other appropriate support from member States, vaccine manufacturers, development banks, charitable organizations, private donors and others in order to implement mechanisms that increase the equitable sharing of benefits. **Consensus**

#### 4. Collective action

4.1 States Parties reaffirm their obligations under the International Health Regulations (2005).

4.2 Global Public Health Security requires collective efforts and [solid] commitment. Aiming to enhance Global Public Health Security, WHO under the leadership of Member States, should work [under the framework] to ensure early detection, timely notification, identification and sharing [of information][viruses], [rapid response to][of] potential global public health concern.

#### 5. Sovereign rights

[5.1 Recognizing the sovereign right of Member States over their biological resources, [the importance of collective actions to mitigate public health risks and the obligations of [Member States][State Parties] under the IHR][ the right of a state to provide access to viruses on a bilateral arrangement is upheld,] [this must be done in agreement with a [MTA] [defined STC]][,taking into consideration the importance of collective actions to mitigate risks for public health.] ]

[5.2 WHO should be granted *permission to use* [ownership (or custodianship, trusteeship, permission to use, or right to use) of] influenza virus-related biological specimens as a means to preserve and facilitate a multilateral approach to virus sharing for risk assessment, rapid vaccine manufacturing, and more equitable sharing of benefits *in accordance with*:

(a) *respect for the sovereign rights of the Member States including prior informed consent and benefit sharing,*

(b) *Terms of reference applicable to all States and non-State Research and Development facilities including WHO Collaborating Centres, National Influenza Centres and essential regulatory laboratories etc.*

*acknowledging the sovereign rights of the originating country and based on the terms agreed in the MTA .]*

[5.3 While Recognizing the sovereign rights of ~~the~~ States over their biological resources and the importance of ~~a~~ collective action to mitigate ~~the~~ risks for public health, no country, including the country of origin or any other entity, may [claim] [exercise] ownership rights over [samples and its derivatives][clinical specimens] submitted to the global influenza surveillance system.]

#### [6. Capacity building and technology transfer]

6.1 Recognition that developing countries have limited capacities and they face economic, financial and administrative constraints, means *effort* to empower and build capacity are urgently required.

6.2 Capacity building [must] [should] include increased involvement, participation and recognition of contribution of scientists from the originating country, in research *and scientific journal publications* related to viruses and specimens *while recognizing the need to establish technically competent WHO CCs in developing countries. Capacity building should also include improvement of technical equipment available for research in developing countries.*

**[7. Intellectual property rights**

*7.1a Intellectual property rights do not and should not prevent Member States from taking measures to protect Public Health]*

or

*[7.1 Intellectual property rights shall be respected. However, MS shall be allowed to make exceptions to Intellectual Property Rights and take measures to protect public health. [must be respected and should not prevent Member States from taking measures to protect public health.]]*

*7.2 No entity can acquire intellectual property rights over viruses, samples and their derivatives, parts thereof and their derivatives in the form received from the multilateral system.]*

**[8. Oversight mechanisms**

*8.1 The need for a robust oversight mechanism.]*

*[8.2 The WHO secretariat will review the functioning of GISN and will analyse its strengths and weakness and will explain the shortcomings that must be overcome under the terms and conditions for the exchange of viruses and the implementation of the monitoring mechanisms as enshrines in the resolution WHA60.28]*

## OPERATIONAL COMPONENTS

*Working document as at 23 November, 13:00*

NOTES:

- (1) Agreed text is marked in ***bold, italics***, followed by the word “***agreed***” in parenthesis.
- (2) Text for which consensus was not reached is bracketed in square brackets [ ].
- (3) Submission of new text from delegation is marked in *italics* with country/region attribution in parenthesis, in ***bold, italics***.
- (4) The section under the heading “STANDARD TERMS AND CONDITIONS” was not discussed by the group. The compilation of texts for the “Standard Terms and Conditions” from **White Paper 3 Rev.1 22 November 2007** is included as an Appendix to this document.

### Compilation of texts

**Virus Sharing**

**Benefit Sharing**

**Financing**

**Oversight Mechanism**

***Capacity building and technology transfer***

***Collective action***

## VIRUS SHARING

### **DEFINITION and SCOPE (Indonesia prefers the term Standard Material Transfer Agreement)**

*Insert definition of viruses and other materials (UK) (to use text from the Glossary prepared by the Secretariat)*

*[Access to virus is provided for a timely vaccine production, including vaccine which will be made available for a vaccine stockpile (Finland) The global stockpile should be formulated by WHO and endorsed by Member States. (IGM/5 Fundamental Elements 1)] (to be reviewed under "Benefit Sharing")*

*Viruses to be shared for surveillance and risk assessment, and production of vaccine, candidate influenza vaccine viruses (H5N1 and novel subtype) as well as development and validation of diagnostics (Norway) (to take text from WHA60.28 for the purpose of use of virus) (agreed)*

*One of the most important benefits derived from virus sharing is WHO's continued ability to assess the global risk of the emergence of a strain of influenza virus with pandemic potential, as required under the International Health Regulations (2005). This global public health benefit requires at a minimum: access to the broadest range of circulating influenza viruses; up-to-date influenza laboratories and specialists; and information systems to provide timely feedback to countries for response. The information derived from risk assessment enables the updating of vaccines, pharmaceuticals and diagnostic materials, all of which contribute to effective global responses to influenza outbreaks. WHO will continue to coordinate provision of this global public health benefit. (IGM/2 Rev.1) (agreed)*

*[All institutions in compliance with STCs and TORs (Chair's proposal) may continue to receive reagents and technical assistance from laboratories within the GISN] (USA electronic submission)*

*[Manufacturers can only obtain [seed virus] candidate influenza vaccine virus (UK) from the system with [prior informed consent] of the originating country and [must commit to benefit sharing]]. (IGM/5 Fundamental Elements 8) (to be discussed under STCs)*

*[Access to specimen/virus must be done through an agreement in the form of a standard Material Transfer Agreement (MTA) agreed by Member States. (IGM/5 Fundamental Elements 2)] (to be discussed under STCs)*

*[Any use of virus outside the Terms of Reference must get prior informed consent from the originating country. (IGM/5 Fundamental Elements 4)]*

*[The virus accessed is to be used only for non-commercial risk assessment and response according to the Terms of Reference which is to be agreed. (IGM/5 Fundamental Elements 3)] (to be discussed under STCs and TORs)*

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*[Virus samples are to pass into and out of the newly reformed/improved GISN that may be recommended, according to STCs and TORs to be agreed to by Member States. Recipients of a virus sample outside of the newly reformed/improved GISN are to pass the sample to another party/(third party) in accordance with these STCs and TORs.] (USA)*

*The originating country agrees to provide to the second party (Thailand) certain materials (e.g. human specimens and wild type viruses (UK) for the uses identified in the STCs. (Thailand) (IGM/6 3) (use text from the Glossary) (to be consistent with the Norway proposal above)*

*The WHO Secretariat is to create an electronic tracking system to record the movements of all virus samples and vaccine candidate strains (USA electronic submission)*

*[The country or institution of origin are to be notified/prior informed consent (Indonesia) immediately of distribution of a virus sample outside of the GISN] (USA electronic submission)*

*Institutions inside and outside of GISN may use virus samples for risk assessment, vaccine development and public health oriented research (USA electronic submission), according to the STCs and TORs (Indonesia) (agreed)*

*The WHO Collaborating centres and other institutions that are the recipient of virus samples are to assure that appropriate laboratories in the country or institution of origin receive the results of risk assessment and copies of isolated virus strains and/or vaccine candidate strains on a timely basis (USA electronic submission) (agreed)*

*Recognizing the need for timely and continuous development of vaccines and anti-viral drugs effective against influenza virus, vaccine manufacturers in both developed and developing countries may obtain candidate vaccine strains free-of-charge from the newly reformed and improved [GISN] (USA electronic submission)/ [prior informed consent] (Indonesia)*

*In addition, these STCs do not provide coverage for use of other agents or pathogens that may be contained in the materials, e.g. respiratory bacteria, non-influenza respiratory viruses. (IGM/6 3)*

*[These STCs are binding on all parties involved.] (IGM/6 3)*

*[All annexes form an integral part of these STCs.] (IGM/6 3)*

*EU Member States are open to consider what we think it would be an alternative option, that would be “to have two parties”, but our main concern should be the leadership of WHO in order to ensure transparency and the right way to achieve this would be to have:*

- (1) a clear vision of all participants and of their relationship and functions;*
- (2) a definition of the number of partners and their TOR*

*In conclusion, we would like to request the WHO to issue a document describing the current stakeholders and framework for sharing viruses and to provide with several proposals on how to improve the system. The document could be the basis for further discussion and taking a decision. (EU submission)*

## **[STANDARD TERMS AND CONDITIONS FOR THE TRANSFER AND USE OF INFLUENZA BIOLOGICAL MATERIALS**

### **Identification of Parties (IGM 6 2)**

This is the STCs between Member States (MS) and the WHO Secretariat (WS) only. **(IGM 6 2)**

The Member States include only members of the WHO and shall be represented by an agency or unit or organization, as to be designated and notified to the WS in writing by the MS. **(IGM 6 2)**

The WHO Secretariat is represented by the Director General (DG) and/or his/her designate(s). The DG of the WHO could designate, and publicly announce, one of his/her deputies or assistants or departments or units to act on his/her own behalf.

*(Remark: Please note that this identification of parties is markedly different from previously-proposed STC because it limits the number of parties to only two. In addition, these STCs do not use the term "GISN", nor does it mention NICs, WHOCCs, WHOH5RLs, etc. The omission of these terms does not mean to undermine or diminish the importance of GISN and its members. The omission is done for the sake of simplicity and clarity. As a matter of fact, the NICs, WHOCCs, and WHOH5RLs have well-defined TORs that could be easily agreed by MS. If the NICs, WHOCCs, and WHOH5RLs play their roles and do the functions as set forth in the TORs, the GISN as a whole will be strengthened automatically, without the need to include the term GISN and the TORs of these GISN-associated entities in these STCs.) **(IGM 6 2)***

### **Rights and Responsibilities of all Parties**

Authority to determine access to influenza viruses rests within the national government and subject to national laws. **(IGM/6 4)**

Access to specimen/virus must be done through an agreement in the form of a standard Material Transfer Agreement (MTA) agreed by Member States. **(IGM/6 2)**

Subsequent transfer of the virus can be done only with the prior informed consent of the originating country. **(IGM/6 5)**

If a subsequent recipient of materials from the WS does not comply with these STCs, the MS, individually or collectively, and/or the WS have the right to deny the recipient with new materials as appropriate. **(IGM/6 8)**

### **Originating Countries (Member States)**

The MS shall provide to the WS or other WS-designated entity the materials that may contain influenza virus or part thereof or antibody to the virus as soon as possible without request from the WS. The provision may be accompanied by a cover letter indicating that such provision is automatically covered by these STCs. **(IGM/6 11)**

If there is a good reason to believe that the WS or any of entities that receive the influenza virus or part thereof or antibody to the virus does not comply with these STCs, the concerned MS(s) has the right to deny the WS or the entity/-ties with the new materials. In addition, the MS(s) may request the



Oversight Mechanism to investigate the incident(s) that may be associated with such non-compliance. **(IGM/6 11)**

The MS has the right to access, at no cost, to information related to influenza virus or part thereof or antibody to the virus, as generated by the WS or any of the entities that subsequently receive the virus or the antibody. **(IGM/6 11)**

The MS has the right to receive, at no cost, all outputs of activities undertaken in relation to the materials provided to the WS or any WS-designated entity including influenza viruses isolated from the materials and sequence data of the influenza viruses. **(IGM/6 11)**

The MS has the right to provide the materials under these STCs to any other non-WS-associated entity/-ties on a bilateral or multilateral basis provided that such provision does not deprive the WS of the right to receive the same under these STCs. **(IGM/6 11)**

The MS has the obligations to strengthen its surveillance and risk assessment system to be able to early and accurate detection of influenza outbreaks. **(IGM/6 11)**

The MS has the obligations to contribute to the Global Influenza Vaccine Fund (GIVF – pronounced “give”). **(IGM/6 11)**

The originating country providing access to virus: (1) retains sovereign rights over the virus and any virus material contained or incorporated in any substances or products created; (2) has the right to get immediately the results of the risk assessment; (3) has the right to timely receive seed virus and isolated virus at no cost; (4) has the right to participate in the execution of research and participate actively in publications; and (5) has the right to be adequately acknowledged. **(IGM 5 Fundamental Elements 6)**

### **Rights and Obligations of the WHO (WS)**

The WS has the right to designate any entity within or outside its organization to receive the materials under these STCs, provided that: **(IGM/6 12)**

- (i) such designation is made in writing **(IGM/6 12)**
- (ii) the use of the materials is consistent with these STCs **(IGM/6 12)**
- (iii) there is a written agreement for each transaction of transfer of the materials or products made out of the materials **(IGM/6 12)**
- (iv) the transaction of transfer of materials is recorded in the real-time tracking system of the WS that is publicly accessible **(IGM/6 12)**
- (v) the recipient of the materials agrees in writing not to subsequently transfer of the materials to any other entity **(IGM/6 12)**
- (vi) the recipient of the materials agrees in writing to contribute to the Global Influenza Vaccine Fund (GIVF) **(IGM/6 12)**

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(vii) the recipient of the materials agrees in writing to participate fully in the Global Influenza Vaccine Benefits Sharing Scheme (GIVBeSS – pronounced “give bes(t)”) **(IGM/6 12)**

(viii) the recipient of the materials agrees in writing not to seek or assert intellectual rights or other rights over substances, processes, products including vaccines, anti-virals, diagnostics or any other inventions derived from the materials, developed through the use or that contain and/or incorporate the materials. **(IGM/6 12)**

The WS shall ensure that, if the recipients of the materials from the WS wish to transfer the materials subsequently to another recipient or recipients, these STCs shall apply and the subsequent transfer of the materials needs prior approval from the WS and is considered “executed by the WS”. **(IGM/6 12)**

The WS and the recipient of the materials through the WS has the right to publish sequence data of the viruses obtained from the MS under these WS in a public-domain database provided that: **(IGM/6 12)**

(i) the WS clearly indicates in the intended publication that such publication is covered by these STCs and use of the publicized data shall be consistent with these STCs **(IGM/6 12)**

(ii) the MS is properly acknowledged in such intended publication **(IGM/6 12)**

(iii) the MS is notified in writing of such intended publication **(IGM/6 12)**

(iv) the MS does/do not object to such intended publication within 14 days of receipt of such written notification. **(IGM/6 12)**

The WS and the recipient of the materials through the WS has the right to present, publish or otherwise disseminate scientific results generated from the materials provided that: **(IGM/6 12)**

(i) the WS clearly indicates in the presentation, publication or dissemination that such presentation, publication, and dissemination are covered by these STCs **(IGM/6 12)**

(ii) the MS and its scientists and/or researchers are properly acknowledged or included as co-authors in the manner that is consistent with the guidelines for authorship and acknowledgement stipulated in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals **(IGM/6 12)**

(iii) the MS is notified in writing of such intended presentation, publication, or dissemination **(IGM/6 12)**

(iv) the MS does/do not object to such intended presentation, publication, and dissemination within 14 days of receipt of such written notification. **(IGM/6 12)**

If the materials provided to the WS by the MS have led to a product or products (e.g. candidate vaccine virus, vaccine seed) that may be used to production of an influenza vaccine, the WS has the obligations to obtain a written agreement from the recipient of the materials that manufacturers of the vaccine or product agree in writing to contribute to the GIVF and the GIVBeSS. **(IGM/6 12)**

The WS has the obligations to develop, within 180 days after these STCs are approved by the World Health Assembly, a real-time tracking system for the materials provided under these STCs and derivatives and products made out of the materials. **(IGM/6 12)**

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The WS has the obligations to develop, together with MS the GIVF and the GIVBeSS. **(IGM/6 12)**

The WS has the obligations to develop, within 180 days after these STCs are approved by the World Health Assembly, an electronic system that renders material transfer agreements between the WS and the recipients of the materials publicly available and accessible within 3 days of execution of the agreements. **(IGM/6 12)**

The WS has the obligations to respond to the inquiry and request from the MS as stipulated in these STCs. **(IGM/6 12)**

Upon request by the MS, the WS shall arrange return or destruction of the materials provided to the WS by the MS without delay. **(IGM/6 10)**

Sequence data must be placed in a database only with the prior informed consent of the originating country. The database will be governed by rules and regulations to prevent misappropriation. **(IGM 5 Fundamental Elements 7)**

## **Rights and obligations of other parties**

### **General Provisions**

*Safety:* All parties shall ensure that all transfers under these STCs will at all times be in compliance with all relevant national and international laws, rules, and regulations governing the handling, safe transfer and use of infectious substances and living microorganisms. **(IGM/6 4)**

*Warranty:* All materials delivered pursuant to these STCs are understood to be experimental in nature and may have hazardous properties. They are provided to recipients without any representation and extends no warranties whatsoever, either express or implied, as to their quality, viability, purity, merchantability, suitability or fitness for a particular purpose or that its use will not infringe any patent, copyright, trademark, or other propriety right. **(IGM/6 4)**

*Indemnity:* Recipients of materials shall assume all liability for any claims, costs, damages or expenses resulting from or otherwise related to the possession and use of the materials. The MS will not be liable for any loss, claim or demand made to or arising from the use, storage or disposal of the materials. **(IGM/6 4)**

*Applicable Law:* The applicable law shall be \_\_\_\_\_. **(IGM/6 4)**

*Dispute Settlement:* Dispute settlement may be initiated by the MS or the WS in relation to their respective relationships in the context of these STCs. Any dispute arising from these STCs shall be resolved through the Oversight Mechanism to be established by the WS and agreed by the MS in a World Health Assembly. **(IGM/6 4)**

### **Termination**

When one of the parties fails to fulfil its obligations or violates any of these STCs and the aggrieved party has given the other party notice of not less than 30 days in writing requiring that the failure or violation be remedied. If the failure or violation is not remedied within the said 30 days, the aggrieved party shall have the right to terminate these STCs. **(IGM/6 5)**

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Upon termination, the WS shall immediately arrange discontinuation of any use of the materials in any manner including either derivation or development of substances, processes, products from the materials, and shall arrange the return or the destruction of any remaining materials. **(IGM/6 4)**

Termination of these STCs shall not affect the accrued rights and obligations that were due prior to the effective date of termination of these STCs. **(IGM/6 4)**

With regard to termination of these STCs, each Member State constitutes one party to the STCs. **(IGM/6 4)**

### **Notices**

Any notices or requests to be made under these STCs shall be in writing and shall, except where it is otherwise stated, be delivered by courier, or by facsimile, or by electronic mail, to the address of the entity to be designated by each party, and shall be deemed to have been received on the date of delivery, if delivered by courier, and on the first business day following the electronic confirmation of the successful transmission of the facsimile or electronic mail, if sent by facsimile or electronic mail. **(IGM/6 6)**

### **Duration of Agreement**

These STCs shall remain in force until otherwise determined by a World Health Assembly. **(IGM/6 7)**

## **VIRUS TRACKING SYSTEM**

WHO shall develop a database accessible to Member States to track movement of all viruses and seed viruses. **(IGM/5 Fundamental Elements 12)**

The WS shall establish a tracking system and database for transfer and movement of materials and their derivatives (including but not limited to throat, nasal, nasopharyngeal, and other swabs; blood or parts thereof; viral isolates and parts thereof including genetic characteristics, biological characteristics, clones, plasmids, and recombinants) on a real-time basis. **(IGM/6 9)]**

## BENEFIT SHARING

### DEFINITION OF BENEFITS

*In the context of pandemic influenza preparedness, the issue of access to benefits arose from the identification of influenza viruses of pandemic potential. In discussion of the benefits provided or leveraged by WHO, the following criteria have been applied: a clear, established link to influenza surveillance, risk assessment or containment/response; a demonstrated need for the benefit by the beneficiary country; and WHO's oversight of the process of establishing, securing and delivering a benefit. (IGM/2 Rev.1)*

*On the basis of these criteria, benefits may be:*

- *increased global public health security, resulting from risk assessment;*
- *access to and transfer of technology for influenza vaccine development and production;*
- *strengthened national capacity related to influenza preparedness and response (USA); and*
- *improved risk management through establishment of stockpiles and/or provision of: pharmaceuticals, personal protective equipment and other supplies necessary during the response to an outbreak; non-commercial diagnostic tests and materials; influenza vaccines and ancillary supplies (e.g. syringes). (IGM/2 Rev.1) (agreed)*
- *[benefits must be concrete, specific and provided to developing countries, especially affected countries and their geographic vicinities (Indonesia)] (to be discussed in the plenary session on principles)*

### SCOPE

#### Global public health security

[One of the important benefits derived from virus sharing is WHO's continued ability to assess the global risk of the emergence of a strain with pandemic potential. This global public health benefit and other benefits are within the context of an equal relationship among countries at the global level. The delivery of such benefits requires among others:

- (1) risk assessment
- (2) access to broadest range of circulating influenza viruses
- (3) up-to-date influenza labs and specialists
- (4) information systems to provide timely feedback to countries for response

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- (5) access to and transfer of technology
- (6) strengthened national capacity
- (7) aim at ensuring fair and equitable access to vaccines and medicines
- (8) access to supplies needed for response]

*Access to and transfer of technology*

*In resolution WHA60.28 the Health Assembly noted the global pandemic influenza action plan to increase vaccine supply, which had been elaborated through a broad consultative process with Member States and vaccine experts. Following receipt of funds from several donors, implementation has begun, with requests for proposals and award of development grants of US\$ 2.0–2.6 million to six companies from developing countries for them to plan, build or strengthen manufacturing capacity for influenza vaccine. On 19 October 2007, WHO convened a meeting of the steering committee of the action plan in order to review activities since May 2006, prioritize the action plan's strategies, revise and update the plan in light of progress in science, technology and preparedness, and facilitate identification of sources of funding for the plan's implementation. The report of the meeting would be considered by WHO's Strategic Advisory Group of Experts. (IGM/2 Rev.1)*

*The type of technology to be transferred depends on the level of development of vaccine manufacturing in the host country: as a first step, "fill and finish" manufacturing facilities; at a later stage, full vaccine-manufacturing capacity may be developed if funding and support of vaccine manufacturers are secured. (IGM/2 Rev.1)*

*Full-scale implementation of the action plan hinges on the availability of funds from Member States and other donors. The Secretariat continues to work with industry in order to explore further areas for transfer of, or broader access to, technology. In that respect, the Organization will pursue its work with public-sector vaccine manufacturers in order to establish a base for the transfer of technology for manufacturing influenza vaccine that includes procurement of equipment and training. (IGM/2 Rev.1)(agreed)*

*Bilateral discussions therefore continue with interested companies and the International Federation of Pharmaceutical Manufacturers and Associations in order to explore collaboration or partnership between the Federation and its counterpart, the Developing Country Vaccine Manufacturers Network. Issues that could be addressed through these entities include development of innovative mechanisms to licence existing or future intellectual property rights and of platforms to promote further access to technology by developing countries. (IGM/2 Rev.1) (agreed)*

[Bilateral discussions therefore continue *between* interested companies affiliated to IFPMA, DCMN, or other influenza vaccine manufacturers. Issues that could be addressed between interested parties include exploitation and use of existing technologies, and, as appropriate, to consider development of innovative mechanisms (IFPMA)/USA ] .

***Strengthened national capacity***

***WHO has several programmes for developing and strengthening the capacity of Member States to conduct risk assessment, thereby contributing to global risk assessment.***

***These programmes focus on strengthening (a) national laboratory and regulatory agency capacity and (b) Member States' core capacity for surveillance and response as required under the International Health Regulations (2005), and include the following: (IGM/2 Rev.1)***

***(a) National laboratory and regulatory agency capacity***

***(i) to strengthen national capacity for risk assessment: activities include monitoring the evolution of influenza viruses, risk information analysis, updating and development of diagnostic protocols and reagents, monitoring susceptibility to antiviral medicines, expanding the network of laboratories working with the newly reformed and improved (France) Global Influenza Surveillance Network, and strengthening the capacity of existing laboratories through targeted training (with, depending on demand from Member States and availability of funding, increased participation, for instance, in Field Epidemiology Training Programmes). Such training could enhance Member States' ability to make preventive public health interventions. (IGM/2 Rev.1)***

***(ii) to strengthen national influenza pandemic preparedness and response, including stronger surveillance and risk assessment systems, greater capacity to detect rapidly and contain potentially pandemic outbreaks, better communication of information about risk, and improved health systems infrastructure: work is also directed towards strengthening national regulatory agencies' ability to assess and approve vaccines. (IGM/2 Rev.1)***

***(iii) to broaden influenza surveillance and build research capacity: activities include participation in vaccine strain selection, clinical trials, involvement of scientists from developing countries in research and publications, and technical training on international regulations for shipping infectious substances. (IGM/2 Rev.1)***

***(b) Member States' core capacity for surveillance and response***

***To detect, assess, notify and report public health events through implementation of the International Health Regulations (2005), Member States will need better laboratories, expanded laboratory capacity and improved surveillance. The Secretariat will continue to work with Member States to upgrade information systems so that they provide full, reliable and timely access to information on the use and flow of specimens and viruses contributed to the Global Influenza Surveillance Network. (IGM/2 Rev.1) (agreed)***

***[(c) Research capacity: involvement of developing countries' scientists in research and publication in scientific journals through a participatory process where developing countries' scientists are involved in the conception and execution of the research and drafting as well as finalization of publications (Indonesia)]***

***or:***

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*[The WHO Collaborating Centres and other institutions are to include scientists from country or institution of origin in research work on relevant samples to the fullest extent feasible; and are to appropriately acknowledge, according to standards of international medical journals, and properly attribute to scientists from the country or institution of origin in any medical or scientific journal or publication of work on relevant samples (USA electronic submission).] (to be agreed)*

#### *Access to Vaccines*

##### *H5N1*

*An international H5N1 vaccine stockpile is being established, and, in June 2007, WHO was offered the first donation of 50 million doses of vaccine. In addition, the Secretariat is drawing up with experts, transparent rules and procedures for the geographical placement, operation (including prioritization of release of vaccine), management and oversight of such a stockpile. The Secretariat will be consulting with Member States, industry and other partners before the present Intergovernmental Meeting. Scheduled meetings include: a global consultation on the use of human H5N1 vaccines (1–3 October 2007) with the aim of developing consensus on policy options for the use of H5 vaccines, including those in an international stockpile. The report of this meeting will be submitted to WHO's Strategic Advisory Group of Experts for consideration. An informal consultation on technical specifications for an international H5N1 vaccine stockpile (17–18 October 2007) was organized in order to try to resolve technical issues such as regulatory and operational questions relevant to stockpiled H5 vaccines. Expected outcomes include: proposals to guide the regulatory oversight and operational management of the H5N1 vaccine stockpile; criteria for acceptance of donations; resources needed for upkeep of the stockpile; and criteria and processes for equitable access to the stockpile. Further studies needed on stockpiled H5 vaccines may be identified. A meeting of the Strategic Advisory Group of Experts (6–9 November 2007) will draw up policy options for the Director-General's consideration. (IGM/2 Rev.1)*

##### *Pandemic vaccine*

*Global capacity to produce influenza vaccine is limited. Extreme time constraints will be faced in developing an influenza vaccine following isolation of the pandemic strain. Best estimates for current vaccine production are less than 500 million doses of trivalent seasonal influenza vaccine (containing 15 µg of each antigen or 45 µg total per dose) in one year. This capacity could produce about 1500 million monovalent pandemic vaccine doses (15 µg antigen per dose). The potency level for an effective pandemic vaccine dose has not, however, been established. (IGM/2 Rev.1)*

*In the event of a pandemic next year, it would take time to produce the first ~~1000 million~~ 9 billion doses of a suitable vaccine. Furthermore, pre-arranged supply contracts between vaccine manufacturers and clients mean that many countries without vaccine production would have no access to a pandemic vaccine from existing manufacturers. (IGM/2 Rev.1)*

*The Secretariat therefore proposes to pursue, with Member States and influenza vaccine manufacturers, an advance commitment mechanism. One possibility would be for Member States in which there are producers of vaccine to agree in advance to release a pre-defined quantity of pandemic influenza vaccine drawn from existing purchase contracts. The vaccine so released would then be available, through purchase or donation, to countries without access to pandemic vaccine. In such a manner, developing countries and countries without manufacturing capacity for influenza vaccine would have some guaranteed access to pandemic influenza vaccine. Possible*



*ways of gaining this type of advance commitment include: pledges made by Member States to release manufacturers within their countries from national legislation and/or supply contracts up to a predefined quantity, thereby making such predefined quantity of pandemic influenza vaccine available for purchase as and when manufacturers produce the actual pandemic vaccine; and funding arrangements such as advance purchase agreements, insurance policies, or bilateral aid commitments by agencies, international lending institutions and other donors. (IGM/2 Rev.1)*

*Many details remain to be worked out, for instance when would the vaccine be available, in what quantity, at what price, and with what financial commitments by donors and countries to pay or fund vaccine purchases. The Secretariat will continue to work with Member States and all potential partners, including the vaccine manufacturing industry, on refining this mechanism. (IGM/2 Rev.1) (agreed)*

#### *Seasonal vaccines*

*Increasing the use of the seasonal vaccine will raise demand and trigger an expansion of manufacturing capacity. The prerequisites of such changes may include: studies of the burden of disease due to influenza, assessment of the capacity of Member States to deliver influenza vaccines, and work with industry in order to reduce the price of seasonal vaccine to a level that is affordable for developing countries. The Secretariat will continue to work with Member States, donors and industry on this matter. (IGM/2 Rev.1) (agreed)*

*[Sequence data from virus samples in the GISN are to be uploaded to a public available database (USA electronic submission)/regulated database, with the permission of the originating country (Indonesia)]*

*Vaccine manufacturers should support benefit sharing (such as preferential pricing policies for relevant products in developing countries, donations to WHO-managed stockpiles, and transfer of technology to developing countries to expand safe and effective influenza vaccine production capacity), and should join in related capacity-building activities for developing country health professionals and laboratories (USA electronic submission) (to be placed elsewhere under Benefit sharing) (agreed)*

#### *Access to Supplies Needed for Response*

*Pharmaceuticals, personal protective equipment and other supplies needed for response to outbreaks*

*In order to develop capacity for the rapid control of a potential influenza pandemic and as a first line of defence against outbreaks due to the H5N1 virus, WHO has created a stockpile of oseltamivir sufficient to treat five million adults. Guidelines are being implemented for the placement of some of the pharmaceutical stockpile at locations in WHO regions and the release of required quantities to Member States to contain outbreaks due to H5N1 virus. The Organization has also put together an outbreak-response kit containing guidance on actions and investigations, personal protective equipment and sampling kits. The kits are stored at locations in all WHO regions and high-risk countries. The Secretariat will work closely with Member States in order to ensure that these stockpiles are replenished as needed. (IGM/2 Rev.1)*

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### *Non-commercial diagnostic materials*

*As members of the Global Influenza Surveillance Network, national influenza centres receive annual supplies, without charge, of non-commercial diagnostic test materials and reagents for the identification and characterization of influenza-related biological specimens collected in their country. (IGM/2 Rev.1) (agreed)*

## **MECHANISM FOR OPERATION**

*[The World Health Organization is to establish and manage a global stockpile of vaccine against novel influenza viruses being perceived as a significant pandemic threat. The purposes of the stockpile are to mount containment operations and to assist in pandemic preparedness efforts in countries affected by novel influenza viruses being perceived as a significant pandemic threat, according to public health needs (EU). The WHO Secretariat is to devise a clear and transparent concept of operations for the use of the stockpile, including clear parameters and procedures for its deployment and an algorithm for prioritization.] (USA)*

*Furthermore, the World Health Organization is to actively explore options that will maximize equitable access to pandemic vaccine according to public health needs in the event of a pandemic. (Norway) (agreed)*

[Framework of benefit sharing is to be developed through agreed terms and conditions to ensure global stockpile of pre-pandemic and pandemic vaccines, accessibility of vaccine at an affordable price, access to and transfer of technology and know-how for production of vaccines, and empowerment and capacity building of vaccine manufacturing in developing countries. **(IGM/5 Fundamental Element 9)** ]

[Distribution of global stockpile of pre-pandemic and pandemic vaccines must be prioritized to developing countries, especially affected countries and their geographic vicinities. **(IGM/5 Fundamental Element 10)** ]

*[Also should be considered as a benefit sharing the technological transfer of vaccine and reagents production as well as the strengthening of the production capacity of manufacturers in developing countries. WHO will promote and address the above mentioned capacities, making sure that the third party that receives the virus for vaccine production will be committed with this obligation. WHO and MS will promote the scientific and technological information and dissemination seeking the development of capacity building on influenza research, epidemiological investigation and laboratory and diagnostic techniques.] (Brazil)*

**ROLE OF WHO** *(described under the STCs)*

**ROLE OF MS** *(described under the STCs)*

**ROLE OF OTHER PARTIES** *(described under the STCs)*

## FINANCING

*Through existing consultative mechanisms, the Secretariat will continue to explore with partners: the sustainability of benefit sharing and mechanisms to stimulate the discovery, development, and production of, and access to, pandemic and other influenza vaccines; and innovative but sustainable financing mechanisms for the timely and affordable procurement of all types of influenza vaccines (H5N1, pandemic and seasonal). Tiered pricing, preferential pricing, bulk purchasing and other procurement mechanisms that take advantage of economies of scale will be discussed and closely reviewed with interested Member States, donors and industry in order to put rapidly in place necessary contractual agreements. (IGM/2 Rev.1 Last paragraph)(agreed)*

### INNOVATIVE FINANCIAL MECHANISMS

*[Global Influenza Vaccine Fund (GIVF (the following is Annex I of IGM/6))*

GIVF is a global fund created specifically to ensure that there are sufficient financial resources to implement these STCs to ensure that influenza virus and part thereof, and antibody to the virus are shared in a timely manner so that influenza vaccines are produced and distributed in a fair and equitable manner as a collective global action to mitigate the risk of an influenza pandemic.

The Fund is made of

- annual assessed contributions from Member States
- annual assessed contributions from influenza vaccine manufacturers
- voluntary contributions from any individual or entity (excluding tobacco-related entity)

#### **Annual assessed contributions from Member States**

Each Member State shall pay annual contribution based on its level of economic advancement and number of population. The Member States are divided into 10 deciles based on their level of Gross Domestic Product per capita. The amount of contribution to the Fund for the Member States is calculated as follows:

1st decile = lowest decile	Contribution =	0.6 US cent x number of population
2nd decile	Contribution =	0.7 US cent x number of population
3rd decile	Contribution =	0.8 US cent x number of population
4th decile	Contribution =	0.9 US cent x number of population
5th decile	Contribution =	1.0 US cent x number of population
6th decile	Contribution =	1.1 US cents x number of population
7th decile	Contribution =	1.2 US cents x number of population

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8th decile	Contribution =	1.3 US cents x number of population
9th decile	Contribution =	1.4 US cents x number of population
10th decile = highest decile	Contribution =	1.5 US cents x number of population.

### **Annual assessed contributions from influenza vaccine manufacturers**

Influenza vaccine manufacturers who have agreed to contribute to the Fund will be assessed at the level of 20 US cents x number of influenza vaccine doses manufactured by them in each year.

### **Management of the Fund**

The Fund is managed by a board composed of 11 members. Six members are selected by the Executive Board of the WHO from nominations by Member States. The six selected members from Member States shall represent the six regions of the WHO. The other five members are selected from nominations from influenza vaccine manufactures by the nominees themselves. The 11 members select a chairperson and a secretary. The chairperson of the board shall be one of the six members representing the Member States. The term of the board is 2-year. The board members can be re-selected. The WHO Secretariat shall facilitate the works of the board.]

### **[Global Influenza Vaccine Benefits Sharing Scheme (GIVBeSS) (the following is Annex II of IGM/6)**

The Global Influenza Vaccine Fund shall be used in the Global Influenza Vaccine Benefits Sharing Scheme for the following activities:

- (1) Use of Fund to secure *20% sufficient* global production capacity of influenza vaccines for use during a pandemic through advance purchase agreement with the vaccine manufacturers and the governments which have reserved the vaccine production capacity with the vaccine manufacturers
- (2) Use of Fund to improve and facilitate transfer of technology of influenza vaccine production among developing countries
- (3) Use of Fund to pay for license fee for transfer of technology of influenza vaccine manufacturing to developing countries at a pre-negotiated rate

### **Calculation of the pre-negotiated rate for license fee for transfer of technology**

#### **For egg-based technology**

The total amount of X (payable for a period of 3-5 years, depending on the duration of influenza vaccine plants design, construction and validation) for license fee for technology transfer is determined by finding the value of X that satisfies the following condition:

“X + investment cost for a new influenza vaccine plant (with a production capacity of 10 million doses per year) is completely offset within 10 years by the margins (profits) generated by the vaccines produced at full capacity and sold at the price half of the average market prices of 5 leading brands of similar vaccines in that country”.

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### **For cell-based technology**

The total amount of X (payable for a period of 3-5 years, depending on the duration of influenza vaccine plants design, construction and validation) for license fee for technology transfer is determined by finding the value of X that satisfies the following condition:

“X + investment cost for a new influenza vaccine plant (with a production capacity of 10 million doses per year) is completely offset within 30 years by the margins (profits) generated by the vaccines produced at full capacity and sold at the price half of the average market prices of 3 leading brands of similar vaccines in that country”.]

## **[OVERSIGHT MECHANISM/ADVISORY COMMITTEE (Indonesia)]**

### **SCOPE**

*The WHO is to establish an independent oversight mechanism, approved by the World Health Assembly (IGM/6 13) to ensure transparency and quality, to monitor and evaluate GISN (Canada), to address disputes that may arise within the newly reformed and improved [GISN] and any collaborating institutions, and impose remedies on parties that contravene the STCs and TORs for the newly reformed and improved [GISN]. (USA) (agreed)*

*The WS shall facilitate the works of the Oversight Mechanism. (IGM/6 13) (agreed)*

*The scope of the Oversight Mechanism covers the functions of the first, second and third (Indonesia) parties. (agreed)*

### **GOALS**

*To ensure the effectiveness of, and maintain the trust in, the WHO GISN (IGM/4) (agreed)*

### **OBJECTIVES**

- To monitor and evaluate the *internal and external* conduct and effectiveness of the newly reformed and improved GISN. [First and Second Parties *and relationships* with Third Parties]
- To monitor and evaluate compliance with the Standard Terms and Conditions and the TORs by GISN entities and [Third Parties]
- To monitor and evaluate proper benefit sharing within the GISN and provision of benefits by [Third Parties ]
- To recommend remedial action to be taken (IGM4)

### **MODE OF OPERATION**

[An Oversight Board is to be established by the World Health Assembly. The Board is composed of [24 members (4 from each WHO region with balanced representation of countries affected and not affected by the current avian influenza outbreaks, and of countries with high and low economic advancements)] or [(take text from IGM/4, appendix 7 – membership)]. The chairperson, the vice chairperson, and the secretary are selected by and among the Board members themselves. At the beginning, one-third of the members shall have a one-year term, another one-third two-year term, and

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the other one-third three-year term. Determination of the duration of term of the Board at this initial stage is done by lottery system. WHO regions of which the Board members have finished their terms have the right to nominate new members for approval at the World Health Assembly. Newly designated members shall have three-year term. **(IGM/6 Annex III)**

*The WHO will devise a mechanism to arbitrate dispute based on article 56 of the IHR (2005).*

The Board has the following responsibilities: **(IGM/6 Annex III)**

1. Establish a mechanism whereby MS can use to petition inconsistency of practice under these STCs **(IGM/6 Annex III)**
2. Establish a monitoring system and an internal audit mechanism for implementation of these STCs with the frequency of audits of not less frequently than biannually **(IGM/6 Annex III)**
3. Request a report from the WS on the status of specific implementation of these STCs as well as obstacles, as needed **(IGM/6 Annex III)**
4. Arrange an investigation of complaints or irregularities in implementation of these STCs **(IGM/6 Annex III)**
5. Provide recommendations as to improve collective actions to share influenza virus and resultant benefits **(IGM/6 Annex III)**
6. Report to the World Health Assembly on execution of its functions on a yearly basis **(IGM/6 Annex III)**

## APPENDIX

**STANDARD TERMS AND CONDITIONS FOR THE TRANSFER AND USE OF INFLUENZA BIOLOGICAL MATERIALS****Identification of Parties (IGM 6 2)**<sup>1</sup> [Note from the Secretariat: See page 96]

This is the STCs between Member States (MS) and the WHO Secretariat (WS) only. **(IGM 6 2)**

The Member States include only members of the WHO and shall be represented by an agency or unit or organization, as to be designated and notified to the WS in writing by the MS. **(IGM 6 2)**

The WHO Secretariat is represented by the Director General (DG) and/or his/her designate(s). The DG of the WHO could designate, and publicly announce, one of his/her deputies or assistants or departments or units to act on his/her own behalf.

*(Remark: Please note that this identification of parties is markedly different from previously-proposed STC because it limits the number of parties to only two. In addition, these STCs do not use the term "GISN", nor does it mention NICs, WHOCCs, WHOH5RLs, etc. The omission of these terms does not mean to undermine or diminish the importance of GISN and its members. The omission is done for the sake of simplicity and clarity. As a matter of fact, the NICs, WHOCCs, WHOH5RLs have well-defined TORs that could be easily agreed by MS. If the NICs, WHOCCs, and WHOH5RLs play their roles and do the functions as set forth in the TORs, the GISN as a whole will be strengthened automatically, without the need to include the term GISN and the TORs of these GISN-associated entities in these STCs.)* **(IGM 6 2)**

**OR**

1. The parties are: **(AFRO Region B1)**

(a) **First Party:** The State or national entity/ies designated and authorised by the State to provide Original Specimens on its behalf. **(AFRO Region B1)**

(b) **Second Party:** Any of the following as applicable, which undertake non commercial activities according to their Terms of References under the [New Framework for Virus Sharing and Benefit Sharing of the WHO] **(AFRO Region B1)**:

(i) WHO Collaborating Centres for Reference and Research on Influenza that have satisfied WHO criteria for designation and have accepted the Terms of Reference attached in Annex 3; **(AFRO Region B1)**

(ii) WHO H5 Reference Laboratories (hereinafter referred to as "H5RLs") that have satisfied WHO criteria for designation and that have accepted the Terms of Reference attached in Annex 4<sup>1</sup>; **(AFRO Region B1)**

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<sup>1</sup> As of .... The H5RL are as follows: .....



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(c) **Third Party:** Institutions/Organisations/Companies that develop and produce Influenza Vaccines and that are approved by WHO to receive Biological Materials for Development as defined below. (*cf. para 3 (b) (c) Sect. STC*) **(AFRO Region B1)**

(d) **The World Health Organization** (hereinafter referred to as “WHO”) **(AFRO Region B1)**

**OR**

The parties include: **(IGM 4 Section B)**

First party: [USA: The United States proposed that we should only refer to this entity as the “First Party” to avoid confusion.], is the State or national entity (NIC or non-NIC) that provides the Specimens. **(IGM 4 Section B)**

(i) “National Influenza Centres” (NICs): National influenza reference laboratories that have been designated by a Ministry of Health and recognized by WHO under defined TORs. **(IGM 4 Section B)**

(ii) “Non-NICs”: laboratories designated by a government, that comply with the same TOR as NICs. **(IGM 4 Section B)**

Second party: “Second Party” is WHO, of which GISN is a programme activity implemented with the following partners:

(i) WHO Collaborating Centres for Reference and Research on Influenza (WHO CC): influenza centres of excellence that have satisfied WHO criteria for designation and have accept defined Terms of Reference (TORs). [Thailand: It should be made clear that St Jude’s Hospital is one of the Third Parties, not one of the Second Parties, in this STCs.] **(IGM 4 Section B)**

(ii) WHO H5 Reference Laboratory (H5RL): an influenza laboratory that has been designated by WHO to fulfill the defined TORs that bridge the gap in H5 diagnostic capacity worldwide. **(IGM 4 Section B)**

(iii) Essential national regulatory laboratories: specialized government laboratories involved in WHO influenza vaccine selection and development process;

(iv) Laboratories involved in specific WHO influenza projects (e.g. WHO Polymerase chain reaction (PCR) working group, WHO External Quality Assurance Project (EQAP)).] [UK: The following sentence seems redundant. Second party is WHO, or entities recognized as designated by WHO, as represented by WHO GIP; WHO CCs, essential national regulatory lab] **(IGM 4 Section B)**

Third party includes but is not limited to influenza vaccine manufacturers, commercial research laboratories and [diagnostic companies], that request and receive GISN Biological Materials or parts thereof. [UK: We understood that GISN Biological Materials would be changed throughout to Biological Materials] **(IGM 4 Section B)**

**Rights and Responsibilities of all Parties**<sup>2</sup> [Note from the Secretariat: See page 96]

Authority to determine access to influenza viruses rests within the national government and subject to national laws. **(IGM/6 4)**

Access to specimen/virus must be done through an agreement in the form of a standard Material Transfer Agreement (MTA) agreed by Member States. **(IGM/6 2)**

Subsequent transfer of the virus can be done only with the prior informed consent of the originating country. **(IGM/6 5)**

If a subsequent recipient of materials from the WS does not comply with these STCs, the MS, individually or collectively, and/or the WS have the right to deny the recipient with new materials as appropriate. **(IGM/6 8)**

**Originating Countries (Member States)**<sup>3</sup> [Note from the Secretariat: See page 96]

The MS shall provide to the WS or other WS-designated entity the materials that may contain influenza virus or part thereof or antibody to the virus as soon as possible without request from the WS. The provision may be accompanied by a cover letter indicating that such provision is automatically covered by these STCs. **(IGM/6 11)**

If there is a good reason to believe that the WS or any of entities that receive the influenza virus or part thereof or antibody to the virus does not comply with these STCs, the concerned MS(s) has the right to deny the WS or the entity/-ties with the new materials. In addition, the MS(s) may request the Oversight Mechanism to investigate the incident(s) that may be associated with such non-compliance. **(IGM/6 11)**

The MS has the right to access, at no cost, to information related to influenza virus or part thereof or antibody to the virus, as generated by the WS or any of the entities that subsequently receive the virus or the antibody. **(IGM/6 11)**

The MS has the right to receive, at no cost, all outputs of activities undertaken in relation to the materials provided to the WS or any WS-designated entity including influenza viruses isolated from the materials and sequence data of the influenza viruses. **(IGM/6 11)**

The MS has the right to provide the materials under these STCs to any other non-WS-associated entity/-ties on a bilateral or multilateral basis provided that such provision does not deprive the WS of the right to receive the same under these STCs. **(IGM/6 11)**

The MS has the obligations to strengthen its surveillance and risk assessment system to be able to early and accurate detection of influenza outbreaks. **(IGM/6 11)**

The MS has the obligations to contribute to the Global Influenza Vaccine Fund (GIVF – *pronounced “give”*). **(IGM/6 11)**

The originating country providing access to virus: (1) retains sovereign rights over the virus and any virus material contained or incorporated in any substances or products created; (2) has the right to get immediately the results of the risk assessment; (3) has the right to timely receive seed virus and

isolated virus at no cost; (4) has the right to participate in the execution of research and participate actively in publications; and (5) has the right to be adequately acknowledged. **(IGM 5 Fundamental Elements 6)**

**OR**

### **Rights And Responsibilities Of The First Party (Afro Section F)**

1. The First Party retains sovereign rights (including the authority to determine access and therefore the terms of the access) to the Biological Material including any Biological Material contained or incorporated in any substances or products created by the Second and Third Parties respectively. **(AFRO Section F)**

2. The First Party shall ensure that documentation accompanying the Original Specimen includes a duly completed Implementing Letter attached in Annex 1 signed by all Parties, properly identifying the “Original Specimen”, a copy of the STC and a traceability number. A copy of the signed Implementing Letter shall be sent to the WHO. **(AFRO Section F)**

3. The First Party shall on delivery of the Original Specimen enter all information in relation to the Original Specimen required into a common database (minimal dataset) that is to be developed by the WHO. **(AFRO Section F)**

5. Original Specimen is to be provided by the First Party to the Second Party at no cost or at an optional transmittal fee to reimburse the First Party on request, for costs of shipping, handling, storage or other direct administrative overheads in preparation of sending the Original Specimen to the Second Party. If the First Party requests transmittal fee, the amount will be indicated in the Implementing Letter. **(AFRO Section F)**

6. The First Party shall establish a focal point for purposes of communication under the STC and provide all the relevant contact details of the focal point to the WHO. The focal point will be the official authorised to sign the Implementing Letter on behalf of the First Party. **(AFRO Section F)**

**OR**

### **Rights And Responsibilities Of The First Party [Germany: In The Following, Only Responsibilities Are Listed, But No Rights – Change Title?] (IGM 4 Section E)**

1. The First Party shall ensure that the Specimens are handled, packed and shipped to a WHO CC of its choice in a timely [USA: See note above regarding the definition of timely] manner in accordance with applicable national and international regulations on the shipment of Infectious Substances. Documentation accompanying Specimens shall properly identify the “Specimens”, and include a traceability[Canada]/tracking[USA] number, as well as a copy of these STCs, and a Specimen submission form signed by the First Party. [UK: We believe that it should be a responsibility of the First Party to ensure as far as possible the integrity of the sample (i.e. that it contains useful infectious material). There should be an SOP to cover this.] **(IGM 4 Section E)**

2. (new para) First Party shall enter information/identification of the Specimen into a common database (minimal dataset), that the WHO Secretariat will develop, along with a system to track viruses through the GISN system. **(IGM 4 Section E)**

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**Rights and Obligations of the WHO (WS)**<sup>4</sup> [Note from the Secretariat: See page 97]

The WS has the right to designate any entity within or outside its organization to receive the materials under these STCs, provided that: **(IGM/6 12)**

- (i) such designation is made in writing **(IGM/6 12)**
- (ii) the use of the materials is consistent with these STCs **(IGM/6 12)**
- (iii) there is a written agreement for each transaction of transfer of the materials or products made out of the materials **(IGM/6 12)**
- (iv) the transaction of transfer of materials is recorded in the real-time tracking system of the WS that is publicly accessible **(IGM/6 12)**
- (v) the recipient of the materials agrees in writing not to subsequently transfer of the materials to any other entity **(IGM/6 12)**
- (vi) the recipient of the materials agrees in writing to contribute to the Global Influenza Vaccine Fund (GIVF) **(IGM/6 12)**
- (vii) the recipient of the materials agrees in writing to participate fully in the Global Influenza Vaccine Benefits Sharing Scheme (GIVBeSS – *pronounced “give bes(t)”*) **(IGM/6 12)**
- (viii) the recipient of the materials agrees in writing not to seek or assert intellectual rights or other rights over substances, processes, products including vaccines, anti-virals, diagnostics or any other inventions derived from the materials, developed through the use or that contain and/or incorporate the materials. **(IGM/6 12)**

The WS shall ensure that, if the recipients of the materials from the WS wish to transfer the materials subsequently to another recipient or recipients, these STCs shall apply and the subsequent transfer of the materials needs prior approval from the WS and is considered “executed by the WS”. **(IGM/6 12)**

The WS and the recipient of the materials through the WS has the right to publish sequence data of the viruses obtained from the MS under these WS in a public-domain database provided that: **(IGM/6 12)**

- (i) the WS clearly indicates in the intended publication that such publication is covered by these STCs and use of the publicized data shall be consistent with these STCs **(IGM/6 12)**
- (ii) the MS is properly acknowledged in such intended publication **(IGM/6 12)**
- (iii) the MS is notified in writing of such intended publication **(IGM/6 12)**
- (iv) the MS does/do not object to such intended publication within 14 days of receipt of such written notification. **(IGM/6 12)**

The WS and the recipient of the materials through the WS has the right to present, publish or otherwise disseminate scientific results generated from the materials provided that: **(IGM/6 12)**

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- (i) the WS clearly indicates in the presentation, publication or dissemination that such presentation, publication, and dissemination are covered by these STCs **(IGM/6 12)**
- (ii) the MS and its scientists and/or researchers are properly acknowledged or included as co-authors in the manner that is consistent with the guidelines for authorship and acknowledgement stipulated in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals **(IGM/6 12)**
- (iii) the MS is notified in writing of such intended presentation, publication, or dissemination **(IGM/6 12)**
- (iv) the MS does/do not object to such intended presentation, publication, and dissemination within 14 days of receipt of such written notification. **(IGM/6 12)**

If the materials provided to the WS by the MS have led to a product or products (e.g. candidate vaccine virus, vaccine seed) that may be used to production of an influenza vaccine, the WS has the obligations to obtain a written agreement from the recipient of the materials that manufacturers of the vaccine or product agree in writing to contribute to the GIVF and the GIVBeSS. **(IGM/6 12)**

The WS has the obligations to develop, within 180 days after these STCs are approved by the World Health Assembly, a real-time tracking system for the materials provided under these STCs and derivatives and products made out of the materials. **(IGM/6 12)**

The WS has the obligations to develop, together with MS the GIVF and the GIVBeSS. **(IGM/6 12)**

The WS has the obligations to develop, within 180 days after these STCs are approved by the World Health Assembly, an electronic system that renders material transfer agreements between the WS and the recipients of the materials publicly available and accessible within 3 days of execution of the agreements. **(IGM/6 12)**

The WS has the obligations to respond to the inquiry and request from the MS as stipulated in these STCs. **(IGM/6 12)**

Upon request by the MS, the WS shall arrange return or destruction of the materials provided to the WS by the MS without delay. **(IGM/6 10)**

Sequence data must be placed in a database only with the prior informed consent of the originating country. The database will be governed by rules and regulations to prevent misappropriation. **(IGM 5 Fundamental Elements 7)**

*OR*

### **Responsibilities Of The WHO (AFRO Section I)**

- (1) The WHO shall prior to granting approval to the request of the Third Party for Biological Materials for Development obtain the prior written consent of the First Party. **(AFRO Section I)**
- (2) The WHO shall enter all information concerning the transfer of Biological Materials for Development to the Third Party into the WHO tracking database. **(AFRO Section I)**

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- (3) The WHO shall develop a database for the NFVSBS to track movement of all the Biological Material, CIVV and Biological Materials for Development, throughout the New Framework. **(AFRO Section I)**
- (4) The WHO shall develop a database for the deposit of sequence data under the STC. Access to the database shall only be allowed to entities, organisations and companies that agree to terms and conditions that are to be developed. **(AFRO Section I)**
- (6) The WHO shall take all measures necessary to ensure compliance by the Third Party of its obligations under the STC, in particular the benefit sharing obligations. WHO shall issue a biannual report on measures taken and mechanisms established to implement the benefit sharing obligations by Third Parties and the results of benefit sharing as well as the challenges faced in implementation. **(AFRO Section I)**

## **Rights And Responsibilities Of The Second Party (AFRO Section G)**

### **1. Permitted Uses**

- (a) The Second Party shall use the Biological Material, solely for purposes listed in the Terms of Reference in Annex 3 where the Second Party is a WHO CC, or for purposes listed in the Terms of Reference in Annex 4 where the Second Party is a H5RL. (*cf. para 18 Sect. STC*) **(AFRO SECTION G)**
- (b) The Second Party shall use the Biological Material only at the Second Party's facility. **(AFRO SECTION G)**
- (c) The Second Party may transfer the Biological Material and/or CIVV to another Recipient Second Party only with the prior written consent of the First Party. The Second Party shall advise the Recipient Second Party that it shall be bound by the terms of the STC. The Recipient Second Party agrees that the First Party has the right to take appropriate action against the Recipient Second Party as allowed by the STC. **(AFRO SECTION G)**
- (d) The Second Party shall transfer at no cost to the Third Party only Biological Materials for Development as authorized by the WHO for transfer to the Third Party on receipt from WHO of a duly completed and signed Request Form/Implementing Letter,. **(AFRO SECTION G)**
- (e) The Second Party shall not transfer by any means, either intentionally or accidentally, the Biological Material, substances or any product derived from the Biological Material or any other substances and products developed through the use of or that contains/incorporates the Biological Material such as CIVV to any other party except in accordance with the Terms of Reference in Annex 3 and 4 as applicable and the STC. **(AFRO SECTION G)**
- (f) Any transfer of Biological Materials for Development in response to receipt of a duly completed and signed Request Form/Implementing shall be clearly labelled as "New Framework Biological Materials for Development" and a copy of the Request Form/Implementing Letter & the STC shall be included in the shipping documents. **(AFRO SECTION G)**
- (g) For any uses of the Biological Material outside the scope of the STC and the respective Terms of Reference in Annex 3 and Annex 4, the Second Party shall refer to the First Party for

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its prior written consent. Such activities are subject to mutually agreed terms. (*cf. para 23 Sect. STC*) **(AFRO SECTION G)**

(h) The Second Party shall not seek to derive any financial gain from use in any way of the Biological Material and other related information including from substances or any product derived from the Biological Material or any other substances and products developed through the use of or that contains/incorporates the Biological Material such as CIVV. (*cf. para 18 Sect. STC*) **(AFRO SECTION G)**

## **2. Reporting & Access to Research Output and Results by WHO and the First Party (AFRO SECTION G)**

(a) The Second Party shall provide to the First Party and to WHO, information as stated in the Terms of References as annexed to the STC as soon as it is available, but no later than fourteen (14) days of obtaining the information (*cf. para 19 Sect. STC*) **(AFRO SECTION G)**

(b) The Second Party shall on request provide at no cost to the First Party all outputs from activities undertaken in relation to the Biological Material including viruses isolated from the Original Specimen, provided by the First Party. **(AFRO SECTION G)**

(c) The Second Party shall provide as soon as available and in confidence only to the First Party all sequence data derived from the Research conducted. **(AFRO SECTION G)**

## **3. Sequence Data (AFRO SECTION G)**

(a) The Second Party shall obtain prior written consent of the First Party before placing any sequence data in any databases. Unless otherwise specified by the First Party, when written consent is given, the Second Party shall within 14 days post the sequence data into [WHO] Regulated Database. **(AFRO SECTION G)**

## **4. Intellectual Property Rights (AFRO SECTION G)**

(a) The Second Party shall not seek or assert intellectual property rights or other rights over the Biological Material in any form. (*cf. para 18 Sect STC*) **(AFRO SECTION G)**

(b) The Second Party shall not seek or assert intellectual property rights or other rights over any substances, processes, products including vaccines, anti-virals, diagnostics and biological derived from the Biological Material, developed through the use of or that contain/incorporate the Biological Material. **(AFRO SECTION G)**

## **5. Publications, Empowerment & Capacity Building (AFRO SECTION G)**

(a) The Second Party shall obtain prior written consent of the First Party, before using of any data, results, or concepts obtained from use of and/or analysis of the Biological Material, in presentations, abstracts, agreements, publications (both peer-reviewed and not peer-reviewed), grant applications or other means of dissemination. **(AFRO SECTION G)**

(b) The Second Party shall properly attribute in presentations, publications, agreements, grant applications and other means of dissemination, the source of the Biological Material, the name and contributions of the scientists and/or researchers and/or laboratories from the First Party.

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Proper attribution of First Party scientists in any medical or scientific journal publication should be done in a manner that is consistent with the guidelines for authorship and acknowledgement stipulated by the International committee of Medical Journal Editors in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. (*cf. para 5(f) of the WHA60.28*) **(AFRO SECTION G)**

(c) The Second Party shall involve scientists from the First Party in the execution of the research and drafting as well as finalization of the publication. **(AFRO SECTION G)**

(d) The Second Party shall allow access to, and transfer, of technology and know how to the First Party, such as technology and know how to identify, characterize and monitor the influenza viruses, new technologies in identification of disease etiologies, and genetic analyses and shall endeavor to empower and build capacity as requested by the First Party or as stated in the Terms of Reference as annexed in the STC. **(AFRO SECTION G)**

#### **6. Non-Assignment or Transfer of Rights (AFRO SECTION G)**

The Second Party shall not assign or otherwise transfer this STC or any rights and obligations under this STC. Any attempted assignment or transfer will be void and of no force or effect. **(AFRO SECTION G)**

*OR*

#### **Rights and Responsibilities of Second Party [Germany: same comment as above](IGM 4 Section F)**

1. Second Party partners receiving, handling or using Biological Materials in their GISN capacity shall use the materials solely in accordance with their GISN TORs, and shall neither seek Intellectual property rights [UK: We disagree on this point. We do not believe it will always be in the interests of the network and Member States as a community to prevent development of IPR rights. There are circumstances in which this could be helpful. In any case, for tidiness, would seem that this point should be dealt with under Ownership and IPR Section.] nor seek to derive financial gain from their use. More specifically, Second Party partners shall not sell, offer for sale or otherwise use for purposes other than those specified in their TORs. [USA: We pointed out the redundancy here.]

2. Second Party partner shall provide the First Party with all necessary information for Risk Assessment derived from their analysis of the Specimens, as soon as possible, as more specifically detailed in the GISN TORs.

3. Second Party partners may transfer Biological Materials [USA: Specifically we need to clarify the definition of biological materials.] to other entities within the Second Party partner and from Second Party partner to First Party for use in accordance with these STCs, and applicable GISN TORs.

4. (new para) WHO shall develop a database for the GISN to track movement of all viruses throughout the GISN system. [USA: Redundant – see para 17.] The Second Party partner shall be responsible for entering data on virus movements into the database.

5. The Second Party partner shall consider ways to promote the involvement, participation and recognition of scientists from the First Party in research related to influenza, and shall properly attribute scientists from the First party in scientific publications through citation of the submitting



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scientist's name and source country on any medical or scientific journal publication, consistent with rules for authorship outlined by the International Committee of Medical Journal Editors.

6. Use or transfer of Biological Materials by a Second Party partner for a purpose, or in a manner, outside the scope of the Second Party partner TORs shall require prior agreement of the First Party. [UK: The impact of this clause depends entirely on what the TORs specify. At present there are no TORs for the non-essential labs, which represent the main interface with vaccine manufacturers. Any requirement for prior agreement from First Parties for transfer of individual vaccine candidate strains to manufacturers would be very damaging to the ability to respond rapidly.][USA: Strike this entire paragraph].

7. Use or transfer of Biological Materials by the Second Party partner for a purpose, or a manner, inconsistent with these STCs or applicable TORs, may subject the Second Party partner to investigation under the GISN Oversight Mechanism if a Member State so requests or if routine monitoring reviews so warrant.

### **Rights and obligations of other parties**

#### **Rights And Responsibilities Of The Third Parties (AFRO Section H)**

##### **1. Request for Biological Materials (AFRO SECTION H)**

(a) A Third Party that wishes to request Biological Materials for Development shall do so by completing and signing the Request Form & Implementing Letter attached in Annex 2, and sending it to the WHO for consideration, with a copy to the First Party. The Third Party shall identify the specific Biological Material for Development requested and state in detail the purpose for which it intends to use each specific material requested. (*Source: para 26 Sect. STC*) (**AFRO SECTION H**)

(b) The Third Party shall have the right to receive/access Biological Materials for Development from the Second Party which are authorized by the WHO. Where the Request Form & Implementing Letter is duly completed and signed by all parties, the Third Party will be bound by the STC. (*cf. para 26 Sect. STC*) (**AFRO SECTION H**)

##### **2. Permitted Use (AFRO SECTION H)**

(a) The Third Party will use the Biological Materials for Development received and any part thereof, solely for the purpose approved on the Request Form & Implementing Letter and for no other purpose. (*cf. para 28 Sect STC*) (**AFRO SECTION H**)

(b) The Third Party shall not transfer the Biological Materials for Development or any part thereof by any means either intentionally or accidentally to any other party including other entities, organisations and companies. (**AFRO SECTION H**)

##### **3. Intellectual Property Rights (AFRO SECTION H)**

(a) The Third Parties shall not seek or assert intellectual property rights or other rights on the Biological Materials for Development received or any part thereof, in any form. (*cf. para 30 Sect. STC*) (**AFRO SECTION H**)

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(b) The Third Party shall not seek or assert intellectual property rights or other rights over any substances, processes, products including vaccines, anti-virals, diagnostics or any other inventions derived from the Biological Materials for Development, developed through the use of or that contain and/or incorporate the Biological Materials for Development. **(AFRO SECTION H)**

**4. Service Providers (AFRO SECTION H)**

(a) Third Party shall bring to the notice of any providers to it of services related to the development and production of vaccines, the terms and conditions contained herein and shall ensure full compliance by the providers with the STC. The Third Party agrees to take full responsibility and liability for any violation of the terms and conditions contained herein, by the providers of service. **(AFRO SECTION H)**

**5. Publication, Empowerment & Capacity Building (AFRO SECTION H)**

(a) The Third Party, its scientists and/or researchers will properly attribute in presentations, publications, agreements, grant applications and other means of dissemination, the source of the Biological Materials for Development and the Biological Material contained therein, the name and contributions of the scientists and/or researchers and/or laboratories from the First Party and Second Party. Proper attribution of First Party and Second Party scientists in any medical or scientific journal publication should be done in a manner that is consistent with the guidelines for authorship and acknowledgement stipulated by the International Committee of Medical Journal Editors in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. (*cf. para 29 Sect. STC*) **(AFRO SECTION H)**

(b) The Third Party will also include the First Party's scientists in the, execution of the research and the drafting as well as finalization of the publication. **(AFRO SECTION H)**

(c) The Third Party shall empower and build capacity of domestic manufacturers of the First Party and shall, on request build capacity and allow domestic manufacturers of the First Party to participate in the activities of the Third Party in relation to the Biological Materials for Development. **(AFRO SECTION H)**

**6. Benefit Sharing (AFRO SECTION H)**

(a) *Royalty Free Licences, Transfer of Technology & Know-How (Source: Sect STC/ Indonesia Proposal)* **(AFRO SECTION H)**

(i) The Third Party will grant on request, a non-exclusive, royalty-free license to any domestic influenza vaccine manufacturer from developing and least developed countries in particular to the First Party to use its intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of influenza vaccine development and production in particular pre-pandemic and pandemic vaccines. **(AFRO SECTION H)**

(ii) The Third Party will on request allow access to and transfer of its technology, know-how, all information and knowledge used in the process of influenza vaccine development and production as well as provide the necessary capacity building, to domestic influenza vaccine manufacturers from developing and least developed countries

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in particular to the First Party in order to encourage domestic manufacturing of influenza vaccines in developing and least developed countries particularly pre-pandemic and pandemic vaccines, to fulfil domestic and regional needs.

(iii) In relation to (ii) the Third Party will provide the access and transfer at no cost [or on terms which are reasonable and favourable to developing countries in particular to the First Party] **(AFRO SECTION H)**

**(b) Pandemic & Pre-pandemic Vaccines (Source: Sect STC/Indonesia proposal) (AFRO SECTION H)**

(i) During the pre-pandemic the Third Party shall priorities and immediately respond to the demands of the WHO international stockpile and the demands of developing and least developed countries in need in particular that of the First Party until the needs for pre-pandemic vaccines are satisfied. X% of every vaccine production cycle, will be provided free of charge to the WHO international stockpile prior to commercialisation, while the rest of the vaccines needed by the WHO stockpile and the developing and least developed countries shall be made available immediately, in adequate quantities and at an affordable price. **(AFRO SECTION H)**

(ii) In the pandemic period, the Third Party shall prioritize and immediately respond to the demands of the WHO international stockpile and the demands of developing countries and least developed countries in need in particular the First Party until the needs for pandemic vaccines are satisfied. X% of every vaccine production cycle, will be provided free of charge to the WHO international stockpile prior to commercialisation, while the rest of the vaccines needed by the WHO stockpile and the developing and least developed countries shall be made available immediately, in adequate quantities and at an affordable price. **(AFRO SECTION H)**

[The Third Party, in pricing its products should [could] consider “Affordable price” for developing countries as a price no higher than marginal cost per unit + X% (e.g. 5%), while for least developed countries at “no profit no loss”.] **(AFRO SECTION H)**

**(c) Payments by Third Parties (Source: Sect. STC) (AFRO SECTION H)**

(i) In the case that the Third Party commercializes substances, processes, products including vaccines, anti-virals, diagnostics or any other products or technologies derived from the Biological Materials for Development, developed through the use of or that contain/incorporate the Biological Materials for Development, the Third Parties shall pay a X% of the Sales of the commercialisation into the mechanism [WHO managed multilateral trust fund] established for this purpose. **(AFRO SECTION H)**

[(ii) The Third Party shall submit to the WHO within sixty (60 days) after each calendar year ending December 31st, an annual report setting forth: **(AFRO SECTION H)**

(a) the Sales of the substances, products, processes by the Third Party, its affiliates, contractors, licensees and lessees for the twelve (12) month period ending on December 31st; **(AFRO SECTION H)**

(b) the amount of the payment due; **(AFRO SECTION H)**

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Payment shall be due and payable upon submission of each annual report. All payments due to the WHO shall be payable in (specified currency) for the account of (the Trust Account or other mechanism established by the WHO)] **(AFRO SECTION H)**

**7. Non-assignments or Transfer of Rights (AFRO SECTION H)**

The Third Party shall not assign, transfer or otherwise dispose, in whole or in part, to any other parties including entities, organisations and companies any of its rights and responsibilities under the STC unless there is prior written consent of the First Party and the WHO. **(AFRO SECTION H)**

*OR*

**Transfer to & Use by Third Parties (IGM 4 Section G)**

Old 23. Second party partners may not transfer Specimens to any entities not listed in Article 19 above without receipt of a duly completed and signed Biological Materials Request Form from the party requesting the Specimens and authorization from the First Party. **(IGM 4 Section G)**

Old 24. WHO CC's may transfer free of charge Candidate Influenza Vaccine Viruses to Third Parties or other GISN Entities upon receipt of a duly completed signed GISN Biological Materials Request Form. The WHO CC shall regularly inform the State Provider of such transfers, including the name of the Third Party Recipient and the Candidate Influenza Vaccine Viruses provided. **(IGM 4 Section G)**

Old 25. WHO CC's may transfer free of charge Seasonal influenza reference viruses to Third Parties or other GISN Entities for non commercial purposes upon receipt of a duly completed signed GISN Biological Materials Request Form. The WHO CC shall regularly inform the State Provider of such transfers, including the name of the Third Party Recipient and the Candidate Influenza Vaccine Viruses provided. **(IGM 4 Section G)**

Third Parties may only request GISN Biological Materials from WHO CCs. Only WHO CCs are authorized to provide GISN Biological Materials to Third Parties. **(IGM 4 Section G)**

1. Requests from a Third Party for GISN Biological Materials will be considered only upon receipt by a WHO CC of a duly completed and signed GISN Biological Materials Request Form from the Third Party. The Request Form includes these STCs and requires the Third Party to identify the specific GISN Biological Materials requested and state the purpose for which it intends to use each specific Material. **(IGM 4 Section G)**

2. Any and all transfers of GISN Biological Materials from WHO CCs to Third Parties shall be subject to these STCs. Any transfer of GISN Biological Materials in response to receipt of a duly completed GISN Biological Materials Request Form shall be clearly labelled as "GISN Specimens" or "GISN Candidate Influenza Vaccine Viruses" or "GISN Seasonal influenza reference viruses" and a copy of these STCs shall be included in the shipping documents. **(IGM 4 Section G)**

3. Third Party Recipients of GISN Biological Materials shall not transfer, sell, offer for sale or otherwise use the Materials for purposes other than those specified on the approved GISN Biological Materials Request Form. Any use of the GISN Biological Materials that differs from or is inconsistent with the purpose stated in the GISN Biological Materials Request Form and/or these STCs will require the agreement of [the State Provider][WHO]. **(IGM 4 Section G)**

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4. Where use of GISN Biological Materials results in publication of an article by a Third Party in a scientific publication, the Third Party shall ensure that proper attribution is given to the State Provider/originating laboratory and include originating country scientists in the conception, execution of the research and the drafting of the article. Proper attribution of State Provider scientists in any medical or scientific journal publication should be done in a manner that is consistent with the guidelines for authorship and acknowledgement stipulated by the International committee of Medical Journal Editors in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. **(IGM 4 Section G)**

### **Ownership & Intellectual Property Rights (IGM 4 Section G)**

No party (including GISN Entities and Third Parties) receiving, handling and using GISN Biological Materials shall claim ownership rights over GISN Biological Materials. **(IGM 4 Section G)**

1. Any Party (including GISN Entities and Third Parties) receiving, handling and using GISN Biological Materials seeking patent protection or other intellectual property rights in respect of such Materials, shall disclose in the patent application, the country from where the Biological Materials were collected and the GISN strain designation provided by the GISN CC. **(IGM 4 Section G)**

2. Any Party that uses GISN Biological Materials in a manner that results in, or may result in, financial gain, shall consult with WHO to identify how such Party will contribute to WHO's Coordinated International Sharing of Influenza Viruses & Benefits and shall sign a Contribution Agreement to that effect. **(IGM 4 Section G)**

### **WHO Determination of a Public Health Emergency of International Concern (IGM 4 Section G)**

1. In the event that the WHO Director General determines the existence of a Public Health Emergency of International Concern (PHEIC) as defined in the International Health Regulations (2005), or under circumstances where the determination of a PHEIC is imminent, these STCs may be abrogated in whole or in part. **(IGM 4 Section G)**

### **General Provisions**

*Safety:* All parties shall ensure that all transfers under these STCs will at all times be in compliance with all relevant national and international laws, rules, and regulations governing the handling, safe transfer and use of infectious substances and living microorganisms. **(IGM/6 4)**

*Warranty:* All materials delivered pursuant to these STCs are understood to be experimental in nature and may have hazardous properties. They are provided to recipients without any representation and extends no warranties whatsoever, either express or implied, as to their quality, viability, purity, merchantability, suitability or fitness for a particular purpose or that its use will not infringe any patent, copyright, trademark, or other propriety right. **(IGM/6 4)**

*Indemnity:* Recipients of materials shall assume all liability for any claims, costs, damages or expenses resulting from or otherwise related to the possession and use of the materials. The MS will not be liable for any loss, claim or demand made to or arising from the use, storage or disposal of the materials. **(IGM/6 4)**

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*Applicable Law:* The applicable law shall be \_\_\_\_\_. **(IGM/6 4)**

*Dispute Settlement:* Dispute settlement may be initiated by the MS or the WS in relation to their respective relationships in the context of these STCs. Any dispute arising from these STCs shall be resolved through the Oversight Mechanism to be established by the WS and agreed by the MS in a World Health Assembly. **(IGM/6 4)**

### **Termination**

When one of the parties fails to fulfil its obligations or violates any of these STCs and the aggrieved party has given the other party notice of not less than 30 days in writing requiring that the failure or violation be remedied. If the failure or violation is not remedied within the said 30 days, the aggrieved party shall have the right to terminate these STCs. **(IGM/6 5)**

Upon termination, the WS shall immediately arrange discontinuation of any use of the materials in any manner including either derivation or development of substances, processes, products from the materials, and shall arrange the return or the destruction of any remaining materials. **(IGM/6 4)**

Termination of these STCs shall not affect the accrued rights and obligations that were due prior to the effective date of termination of these STCs. **(IGM/6 4)**

With regard to termination of these STCs, each Member State constitutes one party to the STCs. **(IGM/6 4)**

### **Notices**

Any notices or requests to be made under these STCs shall be in writing and shall, except where it is otherwise stated, be delivered by courier, or by facsimile, or by electronic mail, to the address of the entity to be designated by each party, and shall be deemed to have been received on the date of delivery, if delivered by courier, and on the first business day following the electronic confirmation of the successful transmission of the facsimile or electronic mail, if sent by facsimile or electronic mail. **(IGM/6 6)**

### **Duration of Agreement**

These STCs shall remain in force until otherwise determined by a World Health Assembly. **(IGM/6 7)**

**OR**

#### **(1) Safety**

All parties shall ensure that all transfers under the STC will at all times be in compliance with all relevant national and international laws, rules and regulations governing the handling, safe transfer and use of infectious substances and living modified organisms resulting from modern biotechnology.<sup>1</sup> *(cf. para 16 Sect STC) (AFRO Section E)*

## **(2) Warranty**

All Biological Material, CIVV, Biological Material for Development delivered pursuant to this STC is understood to be experimental in nature and may have hazardous properties. They are provided to recipients without any representations and extends no warranties whatsoever, either express or implied, as to their quality, viability, purity, merchantability, suitability or fitness for a particular purpose or that its use will not infringe any patent, copyright, trademark, or other proprietary right. (*cf. para 14 Sect. STC*) (**AFRO Section E**)

## **(3) Indemnity**

Recipients of Biological Material, CIVV, and Biological Materials for Development shall assume all liability for any claims, costs, damages or expenses resulting from or otherwise related to the possession and use of the Biological Material, CIVV and Biological Materials for Development. The First Party will not be liable to the Second or Third Party for any loss, claim or demand made by the Second or Third Party, or made against the Second or Third Party by any other party, due to or arising from the use, storage or disposal of the Biological Material, CIVV and Biological Materials for Development. (*Source: para 15 Sect. STC*) (**AFRO Section E**)

## **(4) Dispute Settlement**

(a) Dispute Settlement may be initiated by any of the Parties in relation to their respective relationships in the context of the STC. (**AFRO Section E**)

(b) All Parties agree that the First Party has the right as a “[Contributor and] Beneficiary”, to initiate dispute settlement procedures in relation to the agreement between the WHO and the Third Party. (**AFRO Section E**)

(c) The First Party as the “Beneficiary” also has the right to request all relevant information, biological material and/or samples as necessary, be made available by the Second, Third Parties and the WHO, regarding their obligations in the context of the STC. The WHO, Second Party and the Third Party shall provide any information, biological material and/or samples so requested as the case may be. (**AFRO Section E**)

(d) Any dispute arising from this Agreement shall be resolved in the following manner: (**AFRO Section E**)

(i) Amicable dispute settlement: The parties shall attempt in good faith to resolve the dispute by negotiation. (**AFRO Section E**)

(ii) Mediation: If the dispute is not resolved by negotiation, the parties may choose mediation through a neutral third party mediator, to be mutually agreed. Parties may also agree to refer the dispute to the WHO Director General, who shall make every effort to settle it. (**AFRO Section E**)

Arbitration: If the dispute has not been settled by negotiation or mediation, any party may submit the dispute for arbitration under the Arbitration Rules of an international body as agreed by the parties to the dispute. (**AFRO Section E**)

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Failing such agreement, the party that wishes a dispute to be referred to an arbitration tribunal shall give notice to the other party in writing specifying the person it has appointed as an arbitrator on its part. The other party shall appoint one arbitrator on its part within 60 days from receipt of such notice. The two arbitrators nominated by the parties shall appoint the third arbitrator who shall preside over the arbitration tribunal. Should the two arbitrators fail to appoint a third arbitrator, the Director General of WHO shall appoint the third arbitrator. **(AFRO Section E)**

(iv) All parties shall facilitate the work of the Tribunal and, in particular, using all means at their disposal, shall provide it with all relevant documents, information and facilities; and enable it, when necessary to call witness or experts and receive their evidence. **(AFRO Section E)**

(v) The decision of the arbitration tribunal shall be final and binding on the parties without appeal. **(AFRO Section E)**

## 5. Termination **(AFRO Section E)**

(i) When one of the parties fails to fulfill its obligations or violates any of the Standard Terms and Conditions and the aggrieved party has given the other party notice of not less than 30 days in writing requiring that the failure or violation be remedied. If the failure or violation is not remedied within the said 30 days, the aggrieved party shall have the right to terminate this Agreement. **(AFRO Section E)**

(ii) When an order has been made or resolution has been passed for the winding up or liquidation of the Third Party's establishment, the WHO shall terminate the Agreement **(AFRO Section E)**.

(iii) Upon termination, the Second and Third Parties shall immediately discontinue to make any use of the Biological Material, CIVV or Biological Materials for Development in any manner including either to derive or develop substances, processes, products from the Biological Material, CIVV or Biological Materials for Development and shall return or destroy any remaining Biological Material, CIVV or Biological Materials for Development. **(AFRO Section E)**

(iv) The Second and Third Parties, at its discretion will also either destroy substances and products derived, developed through the use of, or that contains/incorporates the Biological Material, CIVV or Biological Materials for Development or remain bound by the terms of this agreement as they apply to those subject matter.

(v) Termination of the agreement shall not affect the accrued rights and obligations that were due prior to the effective date of termination of the agreement. **(AFRO Section E)**

## 6. Notices

(a) Any notices or requests to made under the STC shall be in writing and shall except where it is otherwise stated be delivered by courier, or by facsimile to the address of the Second and Third Party as set out in the Implementing Letter or to the focal points of the First Party and the WHO. Notices and Requests shall be deemed to have been received on the date of delivery, if



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delivered by courier, and on the first business day following the electronic confirmation of the successful transmission of the facsimile, if sent by facsimile. **(AFRO Section E)**

A copy of any notices or requests given under the STC by the First, Second and Third Party should also be sent to the WHO. **(AFRO Section E)**

### **7. Duration of Agreement**

The STC shall remain in force until otherwise determined by the World Health Assembly **(AFRO Section E)**

**OR**

### **Conditions (IGM 4 Section D)**

2. Specimens are provided free of charge by a First Party (NIC or non-NIC) to the Second Party partners in fulfilment of their public health responsibilities, including those contained in the International Health Regulations (2005). In return, the Second Party partners will provide, free of charge, to the First Party, ~~Candidate Influenza Vaccine Viruses, Influenza Reference Viruses and Diagnostic Reagents~~ [UK: This is acceptable but only if Definition 6 is narrowed as suggested above and in accord with Julie Hall's summary.] , sequence information, outcome of the Risk Assessment, and access to benefits [USA: These benefits are as yet undefined.] **(IGM 4 Section D)**

3. Biological Materials are provided to any recipients without any warranty whatsoever, either express or implied, as to their quality, viability, purity, merchantability, suitability or fitness for a particular purpose. The recipient shall ensure that the ~~B~~biological Materials will at all times be used and/or handled in compliance with all relevant and applicable national and international laws, rules and regulations governing the use of biological materials. The recipient agrees to assume full and sole responsibility for any and all claims and liabilities resulting from or otherwise related to the possession and use of the Biological Materials. **(IGM 4 Section D)**

4. Recipients of Biological Materials shall assume all responsibility for any claims, costs, damages or expenses resulting from or otherwise related to the possession and use of the Biological Materials. Recipients undertake to handle Biological Materials in a safe and proper manner, complying with all relevant national and international laws and regulations applicable to the handling of infectious substances. **(IGM 4 Section D)**

### **Virus Tracking System**

WHO shall develop a database accessible to Member States to track movement of all viruses and seed viruses. **(IGM/5 Fundamental Elements 12)**

The WS shall establish a tracking system and database for transfer and movement of materials and their derivatives (including but not limited to throat, nasal, nasopharyngeal, and other swabs; blood or parts thereof; viral isolates and parts thereof including genetic characteristics, biological characteristics, clones, plasmids, and recombinants) on a real-time basis. **(IGM/6 9)**

**OR**

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Whenever any of the Parties transfers Biological Material or CIVV or Biological Materials for Development in accordance with the STC, relevant information concerning the transfer must be included in the WHO tracking database. **(AFRO Section E)**

**World Health Organization (WHO)**

**Global Influenza Surveillance Network (GISN)**

**GISN BIOLOGICAL MATERIALS REQUEST FORM**

**This Form must be completed, signed and sent by fax or e-mail to a WHO Collaborating Centre for Reference and Research on Influenza**

\* \* \*

**Institution/Company Requesting GISN Biological Materials**

**Name & Address**

**Phone/E-mail Contact Information**

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

GISN Specimens

Seasonal Influenza

Candidate Influenza

Reference Viruses

Vaccine Virus

**GISN Strain Designation of Materials Requested:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Purpose for use of GISN Specimens:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Financial Gain anticipated**

**YES**

**NO**

**from Use of Specimens?**

If **YES** I undertake to consult with WHO as specified in Paragraph 37 of the World Health Organization Global Influenza Surveillance Network Standard Terms and Conditions for Transfer and Use of GISN Specimens (STCs).



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**IGM 4 Annex 2**

Contribution Agreement to  
WHO's Coordinated International Sharing of Influenza Viruses & Benefits

By and between WHO and [COMPANY NAME]

In consideration for the use of GISN Biological Specimens, as defined herein, [COMPANY NAME] agrees to contribute to the following components of the WHO's Coordinated International Sharing of Influenza Viruses & Benefits.

Examples of possible contributions by Manufacturers

1. Cash: as a % of sales or other defined formula contributed to a WHO managed trust fund.

**AND/OR**

2. Access to technology:

**a. Royalty Free Licences**

The Company agrees to grant on request, a non-exclusive, royalty-free license to any domestic influenza vaccine manufacturer from developing and least developed countries to use its intellectual property and other protected substances, products (including technology), know-how, information used in the process of influenza vaccine development and production. A copy of the request should also be sent to WHO.

**AND/OR****b. Transfer of Technology & Know-How**

The Company agrees on request to allow access to and transfer of, its technology and related know-how particularly to domestic influenza vaccine manufacturers from developing and least developed countries especially to the Providing Country and other countries in need. A copy of the request should also be sent to WHO.

**AND/OR****c. Pandemic & Pre-pandemic Vaccines**

The Company agrees to set aside X% of vaccines for developing and least developed countries especially to those in need and particularly during the pandemic period. These vaccines will be made available at an affordable price for developing countries and least developed countries. The Company, in pricing its products should consider "Affordable price" for developing countries as a price no higher than cost per unit + X% (e.g. 5%), while for least developed countries as "no profit no loss", particularly during the pandemic period.

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***AND/OR***

3. Access to diagnostics, antivirals and vaccines
  - a. Contribute to stockpile of H5N1 vaccines and ancillary supplies, support downstream management of this stockpile, equitable distribution,
  - b. Provide antivirals
  - c. Provide funds for advance procurement arrangements for pandemic vaccines
  - d. Donate funds to constitute a supply of safe and effective H5N1 and pandemic vaccines
  - e. Donate or earmark part of the Advanced Market Purchasing (AMP) by some Member States and manufacturers of pandemic vaccines, for access by affected countries during pandemic.
  - f. In the event of a pandemic, the Company agrees to transfer at least 60% of every production batch of vaccines developed to an international stockpile prior to commercialization.
  - g. In pre-pandemic period the Company agrees to transfer at least 40% of every production batch of vaccines developed to an international stockpile prior to commercialisation.

***AND/OR***

4. Vaccine development [for some MS having potential vaccine production capacity but spill-over to all MS]
  - a. Provide access to technologies
    - i. Royalty free license to intellectual property protected technologies
    - ii. Access to and use of regulatory approval data [clinical trial data for registration]
  - b. Transfer technology [clarify which specific technologies, e.g. platform technologies or vaccine production]
  - c. Contribute to fund national investments to increase vaccine production capacity in developing countries.

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**AFRO ANNEX 1**

ANNEX 1

**WORLD HEALTH ORGANIZATION (WHO)**

**NEW FRAMEWORK FOR VIRUS SHARING AND BENEFIT SHARING (NFVSBS)**

**IMPLEMENTING LETTER**

**This document must be duly completed and signed, with a copy sent by fax, courier or email by the First Party to the World Health Organization<sup>1</sup>**

The purpose of this letter is to provide a record of the biological material transfer, to memorialize the agreement between the FIRST PARTY (identified below) and the SECOND PARTY (identified below) to abide by the Standard Terms & Conditions and to certify that the SECOND PARTY (identified below) has accepted and signed an unmodified copy of the Standard Terms and Conditions.

The SECOND PARTY organization's Authorized Official will sign this letter on behalf of the SECOND PARTY's organization. The Authorized Official of SECOND PARTY should sign this letter and return a signed copy by fax or email or courier to the FIRST PARTY.

The FIRST PARTY will forward the biological material to the SECOND PARTY upon receipt of the signed copy from the SECOND PARTY organization. This Implementing Letter is effective when signed by all parties. The parties executing this Implementing Letter certify that their respective organizations have accepted and signed an **unmodified copy of the Standard Terms and Conditions** and further agree to be bound by the terms and conditions, for the transfer of original specimen mentioned below. Please fill in all of the blank lines below:

---

<sup>1</sup> The Implementing Letter should be sent to:  
[World Health Organization contact details]

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<b>1. Original Specimen (Enter description)</b>
<b>2. Optional Transmittal fee</b>  Amount: \$ _____
<b>3. First Party's Authorized Official (State providing the Original Specimen)</b>
a. Name of Authorized Official: b. Address: c. Email Address: d. Tel No: e. Fax No:
<b>4. Second Party's Organisation Certification</b>
I hereby certify that the _____ (name of Second Party's Organisation) has accepted and signed an unmodified copy of the Standard Terms and Conditions.  a. Name and Title: b. Address: c. Tel No: d. Fax No: e. Signature:



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**AFRO ANNEX 2**

**ANNEX 2: (CF. SECT STC)**

**WORLD HEALTH ORGANIZATION (WHO)**

**[GLOBAL INFLUENZA SURVEILLANCE NETWORK (NFVSBS)]**

**BIOLOGICAL MATERIALS REQUEST FORM &  
IMPLEMENTING LETTER**

**This document must be completed and signed and sent by fax, courier or email to the World Health Organization**

The purpose of this document is to provide a record of the request for Biological Materials for Development by the Third Party, and to memorialize the agreement between the THIRD PARTY REQUESTING BIOLOGICAL MATERIALS (identified below and hereinafter referred to as the "THIRD PARTY RECIPIENT") and the WORLD HEALTH ORGANIZATION to abide by the Standard Terms & Conditions and to certify that the THIRD PARTY RECIPIENT has accepted and signed an **unmodified copy of the Standard Terms and Conditions**.

The THIRD PARTY's Authorized Official will sign this letter on behalf of the THIRD PARTY. The Authorized Official of THIRD PARTY requesting Biological Materials for Development will complete and sign the Request Form and submit it by fax or email or courier to WHO for approval. On WHO approving the use and transfer, this Letter will constitute an agreement between the "THIRD PARTY RECIPIENT") and the WORLD HEALTH ORGANIZATION (identified below).

This Implementing Letter is effective when signed by all parties. Parties executing this document certify that their respective institution/company/organization have accepted and signed an unmodified copy of the Standard Terms and Conditions and further agree to be bound by the Standard Terms and Conditions. Please fill in all of the blank lines below.

<b>A. Third Party Requesting Biological Materials for Development</b>
<b>1. Details</b>
<b>a. Name and Title (Authorised Official):</b>
<b>b. Address:</b>
<b>c. Tel No:</b>
<b>d. Fax No:</b>

**e. Signature:**

**2. Biological Materials for Development requested:**

Candidate Influenza Vaccine Virus

**3. Strain Designation of Materials Requested:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**4. Purpose of use:**

Development and Production Seasonal Influenza Vaccine

Development and Production of Pre-pandemic or Pandemic Vaccine development and production

**5. Provide further details of use:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**6. Third Party Recipient Certification:**

**By signing and submitting this document I hereby certify that our Company have read and agree to an unmodified copy of the Standard Terms and Conditions and agree to be bound by the terms. In consideration for receiving the Biological Material for Development, the**

**Company further undertakes to immediately enter into consultations with the WHO to operationalise paras on Benefit Sharing of the Standard Terms and Conditions.**

\_\_\_\_\_  
**(Signature)**

\_\_\_\_\_  
**(Date)**

\_\_\_\_\_  
**(Name)**

\_\_\_\_\_  
**(Title)**

**B. WORLD HEALTH ORGANIZATION**

**1. Approved**

YES  NO

If Yes, provide Specific Details of Approved Use:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
**(Signature)**

\_\_\_\_\_  
**(Date)**

\_\_\_\_\_  
**(Name)**

\_\_\_\_\_  
**(Title)**

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**AFRO ANNEX 3****ANNEX 3 (REVISION TO THE EXISTING TOR)**

All activities by the WHO Collaborating Centres for Reference and Research on Influenza under this Terms of Reference will be subject to the Standard Terms and Conditions.

(a) Provide:

- Recommendations to WHO on suitable influenza vaccine viruses for use in seasonal, pre-pandemic and pandemic influenza vaccine development and production;
- Regular and timely surveillance data to WHO, particularly from local and neighbouring geographical regions;
- Advice to the WHO Global Influenza Surveillance Network (GISN)ii National Influenza Centres and other national laboratories designated by the State on laboratory methods for the diagnosis of influenza, the adoption of new diagnostic approaches, the improvement of laboratory practices and on other operational needs;
- Regular and timely reports of virus characterization to WHO and the country contributing the virus and GISN members;
- Expertise, continuous training and laboratory support to WHO Member States in particular developing countries facing influenza outbreaks to conduct influenza outbreak investigation, risk assessment and response activities, including developing candidate influenza vaccine virus.

And response, especially those with pandemic potential; and

- Expertise to assist WHO on the improvement of global surveillance of influenza viruses causing or with the potential to cause human infections, including the development and revision of relevant policies, recommendations and guidelines.

(b) Conduct:

- Isolation and analysis in both embryonated eggs and cell culture of influenza viruses causing or with the potential to cause human infections;
- Complete antigenic and genetic analysis of influenza viruses causing or with the potential to cause human infections, making the information available to WHO and the originating country in a timely manner;
- Antiviral susceptibility testing and analysis of circulating influenza strains and provide a minimum of two reports each year to WHO and the originating country on the findings;
- Active communication and collaboration with other laboratories, especially with the WHO recognized National Influenza Centres, to ensure that high quality clinical specimens and/or virus isolates are received and information is exchanged;

(c) Develop, produce and distribute:

- Antisera against representative influenza viruses causing or with the potential to cause human infections to WHO laboratories involved in influenza vaccine virus selection, development and other WHO activities; and
- Laboratory diagnostic reagents for circulating influenza viruses to GISN members.

(d) Participate in:

- Bi-annual WHO influenza vaccine composition consultations; and
- WHO process to select, develop and distribute candidate influenza vaccine viruses for influenza pandemic preparedness and response.

**OR**

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IGM 4 ANNEX 4

## APPENDIX 4

### **Core Terms of Reference for WHO Collaborating Centres for Reference and Research on Influenza (including WHO Collaborating Centre on Surveillance, Epidemiology, and Control of Influenza)**

This document has not been agreed by all IDWG participants.

**The title, WHO Collaborating Centre for Reference and Research on Influenza, designates, through a defined WHO application process, centres of excellence on influenza which:**

- Meet all core Terms of Reference (TOR) for WHO Collaborating Centres for Reference and Research on Influenza (WHO CCRRI) listed below. This includes the maintenance of Biosafety Level 2 and Biosafety Level 3 laboratory facilities;
- Work under the coordination of the WHO Global Influenza Programme (GIP);<sup>1</sup> and
- Receive adequate long-term governmental and/or other non-commercial financial support to fulfil the core TOR for WHO CCRRI.

**The core TOR constitute minimum requirements; an individual WHO Collaborating Centre for Reference and Research on Influenza may have additional functions in its TOR in discussion with and agreed upon with WHO GIP.**

#### **Core Terms of Reference**

All influenza clinical specimens, candidate influenza vaccine viruses and other influenza viruses will be distributed subject to Standard Terms and Conditions for Transfer and Use of Specimens (STC).

#### **A. Advisory role**

1. Provide data and advice to WHO concerning suitable influenza viruses for use in vaccines against seasonal, A(H5N1) and other influenza virus with a potential to cause a pandemic; participate in the development and timely availability of the candidate influenza vaccine viruses;
2. Advise the WHO Global Influenza Surveillance Network (GISN)<sup>2</sup> on laboratory methods for diagnosis of influenza, including the adoption of new diagnostic approaches, the improvement of laboratory practices and other operational needs;

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<sup>1</sup> WHO Global Influenza Programme <http://www.who.int/csr/disease/influenza/en/>.

<sup>2</sup> The WHO Global Influenza Surveillance Network  
<http://www.who.int/csr/disease/influenza/surveillance/en/index.html>.

3. Serve as ready technical resources globally to WHO on routine influenza surveillance and influenza emergencies, especially on influenza outbreaks with pandemic potential.

## **B. Technical performance**

### **1. Strengthening the WHO Global Influenza Surveillance Network**

- (a) Maintain and strengthen active communication and collaboration with National Influenza Centres (NICs)<sup>1</sup> and other national influenza laboratories to ensure that high quality clinical specimens and/or viruses are received and up-to-date information is exchanged;
- (b) Conduct training and provide support to NICs and other national influenza laboratories, especially those in developing countries, on laboratory techniques and skills, including diagnosis, data analyses, risk assessment and other critical capacities;
- (c) Develop, update and produce laboratory diagnostic reagents for circulating influenza viruses and distribute to NICs and other national influenza laboratories;

### **2. Laboratory analyses and other related activities**

- (a) Isolate in both cell culture and embryonated eggs influenza viruses causing or with the potential to cause human infections;
- (b) Develop and produce antisera in ferrets against representative influenza viruses causing or with the potential to cause human infections;
- (c) Conduct complete antigenic and genetic analyses of influenza viruses causing or with the potential to cause human infections;
- (d) Develop data for recommending appropriate vaccine viruses for use globally, including semi-annual data for seasonal influenza vaccine viruses and, for pandemic preparedness, ongoing data for influenza vaccine viruses with a potential to cause a pandemic;
- (e) Participate in the development of candidate influenza vaccine viruses for seasonal influenza semi-annually and for influenza pandemic preparedness;
- (f) Conduct antiviral susceptibility testing of circulating influenza strains, as part of routine surveillance, and provide findings to WHO at least twice every year;
- (g) Select, maintain and update a group of influenza reference viruses, including seasonal, A(H5N1) and other influenza viruses with pandemic potential, and corresponding antisera if available; update the availability of reference viruses and corresponding antisera, if any, to WHO, which will maintain a web page on the WHO web site;
- (h) Actively initiate research on influenza viruses, engaging laboratories providing clinical specimens and/or viruses; rapidly share findings of public health significance with WHO.

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<sup>1</sup> WHO designated National Influenza Centers <http://www.who.int/csr/disease/influenza/centres/en/index.html>.

### 3. Global influenza response and preparedness

- (a) Provide expertise and laboratory support, in coordination with WHO, to Member States to assist in influenza outbreak response, especially those associated with influenza viruses having pandemic potential;
- (b) Assist WHO in the development of standards, recommendations and policies concerning the broad areas of influenza surveillance, response and preparedness.

## C. Communication and distribution of viruses and/or clinical specimens

### 1. Laboratory analyses and results

- (a) Provide data and/or results timely to originating laboratories/countries providing clinical specimens and/or viruses and to WHO;
- (b) Alert WHO and the country from which the specimens were provided on unusual findings, especially those related to seasonal or pandemic influenza risks obtained from the analysis of the specimens.

### 2. Gene sequences

- (a) Seasonal influenza
  - Upload available sequences of HA and NA genes, and other genes, to a publicly accessible database after each WHO semi-annual vaccine composition consultations, unless otherwise instructed by the laboratory or country providing the specimens.
- (b) A(H5N1) and other influenza viruses with pandemic potential
  - Upload available sequences of HA and NA genes, and other genes, to a publicly accessible database within 3 months after sequencing done, unless otherwise instructed by the laboratory or country providing the specimens. **[Germany: What is the rationale for 3 months?]**
  -
- (c) Post a list of virus isolates/specimens analysed but not approved for public use.
- (d) (old c) Appropriately acknowledge originating laboratories/countries providing clinical specimens and/or viruses.

### 3. Scientific presentations and publications

- (a) Actively engage scientists from originating laboratories/countries in scientific projects associated with research on specimens from these countries and engage them actively in preparation of manuscripts for presentations and publications;
- (b) Appropriately acknowledge in the presentations and publications the contributions of various collaborators, including laboratories/countries providing clinical specimens, viruses or reagents.



#### 4. **Influenza clinical specimens and influenza viruses**

Share **influenza clinical specimens and influenza viruses, in a timely and unrestricted manner**, with laboratories working in coordination and in collaboration with GIP, including

- i. Other WHO CCs for laboratory analyses as defined above;
- ii Other laboratories involved in WHO coordinated specialized activities, (e.g. the WHO External Quality Assessment Project for the detection of subtype influenza A viruses using PCR; the WHO influenza PCR primer updating), and other activities whose purpose is to strengthen global influenza surveillance and other risk assessment and risk response; as well as capacity building.
- iii Key national regulatory laboratories, including FDA, NIBSC and TGA, which are involved in the WHO process of candidate influenza vaccine virus selection and development, as well as vaccine potency reagent development.

**5. Candidate influenza vaccine viruses** are selected and developed under the coordination of WHO, for development and production of vaccines against seasonal, A(H5N1) and other influenza viruses with a potential to cause a pandemic. The candidate influenza vaccine viruses include wild type viruses and high-growth reassortant viruses, including those prepared by reverse genetics.

- (a) Distribute to appropriate recipients on request, including influenza vaccine manufacturers, diagnostic companies, research institutes and others interested in receiving influenza vaccine viruses;
- (b) Report the distribution status to WHO, which will maintain a list of recipients on the WHO web site.

**6. Influenza reference viruses** are a group of viruses selected, maintained and updated by WHO CCs as antigenically and genetically representative of important groups of viruses, including seasonal, A(H5N1) and other influenza viruses with pandemic potential. These viruses are often used to generate corresponding antisera. Both reference viruses and corresponding antisera will be:

- (a) Distribute, on request, to NICs and research institutes for non-commercial activities including surveillance, reference and research; the laboratories/countries providing the original clinical specimens and/or viruses will be notified of the distribution;

**7.** Distribution of influenza clinical specimens and influenza viruses, for purposes beyond those described above, will require approval from the laboratories/countries providing the original clinical specimens and/or viruses.

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**AFRO ANNEX 4****ANNEX 4 (REVISION TO EXISTING TOR)****TERMS OF REFERENCE FOR WHO H5 REFERENCE LABORATORIES**

In 2004, the WHO H5 Reference Laboratory Network was established, as an ad hoc component of the WHO Global Influenza Surveillance Network (GISN)<sup>1</sup>, in response to the public health needs arising from avian influenza A(H5N1) infection in humans and influenza pandemic preparedness. The laboratories involved to date<sup>2</sup> include the four WHO Collaborating Centres for Reference and Research on Influenza, the WHO Collaborating Centre for Studies on the Ecology of Influenza in Animals and other laboratories with internationally recognized expertise in avian influenza.

The addition of new laboratories to the Network is based on an overall assessment of global public health needs, the ability of candidate laboratories to fulfil the Terms of Reference listed below, and, in particular, the added value that inclusion of candidate laboratories would bring to the Network.

Membership in the WHO H5 Reference Laboratory Network is ad hoc and will be reviewed periodically to ensure the Network's optimum effectiveness in meeting emerging public health risks.

**A. Provide**

1. accurate laboratory diagnosis of influenza infection in humans to assist in rapid outbreak response, especially those suspected of being associated with avian influenza A (H5) viruses;
2. expertise and laboratory support in response to A (H5) avian influenza outbreaks
3. immediately report to WHO and the originating laboratory the results of laboratory diagnostic tests, especially the detection of A (H5) viruses and any other important findings;
4. feedback to WHO on the use of WHO recommended diagnostic protocols and primers to assist WHO in the update of laboratory diagnostic recommendations.

**B. Actively seek approval from the Ministry of Health of the originating laboratory for sharing the A (H5) clinical specimens and/or viruses with any other entity.**

OR

## APPENDIX 6

**Terms of Reference for WHO H5 Reference Laboratories**

This document has not been agreed by all IDWG participants.

The title, **WHO H5 Reference Laboratory**, designates, through a defined WHO process, on an ad hoc basis,<sup>1</sup> a national influenza laboratory which:

- Meets the WHO Criteria for accepting positive results of H5 infection in humans,<sup>2</sup> which ensures that the laboratory conducts reliable diagnosis of influenza A(H5) infection in humans, and that the positive results of A(H5) detection are accepted by WHO as confirmatory without external verification in a WHO Collaborating Center (CC) for Reference and Research on Influenza (RRI); and
- Fulfills the Terms of Reference (TOR) for WHO H5 Reference Laboratories.

**Terms of Reference for WHO H5 Reference Laboratories****A. Core functions**

1. Provide accurate laboratory diagnosis of influenza infection in humans to assist in rapid outbreak response, especially those suspected of being associated with avian influenza A(H5) viruses; and
2. Provide A(H5) laboratory diagnostic services to its own country and beyond when needed.

**B. Technical performance**

1. Provide advice to clinics, hospitals and other specimen collection sites on safe and appropriate clinical specimen collection, storage, packaging and shipping;
2. Conduct accurate laboratory diagnosis of specimens received, typing and subtyping influenza viruses, especially the confirmation of A(H5) human infections; and
3. Provide expertise and laboratory support in response to A(H5) avian influenza outbreaks.

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<sup>1</sup> WHO maintains an up-to-date list of WHO H5 Reference Laboratories.

<sup>2</sup> Web-link to Criteria.

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**C. Communication and exchange**

1. Report immediately to WHO and the originating laboratory the results of laboratory diagnostic tests, especially the detection of A(H5) viruses and any other important findings;
2. Actively seek approval from the Ministry of Health of the originating laboratory for sharing the A(H5) clinical specimens and/or viruses with WHO for further characterization in the WHO CCRRI; and
3. Provide feedback to WHO on the use of WHO recommended diagnostic protocols and primers to assist WHO in the update of laboratory diagnostic recommendations.

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**IGM 4 APPENDIX 5**

## APPENDIX 5

**Terms of Reference for National Influenza Centers**

This document has not been agreed by all IDWG participants.

**The title, National Influenza Center(NIC), recognizes, through a defined WHO process, national influenza laboratories which:**

- Function as members of the WHO Global Influenza Surveillance Network (GISN)<sup>1</sup> in coordination with the WHO Global Influenza Programme (GIP);<sup>2</sup>
- Are formally designated by the country Ministry of Health and officially recognized by WHO; and
- Fulfill the Terms of Reference (TOR) for NICs.

**The TOR constitutes minimum requirements for a NIC being a member of the WHO GISN; an individual NIC may have additional obligations under the authority of its Ministry of Health.**

**Terms of Reference for National Influenza Centres as members of the WHO Global Influenza Surveillance Network****D. Core functions**

1. Serve as the key reference point between WHO and the country of origin on all issues related to influenza virological surveillance, laboratory diagnosis of influenza infection in humans and sharing of influenza clinical specimens and/or viruses with WHO;
2. Participate actively in WHO global influenza surveillance activities and maintain active communication and collaboration with other members of the WHO GISN, including WHO Collaborating Centers and other National Influenza Centers.

**E. Technical performance**

4. Collect appropriate clinical specimens from patients year-round and especially during influenza seasons and outbreaks;
5. Act as a collection point for influenza viruses where available from laboratories within the country;

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<sup>1</sup> <http://www.who.int/csr/disease/influenza/surveillance/en/index.html>.

<sup>2</sup> <http://www.who.int/csr/disease/influenza/en/>.

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6. Review, expand and maintain sufficient coverage of influenza virological surveillance in the country;
7. Isolate in cell culture and/or embryonated eggs seasonal/influenza viruses under appropriate laboratory containment;
8. Conduct preliminary characterization of influenza virus type and subtype;
9. Store original influenza positive clinical specimens for at least 18 months at -70 °C;
10. Provide technical advice and support to other influenza laboratories in the country, on specimen collection and shipment logistics, laboratory diagnosis, laboratory biosafety and other operational procedures related to influenza virological surveillance;
11. Select seasonal/influenza viruses, especially those of geographical and possibly antigenic and genetic representativeness, for further characterization in WHO Collaborating Centers for Reference and Research on Influenza (CC RRI).

#### **F. Communication and exchange**

4. Alert WHO GIP immediately on the emergence of unusual outbreaks of influenza or influenza-like illness, the detection/isolation from humans of A(H5) or other influenza viruses with a potential to cause a pandemic, or of influenza viruses that cannot be readily identified with WHO diagnostic reagents provided through the WHO GISN;
5. Report regularly to WHO FluNet,<sup>1</sup> weekly during influenza seasons, the extent of influenza activity in the country, virological surveillance data and other relevant information of public health importance;
6. Provide to national authorities and the general public, information on influenza viruses circulating in the country;
7. At least twice every year make shipments to WHO CCRRI of a selection of representative seasonal influenza virus isolates and all influenza virus isolates which gave low titres in HI tests using WHO diagnostic reagents provided through the WHO GISN:
  - (a) For northern hemisphere countries, once in November and once in early January;
  - (b) For southern hemisphere countries, once in June and once in mid-August;
  - (c) For tropical countries, depending on influenza activity, make shipments of recent virus isolates timely to be included in the next WHO vaccine composition recommendation, either for northern hemisphere or southern hemisphere; and
  - (d) For all countries, make shipments of any unusual viruses within one week after detection.

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<sup>1</sup> <http://gamapserver.who.int/GlobalAtlas/home.asp>.

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8. Initiate shipments to WHO CCRRI of clinical specimens and/or viruses from all suspected/confirmed infections of A(H5) and other influenza in humans, within two weeks after detection or isolation of the virus with potential to cause a pandemic; include in the shipment information of time, geographical, epidemiological and clinical factors associated with the suspected/confirmed human infections, for the purpose of ongoing and rapid WHO global pandemic risk assessment and response, as well as and pandemic preparedness.

## TERMS OF REFERENCE FOR WHO COLLABORATING CENTRES (CC), NATIONAL INFLUENZA CENTRES (NIC) AND WHO H5 REFERENCE LABORATORIES

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### <sup>1</sup> IDENTIFICATION OF PARTIES

We believe that the parties should be defined in the same way as in IGM 4. There should be a strong link between the first and the second parties in order to strengthen and improve the collaboration within the GISN. (EU comments received on 22 November 2007)

### RIGHTS AND RESPONSIBILITIES OF ALL PARTIES

#### <sup>2</sup> EU comments received on 22 November 2007:

- The WHO glossary of terms should be used as the basis for descriptions in the Standard Terms and Conditions. Rights and responsibilities should be in accordance with the IHR., based on this principle:
  - Instead of “*Authority to determine access to influenza viruses*” the term “*authority to determine access to specimens*” should be used.
  - Instead of “*specimens/virus*” the term “*clinical specimens and/wild type virus derived from them*” should be used. The term “*within the STC*” should be added at the end of the second paragraph.
- We disagree with the third paragraph on the basis of the document on IGM 1, on prior informed consent.
- The right to deny access should rest with the oversight mechanism and not with the member states.

### ORIGINATING COUNTRIES (MEMBER STATES)

#### <sup>3</sup> EU comments received on 22 November 2007:

- Title should read “*rights and obligations of member states*”.
- Instead of “*materials*” it should read “*clinical specimens or wild type viruses derived from them*”.
- Paragraph 7 should read “*Concerning the new global fund for vaccines, we would prefer to ask WHO to further explore the possibility of voluntary system for finance*”.
- Paragraph 8: has already been stated in the document on principles. This paragraph should therefore be deleted.



## RIGHTS AND OBLIGATIONS OF THE WHO (WS)

### <sup>4</sup> EU comments received on 22 November 2007:

- Instead of “*receive of materials*” read “*candidate vaccine viruses, reference viruses and wild type viruses provided that international regulations on safety are respected*”.
- Paragraph 1, sub-paragraph 7 should be replaced by “Concerning the new global fund for vaccines, we would prefer to ask WHO to further explore the possibility of voluntary system for finance”.



World Health  
Organization

INTERGOVERNMENTAL MEETING ON PANDEMIC  
INFLUENZA PREPAREDNESS: SHARING OF  
INFLUENZA VIRUSES AND ACCESS TO VACCINES  
AND OTHER BENEFITS  
Agenda item 2

A/PIP/IGM/INF.DOC./3  
23 November 2007

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## Dictionary of terms

### SCIENTIFIC TERMS

**Candidate influenza vaccine viruses (H5N1).** These are influenza viruses developed and modified by reverse genetics by WHO Collaborating Centres and the National Institute of Biological Standards and Control (United Kingdom of Great Britain and Northern Ireland) for Human vaccine development.

**Candidate influenza vaccine viruses (seasonal).** These are influenza viruses approved by WHO as suitable for making influenza vaccine. Most are modified in **seasonal vaccine virus reassortment laboratories** by “classical” reassortment from **WHO-recommended viruses**.

**“Classical” reassortment.** This is a non-patented laboratory technique that is often used to make (seasonal) candidate vaccine viruses.

**Clinical specimens (original).** These are materials collected from humans, generally in order to confirm a diagnosis. For influenza, most commonly, clinical specimens are taken from the respiratory tract (for example, swabs and aspirated fluid) but they can be from other locations. Clinical specimens can be frozen and stored for later use.

**Genetic reassortment.** In this process genes from two or more influenza viruses are mixed in different combinations, resulting in hybrid viruses with genetic characteristics of each parent virus. This process occurs in nature but can also be done in a laboratory using “classical” reassortment or **reverse genetics**.

**High-growth reassortant viruses.** These are influenza viruses that have been genetically modified to grow better in eggs for optimal vaccine production.

**Influenza reference viruses.** These are **wild-type influenza viruses** that WHO has selected as representative of important groups of influenza viruses on the basis of extensive antigenic and genetic studies and comparisons with viruses from many countries. As the influenza viruses evolve in nature, new reference viruses are selected.

**Influenza virus subtypes.** Type A influenza viruses are further classified according to their combinations of haemagglutinin (H) and neuraminidase (N) antigens (i.e. specific proteins on the virus surface), e.g. H5N1; 16 H subtypes and nine N subtypes have been distinguished.

**Novel (new) subtype of human influenza A virus.** This term refers to human influenza viruses that have haemagglutinin and neuraminidase antigens that are distinct from seasonal influenza viruses and have the potential to cause a pandemic.

**Reagents for influenza vaccine standardization.** These reagents are used to standardize the amount of haemagglutinin protein in influenza vaccines as required by regulatory agencies. The reagents have to be produced in large quantities so that all vaccine batches can be tested.

**Reverse genetics.** This is a laboratory technique that is used to construct or modify influenza viruses and is protected by patents in several countries. It is used to render highly pathogenic H5N1 viruses less dangerous.

**Seed viruses.** These are influenza viruses prepared from **candidate influenza vaccine viruses** by individual manufacturers for the manufacturer's specific vaccine-production process.

**WHO molecular diagnostic reagents.** These reagents are used for real-time polymerase chain reaction diagnosis, and are available free of charge.

**WHO reagent kits.** These kits consist of inactivated **influenza reference viruses** or purified protein from reference viruses and corresponding antibodies, and are used for the identification of influenza viruses. They are available free of charge.

**WHO-recommended viruses for vaccine use.** These are **wild-type influenza viruses** that are recommended by WHO as the basis for an influenza vaccine.

**Wild-type influenza viruses** (*synonym: virus isolates*). These are influenza viruses that have been cultured either in eggs or cells (i.e. isolated) directly from **clinical specimens** and have not been modified.

## INSTITUTIONS AND ORGANIZATIONS

**Essential regulatory laboratories.** These influenza laboratories, located in national regulatory agencies, have a critical role at the global level for developing, regulating and standardizing influenza vaccines and in this capacity they work closely with WHO and industry. They do not have formal Terms of Reference within the **Global Influenza Surveillance Network**.

**Global Influenza Surveillance Network.** This is an international network coordinated by WHO to undertake surveillance for many public health functions, including pandemic risk assessment and preparedness. It comprises **National Influenza Centres, WHO Collaborating Centres on influenza and WHO H5 Reference Laboratories**.

**Influenza vaccine manufacturers.** These are commercial institutions that develop and produce human influenza vaccines for seasonal, H5N1 and other influenza subtypes with pandemic potential.

**Laboratories involved in specific WHO influenza projects.** WHO's current projects are the WHO polymerase chain reaction (PCR) working group, which assists WHO in the updating of PCR diagnostic protocols for circulating H5N1 viruses, and External quality assessment project for detecting influenza A viruses using PCR.

**National Influenza Centres.** These are influenza laboratories designated by national authorities and recognized by WHO to perform certain roles within the **Global Influenza Surveillance Network** as defined by formal Terms of Reference.

**Seasonal vaccine virus reassortment laboratories.** These are laboratories (currently three) that develop **high-growth reassortant viruses** for seasonal influenza vaccine development and production, supported by industry funds.

**WHO Collaborating Centres.** These are influenza laboratories designated by WHO and fully supported by national authorities to perform certain roles within the **Global Influenza Surveillance Network** defined by formal Terms of Reference. In general, they differ from **National Influenza Centres** in having global responsibilities and more extensive technical capacities. Currently, there are four Collaborating Centres that focus primarily (but not exclusively) on human influenza and one that, in its role as a WHO Collaborating Centre, focuses primarily on animal influenza viruses that threaten people.

**WHO Global Influenza Programme.** This is WHO's main technical programme on influenza (in the Department of Epidemic and Pandemic Alert and Response, Health, Security and Environment cluster). It functions as the coordinating secretariat for the **Global Influenza Surveillance Network**.

**WHO H5 Reference Laboratories.** These are influenza laboratories that have been designated by WHO in order to strengthen national and regional capacity for reliably diagnosing H5 virus infection until this capacity is more widespread.

## OTHER TERMS

**Benefit.** Advantage, profit, good (*Oxford English Dictionary, 2nd ed., 1989*).

**Global public health security.** This term comprises the activities, both proactive and reactive, required to minimize vulnerability to acute public health events that endanger the collective health of populations living across geographical regions and international boundaries.

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