WHO WPRO-Yonsei University

Training Modules for Local Researchers

ASSESS THE CURRENT STATUS OF PUBLIC HEALTH LAW AND LEGISLATION IN LAO PDR, MALAYSIA, MONGOLIA, PNG AND SOLOMON ISLANDS USING THE WHO DEVELOPED LEGAL ANALYSIS TOOL.

Time: 13-15 June 2013
Venue: #303 Administration B/D Yonsei University Health System, Seoul, Republic of Korea

World Health Organization

ASIAN INSTITUTE FOR BIOETHICS AND HEALTH LAW
YONSEI UNIVERSITY

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Friday 14 June 2013

9:10a.m.-11:50a.m. Session 1

1. Opening Remarks
   Mr. Sjoerd Postma, Team Leader, Health Services Development, WHO/WPRO

2. Role of law in Public Health
   Dr. Roy Beran, Secretary-General, WAML

3. Can Adoption of a Model Public Health Law within the Pacific Region improve Public Health Stewardship?:
   Ms. Genevieve Howse, Expert Panel

4. Introduction of the Regulatory Framework to Assess the Domestic Health Law
   Dr. So Yoon Kim, Professor of Department of Medical Law and Ethics, Yonsei University

5. WHO/WPRO Tool to Assess Health Law in Countries, Pilot Implementation in the Kingdom of Cambodia
   Prof. Ki-Hyun Hahm, Department of Medical Humanities and Social Medicine, Ajou University

Group Photo

11:30a.m.-1:30p.m.: Lunch

2:00p.m.-5:00p.m. Session 2

6. Introduction of the Analysis Tool and Assessment Process
   Dr. Yuri Lee, Technical Officer for Health Legislation, Health Services Development, WHO/WPRO

7. Pilot of Public Health Legislation Assessment Tool

Mr. David Clarke, Expert Panel

8. Experience of pilot test in EMRO
   Dr. Hala Abou-Taleb, EMRO

Breaktime

Questions and Answers(Q&A)

Free Discussion(all attendance)

9. Closing Remarks
   Mr. Sjoerd Postma, Team Leader, Health Services Development, WHO/WPRO

7:00p.m. ~ : Welcome Reception Dinner

Saturday 15 June 2013

9:00a.m.-12:30p.m. Session 3

1. Opening Remarks

   Prof. SOHN Myongsei, Dean of Graduate School of Public Health, Yonsei University

2. Introduction of Objective of program including discussion points

   Dr. So Yoon Kim, Professor of Department of Medical Law and Ethics, Yonsei University

3. Technical presentation: Report on 6 countries′ public health law

   Mr. Sjoerd Postma, Team Leader, Health Services Development

4. Panel Discussion

   Ms. Genevieve Howse, Mr. David Clarke, Mr. Bounfeng Phoummalaysith, Dr. Khieve Hok, Dr. Hala Abou-Taleb

5. Technical Presentation: The Future Direction of Regulatory Framework

   Dr. So Yoon Kim, Professor of Department of Medical Law and Ethics, Yonsei University

Free Discussion:

Public Officers of MoH Public Health Law Experts Panels WHO/WPRO Secretariats, WHO/EMRO Secretariats, Yonsei University Experts

Wrap Up:

Prof SOHN Myongsei, Dean of Graduate School of Public Health, Yonsei University

12:30p.m.-2:00p.m.: Lunch

WORLD HEALTH ORGANIZATION
WESTERN PACIFIC REGIONAL OFFICE

TOOL TO ASSESS HEALTH LAW

OVERVIEW

Health law is a central component of every country's attempts to detect, assess and respond to health threats for the improvement and promotion of health for its citizens.

WHO/WPRO has developed a tool to assess health law in countries. The 1st Expert Consultation on Public Health Law convened in May 2011 to review the tool in terms of its goals and objectives, as well as the basic theory and structure. The tool was then pilot tested in four countries: Republic of Korea, Vanuatu, Samoa, and the Philippines. The 2nd Expert Consultation convened in October 2012 to refine the tool based on the results of the pilot test and other relevant resources.

The primary purpose of the tool is to determine the comprehensiveness of a country's health law through a series of questions asking whether law(s) (e.g., legislation, regulation) have been enacted for specific areas relating to health (e.g., HIV/AIDS). Gaps in the country's system may be identified through the absence of relevant law. In addition, the information may be compared across multiple countries. During the process of completing the tool, the relevant provisions of law will also be compiled to build a central database of laws for more detailed analysis. For each country, the final step of implementation will include a report that summarizes the findings and makes recommendations as necessary.

The tool currently comprises 4 modules: Module 1 is based on WHO International Digest of Health Legislation (IDHL); Module 2 concerns Health Systems based on Primary Health Care (PHC) Values; Module 3 concerns the International Health Regulations 2005 (IHR), and Module 4 concerns the Framework Convention on Tobacco Control (FCTC). Because each module has been designed to be self-standing, certain questions may overlap in subject matter across different modules. Additional modules covering different specific areas of health law may later be developed and added to the tool.

GUIDELINES

1. For each of the questions in the modules below, please respond by checking the "Y" box with a lower case "x" if your country has law(s) specifically relating to the subject area and currently in force.

   The tool is concerned primarily with the following types of law: (i) *constitutional provisions* (e.g., bill of rights) adopted by the government; (ii) *primary legislation* (e.g., acts, codes, statutes) enacted by the main law-making body of the government (e.g., parliament); (iii) *subsidiary legislation* (e.g., regulations, orders, decrees) promulgated by executive bodies (e.g., ministries, agencies); (iv) *by-laws* (e.g., ordinances) issued by local authorities (e.g., city councils, district offices); and (v) *international instruments* (e.g., treaties, conventions) signed and ratified by your country.

2. If a current law is partially related to a subject area, please respond "Y" and provide further explanation in the box for "explanatory note."

   A law that is "partially related" to a subject area may include one or more of the following situations: (i) the law covers certain aspects of the subject area but not all or most of the pertinent aspects as would generally be expected of such a law; or (ii) the subject area is not covered by a law relating exclusively to the subject area per se but instead referenced

specifically in a broader law (e.g., framework act) or tangentially related law (e.g., criminal code).

3. In the box for "explanatory note," please cite the relevant law(s), including name, year of enactment/revision, and code section, as well as any additional reference markers employed by your legal system.

4. Also in the box for "explanatory note," please indicate the format(s) by which the texts of the relevant law(s) may be accessed.

   Access may take one or more of the following formats: (i) hyperlink to an on-line database; (ii) electronic document; (iii) electronic scan of the text; or (iv) photocopy of the text.

5. Along with the completed tool, please attach hardcopy versions of the texts as appendices following each module.

6. Also in the box for "explanatory note," please indicate the language(s) in which the texts are available.

   The language(s) may be categorized as one or more of the following: (i) local language; (ii) official English translation sanctioned by the government; (iii) unofficial English translation made for informal research/reference purposes (include information on authorship, source, and date).

7. If your country does not have a current law as described above that specifically or partially relates to the subject area, please respond by checking the "N" box with a lower case "x."

8. In the box for "explanatory note," please provide additional explanation where appropriate to provide context for the "N" response.

   Additional explanation of a "no" response may be helpful in one or more of the following situations: (i) a law relating to the subject area once existed but has since been repealed or otherwise invalidated; (ii) a draft form of law (e.g., bill) relating to the subject area is currently being processed but not yet finalized; (iii) the subject area is covered by a governmental program, policy, or set of procedures that has no direct basis in one of the aforementioned types of law; (iv) the subject area has been addressed in a judicial decision that continues to influence activities and/or has the force of law in the subject area; (v) the subject area is covered by tribal/village/customary law(s) applicable to a limited group of people; or (vi) the subject area is "not applicable" to your country (e.g., maritime issues for a landlocked country).

NOTES to LOCAL RESEARCHER

As described in the Agreement for Performance of Work and Terms of Reference between Yonsei University and you in your capacity as the Local Researcher, you are responsible for completing a preliminary desk review of the tool according to the guidelines above. You are expected to provide accurate responses to the best of your knowledge, making full use of the resources at your disposal. The additional explanations that accompany your responses, where necessary, as well as the citations to and texts of the laws themselves, are also to be considered an essential part of the task. While your responses and explanations may be used in various summaries, analyses, and reports, no direct attribution will be made to the Local Researcher by name.

Upon completion of your desk review, please submit the tool in electronic form to:
(i) Mr. Sjieuwke POSTMA (Team Leader, HSD unit, WPRO/WHO): hawkenl@wpro.who.int;

(ii) Dr. Yuri LEE (Technical Officer (Legal), WPRO/WHO): leeyu@wpro.who.int;
(iii) Dr. Soyoon KIM (Professor, Yonsei University): syoonkim@yuhs.ac; and
(iv) Ms KyungYun Sunu (AIBHL researcher) kyungyun@yuhs.ac

Please supply information for the following individuals:

Local Researcher

Name	[e.g., Mr./Ms./Dr.] [Given Name] [FAMILY NAME]
Current post/title	[e.g., Professor/Researcher]
Current affiliation	[e.g., Ministry of Health, Health Services Division]
E-mail address	
Telephone	[+country code] [local number]

Additional respondent(s) (other than Local Researcher, persons who completed sections of the tool, if any) (insert additional tables consecutively, one for every additional respondent, if necessary)

Name	[e.g., Mr./Ms./Dr.] [Given Name] [FAMILY NAME]
Current post/title	[e.g., Professor/Researcher]
Current affiliation	[e.g., Ministry of Health, Health Services Division]
E-mail address	
Telephone	[+country code] [local number]
Sections	[e.g., Module 1: questions 21-23, Module 4: all]

Local consultant(s) (persons consulted as resources of information in completing the tool and/or acquiring texts of laws, if any) (insert additional tables consecutively, one for every additional expert, if necessary)

Name	[e.g., Mr./Ms./Dr.] [Given Name] [FAMILY NAME]
Current post/title	[e.g., Professor/Researcher]
Current affiliation	[e.g., Ministry of Health, Health Services Division]
E-mail address	
Telephone	[+country code] [local number]
Sections	[e.g., Module 1: questions 21-23, Module 4: all]

Module 1:
International Digest of Health Legislation

- The objective of this module is to assess each country's breadth of coverage for laws pertaining to health and health-related issues vis-à-vis the WHO *International Digest of Health Legislation* (IDHL).
- For convenience, the order, content, and wordings of the questions below generally follow the subject headings of the IDHL, though certain subject areas have been broken down into more specific sub-issues (e.g., (Question 10) communicable diseases and (Question 11) HIV/AIDS) or merged into a single question (e.g., (Question 24) biomedical ethics and professional responsibility).
- The IDHL (in English) is available on-line at: http://apps.who.int/idhl-rils/frame.cfm?language=english. See also Annex 1.

MODULE 1: International Digest of Health Legislation			
Question	**Y**	**N**	**Explanatory Note**
1. Does your country have constitutional provisions relating to health?			
2. Does your country have law(s) relating to human rights and other fundamental rights that pertain to health?			
3. Does your country have law(s) relating to international treaties and other international instruments that pertain to health? (If so, please provide a brief overview of your legal system and explain how such international obligations are incorporated into the system. Also, please list the international treaties and instruments to which your country is a signatory.)			
4. Does your country have law(s) relating to the organization and/or administration of health care (e.g., general governmental health and public health agencies, including ministries, boards, councils)? [This question generally addresses the same subject matter as Module 2, Questions 1-3.]			
5. Does your country have law(s) relating to health financing (e.g., taxation, social security, health insurance, cost containment)? [This question generally addresses the same subject matter as Module 2, Questions 4-6.]			

MODULE 1: International Digest of Health Legislation			
Question	**Y**	**N**	**Explanatory Note**
6. Does your county have law(s) relating to health research (e.g., government support, permits)? [This question differs from but partially addresses the same subject matter as Module 1, Question 24.]			
7. Does your country have law(s) relating to health education (e.g., information the public, health promotion, access to information)? [This question generally addresses the same subject matter as Module 2, Questions 7-10.]			
8. Does your country have law(s) relating to quality control of health workers (e.g., regulation and licensing, access, specialization, training and education, monitoring)? [This question differs from but partially addresses the same subject matter as Module 1, Question 24.]			
9. Does your country have law(s) relating to health care facilities, related institutions, and/or services?			
10. Does your country have law(s) relating to communicable diseases? [This question generally addresses the same subject matter as Module 3 overall.]			
11. Does your country have law(s) relating specifically to HIV/AIDS, including criminal laws, immigration laws, and/or family laws?			
12. Does your country have law(s) relating to organ transplantation and/or human tissues, including blood and blood products?			
13. Does your country have law(s) relating to non-communicable diseases?			
14. Does your country have law(s) relating to oral health (e.g., fluoridation)?			
15. Does your country have law(s) relating to family health (e.g., family counseling, genetic counseling, maternal health and care programs, prenatal care, prenuptial examinations, sex education)? [This question differs from but generally addresses the same subject matter as Module 1, Question 17.]			

MODULE 1: International Digest of Health Legislation			
Question	**Y**	**N**	**Explanatory Note**
16. Does your country have law(s) relating to child health (e.g., abuse of children, adolescent health, child labor, daycare facilities, infant care, school health program)?			
17. Does your country have law(s) relating to human reproduction and/or population control?			
18. Does your country have law(s) relating to care of the elderly (e.g., basic care arrangements, geriatric programs, old-age homes)?			
19. Does your country have law(s) relating to care of the disabled and/or rehabilitation (e.g., basic care arrangements, mobility and access arrangements, sheltered workshops)?			
20. Does your country have law(s) relating to mental health?			
21. Does your country have law(s) relating to the control of smoking and/or use of other tobacco products? [This question generally addresses the same subject matter as Module 4 overall.]			
22. Does your country have law(s) relating to the control of alcohol use?			
23. Does your country have law(s) relating to the control of drug abuse (e.g., control of narcotics and other illegal substances, addition treatment, criminalization)?			
24. Does your country have law(s) relating to biomedical ethics and/or professional responsibility (e.g., research ethics, confidentiality, advertising, codes of conduct, disciplinary measures, civil and/or criminal liability for wrongdoing)? [This question differs from but partially addresses the same subject matter as Module 1, Questions 6 and 8.]			

MODULE 1: International Digest of Health Legislation			
Question	**Y**	**N**	**Explanatory Note**
25. Does your country have law(s) relating to death and dying (e.g., euthanasia, living wills, determination of death, registration of death)?			
26. Does your country have law(s) relating to post-mortem examinations?			
27. Does your country have law(s) relating to the disposal of the dead?			
28. Does your country have law(s) relating to nutrition (e.g., food fortification, infant foods, malnutrition, nutritional services and education)?			
29. Does your country have law(s) relating to food safety (e.g., adulteration and additives, inspection, irradiation, import and export controls, packaging and advertising, pesticides and veterinary pharmaceutical residues, handling and distribution)?			
30. Does your country have law(s) relating to the safety of consumer products (e.g., toys, kitchen utensils, appliances, ceramics)?			
31. Does your country have law(s) relating to pharmaceuticals and/or related products? [This generally addresses the same subject matter as Module 2, Questions 13-14.]			
32. Does your country have law(s) relating to traditional medicines?			
33. Does your country have country law(s) relating to medical devices?			
34. Does your country have law(s) relating to poisons and/or other hazardous substances?			
35. Does your country have law(s) relating to occupational health and safety?			
36. Does your country have law(s) relating to environmental protection as it pertains specifically to human health (e.g., sanitary standards for housing, water/air quality, pollution, waste disposal)?			

MODULE 1: International Digest of Health Legislation			
Question	**Y**	**N**	**Explanatory Note**
37. Does your country have law(s) relating to radiation protection?			
38. Does your country have law(s) relating to accident prevention (e.g., health requirements for drivers, educational programs, road safety, safety in air travel)?			
39. Does your country have law(s) relating to sports and recreation (e.g., doping, safety/hygiene of swimming pools, sports medicine)?			
40. Does your country have law(s) relating to health information (e.g., vital statistics, notification of disease), including provisions relating to the role of the private sector in obtaining and/or maintaining such information and statistics?			

Module 2:
Health Systems based on Primary Health Care Values

- The objective of this module is to assess each country's efforts via law to develop a primary health care system in relation to the WHO *Western Pacific Regional Strategy for Health Systems Based on the Values of Primary Health Care* (Strategy).
- The questions below derive from the Strategy, specifically those issues that historically have been and/or can be regulated by law.
- The Strategy (in English) is available on-line at: http://www.wpro.who.int/NR/rdonlyres/89BE3251-DD0F-4E61-992B-7C54AD83C048/0/RS_Health_Systems_web.pdf . See also Annex 2.

MODULE 2: Health Systems based on Primary Health Care Values			
Question	**Y**	**N**	**Explanatory Note**
1. Does your country have law(s) mandating health authority to develop national health plans, policies, strategies, and/or frameworks?			
2. Does your country have law(s) mandating health authority to implement and monitor nation health plans, policies, strategies, and/or frameworks?			
3. Does your country have law(s) mandating health authority to engage in coalition-building with stakeholders outside the health sector?			
4. Does your country have law(s) relating to the provision of health financing (e.g., taxation, social security, health insurance, cost containment)?			
5. Does your country have law(s) relating to the provision of minimum health services for your citizens?			
6. Does your country have law(s) relating to safety-net mechanisms for your citizens to protect them from financial disaster due to health expenditures?			

MODULE 2: Health Systems based on Primary Health Care Values			
Question	**Y**	**N**	**Explanatory Note**
7. Does your country have law(s) relating to maintaining numbers of health workers (e.g., production, deployment and retirement, international recruitment)?			
8. Does your country have law(s) relating to classification among various types of health workers?			
9. Does your country have law(s) relating to the distribution of health workers?			
10. Does your country have law(s) relating to quality control of health workers (e.g., regulation and licensing, access, specialization, training and education, monitoring)?			
11. Does your country have law(s) relating to the protection of patients as health consumers (e.g. patient bill of rights, including access to services and medical technologies, right to receive health interventions at a time and location of their choosing)			
12. Does your country have law(s) relating to monitoring the performance of your health system (e.g., quality control of services)?			
13. Does your country have law(s) relating to the access of essential medicines?			
14. Does your country have law(s) relating to quality control, cost effectiveness, safety, efficacy of medicines and medical technologies?			
15. Does your country have law(s) relating to the access of vaccines?			
16. Does your country have law(s) relating to quality control of vaccines (e.g., cold chain requirements)?			

MODULE 2: Health Systems based on Primary Health Care Values			
Question	**Y**	**N**	**Explanatory Note**
17. Does your country have law(s) relating to the use of information technology in health care?			

Module 3:
International Health Regulations (2005)

- The objective of this module is to assess each country's efforts via law towards fulfilling the requirements under the WHO *International Health Regulations (2005)* (IHR).
- The questions below derive from the IHR, specifically those issues that historically have been and/or can be regulated by law.
- The IHR (in English) is available on-line at: http://whqlibdoc.who.int/publications/2008/9789241580410_eng.pdf. See also Annex 3.

MODULE 3: International Health Regulations (2005)			
Questions	**Y**	**N**	**Explanatory Note**
1. Does your country have law(s) relating to the designation or establishment of a National IHR Focal Point? (See Article 4)			
2. Does your country have law(s) relating to the designation of the authorities responsible for public health risks and public health emergencies of international concern? (See Article 4)			
3. Does your country have law(s) relating to the capacities for surveillance and notification of public health risks and public health emergencies of international concern? (See Articles 5-10, Annex 1)			
4. Does your country have law(s) relating to the capacities for public health response to public health risks and public health emergencies of international concern? (See Article 13, Annex 1)			
5. Does your country have law(s) relating to the capacities for public health response at designated points of entry, including airports, ports, and ground crossings? (See Articles 19-22, Annex 1)			

MODULE 3: International Health Regulations (2005)			
Questions	**Y**	**N**	**Explanatory Note**
6. Does your country have law(s) relating to health measures for travelers? (See Articles 23, 30-32, 35, 42-43)			
7. Does your country have law(s) relating to certificates of vaccination or other prophylaxis for travelers? (See Article 36)			
8. Does your country have law(s) relating to charges for health measures regarding travelers? (See Article 40)			
9. Does your country have law(s) relating to health measures for baggage, cargo, containers, conveyances, goods, postal parcels, and/or human remains? (See Articles 23, 33, 35, 43)			
10. Does your country have law(s) relating to charges for health measures regarding baggage, cargo, containers, conveyances, goods, postal parcels, and/or human remains? (See Article 41)			
11. Does your country have law(s) relating to the application of health measures on containers and/or container loading areas? (See Article 34)			
12. Does your country have law(s) relating to the responsibilities of conveyance operators with respect to health measures? (See Articles 23, 24, 35, 42-43)			
13. Does your country have law(s) relating to health measures for conveyances in transit? (See Articles 23, 25-26, 27, 42-43)			
14. Does your country have law(s) relating to health measures for conveyances at points of entry? (See Articles 23, 27, 28-29, 35, 37-39, 42-43)			
15. Does your country have law(s) relating to health documents for conveyances? (See Articles 37-39)			

MODULE 3: International Health Regulations (2005)			
Questions	**Y**	**N**	**Explanatory Note**
16. Does your country have law(s) relating to collaboration and assistance with other States Parties and/or WHO with regard to public health risks and public health emergencies of international concern? (See Article 44)			
17. Does your country have law(s) relating to the treatment of personal data received from another State Party and/or WHO with regard to public health risks and public health emergencies of international concern? (See Article 45)			
18. Does your country have law(s) relating to biological substances, reagents, and materials for diagnostic purposes with regard to public health risks and public health emergencies of international concern? (See Article 46)			

Module 4:
Framework Convention on Tobacco Control

- The objective of this module is to assess each country's efforts via law towards fulfilling the requirements under the WHO *Framework Convention on Tobacco Control* (FCTC).
- The questions below derive from the FCTC, specifically those issues that historically have been and/or can be regulated by law.
- The FCTC (in English) is available on-line at: http://whqlibdoc.who.int/publications/2003/9241591013.pdf. See also Annex 4.

MODULE 4: Framework Convention on Tobacco Control			
Questions	**Y**	**N**	**Explanatory Note**
1. Does your country have law(s) relating to national tobacco control strategies, plans, or programs? (See Article 5)			
2. Does your country have law(s) relating to the pricing and/or taxation of tobacco products? (See Article 6)			
3. Does your country have law(s) relating to the protection from exposure to tobacco smoke? (See Article 8)			
4. Does your country have law(s) relating to the regulation of the contents of tobacco products? (See Article 9)			
5. Does your country have law(s) relating to the regulation of tobacco product disclosure? (See Article 10)			
6. Does your country have law(s) relating to the packaging and labeling of tobacco products? (See Article 11)			
7. Does your country have law(s) relating to education, communication, training, and/or public awareness of tobacco issues? (See Article 12)			

MODULE 4: Framework Convention on Tobacco Control			
Questions	**Y**	**N**	**Explanatory Note**
8. Does your country have law(s) relating to tobacco marketing, including advertising, promotion, and sponsorship? (See Article 13)			
9. Does your country have law(s) relating to tobacco dependence and cessation? (See Article 14)			
10. Does your country have law(s) relating to illicit trade in tobacco products? (See Article 15)			
11. Does your country have law(s) relating to sales to and by minors? (See Article 16)			
12. Does your country have law(s) relating to the provision of support for economically viable alternatives for tobacco workers, growers, and/or individual sellers? (See Article 17)			
13. Does your country have law(s) relating to the protection of the environment and the health of persons in respect of tobacco cultivation and manufacture? (See Article 18)			
14. Does your country have law(s) relating to criminal and/or civil liability, including compensation, with respect to tobacco products? (See Article 19)			
15. Does your country have law(s) relating to research, surveillance, and exchange of information with respect to tobacco consumption? (See Articles 20-22)			

Annex 1

International Digest of Health Legislation

I. GENERAL PROVISIONS

A. General health codes, laws, and constitutional and other fundamental provisions

B. Organization and administration of health care

- Includes administration; general governmental health agencies (ministries, boards, councils, etc.); nongovernmental agencies; planning; public health agencies; strategies for primary health care.

C. Health financing

- Includes social security, health insurance, cost containment.

D. Health research

- Includes government support and encouragement; organizational aspects.
- For ethical issues in research, see XI-A.

E. Health education

- Includes general texts only.
- For educational and information programmes on specific subjects (e.g. alcoholism, maternal care, contraception, etc.), see appropriate category.

F. International treaties and other legal instruments

- Includes general texts only.
- For texts on specific subjects, see appropriate category.

II. HEALTH MANPOWER

- Includes all specific health professions, including allied health professions; comprehensive health manpower programmes; professional practice; registration and licensing; regulation of access to health professions; specialization; training and education.
- For professional and legal responsibility, malpractice, and professional codes and rules of ethics, see XI-B.

III. HEALTH CARE FACILITIES AND SERVICES

A. Hospitals and related institutions

- Includes clinics and outpatient facilities; health resorts, spas, and similar facilities; hospitals and sanatoria (administration, standards, governmental assistance and regulation, etc.).
- For day-care centres and other children's institutions, see VI-B.
- For old-age homes, see VIII.A.
- For homes for the disabled, see VIII-B.
- For patients' rights, see XI-A.

B. Services

- Includes ambulance services; blood banks and blood-processing facilities; clinical and public health laboratories (standards, licensing, inspection, and regulation); emergency and disaster services; first aid; organ and tissue storage facilities; X-ray and other radiological services.
- For pharmacies and drugstores, see XV-A.
- For radiation hazards from radiation-emitting devices, see XIX.

IV. DISEASE CONTROL AND MEDICAL CARE

A1. Communicable diseases

- Includes epidemic control measures (quarantine, frontier health controls, etc.); immunization and vaccination; notification requirements; prevention and control measures.

A2. Communicable diseases: HIV/AIDS.

- Includes texts dealing specifically or primarily with HIV/AIDS, as well as texts covering HIV/AIDS as one of several subjects.

B. Noncommunicable diseases

- For dental health, see V.
- For prenuptial examinations and genetic counselling, see VI-A
- For mental health, see IX.
- For diseases related to specific occupations, see XVII.
- For prevention of radiation-induced diseases, see XIX.

C. Procedures

- Includes anaesthesia; blood transfusion; organ and tissue transplantation; renal dialysis.

V. ORAL HEALTH

- Includes fluoridation; prevention and treatment.
- For dentists and other dental personnel, see II.
- For dental health programmes in schools, etc., see VI-B.

VI. FAMILY HEALTH

A. General

- Includes family counselling; genetic counselling; maternal health and care programmes; prenatal care; prenuptial examinations; sex education.
- For human reproduction and population policies, see VII.

B. Child health

- Includes abuse of children; adolescent health; child labour; day-care facilities; infant care; school health programmes.
- For child psychiatry, see IX.
- For infant foods and feeding, see XIII-A.
- For health and safety standards for toys, see XIV.

VII. HUMAN REPRODUCTION AND POPULATION POLICIES

- Includes abortion; artificial insemination; contraception; contraceptives and abortifacients; family planning programmes; menstrual regulation; population planning and policies; sterilization.
- For genetic counselling, see VI-A.
- For medically assisted procreation, see XI-A.

VIII. CARE OF THE ELDERLY AND REHABILITATION

A. Care of the elderly and geriatrics

- Includes basic care arrangements; geriatric programmes; old-age homes.

B. Care of the disabled

- Includes basic care arrangements; mobility and access arrangements; rehabilitation; sheltered workshops.

IX. MENTAL HEALTH

- Includes care of mental patients; child psychiatry; commitment procedures; mental health programmes; psychological testing and counselling services; psychosurgery and behaviour modification; regulation of therapy; right to treatment.
- For mental health and related professions and personnel, see II.
- For mental hospitals and related institutions, see III-A.

X. CONTROL OF SMOKING, ALCOHOLISM, AND DRUG ABUSE

- Includes public education programmes; regulation of manufacture, distribution and use (advertising, age limitations, fiscal measures, import controls, etc.); therapeutic and rehabilitation

programmes. Texts in this category are classified under the following subcategories:

A. Smoking

B. Alcoholism

C. Drug abuse (narcotics, psychotropic drugs, and other dependence-producing drugs)

- For regulation of other controlled drugs, see XV-A.
- For alcohol consumption and drug use in relation to road safety, see XX.
- For drug abuse in sports, see XXI.

XI. ETHICAL ISSUES AND PROFESSIONAL RESPONSIBILITY

A. General issues

- Includes bioethical issues in research (e.g. medical and behavioural experimentation, fetal research, genetic manipulation); confidentiality (of physician-patient relationship, and of medical data and records); medically assisted procreation; patients' rights.
- For blood transfusion and organ and tissue transplantation, see IV-C.
- For the right of institutionalized mental patients to treatment, see IX.
- For ethical issues relating to death and dying, see XII-A.

B. Professional and personnel issues

- Includes advertising; disciplinary measures; professional codes and rules of ethics; professional and legal responsibility of personnel (civil responsibility and malpractice, criminal and administrative liability).

XII. DEATH AND RELATED ISSUES

A. Death and dying

- Includes criteria for death; euthanasia; procedures for determination of death; the right to die.

B. Post-mortem examinations

- Includes anatomical procedures in medical education and research.

C. Disposal of the dead

- Includes control of cemeteries and crematoria.

XIII. NUTRITION AND FOOD

A. Nutrition

- Includes food fortification; infant foods and feeding; malnutrition; nutritional services and education.

B. Food safety

- Includes animal feeding stuffs; food adulteration and additives; food inspection; food irradiation; foods for special dietary uses; import and export controls on food; packaging and advertising of foods; pesticide residues and veterinary pharmaceuticals in foods; regulation of food handling and distribution; slaughterhouses and veterinary inspection.
- For general aspects of control of pesticides and poisons, see XVI.
- For drinking-water quality, see XVIII.
- For radiation contamination of food, see XIX.

XIV. CONSUMER PROTECTION

- Includes labelling and advertising affecting health; product safety (toys, kitchen utensils, ceramics, etc.).
- For food safety, see XIII-B.
- For cosmetics and toiletries, see XVI.
- For pesticides, poisons, and hazardous substances, see XVI.
- For radiation hazards in products, see XIX.

XV. PHARMACEUTICALS AND MEDICAL DEVICES

A. Pharmaceuticals and related products

- Includes cosmetics and toiletries; manufacture, marketing, distribution, advertising, etc. of pharmaceuticals; national drug policies; new drug development (research, manufacture, testing, and registration/licensing procedures); operation of pharmacies.
- For pharmacists, see II.
- For narcotics and psychotropic drugs, see X-C.
- For veterinary pharmaceuticals, see XIII-B.
- For poisons and hazardous substances, see XVI.

B. Traditional medicines

C. Medical devices

- Includes manufacture, marketing, distribution, advertising, etc. of devices; new device development (research, manufacture, testing, and registration/licensing procedures).
- For contraceptives and abortifacients, see VII.
- for product safety aspects of medical devices, see also XIV.

XVI. POISONS AND OTHER HAZARDOUS SUBSTANCES

- Includes export policies in regard to hazardous substances; pesticides; regulation and control of poisons and other hazardous substances; toxic chemicals.

- For radioactive substances, see XIX.

XVII. OCCUPATIONAL HEALTH AND SAFETY

- Includes health and sanitary conditions in workplaces; health services in workplaces; occupational diseases; protection against contaminants in the workplace; work-related injuries.
- For maternal health in workplaces, see VI-A.
- For child labour, see VI-B.
- For radiation-induced diseases in occupationally exposed persons, see XIX.

XVIII. ENVIRONMENTAL PROTECTION

- Includes air pollution; domestic hygiene and associated sanitary standards for housing; drinking-water; noise pollution; public nuisances affecting health; soil pollution; waste disposal (sewerage, solid wastes, and chemical wastes); water pollution; water supply.
- For fluoridation of water supplies, see V.
- For disposal of the dead, see XII-C.
- For radiation hazards and radioactive wastes, see XIX.
- For hygiene of campsites and recreational facilities, see XXI.

XIX. RADIATION PROTECTION

- Includes radiation hazards in the workplace; disposal of radioactive wastes; non-ionizing radiation; nuclear installations; transportation of radioactive materials; X-ray and other radiation-emitting installations.
- For X-ray and other radiological services, see III-B.
- For food irradiation, see XIII-B.

XX. ACCIDENT PREVENTION

- Includes health requirements for drivers; policies and educational programmes for accident prevention; road safety; safety in air travel.
- For product safety, see XIV.
- For transportation of hazardous substances, see XVI.
- For occupational accidents, see XVII.
- For nuclear accidents, see XIX.

XXI. SPORTS AND RECREATION

- Includes drug abuse in sports; hygiene of campsites and recreation facilities; sports medicine.

XXII. HEALTH INFORMATION AND STATISTICS

- Includes health reporting and statistics; vital statistics (births, stillbirths, deaths, etc.). For notification of communicable and non-communicable diseases, see IV-A and IV-B.

Annex 2

WHO Western Pacific Regional Strategy

for Health Systems Based on the Values of Primary Health Care

Executive Summary

The WHO Constitution states that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being". Effective and efficient health systems contribute to the progressive realization of that right. Health systems do better at attaining that standard if they are underpinned by core values such as equity, social justice, universality, people-centredness, community protection, participation, scientific soundness, personal responsibility, self-determination and selfreliance. Values such as these have been a part of the primary health care agenda since they were articulated in the *Declaration of Alma-Ata* adopted
at the International Conference on Primary Health Care in 1978. Although there are wide variations in political, social and health systems both globally and within the Western Pacific Region, there is an increasing body of evidence that proves adherence to these core principles or values leads to better health systems and better health outcomes.

Evidence-based statements about international norms for health systems may help national leaders navigate among competing interests in the health sector. The *Western Pacific Regional Strategy for Health Systems Based on the Values of Primary Health Care* provides guidance that may assist national decision-makers overseeing the design and implementation of health systems adapted to their particular situations.

The people of the Western Pacific Region deserve to live their lives in the highest state of health possible. While there can be no guarantee of individual health, all people have a right to quality health services that are available, accessible, affordable and acceptable.

The four goals of a health system are:

(1) health, both the absolute level across the entire population and equity across socioeconomic groups;
(2) social and financial risk protection in health;
(3) responsiveness and people-centredness;
(4) efficiency.

Thirty years after the *Declaration of Alma-Ata*, a worldwide process of reflection on primary health care (PHC) culminated in *The World Health Report 2008: Primary Health Care, Now More Than Ever*. It concluded that countries that have organized their health systems on PHC principles have achieved better health outcomes in relation to the funds expended than those countries with health systems that are not based on PHC values. The report also found that the goals and values of PHC are as valid as they were in 1978.

Primary health care is closely related to but not synonymous with primary care. A strong primary care system is the foundation for a health system based on PHC values, but secondary and tertiary services that connect to the primary care system are also vital.

Four areas of reform, policy and action that foster the development of PHC-oriented health systems are described in *The World Health Report 2008*: (1) universal coverage intended to improve health equity and financial risk protection; (2) service delivery that is people centred, responsive and supports universal coverage; (3) leadership aimed at making health authorities more reliable and accountable to those they serve; and (4) public policy implemented across all sectors in ways that promote and protect the health of communities and individuals. People and their participation remain at the centre of PHC. Different countries and areas have plotted their own paths towards PHC implementation using different routes and concepts, such as universal coverage or "Healthy Islands" initiative.

A whole-of-system approach based on the values of primary health care is proposed as the most effective and sustainable way of strengthening health systems. The WHO framework of six building blocks for health systems strengthening is used as a tool to analyse health systems, although other frameworks are available. The important issue is that health systems are analysed holistically. Key issues in each of the six building blocks include:

(1) **Leadership and governance** – policy frameworks and health planning, managing the health sector, accountability and transparency, generating and interpreting information, building coalitions outside the health sector, and aid effectiveness.
(2) **Health care financing** – increasing investment and public spending, aid effectiveness, efficiency, prepayment and risk pooling, provider payment methods, safety nets, evidence for policy-making, and monitoring and evaluation.
(3) **Health workforce** – preparing the workforce with sufficient numbers, skill mix and quality with appropriate deployment; enhancing performance through job descriptions, codes of conduct, adequate support systems, including remuneration, and supportive supervision, and an enabling work environment that includes lifelong learning and accountability; and managing migration and attrition.
(4) **Medical products and technologies** – rational selection and use, affordable pricing, sustainable financing, ensuring access, coherent supply and management, quality assurance, capacity-building, improving safety and supporting research.
(5) **Information and research** – national strategic planning, utilization, avoidance of duplication, sufficient disaggregation, monitoring of health system performance, research to meet national needs, and appropriate use of information technology.
(6) **Service delivery** – definition of the service delivery model, emphasis on primary health care teams, management, integrated service delivery packages at multiple levels adapted to socioeconomic reality, patient safety and infrastructure.

A set of core indicators agreed upon internationally or regionally is proposed for each building block. Adaptation of the indicators to individual Member States will be needed, including setting targets that are relevant to the country context. Additional indicators developed specifically by each Member State to fit its own situation and management needs are desirable.

A value-based strategy alone is not enough. The move from strategy to action is crucial. Each Member State has a responsibility to define its national health policy or strategy and the means through which policy and strategy are translated into action at the operational level. Details will be specific to each Member State, although the values will be universal.

Management of health services is a core function. It requires an adequate number of managers, sufficient skills, an enabling work environment and functional support systems. In low-resource settings, choosing priorities so that resources are expended on those actions that provide the greatest health gains is particularly important. This is crucial if the Millennium Development Goals are to be met.

Each Member State must determine its own path towards the vision it defines for its own health system so that its people progressively realize the right to health. That path is likely to include an ongoing process of policy dialogue, a robust national health strategy and planning process, and the will to take strategy on to implementation in a feasible and realistic manner.

Annex 3

INTERNATIONAL HEALTH REGULATIONS (2005)

PART I – DEFINITIONS, PURPOSE AND SCOPE, PRINCIPLES AND RESPONSIBLE AUTHORITIES

Article 1 Definitions

1. For the purposes of the International Health Regulations (hereinafter "the IHR" or "Regulations"):

"affected" means persons, baggage, cargo, containers, conveyances, goods, postal parcels or human emains that are infected or contaminated, or carry sources of infection or contamination, so as to constitute a public health risk;

"affected area" means a geographical location specifically for which health measures have been recommended by WHO under these Regulations;

"aircraft" means an aircraft making an international voyage;

"airport" means any airport where international flights arrive or depart;

"arrival" of a conveyance means:

(a) in the case of a seagoing vessel, arrival or anchoring in the defined area of a port;

(b) in the case of an aircraft, arrival at an airport;

(c) in the case of an inland navigation vessel on an international voyage, arrival at a point of entry;

(d) in the case of a train or road vehicle, arrival at a point of entry;

"baggage" means the personal effects of a traveller;

"cargo" means goods carried on a conveyance or in a container;

"competent authority" means an authority responsible for the implementation and application of health measures under these Regulations;

"container" means an article of transport equipment:

(a) of a permanent character and accordingly strong enough to be suitable for repeated use;

(b) specially designed to facilitate the carriage of goods by one or more modes of transport, without intermediate reloading;

(c) fitted with devices permitting its ready handling, particularly its transfer from one mode of transport to another; and

(d) specially designed as to be easy to fill and empty;

"container loading area" means a place or facility set aside for containers used in international traffic;

"contamination" means the presence of an infectious or toxic agent or matter on a human or animal body surface, in or on a product prepared for consumption or on other inanimate objects, including conveyances, that may constitute a public health risk;

"conveyance" means an aircraft, ship, train, road vehicle or other means of transport on an international voyage;

"conveyance operator" means a natural or legal person in charge of a conveyance or their agent;

"crew" means persons on board a conveyance who are not passengers;

"decontamination" means a procedure whereby health measures are taken to eliminate an infectious or toxic agent or matter on a human or animal body surface, in or on a product prepared for consumption or on other inanimate objects, including conveyances, that may constitute a public health risk;

"departure" means, for persons, baggage, cargo, conveyances or goods, the act of leaving a territory;

"deratting" means the procedure whereby health measures are taken to control or kill rodent vectors of human disease present in baggage, cargo, containers, conveyances, facilities, goods and postal parcels at the point of entry;

"Director-General" means the Director-General of the World Health Organization;

“disease” means an illness or medical condition, irrespective of origin or source, that presents or could present significant harm to humans;
“disinfection” means the procedure whereby health measures are taken to control or kill infectious agents on a human or animal body surface or in or on baggage, cargo, containers, conveyances, goods and postal parcels by direct exposure to chemical or physical agents;
“disinsection” means the procedure whereby health measures are taken to control or kill the nsect vectors of human diseases present in baggage, cargo, containers, conveyances, goods and postal arcels;
“event” means a manifestation of disease or an occurrence that creates a potential for disease;
“*free pratique*” means permission for a ship to enter a port, embark or disembark, discharge or oad cargo or stores; permission for an aircraft, after landing, to embark or disembark, discharge or oad cargo or stores; and permission for a ground transport vehicle, upon arrival, to embark or isembark, discharge or load cargo or stores;
“goods” mean tangible products, including animals and plants, transported on an international voyage, including for utilization on board a conveyance;
“ground crossing” means a point of land entry in a State Party, including one utilized by road vehicles and trains;
“ground transport vehicle” means a motorized conveyance for overland transport on an international voyage, including trains, coaches, lorries and automobiles;
“health measure” means procedures applied to prevent the spread of disease or contamination; a health measure does not include law enforcement or security measures;
“ill person” means an individual suffering from or affected with a physical ailment that may pose a public health risk;
“infection” means the entry and development or multiplication of an infectious agent in the body of humans and animals that may constitute a public health risk;
“inspection” means the examination, by the competent authority or under its supervision, of areas, baggage, containers, conveyances, facilities, goods or postal parcels, including relevant data and documentation, to determine if a public health risk exists;
“international traffic” means the movement of persons, baggage, cargo, containers, conveyances, goods or postal parcels across an international border, including international trade;
“international voyage” means:
(a) in the case of a conveyance, a voyage between points of entry in the territories of more than one State, or a voyage between points of entry in the territory or territories of the same State if the conveyance has contacts with the territory of any other State on its voyage but only as regards those contacts;
(b) in the case of a traveller, a voyage involving entry into the territory of a State other than the territory of the State in which that traveller commences the voyage;
“intrusive” means possibly provoking discomfort through close or intimate contact or questioning;
“invasive” means the puncture or incision of the skin or insertion of an instrument or foreign material into the body or the examination of a body cavity. For the purposes of these Regulations, medical examination of the ear, nose and mouth, temperature assessment using an ear, oral or cutaneous thermometer, or thermal imaging; medical inspection; auscultation; external palpation; retinoscopy; external collection of urine, faeces or saliva samples; external measurement of blood pressure; and electrocardiography shall be considered to be non-invasive;
“isolation” means separation of ill or contaminated persons or affected baggage, containers, conveyances, goods or postal parcels from others in such a manner as to prevent the spread of infection or contamination;
“medical examination” means the preliminary assessment of a person by an authorized health worker or by a person under the direct supervision of the competent authority, to determine the person’s health status and potential public health risk to others, and may include the scrutiny of health documents, and a physical examination when justified by the circumstances of the individual case;
“National IHR Focal Point” means the national centre, designated by each State Party, which shall be accessible at all times for communications with WHO IHR Contact Points under these Regulations;
“Organization” or “WHO” means the World Health Organization;
“permanent residence” has the meaning as determined in the national law of the State Party concerned;

"personal data" means any information relating to an identified or identifiable natural person;
"point of entry" means a passage for international entry or exit of travellers, baggage, cargo, containers, conveyances, goods and postal parcels as well as agencies and areas providing services to them on entry or exit;
"port" means a seaport or a port on an inland body of water where ships on an international voyage arrive or depart;
"postal parcel" means an addressed article or package carried internationally by postal or courier services;
"public health emergency of international concern" means an extraordinary event which is determined, as provided in these Regulations:
(i) to constitute a public health risk to other States through the international spread of disease and
(ii) to potentially require a coordinated international response;
"public health observation" means the monitoring of the health status of a traveller over time for the purpose of determining the risk of disease transmission;
"public health risk" means a likelihood of an event that may affect adversely the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger;
"quarantine" means the restriction of activities and/or separation from others of suspect persons who are not ill or of suspect baggage, containers, conveyances or goods in such a manner as to prevent the possible spread of infection or contamination;
"recommendation" and "recommended" refer to temporary or standing recommendations issued under these Regulations;
"reservoir" means an animal, plant or substance in which an infectious agent normally lives and whose presence may constitute a public health risk;
"road vehicle" means a ground transport vehicle other than a train;
"scientific evidence" means information furnishing a level of proof based on the established and accepted methods of science;
"scientific principles" means the accepted fundamental laws and facts of nature known through the methods of science;
"ship" means a seagoing or inland navigation vessel on an international voyage;
"standing recommendation" means non-binding advice issued by WHO for specific ongoing public health risks pursuant to Article 16 regarding appropriate health measures for routine or periodic application needed to prevent or reduce the international spread of disease and minimize interference with international traffic;
"surveillance" means the systematic ongoing collection, collation and analysis of data for public health purposes and the timely dissemination of public health information for assessment and public health response as necessary;
"suspect" means those persons, baggage, cargo, containers, conveyances, goods or postal parcels considered by a State Party as having been exposed, or possibly exposed, to a public health risk and that could be a possible source of spread of disease;
"temporary recommendation" means non-binding advice issued by WHO pursuant to Article 15 for application on a time-limited, risk-specific basis, in response to a public health emergency of international concern, so as to prevent or reduce the international spread of disease and minimize interference with international traffic;
"temporary residence" has the meaning as determined in the national law of the State Party concerned;
"traveller" means a natural person undertaking an international voyage;
"vector" means an insect or other animal which normally transports an infectious agent that constitutes a public health risk;
"verification" means the provision of information by a State Party to WHO confirming the status of an event within the territory or territories of that State Party;
"WHO IHR Contact Point" means the unit within WHO which shall be accessible at all times for communications with the National IHR Focal Point.
2. Unless otherwise specified or determined by the context, reference to these Regulations includes the

annexes thereto.

Article 2 Purpose and scope
The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.

Article 3 Principles
1. The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons.
2. The implementation of these Regulations shall be guided by the Charter of the United Nations and the Constitution of the World Health Organization.
3. The implementation of these Regulations shall be guided by the goal of their universal application for the protection of all people of the world from the international spread of disease.
4. States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to legislate and to implement legislation in pursuance of their health policies. In doing so they should uphold the purpose of these Regulations.

Article 4 Responsible authorities
1. Each State Party shall designate or establish a National IHR Focal Point and the authorities responsible within its respective jurisdiction for the implementation of health measures under these Regulations.
2. National IHR Focal Points shall be accessible at all times for communications with the WHO IHR Contact Points provided for in paragraph 3 of this Article. The functions of National IHR Focal Points shall include:
(a) sending to WHO IHR Contact Points, on behalf of the State Party concerned, urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12; and
(b) disseminating information to, and consolidating input from, relevant sectors of the administration of the State Party concerned, including those responsible for surveillance and reporting, points of entry, public health services, clinics and hospitals and other government departments.
3. WHO shall designate IHR Contact Points, which shall be accessible at all times for communications with National IHR Focal Points. WHO IHR Contact Points shall send urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12, to the National IHR Focal Point of the States Parties concerned. WHO IHR Contact Points may be designated by WHO at the headquarters or at the regional level of the Organization.
4. States Parties shall provide WHO with contact details of their National IHR Focal Point and WHO shall provide States Parties with contact details of WHO IHR Contact Points. These contact details shall be continuously updated and annually confirmed. WHO shall make available to all States Parties the contact details of National IHR Focal Points it receives pursuant to this Article.

PART II – INFORMATION AND PUBLIC HEALTH RESPONSE

Article 5 Surveillance
1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1.
2. Following the assessment referred to in paragraph 2, Part A of Annex 1, a State Party may report to WHO on the basis of a justified need and an implementation plan and, in so doing, obtain an extension of two years in which to fulfil the obligation in paragraph 1 of this Article. In exceptional circumstances, and supported by a new implementation plan, the State Party may request a further extension not exceeding two years from the Director-General, who shall make the decision, taking into account the technical advice of the Committee established under Article 50 (hereinafter the "Review Committee"). After the period mentioned in paragraph 1 of this Article, the State Party that has obtained an extension shall report annually

to WHO on progress made towards the full implementation.
3. WHO shall assist States Parties, upon request, to develop, strengthen and maintain the capacities referred to in paragraph 1 of this Article.
4. WHO shall collect information regarding events through its surveillance activities and assess their potential to cause international disease spread and possible interference with international traffic. Information received by WHO under this paragraph shall be handled in accordance with Articles 11 and 45 where appropriate.

Article 6 Notification
1. Each State Party shall assess events occurring within its territory by using the decision instrument in Annex 2. Each State Party shall notify WHO, by the most efficient means of communication available, by way of the National IHR Focal Point, and within 24 hours of assessment of public health information, of all events which may constitute a public health emergency of international concern within its territory in accordance with the decision instrument, as well as any health measure implemented in response to those events. If the notification received by WHO involves the competency of the International Atomic Energy Agency (IAEA), WHO shall immediately notify the IAEA.
2. Following a notification, a State Party shall continue to communicate to WHO timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern.

Article 7 Information-sharing during unexpected or unusual public health events
If a State Party has evidence of an unexpected or unusual public health event within its territory, irrespective of origin or source, which may constitute a public health emergency of international concern, it shall provide to WHO all relevant public health information. In such a case, the provisions of Article 6 shall apply in full.

Article 8 Consultation
In the case of events occurring within its territory not requiring notification as provided in Article 6, in particular those events for which there is insufficient information available to complete the decision instrument, a State Party may nevertheless keep WHO advised thereof through the National IHR Focal Point and consult with WHO on appropriate health measures. Such communications shall be treated in accordance with paragraphs 2 to 4 of Article 11. The State Party in whose territory the event has occurred may request WHO assistance to assess any epidemiological evidence obtained by that State Party.

Article 9 Other reports
1. WHO may take into account reports from sources other than notifications or consultations and shall assess these reports according to established epidemiological principles and then communicate information on the event to the State Party in whose territory the event is allegedly occurring. Before taking any action based on such reports, WHO shall consult with and attempt to obtain verification from the State Party in whose territory the event is allegedly occurring in accordance with the procedure set forth in Article 10. To this end, WHO shall make the information received available to the States Parties and only where it is duly justified may WHO maintain the confidentiality of the source. This information will be used in accordance with the procedure set forth in Article 11.
2. States Parties shall, as far as practicable, inform WHO within 24 hours of receipt of evidence of a public health risk identified outside their territory that may cause international disease spread, as manifested by exported or imported:
(a) human cases;
(b) vectors which carry infection or contamination; or
(c) goods that are contaminated.

Article 10 Verification

1. WHO shall request, in accordance with Article 9, verification from a State Party of reports from sources other than notifications or consultations of events which may constitute a public health emergency of international concern allegedly occurring in the State's territory. In such cases, WHO shall inform the State Party concerned regarding the reports it is seeking to verify.
2. Pursuant to the foregoing paragraph and to Article 9, each State Party, when requested by WHO, shall verify and provide:
(a) within 24 hours, an initial reply to, or acknowledgement of, the request from WHO;
(b) within 24 hours, available public health information on the status of events referred to in WHO's request; and
(c) information to WHO in the context of an assessment under Article 6, including relevant information as described in that Article.
3. When WHO receives information of an event that may constitute a public health emergency of international concern, it shall offer to collaborate with the State Party concerned in assessing the potential for international disease spread, possible interference with international traffic and the adequacy of control measures. Such activities may include collaboration with other standard-setting organizations and the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.
4. If the State Party does not accept the offer of collaboration, WHO may, when justified by the magnitude of the public health risk, share with other States Parties the information available to it, whilst encouraging the State Party to accept the offer of collaboration by WHO, taking into account the views of the State Party concerned.

Article 11 Provision of information by WHO

1. Subject to paragraph 2 of this Article, WHO shall send to all States Parties and, as appropriate, to relevant intergovernmental organizations, as soon as possible and by the most efficient means available, in confidence, such public health information which it has received under Articles 5 to 10 inclusive and which is necessary to enable States Parties to respond to a public health risk. WHO should communicate information to other States Parties that might help them in preventing the occurrence of similar incidents.
2. WHO shall use information received under Articles 6 and 8 and paragraph 2 of Article 9 for verification, assessment and assistance purposes under these Regulations and, unless otherwise agreed with the States Parties referred to in those provisions, shall not make this information generally available to other States Parties, until such time as:
(a) the event is determined to constitute a public health emergency of international concern in accordance with Article 12; or
(b) information evidencing the international spread of the infection or contamination has been confirmed by WHO in accordance with established epidemiological principles; or
(c) there is evidence that:
(i) control measures against the international spread are unlikely to succeed because of the nature of the contamination, disease agent, vector or reservoir; or
(ii) the State Party lacks sufficient operational capacity to carry out necessary measures to prevent further spread of disease; or
(d) the nature and scope of the international movement of travellers, baggage, cargo, containers, conveyances, goods or postal parcels that may be affected by the infection or contamination requires the immediate application of international control measures.
3. WHO shall consult with the State Party in whose territory the event is occurring as to its intent to make information available under this Article.
4. When information received by WHO under paragraph 2 of this Article is made available to States Parties in accordance with these Regulations, WHO may also make it available to the public if other information about the same event has already become publicly available and there is a need for the dissemination of

authoritative and independent information.

Article 12 Determination of a public health emergency of international concern

1. The Director-General shall determine, on the basis of the information received, in particular from the State Party within whose territory an event is occurring, whether an event constitutes a public health emergency of international concern in accordance with the criteria and the procedure set out in these Regulations.
2. If the Director-General considers, based on an assessment under these Regulations, that a public health emergency of international concern is occurring, the Director-General shall consult with the State Party in whose territory the event arises regarding this preliminary determination. If the Director-General and the State Party are in agreement regarding this determination, the Director-General shall, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the "Emergency Committee") on appropriate temporary recommendations.
3. If, following the consultation in paragraph 2 above, the Director-General and the State Party in whose territory the event arises do not come to a consensus within 48 hours on whether the event constitutes a public health emergency of international concern, a determination shall be made in accordance with the procedure set forth in Article 49.
4. In determining whether an event constitutes a public health emergency of international concern, the Director-General shall consider:
(a) information provided by the State Party;
(b) the decision instrument contained in Annex 2;
(c) the advice of the Emergency Committee;
(d) scientific principles as well as the available scientific evidence and other relevant information; and
(e) an assessment of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic.
5. If the Director-General, following consultations with the State Party within whose territory the public health emergency of international concern has occurred, considers that a public health emergency of international concern has ended, the Director-General shall take a decision in accordance with the procedure set out in Article 49.

Article 13 Public health response

1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to respond promptly and effectively to public health risks and public health emergencies of international concern as set out in Annex 1. WHO shall publish, in consultation with Member States, guidelines to support States Parties in the development of public health response capacities.
2. Following the assessment referred to in paragraph 2, Part A of Annex 1, a State Party may report to WHO on the basis of a justified need and an implementation plan and, in so doing, obtain an extension of two years in which to fulfil the obligation in paragraph 1 of this Article. In exceptional circumstances and supported by a new implementation plan, the State Party may request a further extension not exceeding two years from the Director-General, who shall make the decision, taking into account the technical advice of the Review Committee. After the period mentioned in paragraph 1 of this Article, the State Party that has obtained an extension shall report annually to WHO on progress made towards the full implementation.
3. At the request of a State Party, WHO shall collaborate in the response to public health risks and other events by providing technical guidance and assistance and by assessing the effectiveness of the control measures in place, including the mobilization of international teams of experts for on-site assistance, when necessary.
4. If WHO, in consultation with the States Parties concerned as provided in Article 12, determines that a public health emergency of international concern is occurring, it may offer, in addition to the support indicated in paragraph 3 of this Article, further assistance to the State Party, including an assessment of the severity of the international risk and the adequacy of control measures. Such collaboration may include the offer to mobilize international assistance in order to support the national authorities in conducting and

coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.
5. When requested by WHO, States Parties should provide, to the extent possible, support to WHO-coordinated response activities.
6. When requested, WHO shall provide appropriate guidance and assistance to other States Parties affected or threatened by the public health emergency of international concern.

Article 14 Cooperation of WHO with intergovernmental organizations and international bodies
1. WHO shall cooperate and coordinate its activities, as appropriate, with other competent intergovernmental organizations or international bodies in the implementation of these Regulations, including through the conclusion of agreements and other similar arrangements.
2. In cases in which notification or verification of, or response to, an event is primarily within the competence of other intergovernmental organizations or international bodies, WHO shall coordinate its activities with such organizations or bodies in order to ensure the application of adequate measures for the protection of public health.
3. Notwithstanding the foregoing, nothing in these Regulations shall preclude or limit the provision by WHO of advice, support, or technical or other assistance for public health purposes.

PART III – RECOMMENDATIONS

Article 15 Temporary recommendations
1. If it has been determined in accordance with Article 12 that a public health emergency of international concern is occurring, the Director-General shall issue temporary recommendations in accordance with the procedure set out in Article 49. Such temporary recommendations may be modified or extended as appropriate, including after it has been determined that a public health emergency of international concern has ended, at which time other temporary recommendations may be issued as necessary for the purpose of preventing or promptly detecting its recurrence.
2. Temporary recommendations may include health measures to be implemented by the State Party experiencing the public health emergency of international concern, or by other States Parties, regarding persons, baggage, cargo, containers, conveyances, goods and/or postal parcels to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic.
3. Temporary recommendations may be terminated in accordance with the procedure set out in Article 49 at any time and shall automatically expire three months after their issuance. They may be modified or extended for additional periods of up to three months. Temporary recommendations may not continue beyond the second World Health Assembly after the determination of the public health emergency of international concern to which they relate.

Article 16 Standing recommendations
WHO may make standing recommendations of appropriate health measures in accordance with Article 53 for routine or periodic application. Such measures may be applied by States Parties regarding persons, baggage, cargo, containers, conveyances, goods and/or postal parcels for specific, ongoing public health risks in order to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic. WHO may, in accordance with Article 53, modify or terminate such recommendations, as appropriate.

Article 17 Criteria for recommendations
When issuing, modifying or terminating temporary or standing recommendations, the Director-General shall consider:
(a) the views of the States Parties directly concerned;
(b) the advice of the Emergency Committee or the Review Committee, as the case may be;
(c) scientific principles as well as available scientific evidence and information;
(d) health measures that, on the basis of a risk assessment appropriate to the circumstances, are not more

restrictive of international traffic and trade and are not more intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection;
(e) relevant international standards and instruments;
(f) activities undertaken by other relevant intergovernmental organizations and international bodies; and
(g) other appropriate and specific information relevant to the event.
With respect to temporary recommendations, the consideration by the Director-General of subparagraphs (e) and (f) of this Article may be subject to limitations imposed by urgent circumstances.

Article 18 Recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels
1. Recommendations issued by WHO to States Parties with respect to persons may include the following advice:
– no specific health measures are advised;
– review travel history in affected areas;
– review proof of medical examination and any laboratory analysis;
– require medical examinations;
– review proof of vaccination or other prophylaxis;
– require vaccination or other prophylaxis;
– place suspect persons under public health observation;
– implement quarantine or other health measures for suspect persons;
– implement isolation and treatment where necessary of affected persons;
– implement tracing of contacts of suspect or affected persons;
– refuse entry of suspect and affected persons;
– refuse entry of unaffected persons to affected areas; and
– implement exit screening and/or restrictions on persons from affected areas.
2. Recommendations issued by WHO to States Parties with respect to baggage, cargo, containers, conveyances, goods and postal parcels may include the following advice:
– no specific health measures are advised;
– review manifest and routing;
– implement inspections;
– review proof of measures taken on departure or in transit to eliminate infection or contamination;
– implement treatment of the baggage, cargo, containers, conveyances, goods, postal parcels or human remains to remove infection or contamination, including vectors and reservoirs;
– the use of specific health measures to ensure the safe handling and transport of human remains;
– implement isolation or quarantine;
– seizure and destruction of infected or contaminated or suspect baggage, cargo, containers, conveyances, goods or postal parcels under controlled conditions if no available treatment or process will otherwise be successful; and
– refuse departure or entry.

PART IV – POINTS OF ENTRY

Article 19 General obligations
Each State Party shall, in addition to the other obligations provided for under these Regulations:
(a) ensure that the capacities set forth in Annex 1 for designated points of entry are developed within the timeframe provided in paragraph 1 of Article 5 and paragraph 1 of Article 13;
(b) identify the competent authorities at each designated point of entry in its territory; and
(c) furnish to WHO, as far as practicable, when requested in response to a specific potential public health risk, relevant data concerning sources of infection or contamination, including vectors and reservoirs, at its points of entry, which could result in international disease spread.

Article 20 Airports and ports

1. States Parties shall designate the airports and ports that shall develop the capacities provided in Annex 1.
2. States Parties shall ensure that Ship Sanitation Control Exemption Certificates and Ship Sanitation Control Certificates are issued in accordance with the requirements in Article 39 and the model provided in Annex 3.
3. Each State Party shall send to WHO a list of ports authorized to offer:
(a) the issuance of Ship Sanitation Control Certificates and the provision of the services referred to in Annexes 1 and 3; or
(b) the issuance of Ship Sanitation Control Exemption Certificates only; and
(c) extension of the Ship Sanitation Control Exemption Certificate for a period of one month until the arrival of the ship in the port at which the Certificate may be received. Each State Party shall inform WHO of any changes which may occur to the status of the listed ports. WHO shall publish the information received under this paragraph.
4. WHO may, at the request of the State Party concerned, arrange to certify, after an appropriate investigation, that an airport or port in its territory meets the requirements referred to in paragraphs 1 and 3 of this Article. These certifications may be subject to periodic review by WHO, in consultation with the State Party.
5. WHO, in collaboration with competent intergovernmental organizations and international bodies, shall develop and publish the certification guidelines for airports and ports under this Article. WHO shall also publish a list of certified airports and ports.

Article 21 Ground crossings
1. Where justified for public health reasons, a State Party may designate ground crossings that shall develop the capacities provided in Annex 1, taking into consideration:
(a) the volume and frequency of the various types of international traffic, as compared to other points of entry, at a State Party's ground crossings which might be designated; and
(b) the public health risks existing in areas in which the international traffic originates, or through which it passes, prior to arrival at a particular ground crossing.
2. States Parties sharing common borders should consider:
(a) entering into bilateral or multilateral agreements or arrangements concerning prevention or control of international transmission of disease at ground crossings in accordance with Article 57; and
(b) joint designation of adjacent ground crossings for the capacities in Annex 1 in accordance with paragraph 1 of this Article.

Article 22 Role of competent authorities
1. The competent authorities shall:
(a) be responsible for monitoring baggage, cargo, containers, conveyances, goods, postal parcels and human remains departing and arriving from affected areas, so that they are maintained in such a condition that they are free of sources of infection or contamination, including vectors and reservoirs;
(b) ensure, as far as practicable, that facilities used by travellers at points of entry are maintained in a sanitary condition and are kept free of sources of infection or contamination, including vectors and reservoirs;
(c) be responsible for the supervision of any deratting, disinfection, disinsection or decontamination of baggage, cargo, containers, conveyances, goods, postal parcels and human remains or sanitary measures for persons, as appropriate under these Regulations;
(d) advise conveyance operators, as far in advance as possible, of their intent to apply control measures to a conveyance, and shall provide, where available, written information concerning the methods to be employed;
(e) be responsible for the supervision of the removal and safe disposal of any contaminated water or food, human or animal dejecta, wastewater and any other contaminated matter from a conveyance;
(f) take all practicable measures consistent with these Regulations to monitor and control the discharge by ships of sewage, refuse, ballast water and other potentially disease-causing matter which might contaminate the waters of a port, river, canal, strait, lake or other international waterway;

(g) be responsible for supervision of service providers for services concerning travellers, baggage, cargo, containers, conveyances, goods, postal parcels and human remains at points of entry, including the conduct of inspections and medical examinations as necessary;
(h) have effective contingency arrangements to deal with an unexpected public health event; and
(i) communicate with the National IHR Focal Point on the relevant public health measures taken pursuant to these Regulations.
2. Health measures recommended by WHO for travellers, baggage, cargo, containers, conveyances, goods, postal parcels and human remains arriving from an affected area may be reapplied on arrival, if there are verifiable indications and/or evidence that the measures applied on departure from the affected area were unsuccessful.
3. Disinsection, deratting, disinfection, decontamination and other sanitary procedures shall be carried out so as to avoid injury and as far as possible discomfort to persons, or damage to the environment in a way which impacts on public health, or damage to baggage, cargo, containers, conveyances, goods and postal parcels.

PART V – PUBLIC HEALTH MEASURES

Chapter I – General provisions

Article 23 Health measures on arrival and departure

1. Subject to applicable international agreements and relevant articles of these Regulations, a State Party may require for public health purposes, on arrival or departure:
(a) with regard to travellers:
(i) information concerning the traveller's destination so that the traveller may be contacted;
(ii) information concerning the traveller's itinerary to ascertain if there was any travel in or near an affected area or other possible contacts with infection or contamination prior to arrival, as well as review of the traveller's health documents if they are required under these Regulations; and/or
(iii) a non-invasive medical examination which is the least intrusive examination that would achieve the public health objective;
(b) inspection of baggage, cargo, containers, conveyances, goods, postal parcels and human remains.
2. On the basis of evidence of a public health risk obtained through the measures provided in paragraph 1 of this Article, or through other means, States Parties may apply additional health measures, in accordance with these Regulations, in particular, with regard to a suspect or affected traveller, on a case-by-case basis, the least intrusive and invasive medical examination that would achieve the public health objective of preventing the international spread of disease.
3. No medical examination, vaccination, prophylaxis or health measure under these Regulations shall be carried out on travellers without their prior express informed consent or that of their parents or guardians, except as provided in paragraph 2 of Article 31, and in accordance with the law and international obligations of the State Party.
4. Travellers to be vaccinated or offered prophylaxis pursuant to these Regulations, or their parents or guardians, shall be informed of any risk associated with vaccination or with non-vaccination and with the use or non-use of prophylaxis in accordance with the law and international obligations of the State Party. States Parties shall inform medical practitioners of these requirements in accordance with the law of the State Party.
5. Any medical examination, medical procedure, vaccination or other prophylaxis which involves a risk of disease transmission shall only be performed on, or administered to, a traveller in accordance with established national or international safety guidelines and standards so as to minimize such a risk.

Chapter II – Special provisions for conveyances and conveyance operators

Article 24 Conveyance operators

1. States Parties shall take all practicable measures consistent with these Regulations to ensure that conveyance operators:
(a) comply with the health measures recommended by WHO and adopted by the State Party;
(b) inform travellers of the health measures recommended by WHO and adopted by the State Party for application on board; and
(c) permanently keep conveyances for which they are responsible free of sources of infection or contamination, including vectors and reservoirs. The application of measures to control sources of infection or contamination may be required if evidence is found.
2. Specific provisions pertaining to conveyances and conveyance operators under this Article are provided in Annex 4. Specific measures applicable to conveyances and conveyance operators with regard to vector-borne diseases are provided in Annex 5.

Article 25 Ships and aircraft in transit
Subject to Articles 27 and 43 or unless authorized by applicable international agreements, no health measure shall be applied by a State Party to:
(a) a ship not coming from an affected area which passes through a maritime canal or waterway in the territory of that State Party on its way to a port in the territory of another State. Any such ship shall be permitted to take on, under the supervision of the competent authority, fuel, water, food and supplies;
(b) a ship which passes through waters within its jurisdiction without calling at a port or on the coast; and
(c) an aircraft in transit at an airport within its jurisdiction, except that the aircraft may be restricted to a particular area of the airport with no embarking and disembarking or loading and discharging. However, any such aircraft shall be permitted to take on, under the supervision of the competent authority, fuel, water, food and supplies.

Article 26 Civilian lorries, trains and coaches in transit
Subject to Articles 27 and 43 or unless authorized by applicable international agreements, no health measure shall be applied to a civilian lorry, train or coach not coming from an affected area which passes through a territory without embarking, disembarking, loading or discharging.

Article 27 Affected conveyances
1. If clinical signs or symptoms and information based on fact or evidence of a public health risk, including sources of infection and contamination, are found on board a conveyance, the competent authority shall consider the conveyance as affected and may:
(a) disinfect, decontaminate, disinsect or derat the conveyance, as appropriate, or cause these measures to be carried out under its supervision; and
(b) decide in each case the technique employed to secure an adequate level of control of the public health risk as provided in these Regulations. Where there are methods or materials advised by WHO for these procedures, these should be employed, unless the competent authority determines that other methods are as safe and reliable. The competent authority may implement additional health measures, including isolation of the conveyances, as necessary, to prevent the spread of disease. Such additional measures should be reported to the National IHR Focal Point.
2. If the competent authority for the point of entry is not able to carry out the control measures required under this Article, the affected conveyance may nevertheless be allowed to depart, subject to the following conditions:
(a) the competent authority shall, at the time of departure, inform the competent authority for the next known point of entry of the type of information referred to under subparagraph (b); and (b) in the case of a ship, the evidence found and the control measures required shall be noted in the Ship Sanitation Control Certificate. Any such conveyance shall be permitted to take on, under the supervision of the competent authority, fuel, water, food and supplies.
3. A conveyance that has been considered as affected shall cease to be regarded as such when the competent authority is satisfied that:

(a) the measures provided in paragraph 1 of this Article have been effectively carried out; and
(b) there are no conditions on board that could constitute a public health risk.

Article 28 Ships and aircraft at points of entry
1. Subject to Article 43 or as provided in applicable international agreements, a ship or an aircraft shall not be prevented for public health reasons from calling at any point of entry. However, if the point of entry is not equipped for applying health measures under these Regulations, the ship or aircraft may be ordered to proceed at its own risk to the nearest suitable point of entry available to it, unless the ship or aircraft has an operational problem which would make this diversion unsafe.
2. Subject to Article 43 or as provided in applicable international agreements, ships or aircraft shall not be refused *free pratique* by States Parties for public health reasons; in particular they shall not be prevented from embarking or disembarking, discharging or loading cargo or stores, or taking on fuel, water, food and supplies. States Parties may subject the granting of *free pratique* to inspection and, if a source of infection or contamination is found on board, the carrying out of necessary disinfection, decontamination, disinsection or deratting, or other measures necessary to prevent the spread of the infection or contamination.
3. Whenever practicable and subject to the previous paragraph, a State Party shall authorize the granting of *free pratique* by radio or other communication means to a ship or an aircraft when, on the basis of information received from it prior to its arrival, the State Party is of the opinion that the arrival of the ship or aircraft will not result in the introduction or spread of disease.
4. Officers in command of ships or pilots in command of aircraft, or their agents, shall make known to the port or airport control as early as possible before arrival at the port or airport of destination any cases of illness indicative of a disease of an infectious nature or evidence of a public health risk on board as soon as such illnesses or public health risks are made known to the officer or pilot. This information must be immediately relayed to the competent authority for the port or airport. In urgent circumstances, such information should be communicated directly by the officers or pilots to the relevant port or airport authority.
5. The following shall apply if a suspect or affected aircraft or ship, for reasons beyond the control of the pilot in command of the aircraft or the officer in command of the ship, lands elsewhere than at the airport at which the aircraft was due to land or berths elsewhere than at the port at which the ship was due to berth:
(a) the pilot in command of the aircraft or the officer in command of the ship or other person in charge shall make every effort to communicate without delay with the nearest competent authority;
(b) as soon as the competent authority has been informed of the landing it may apply health measures recommended by WHO or other health measures provided in these Regulations;
(c) unless required for emergency purposes or for communication with the competent authority, no traveller on board the aircraft or ship shall leave its vicinity and no cargo shall be removed from that vicinity, unless authorized by the competent authority; and
(d) when all health measures required by the competent authority have been completed, the aircraft or ship may, so far as such health measures are concerned, proceed either to the airport or port at which it was due to land or berth, or, if for technical reasons it cannot do so, to aconveniently situated airport or port.
6. Notwithstanding the provisions contained in this Article, the officer in command of a ship or pilot in command of an aircraft may take such emergency measures as may be necessary for the health and safety of travellers on board. He or she shall inform the competent authority as early as possible concerning any measures taken pursuant to this paragraph.

Article 29 Civilian lorries, trains and coaches at points of entry
WHO, in consultation with States Parties, shall develop guiding principles for applying health measures to civilian lorries, trains and coaches at points of entry and passing through ground crossings.

Chapter III – Special provisions for travelers

Article 30 Travellers under public health observation

Subject to Article 43 or as authorized in applicable international agreements, a suspect traveler who on arrival is placed under public health observation may continue an international voyage, if the traveller does not pose an imminent public health risk and the State Party informs the competent authority of the point of entry at destination, if known, of the traveller's expected arrival. On arrival, the traveller shall report to that authority.

Article 31 Health measures relating to entry of travellers

1. Invasive medical examination, vaccination or other prophylaxis shall not be required as a condition of entry of any traveller to the territory of a State Party, except that, subject to Articles 32, 42 and 45, these Regulations do not preclude States Parties from requiring medical examination, vaccination or other prophylaxis or proof of vaccination or other prophylaxis:
(a) when necessary to determine whether a public health risk exists;
(b) as a condition of entry for any travellers seeking temporary or permanent residence;
(c) as a condition of entry for any travellers pursuant to Article 43 or Annexes 6 and 7; or
(d) which may be carried out pursuant to Article 23.
2. If a traveller for whom a State Party may require a medical examination, vaccination or other prophylaxis under paragraph 1 of this Article fails to consent to any such measure, or refuses to provide the information or the documents referred to in paragraph 1(a) of Article 23, the State Party concerned may, subject to Articles 32, 42 and 45, deny entry to that traveller. If there is evidence of an imminent public health risk, the State Party may, in accordance with its national law and to the extent necessary to control such a risk, compel the traveller to undergo or advise the traveller, pursuant to paragraph 3 of Article 23, to undergo:
(a) the least invasive and intrusive medical examination that would achieve the public health objective;
(b) vaccination or other prophylaxis; or
(c) additional established health measures that prevent or control the spread of disease, including isolation, quarantine or placing the traveller under public health observation.

Article 32 Treatment of travellers

In implementing health measures under these Regulations, States Parties shall treat travelers with respect for their dignity, human rights and fundamental freedoms and minimize any discomfort or distress associated with such measures, including by:
(a) treating all travellers with courtesy and respect;
(b) taking into consideration the gender, sociocultural, ethnic or religious concerns of travellers; and
(c) providing or arranging for adequate food and water, appropriate accommodation and clothing, protection for baggage and other possessions, appropriate medical treatment, means of necessary communication if possible in a language that they can understand and other appropriate assistance for travellers who are quarantined, isolated or subject to medical examinations or other procedures for public health purposes.

Chapter IV – Special provisions for goods, containers and container loading areas

Article 33 Goods in transit

Subject to Article 43 or unless authorized by applicable international agreements, goods, other than live animals, in transit without transhipment shall not be subject to health measures under these Regulations or detained for public health purposes.

Article 34 Container and container loading areas

1. States Parties shall ensure, as far as practicable, that container shippers use international traffic containers that are kept free from sources of infection or contamination, including vectors and reservoirs, particularly during the course of packing.
2. States Parties shall ensure, as far as practicable, that container loading areas are kept free from sources of infection or contamination, including vectors and reservoirs.

3. Whenever, in the opinion of a State Party, the volume of international container traffic is sufficiently large, the competent authorities shall take all practicable measures consistent with these Regulations, including carrying out inspections, to assess the sanitary condition of container loading areas and containers in order to ensure that the obligations contained in these Regulations are implemented.
4. Facilities for the inspection and isolation of containers shall, as far as practicable, be available at container loading areas.
5. Container consignees and consignors shall make every effort to avoid cross-contamination when multiple-use loading of containers is employed.

PART VI – HEALTH DOCUMENTS

Article 35 General rule
No health documents, other than those provided for under these Regulations or in recommendations issued by WHO, shall be required in international traffic, provided however that this Article shall not apply to travellers seeking temporary or permanent residence, nor shall it apply to document requirements concerning the public health status of goods or cargo in international trade pursuant to applicable international agreements. The competent authority may request travellers to complete contact information forms and questionnaires on the health of travellers, provided that they meet the requirements set out in Article 23.

Article 36 Certificates of vaccination or other prophylaxis
1. Vaccines and prophylaxis for travellers administered pursuant to these Regulations, or to recommendations and certificates relating thereto, shall conform to the provisions of Annex 6 and, when applicable, Annex 7 with regard to specific diseases.
2. A traveller in possession of a certificate of vaccination or other prophylaxis issued in conformity with Annex 6 and, when applicable, Annex 7, shall not be denied entry as a consequence of the disease to which the certificate refers, even if coming from an affected area, unless the competent authority has verifiable indications and/or evidence that the vaccination or other prophylaxis was not effective.

Article 37 Maritime Declaration of Health
1. The master of a ship, before arrival at its first port of call in the territory of a State Party, shall ascertain the state of health on board, and, except when that State Party does not require it, the master shall, on arrival, or in advance of the vessel's arrival if the vessel is so equipped and the State Party requires such advance delivery, complete and deliver to the competent authority for that port a Maritime Declaration of Health which shall be countersigned by the ship's surgeon, if one is carried.
2. The master of a ship, or the ship's surgeon if one is carried, shall supply any information required by the competent authority as to health conditions on board during an international voyage.
3. A Maritime Declaration of Health shall conform to the model provided in Annex 8.
4. A State Party may decide:
(a) to dispense with the submission of the Maritime Declaration of Health by all arriving ships; or
(b) to require the submission of the Maritime Declaration of Health under a recommendation concerning ships arriving from affected areas or to require it from ships which might otherwise carry infection or contamination. The State Party shall inform shipping operators or their agents of these requirements.

Article 38 Health Part of the Aircraft General Declaration
1. The pilot in command of an aircraft or the pilot's agent, in flight or upon landing at the first airport in the territory of a State Party, shall, to the best of his or her ability, except when that State Party does not require it, complete and deliver to the competent authority for that airport the Health Part of the Aircraft General Declaration which shall conform to the model specified in Annex 9.
2. The pilot in command of an aircraft or the pilot's agent shall supply any information required by the State Party as to health conditions on board during an international voyage and any health measure applied to the aircraft.

3. A State Party may decide:
(a) to dispense with the submission of the Health Part of the Aircraft General Declaration by all arriving aircraft; or
(b) to require the submission of the Health Part of the Aircraft General Declaration under a recommendation concerning aircraft arriving from affected areas or to require it from aircraft which might otherwise carry infection or contamination. The State Party shall inform aircraft operators or their agents of these requirements.

Article 39 Ship sanitation certificates
1. Ship Sanitation Control Exemption Certificates and Ship Sanitation Control Certificates shall be valid for a maximum period of six months. This period may be extended by one month if the inspection or control measures required cannot be accomplished at the port.
2. If a valid Ship Sanitation Control Exemption Certificate or Ship Sanitation Control Certificate is not produced or evidence of a public health risk is found on board a ship, the State Party may proceed as provided in paragraph 1 of Article 27.
3. The certificates referred to in this Article shall conform to the model in Annex 3.
4. Whenever possible, control measures shall be carried out when the ship and holds are empty. In the case of a ship in ballast, they shall be carried out before loading.
5. When control measures are required and have been satisfactorily completed, the competent authority shall issue a Ship Sanitation Control Certificate, noting the evidence found and the control measures taken.
6. The competent authority may issue a Ship Sanitation Control Exemption Certificate at any port specified under Article 20 if it is satisfied that the ship is free of infection and contamination, including vectors and reservoirs. Such a certificate shall normally be issued only if the inspection of the ship has been carried out when the ship and holds are empty or when they contain only ballast or other material, of such a nature or so disposed as to make a thorough inspection of the holds possible.
7. If the conditions under which control measures are carried out are such that, in the opinion of the competent authority for the port where the operation was performed, a satisfactory result cannot be obtained, the competent authority shall make a note to that effect on the Ship Sanitation Control Certificate.

PART VII – CHARGES

Article 40 Charges for health measures regarding travellers
1. Except for travellers seeking temporary or permanent residence, and subject to paragraph 2 of this Article, no charge shall be made by a State Party pursuant to these Regulations for the following measures for the protection of public health:
(a) any medical examination provided for in these Regulations, or any supplementary examination which may be required by that State Party to ascertain the health status of the traveller examined;
(b) any vaccination or other prophylaxis provided to a traveller on arrival that is not a published requirement or is a requirement published less than 10 days prior to provision of the vaccination or other prophylaxis;
(c) appropriate isolation or quarantine requirements of travellers;
(d) any certificate issued to the traveller specifying the measures applied and the date of application; or
(e) any health measures applied to baggage accompanying the traveller.
2. States Parties may charge for health measures other than those referred to in paragraph 1 of this Article, including those primarily for the benefit of the traveller.
3. Where charges are made for applying such health measures to travellers under these Regulations, there shall be in each State Party only one tariff for such charges and every charge shall:
(a) conform to this tariff;
(b) not exceed the actual cost of the service rendered; and
(c) be levied without distinction as to the nationality, domicile or residence of the traveler concerned.
4. The tariff, and any amendment thereto, shall be published at least 10 days in advance of any levy thereunder.

5. Nothing in these Regulations shall preclude States Parties from seeking reimbursement for expenses incurred in providing the health measures in paragraph 1 of this Article:
(a) from conveyance operators or owners with regard to their employees; or
(b) from applicable insurance sources.
6. Under no circumstances shall travellers or conveyance operators be denied the ability to depart from the territory of a State Party pending payment of the charges referred to in paragraphs 1 or 2 of this Article.

Article 41 Charges for baggage, cargo, containers, conveyances, goods or postal parcels
1. Where charges are made for applying health measures to baggage, cargo, containers, conveyances, goods or postal parcels under these Regulations, there shall be in each State Party only one tariff for such charges and every charge shall:
(a) conform to this tariff;
(b) not exceed the actual cost of the service rendered; and
(c) be levied without distinction as to the nationality, flag, registry or ownership of the baggage, cargo, containers, conveyances, goods or postal parcels concerned. In particular, there shall be no distinction made between national and foreign baggage, cargo, containers, conveyances, goods or postal parcels.
2. The tariff, and any amendment thereto, shall be published at least 10 days in advance of any levy thereunder.

PART VIII – GENERAL PROVISIONS

Article 42 Implementation of health measures
Health measures taken pursuant to these Regulations shall be initiated and completed without delay, and applied in a transparent and non-discriminatory manner.

Article 43 Additional health measures
1. These Regulations shall not preclude States Parties from implementing health measures, in accordance with their relevant national law and obligations under international law, in response to specific public health risks or public health emergencies of international concern, which:
(a) achieve the same or greater level of health protection than WHO recommendations; or
(b) are otherwise prohibited under Article 25, Article 26, paragraphs 1 and 2 of Article 28, Article 30, paragraph 1(c) of Article 31 and Article 33, provided such measures are otherwise consistent with these Regulations. Such measures shall not be more restrictive of international traffic and not more invasive or intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection.
2. In determining whether to implement the health measures referred to in paragraph 1 of this Article or additional health measures under paragraph 2 of Article 23, paragraph 1 of Article 27, paragraph 2 of Article 28 and paragraph 2(c) of Article 31, States Parties shall base their determinations upon:
(a) scientific principles;
(b) available scientific evidence of a risk to human health, or where such evidence is insufficient, the available information including from WHO and other relevant intergovernmental organizations and international bodies; and
(c) any available specific guidance or advice from WHO.
3. A State Party implementing additional health measures referred to in paragraph 1 of this Article which significantly interfere with international traffic shall provide to WHO the public health rationale and relevant scientific information for it. WHO shall share this information with other States Parties and shall share information regarding the health measures implemented. For the purpose of this Article, significant interference generally means refusal of entry or departure of international travellers, baggage, cargo, containers, conveyances, goods, and the like, or their delay, for more than 24 hours.
4. After assessing information provided pursuant to paragraph 3 and 5 of this Article and other relevant information, WHO may request that the State Party concerned reconsider the application of the measures.
5. A State Party implementing additional health measures referred to in paragraphs 1 and 2 of this Article

that significantly interfere with international traffic shall inform WHO, within 48 hours of implementation, of such measures and their health rationale unless these are covered by a temporary or standing recommendation.
6. A State Party implementing a health measure pursuant to paragraph 1 or 2 of this Article shall within three months review such a measure taking into account the advice of WHO and the criteria in paragraph 2 of this Article**.**
7. Without prejudice to its rights under Article 56, any State Party impacted by a measure taken pursuant to paragraph 1 or 2 of this Article may request the State Party implementing such a measure to consult with it. The purpose of such consultations is to clarify the scientific information and public health rationale underlying the measure and to find a mutually acceptable solution.
8. The provisions of this Article may apply to implementation of measures concerning travelers taking part in mass congregations.

Article 44 Collaboration and assistance
1. States Parties shall undertake to collaborate with each other, to the extent possible, in:
(a) the detection and assessment of, and response to, events as provided under these Regulations;
(b) the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the public health capacities required under these Regulations;
(c) the mobilization of financial resources to facilitate implementation of their obligations under these Regulations; and
(d) the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations.
2. WHO shall collaborate with States Parties, upon request, to the extent possible, in:
(a) the evaluation and assessment of their public health capacities in order to facilitate the effective implementation of these Regulations;
(b) the provision or facilitation of technical cooperation and logistical support to States Parties; and
(c) the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex 1.
3. Collaboration under this Article may be implemented through multiple channels, including bilaterally, through regional networks and the WHO regional offices, and through intergovernmental organizations and international bodies.

Article 45 Treatment of personal data
1. Health information collected or received by a State Party pursuant to these Regulations from another State Party or from WHO which refers to an identified or identifiable person shall be kept confidential and processed anonymously as required by national law.
2. Notwithstanding paragraph 1, States Parties may disclose and process personal data where essential for the purposes of assessing and managing a public health risk, but State Parties, in accordance with national law, and WHO must ensure that the personal data are:
(a) processed fairly and lawfully, and not further processed in a way incompatible with that purpose;
(b) adequate, relevant and not excessive in relation to that purpose;
(c) accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that data which are inaccurate or incomplete are erased or rectified; and
(d) not kept longer than necessary.
3. Upon request, WHO shall as far as practicable provide an individual with his or her personal data referred to in this Article in an intelligible form, without undue delay or expense and, when necessary, allow for correction.

Article 46 Transport and handling of biological substances, reagents and materials for diagnostic purposes
States Parties shall, subject to national law and taking into account relevant international guidelines,

facilitate the transport, entry, exit, processing and disposal of biological substances and diagnostic specimens, reagents and other diagnostic materials for verification and public health response purposes under these Regulations.

PART IX – THE IHR ROSTER OF EXPERTS, THE EMERGENCY COMMITTEE AND THE REVIEW COMMITTEE

Chapter I – The IHR Roster of Experts

Article 47 Composition

The Director-General shall establish a roster composed of experts in all relevant fields of expertise (hereinafter the "IHR Expert Roster"). The Director-General shall appoint the members of the IHR Expert Roster in accordance with the WHO Regulations for Expert Advisory Panels and Committees (hereinafter the "WHO Advisory Panel Regulations"), unless otherwise provided in these Regulations. In addition, the Director-General shall appoint one member at the request of each State Party and, where appropriate, experts proposed by relevant intergovernmental and regional economic integration organizations. Interested States Parties shall notify the Director-General of the qualifications and fields of expertise of each of the experts they propose for membership. The Director-General shall periodically inform the States Parties, and relevant intergovernmental and regional economic integration organizations, of the composition of the IHR Expert Roster.

Chapter II – The Emergency Committee

Article 48 Terms of reference and composition

1. The Director-General shall establish an Emergency Committee that at the request of the Director-General shall provide its views on:
(a) whether an event constitutes a public health emergency of international concern;
(b) the termination of a public health emergency of international concern; and
(c) the proposed issuance, modification, extension or termination of temporary recommendations.
2. The Emergency Committee shall be composed of experts selected by the Director-General from the IHR Expert Roster and, when appropriate, other expert advisory panels of the Organization. The Director-General shall determine the duration of membership with a view to ensuring its continuity in the consideration of a specific event and its consequences. The Director-General shall select the members of the Emergency Committee on the basis of the expertise and experience required for any particular session and with due regard to the principles of equitable geographical representation. At least one member of the Emergency Committee should be an expert nominated by a State Party within whose territory the event arises.
3. The Director-General may, on his or her own initiative or at the request of the Emergency Committee, appoint one or more technical experts to advise the Committee.

Article 49 Procedure

1. The Director-General shall convene meetings of the Emergency Committee by selecting a number of experts from among those referred to in paragraph 2 of Article 48, according to the fields of expertise and experience most relevant to the specific event that is occurring. For the purpose of this Article, "meetings" of the Emergency Committee may include teleconferences, videoconferences or electronic communications.
2. The Director-General shall provide the Emergency Committee with the agenda and any relevant information concerning the event, including information provided by the States Parties, as well as any temporary recommendation that the Director-General proposes for issuance.
3. The Emergency Committee shall elect its Chairperson and prepare following each meeting a brief summary report of its proceedings and deliberations, including any advice on recommendations.

4. The Director-General shall invite the State Party in whose territory the event arises to present its views to the Emergency Committee. To that effect, the Director-General shall notify to it the dates and the agenda of the meeting of the Emergency Committee with as much advance notice as necessary. The State Party concerned, however, may not seek a postponement of the meeting of the Emergency Committee for the purpose of presenting its views thereto.
5. The views of the Emergency Committee shall be forwarded to the Director-General for consideration. The Director-General shall make the final determination on these matters.
6. The Director-General shall communicate to States Parties the determination and the termination of a public health emergency of international concern, any health measure taken by the State Party concerned, any temporary recommendation, and the modification, extension and termination of such recommendations, together with the views of the Emergency Committee. The Director-General shall inform conveyance operators through States Parties and the relevant international agencies of such temporary recommendations, including their modification, extension or termination. The Director-General shall subsequently make such information and recommendations available to the general public.
7. States Parties in whose territories the event has occurred may propose to the Director-General the termination of a public health emergency of international concern and/or the temporary recommendations, and may make a presentation to that effect to the Emergency Committee.

Chapter III – The Review Committee

Article 50 Terms of reference and composition
1. The Director-General shall establish a Review Committee, which shall carry out the following functions:
(a) make technical recommendations to the Director-General regarding amendments to these Regulations;
(b) provide technical advice to the Director-General with respect to standing recommendations, and any modifications or termination thereof;
(c) provide technical advice to the Director-General on any matter referred to it by the Director-General regarding the functioning of these Regulations.
2. The Review Committee shall be considered an expert committee and shall be subject to the WHO Advisory Panel Regulations, unless otherwise provided in this Article.
3. The Members of the Review Committee shall be selected and appointed by the Director-General from among the persons serving on the IHR Expert Roster and, when appropriate, other expert advisory panels of the Organization.
4. The Director-General shall establish the number of members to be invited to a meeting of the Review Committee, determine its date and duration, and convene the Committee.
5. The Director-General shall appoint members to the Review Committee for the duration of the work of a session only.
6. The Director-General shall select the members of the Review Committee on the basis of the principles of equitable geographical representation, gender balance, a balance of experts from developed and developing countries, representation of a diversity of scientific opinion, approaches and practical experience in various parts of the world, and an appropriate interdisciplinary balance.

Article 51 Conduct of business
1. Decisions of the Review Committee shall be taken by a majority of the members present and voting.
2. The Director-General shall invite Member States, the United Nations and its specialized agencies and other relevant intergovernmental organizations or nongovernmental organizations in official relations with WHO to designate representatives to attend the Committee sessions. Such representatives may submit memoranda and, with the consent of the Chairperson, make statements on the subjects under discussion. They shall not have the right to vote.

Article 52 Reports
1. For each session, the Review Committee shall draw up a report setting forth the Committee's views and

advice. This report shall be approved by the Review Committee before the end of the session. Its views and advice shall not commit the Organization and shall be formulated as advice to the Director-General. The text of the report may not be modified without the Committee's consent.
2. If the Review Committee is not unanimous in its findings, any member shall be entitled to express his or her dissenting professional views in an individual or group report, which shall state the reasons why a divergent opinion is held and shall form part of the Committee's report.
3. The Review Committee's report shall be submitted to the Director-General, who shall communicate its views and advice to the Health Assembly or the Executive Board for their consideration and action.

Article 53 Procedures for standing recommendations
When the Director-General considers that a standing recommendation is necessary and appropriate for a specific public health risk, the Director-General shall seek the views of the Review Committee. In addition to the relevant paragraphs of Articles 50 to 52, the following provisions shall apply:
(a) proposals for standing recommendations, their modification or termination may be submitted to the Review Committee by the Director-General or by States Parties through the Director-General;
(b) any State Party may submit relevant information for consideration by the Review Committee;
(c) the Director-General may request any State Party, intergovernmental organization or nongovernmental organization in official relations with WHO to place at the disposal of the Review Committee information in its possession concerning the subject of the proposed standing recommendation as specified by the Review Committee;
(d) the Director-General may, at the request of the Review Committee or on the Director-General's own initiative, appoint one or more technical experts to advise the Review Committee. They shall not have the right to vote;
(e) any report containing the views and advice of the Review Committee regarding standing recommendations shall be forwarded to the Director-General for consideration and decision. The Director-General shall communicate the Review Committee's views and advice to the Health Assembly;
(f) the Director-General shall communicate to States Parties any standing recommendation, as well as the modifications or termination of such recommendations, together with the views of the Review Committee;
(g) standing recommendations shall be submitted by the Director-General to the subsequent Health Assembly for its consideration.

PART X – FINAL PROVISIONS

Article 54 Reporting and review
1. States Parties and the Director-General shall report to the Health Assembly on the implementation of these Regulations as decided by the Health Assembly.
2. The Health Assembly shall periodically review the functioning of these Regulations. To that end it may request the advice of the Review Committee**,** through the Director-General. The first such review shall take place no later than five years after the entry into force of these Regulations.
3. WHO shall periodically conduct studies to review and evaluate the functioning of Annex 2. The first such review shall commence no later than one year after the entry into force of these Regulations. The results of such reviews shall be submitted to the Health Assembly for its consideration, as appropriate.

Article 55 Amendments
1. Amendments to these Regulations may be proposed by any State Party or by the Director-General. Such proposals for amendments shall be submitted to the Health Assembly for its consideration.
2. The text of any proposed amendment shall be communicated to all States Parties by the Director-General at least four months before the Health Assembly at which it is proposed for consideration.
3. Amendments to these Regulations adopted by the Health Assembly pursuant to this Article shall come into force for all States Parties on the same terms, and subject to the same rights and obligations, as provided for in Article 22 of the Constitution of WHO and Articles 59 to 64 of these Regulations.

Article 56 Settlement of disputes

1. In the event of a dispute between two or more States Parties concerning the interpretation or application of these Regulations, the States Parties concerned shall seek in the first instance to settle the dispute through negotiation or any other peaceful means of their own choice, including good offices, mediation or conciliation. Failure to reach agreement shall not absolve the parties to the dispute from the responsibility of continuing to seek to resolve it.
2. In the event that the dispute is not settled by the means described under paragraph 1 of this Article, the States Parties concerned may agree to refer the dispute to the Director-General, who shall make every effort to settle it.
3. A State Party may at any time declare in writing to the Director-General that it accepts arbitration as compulsory with regard to all disputes concerning the interpretation or application of these Regulations to which it is a party or with regard to a specific dispute in relation to any other State Party accepting the same obligation. The arbitration shall be conducted in accordance with the Permanent Court of Arbitration Optional Rules for Arbitrating Disputes between Two States applicable at the time a request for arbitration is made. The States Parties that have agreed to accept arbitration as compulsory shall accept the arbitral award as binding and final. The Director-General shall inform the Health Assembly regarding such action as appropriate.
4. Nothing in these Regulations shall impair the rights of States Parties under any international agreement to which they may be parties to resort to the dispute settlement mechanisms of other intergovernmental organizations or established under any international agreement.
5. In the event of a dispute between WHO and one or more States Parties concerning the interpretation or application of these Regulations, the matter shall be submitted to the Health Assembly.

Article 57 Relationship with other international agreements

1. States Parties recognize that the IHR and other relevant international agreements should be interpreted so as to be compatible. The provisions of the IHR shall not affect the rights and obligations of any State Party deriving from other international agreements.
2. Subject to paragraph 1 of this Article, nothing in these Regulations shall prevent States Parties having certain interests in common owing to their health, geographical, social or economic conditions, from concluding special treaties or arrangements in order to facilitate the application of these Regulations, and in particular with regard to:
(a) the direct and rapid exchange of public health information between neighbouring territories of different States;
(b) the health measures to be applied to international coastal traffic and to international traffic in waters within their jurisdiction;
(c) the health measures to be applied in contiguous territories of different States at their common frontier;
(d) arrangements for carrying affected persons or affected human remains by means of transport specially adapted for the purpose; and
(e) deratting, disinsection, disinfection, decontamination or other treatment designed to render goods free of disease-causing agents.
3. Without prejudice to their obligations under these Regulations, States Parties that are members of a regional economic integration organization shall apply in their mutual relations the common rules in force in that regional economic integration organization.

Article 58 International sanitary agreements and regulations

1. These Regulations, subject to the provisions of Article 62 and the exceptions hereinafter provided, shall replace as between the States bound by these Regulations and as between these States and WHO, the provisions of the following international sanitary agreements and regulations:
(a) International Sanitary Convention, signed in Paris, 21 June 1926;
(b) International Sanitary Convention for Aerial Navigation, signed at The Hague, 12 April 1933;
(c) International Agreement for dispensing with Bills of Health, signed in Paris, 22 December 1934;
(d) International Agreement for dispensing with Consular Visas on Bills of Health, signed in Paris, 22

December 1934;
(e) Convention modifying the International Sanitary Convention of 21 June 1926, signed in Paris, 31 October 1938;
(f) International Sanitary Convention, 1944, modifying the International Sanitary Convention of 21 June 1926, opened for signature in Washington, 15 December 1944;
(g) International Sanitary Convention for Aerial Navigation, 1944, modifying the International Sanitary Convention of 12 April 1933, opened for signature in Washington, 15 December 1944;
(h) Protocol of 23 April 1946 to prolong the International Sanitary Convention, 1944, signed in Washington;
(i) Protocol of 23 April 1946 to prolong the International Sanitary Convention for Aerial Navigation, 1944, signed in Washington;
(j) International Sanitary Regulations, 1951, and the Additional Regulations of 1955, 1956, 1960, 1963 and 1965; and
(k) the International Health Regulations of 1969 and the amendments of 1973 and 1981.
2. The Pan American Sanitary Code, signed at Havana, 14 November 1924, shall remain in force with the exception of Articles 2, 9, 10, 11, 16 to 53 inclusive, 61 and 62, to which the relevant part of paragraph 1 of this Article shall apply.

Article 59 Entry into force; period for rejection or reservations
1. The period provided in execution of Article 22 of the Constitution of WHO for rejection of, or reservation to, these Regulations or an amendment thereto, shall be 18 months from the date of the notification by the Director-General of the adoption of these Regulations or of an amendment to these Regulations by the Health Assembly. Any rejection or reservation received by the Director-General after the expiry of that period shall have no effect.
2. These Regulations shall enter into force 24 months after the date of notification referred to in paragraph 1 of this Article, except for:
(a) a State that has rejected these Regulations or an amendment thereto in accordance with Article 61;
(b) a State that has made a reservation, for which these Regulations shall enter into force as provided in Article 62;
(c) a State that becomes a Member of WHO after the date of the notification by the Director-General referred to in paragraph 1 of this Article, and which is not already a party to these Regulations, for which these Regulations shall enter into force as provided in Article 60; and
(d) a State not a Member of WHO that accepts these Regulations, for which they shall enter into force in accordance with paragraph 1 of Article 64.
3. If a State is not able to adjust its domestic legislative and administrative arrangements fully with these Regulations within the period set out in paragraph 2 of this Article, that State shall submit within the period specified in paragraph 1 of this Article a declaration to the Director-General regarding the outstanding adjustments and achieve them no later than 12 months after the entry into force of these Regulations for that State Party.

Article 60 New Member States of WHO
Any State which becomes a Member of WHO after the date of the notification by the Director-General referred to in paragraph 1 of Article 59, and which is not already a party to these Regulations, may communicate its rejection of, or any reservation to, these Regulations within a period of twelve months from the date of the notification to it by the Director-General after becoming a Member of WHO. Unless rejected, these Regulations shall enter into force with respect to that State, subject to the provisions of Articles 62 and 63, upon expiry of that period. In no case shall these Regulations enter into force in respect to that State earlier than 24 months after the date of notification referred to in paragraph 1 of Article 59.

Article 61 Rejection
If a State notifies the Director-General of its rejection of these Regulations or of an amendment thereto within the period provided in paragraph 1 of Article 59, these Regulations or the amendment concerned

shall not enter into force with respect to that State. Any international sanitary agreement or regulations listed in Article 58 to which such State is already a party shall remain in force as far as such State is concerned.

Article 62 Reservations

1. States may make reservations to these Regulations in accordance with this Article. Such reservations shall not be incompatible with the object and purpose of these Regulations.
2. Reservations to these Regulations shall be notified to the Director-General in accordance with paragraph 1 of Article 59 and Article 60, paragraph 1 of Article 63 or paragraph 1 of Article 64, as the case may be. A State not a Member of WHO shall notify the Director-General of any reservation with its notification of acceptance of these Regulations. States formulating reservations should provide the Director-General with reasons for the reservations.
3. A rejection in part of these Regulations shall be considered as a reservation.
4. The Director-General shall, in accordance with paragraph 2 of Article 65, issue notification of each reservation received pursuant to paragraph 2 of this Article. The Director-General shall:
(a) if the reservation was made before the entry into force of these Regulations, request those Member States that have not rejected these Regulations to notify him or her within six months of any objection to the reservation, or
(b) if the reservation was made after the entry into force of these Regulations, request States Parties to notify him or her within six months of any objection to the reservation. States objecting to a reservation should provide the Director-General with reasons for the objection.
5. After this period, the Director-General shall notify all States Parties of the objections he or she has received with regard to reservations. Unless by the end of six months from the date of the notification referred to in paragraph 4 of this Article a reservation has been objected to by one-third of the States referred to in paragraph 4 of this Article, it shall be deemed to be accepted and these Regulations shall enter into force for the reserving State, subject to the reservation.
6. If at least one-third of the States referred to in paragraph 4 of this Article object to the reservation by the end of six months from the date of the notification referred to in paragraph 4 of this Article, the Director-General shall notify the reserving State with a view to its considering withdrawing the reservation within three months from the date of the notification by the Director-General.
7. The reserving State shall continue to fulfil any obligations corresponding to the subject matter of the reservation, which the State has accepted under any of the international sanitary agreements or regulations listed in Article 58.
8. If the reserving State does not withdraw the reservation within three months from the date of the notification by the Director-General referred to in paragraph 6 of this Article, the Director-General shall seek the view of the Review Committee if the reserving State so requests. The Review Committee shall advise the Director-General as soon as possible and in accordance with Article 50 on the practical impact of the reservation on the operation of these Regulations.
9. The Director-General shall submit the reservation, and the views of the Review Committee if applicable, to the Health Assembly for its consideration. If the Health Assembly, by a majority vote, objects to the reservation on the ground that it is incompatible with the object and purpose of these Regulations, the reservation shall not be accepted and these Regulations shall enter into force for the reserving State only after it withdraws its reservation pursuant to Article 63. If the Health Assembly accepts the reservation, these Regulations shall enter into force for the reserving State, subject to its reservation.

Article 63 Withdrawal of rejection and reservation

1. A rejection made under Article 61 may at any time be withdrawn by a State by notifying the Director-General. In such cases, these Regulations shall enter into force with regard to that State upon receipt by the Director-General of the notification, except where the State makes a reservation when withdrawing its rejection, in which case these Regulations shall enter into force as provided in Article 62. In no case shall these Regulations enter into force in respect to that State earlier than 24 months after the date of notification referred to in paragraph 1 of Article 59.

2. The whole or part of any reservation may at any time be withdrawn by the State Party concerned by notifying the Director-General. In such cases, the withdrawal will be effective from the date of receipt by the Director-General of the notification.

Article 64 States not Members of WHO

1. Any State not a Member of WHO, which is a party to any international sanitary agreement or regulations listed in Article 58 or to which the Director-General has notified the adoption of these Regulations by the World Health Assembly, may become a party hereto by notifying its acceptance to the Director-General and, subject to the provisions of Article 62, such acceptance shall become effective upon the date of entry into force of these Regulations, or, if such acceptance is notified after that date, three months after the date of receipt by the Director-General of the notification of acceptance.
2. Any State not a Member of WHO which has become a party to these Regulations may at any time withdraw from participation in these Regulations, by means of a notification addressed to the Director-General which shall take effect six months after the Director-General has received it. The State which has withdrawn shall, as from that date, resume application of the provisions of any international sanitary agreement or regulations listed in Article 58 to which it was previously a party.

Article 65 Notifications by the Director-General

1. The Director-General shall notify all States Members and Associate Members of WHO, and also other parties to any international sanitary agreement or regulations listed in Article 58, of the adoption by the Health Assembly of these Regulations.
2. The Director-General shall also notify these States, as well as any other State which has become a party to these Regulations or to any amendment to these Regulations, of any notification received by WHO under Articles 60 to 64 respectively, as well as of any decision taken by the Health Assembly under Article 62.

Article 66 Authentic texts

1. The Arabic, Chinese, English, French, Russian and Spanish texts of these Regulations shall be equally authentic. The original texts of these Regulations shall be deposited with WHO.
2. The Director-General shall send, with the notification provided in paragraph 1 of Article 59, certified copies of these Regulations to all Members and Associate Members, and also to other parties to any of the international sanitary agreements or regulations listed in Article 58.
3. Upon the entry into force of these Regulations, the Director-General shall deliver certified copies thereof to the Secretary-General of the United Nations for registration in accordance with Article 102 of the Charter of the United Nations.

Annex 4

WHO Framework Convention on Tobacco Control

Preamble

The Parties to this Convention,

Determined to give priority to their right to protect public health,

Recognizing that the spread of the tobacco epidemic is a global problem with serious consequences for public health that calls for the widest possible international cooperation and the participation of all countries in an effective, appropriate and comprehensive international response,

Reflecting the concern of the international community about the devastating worldwide health, social, economic and environmental consequences of tobacco consumption and exposure to tobacco smoke,

Seriously concerned about the increase in the worldwide consumption and production of cigarettes and other tobacco products, particularly in developing countries, as well as about the burden this places on families, on the poor, and on national health systems,

Recognizing that scientific evidence has unequivocally established that tobacco consumption and exposure to tobacco smoke cause death, disease and disability, and that there is a time lag between the exposure to smoking and the other uses of tobacco products and the onset of tobacco-related diseases,

Recognizing also that cigarettes and some other products containing tobacco are highly engineered so as to create and maintain dependence, and that many of the compounds they contain and the smoke they produce are pharmacologically active, toxic, mutagenic and carcinogenic, and that tobacco dependence is separately classified as a disorder in major international classifications of diseases,

Acknowledging that there is clear scientific evidence that prenatal exposure to tobacco smoke causes adverse health and developmental conditions for children,

Deeply concerned about the escalation in smoking and other forms of tobacco consumption by children and adolescents worldwide, particularly smoking at increasingly early ages,

Alarmed by the increase in smoking and other forms of tobacco consumption by women and young girls worldwide and keeping in mind the need for full participation of women at all levels of policy-making and implementation and the need for gender-specific tobacco control strategies, *Deeply concerned* about the high levels of smoking and other forms of tobacco consumption by indigenous peoples,

Seriously concerned about the impact of all forms of advertising, promotion and sponsorship aimed at encouraging the use of tobacco products,

Recognizing that cooperative action is necessary to eliminate all forms of illicit trade in cigarettes and other tobacco products, including smuggling, illicit manufacturing and counterfeiting,

Acknowledging that tobacco control at all levels and particularly in developing countries and in countries with economies in transition requires sufficient financial and technical resources commensurate with the current and projected need for tobacco control activities,

Recognizing the need to develop appropriate mechanisms to address the long-term social and economic implications of successful tobacco demand reduction strategies,

Mindful of the social and economic difficulties that tobacco control programmes may engender in the medium and long term in some developing countries and countries with economies in transition, and recognizing their need for technical and financial assistance in the context of nationally developed strategies for sustainable development,

Conscious of the valuable work being conducted by many States on tobacco control and commending the leadership of the World Health Organization as well as the efforts of other organizations and bodies of the United Nations system and other international and regional intergovernmental organizations in developing measures on tobacco control,

Emphasizing the special contribution of nongovernmental organizations and other members of civil society not affiliated with the tobacco industry, including health professional bodies, women's, youth, environmental and consumer groups, and academic and health care institutions, to tobacco control efforts

nationally and internationally and the vital importance of their participation in national and international tobacco control efforts,
Recognizing the need to be alert to any efforts by the tobacco industry to undermine or subvert tobacco control efforts and the need to be informed of activities of the tobacco industry that have a negative impact on tobacco control efforts,
Recalling Article 12 of the International Covenant on Economic, Social and Cultural Rights, adopted by the United Nations General Assembly on 16 December 1966, which states that it is the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, *Recalling also* the preamble to the Constitution of the World Health Organization, which states that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition,
Determined to promote measures of tobacco control based on current and relevant scientific, technical and economic considerations,
Recalling that the Convention on the Elimination of All Forms of Discrimination against Women, adopted by the United Nations General Assembly on 18 December 1979, provides that States Parties to that Convention shall take appropriate measures to eliminate discrimination against women in the field of health care,
Recalling further that the Convention on the Rights of the Child, adopted by the United Nations General Assembly on 20 November 1989, provides that States Parties to that Convention recognize the right of the child to the enjoyment of the highest attainable standard of health,
Have agreed, as follows:

PART I: INTRODUCTION

Article 1 Use of terms
For the purposes of this Convention:
(a) "illicit trade" means any practice or conduct prohibited by law and which relates to production, shipment, receipt, possession, distribution, sale or purchase including any practice or conduct intended to facilitate such activity;
(b) "regional economic integration organization" means an organization that is composed of several sovereign states, and to which its Member States have transferred competence over a range of matters, including the authority to make decisions binding on its Member States in respect of those matters;1
(c) "tobacco advertising and promotion" means any form of commercial communication, recommendation or action with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly;
(d) "tobacco control" means a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke;
(e) "tobacco industry" means tobacco manufacturers, wholesale distributors and importers of tobacco products;
(f) "tobacco products" means products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing;
(g) "tobacco sponsorship" means any form of contribution to any event, activity or individual with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly;

Article 2 Relationship between this Convention and other agreements and legal instruments
1. In order to better protect human health, Parties are encouraged to implement measures beyond those required by this Convention and its protocols, and nothing in these instruments shall prevent a Party from imposing stricter requirements that are consistent with their provisions and are in accordance with international law.
2. The provisions of the Convention and its protocols shall in no way affect the right of Parties to enter into bilateral or multilateral agreements, including regional or subregional agreements, on issues relevant or

additional to the Convention and its protocols, provided that such agreements are compatible with their obligations under the Convention and its protocols. The Parties concerned shall communicate such agreements to the Conference of the Parties through the Secretariat.

PART II: OBJECTIVE, GUIDING PRINCIPLES AND GENERAL OBLIGATIONS

Article 3 Objective

The objective of this Convention and its protocols is to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke.

Article 4 Guiding principles

To achieve the objective of this Convention and its protocols and to implement its provisions, the Parties shall be guided, *inter alia*, by the principles set out below:

1. Every person should be informed of the health consequences, addictive nature and mortal threat posed by tobacco consumption and exposure to tobacco smoke and effective legislative, executive, administrative or other measures should be contemplated at the appropriate governmental level to protect all persons from exposure to tobacco smoke.
2. Strong political commitment is necessary to develop and support, at the national, regional and international levels, comprehensive multisectoral measures and coordinated responses, taking into consideration:

(a) the need to take measures to protect all persons from exposure to tobacco smoke;
(b) the need to take measures to prevent the initiation, to promote and support cessation, and to decrease the consumption of tobacco products in any form;
(c) the need to take measures to promote the participation of indigenous individuals and communities in the development, implementation and evaluation of tobacco control programmes that are socially and culturally appropriate to their needs and perspectives; and
(d) the need to take measures to address gender-specific risks when developing tobacco control strategies.

3. International cooperation, particularly transfer of technology, knowledge and financial assistance and provision of related expertise, to establish and implement effective tobacco control programmes, taking into consideration local culture, as well as social, economic, political and legal factors, is an important part of the Convention.
4. Comprehensive multisectoral measures and responses to reduce consumption of all tobacco products at the national, regional and international levels are essential so as to prevent, in accordance with public health principles, the incidence of diseases, premature disability and mortality due to tobacco consumption and exposure to tobacco smoke.
5. Issues relating to liability, as determined by each Party within its jurisdiction, are an important part of comprehensive tobacco control.
6. The importance of technical and financial assistance to aid the economic transition of tobacco growers and workers whose livelihoods are seriously affected as a consequence of tobacco control programmes in developing country Parties, as well as Parties with economies in transition, should be recognized and addressed in the context of nationally developed strategies for sustainable development.
7. The participation of civil society is essential in achieving the objective of the Convention and its protocols.

Article 5 General obligations

1. Each Party shall develop, implement, periodically update and review comprehensive multisectoral national tobacco control strategies, plans and programmes in accordance with this Convention and the protocols to which it is a Party.

2. Towards this end, each Party shall, in accordance with its capabilities:
(a) establish or reinforce and finance a national coordinating mechanism or focal points for tobacco control; and
(b) adopt and implement effective legislative, executive, administrative and/or other measures and cooperate, as appropriate, with other Parties in developing appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke.
3. In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.
4. The Parties shall cooperate in the formulation of proposed measures, procedures and guidelines for the implementation of the Convention and the protocols to which they are Parties.
5. The Parties shall cooperate, as appropriate, with competent international and regional intergovernmental organizations and other bodies to achieve the objectives of the Convention and the protocols to which they are Parties.
6. The Parties shall, within means and resources at their disposal, cooperate to raise financial resources for effective implementation of the Convention through bilateral and multilateral funding mechanisms.

PART III: MEASURES RELATING TO THE REDUCTION OF DEMAND FOR TOBACCO

Article 6 Price and tax measures to reduce the demand for tobacco
1. The Parties recognize that price and tax measures are an effective and important means of reducing tobacco consumption by various segments of the population, in particular young persons.
2. Without prejudice to the sovereign right of the Parties to determine and establish their taxation policies, each Party should take account of its national health objectives concerning tobacco control and adopt or maintain, as appropriate, measures which may include:
(a) implementing tax policies and, where appropriate, price policies, on tobacco products so as to contribute to the health objectives aimed at reducing tobacco consumption; and
(b) prohibiting or restricting, as appropriate, sales to and/or importations by international travellers of tax- and duty-free tobacco products.
3. The Parties shall provide rates of taxation for tobacco products and trends in tobacco consumption in their periodic reports to the Conference of the Parties, in accordance with Article 21.

Article 7 Non-price measures to reduce the demand for tobacco
The Parties recognize that comprehensive non-price measures are an effective and important means of reducing tobacco consumption. Each Party shall adopt and implement effective legislative, executive, administrative or other measures necessary to implement its obligations pursuant to Articles 8 to 13 and shall cooperate, as appropriate, with each other directly or through competent international bodies with a view to their implementation. The Conference of the Parties shall propose appropriate guidelines for the implementation of the provisions of these Articles.

Article 8 Protection from exposure to tobacco smoke
1. Parties recognize that scientific evidence has unequivocally established that exposure to tobacco smoke causes death, disease and disability.
2. Each Party shall adopt and implement in areas of existing national jurisdiction as determined by national law and actively promote at other jurisdictional levels the adoption and implementation of effective legislative, executive, administrative and/or other measures, providing for protection from exposure to tobacco smoke in indoor workplaces, public transport, indoor public places and, as appropriate, other public places.

Article 9 Regulation of the contents of tobacco products
The Conference of the Parties, in consultation with competent international bodies, shall propose guidelines

for testing and measuring the contents and emissions of tobacco products, and for the regulation of these contents and emissions. Each Party shall, where approved by competent national authorities, adopt and implement effective legislative, executive and administrative or other measures for such testing and measuring, and for such regulation.

Article 10 Regulation of tobacco product disclosures

Each Party shall, in accordance with its national law, adopt and implement effective legislative, executive, administrative or other measures requiring manufacturers and importers of tobacco products to disclose to governmental authorities information about the contents and emissions of tobacco products. Each Party shall further adopt and implement effective measures for public disclosure of information about the toxic constituents of the tobacco products and the emissions that they may produce.

Article 11 Packaging and labelling of tobacco products

1. Each Party shall, within a period of three years after entry into force of this Convention for that Party, adopt and implement, in accordance with its national law, effective measures to ensure that:
(a) tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products. These may include terms such as "low tar", "light", "ultra-light", or "mild"; and
(b) each unit packet and package of tobacco products and any outside packaging and labelling of such products also carry health warnings describing the harmful effects of tobacco use, and may include other appropriate messages. These warnings and messages:
(i) shall be approved by the competent national authority,
(ii) shall be rotating,
(iii) shall be large, clear, visible and legible,
(iv) should be 50% or more of the principal display areas but shall be no lessthan 30% of the principal display areas,
(v) may be in the form of or include pictures or pictograms.
2. Each unit packet and package of tobacco products and any outside packaging and labelling of such products shall, in addition to the warnings specified in paragraph 1(b) of this Article, contain information on relevant constituents and emissions of tobacco products as defined by national authorities.
3. Each Party shall require that the warnings and other textual information specified in paragraphs 1(b) and paragraph 2 of this Article will appear on each unit packet and package of tobacco products and any outside packaging and labelling of such products in its principal language or languages.
4. For the purposes of this Article, the term "outside packaging and labelling" in relation to tobacco products applies to any packaging and labelling used in the retail sale of the product.

Article 12 Education, communication, training and public awareness

Each Party shall promote and strengthen public awareness of tobacco control issues, using all available communication tools, as appropriate. Towards this end, each Party shall adopt and implement effective legislative, executive, administrative or other measures to promote:
(a) broad access to effective and comprehensive educational and public awareness programmes on the health risks including the addictive characteristics of tobacco consumption and exposure to tobacco smoke;
(b) public awareness about the health risks of tobacco consumption and exposure to tobacco smoke, and about the benefits of the cessation of tobacco use and tobacco-free lifestyles as specified in Article 14.2;
(c) public access, in accordance with national law, to a wide range of information on the tobacco industry as relevant to the objective of this Convention;
(d) effective and appropriate training or sensitization and awareness programmes ontobacco control addressed to persons such as health workers, community workers, social workers, media professionals, educators, decision-makers, administrators and other concerned persons;
(e) awareness and participation of public and private agencies and nongovernmental organizations not

affiliated with the tobacco industry in developing and implementing intersectoral programmes and strategies for tobacco control; and
(f) public awareness of and access to information regarding the adverse health, economic, and environmental consequences of tobacco production and consumption.

Article 13Tobacco advertising, promotion and sponsorship
1. Parties recognize that a comprehensive ban on advertising, promotion and sponsorship would reduce the consumption of tobacco products.
2. Each Party shall, in accordance with its constitution or constitutional principles, undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship. This shall include, subject to the legal environment and technical means available to that Party, a comprehensive ban on cross-border advertising, promotion and sponsorship originating from its territory. In this respect, within the period of five years after entry into force of this Convention for that Party, each Party shall undertake appropriate legislative, executive, administrative and/or other measures and report accordingly in conformity with Article 21.
3. A Party that is not in a position to undertake a comprehensive ban due to its constitution or constitutional principles shall apply restrictions on all tobacco advertising, promotion and sponsorship. This shall include, subject to the legal environment and technical means available to that Party, restrictions or a comprehensive ban on advertising, promotion and sponsorship originating from its territory with cross-border effects. In this respect, each Party shall undertake appropriate legislative, executive, administrative and/or other measures and report accordingly in conformity with Article 21.
4. As a minimum, and in accordance with its constitution or constitutional principles, each Party shall:
(a) prohibit all forms of tobacco advertising, promotion and sponsorship that promote a tobacco product by any means that are false, misleading or deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions;
(b) require that health or other appropriate warnings or messages accompany all tobacco advertising and, as appropriate, promotion and sponsorship;
(c) restrict the use of direct or indirect incentives that encourage the purchase of tobacco products by the public;
(d) require, if it does not have a comprehensive ban, the disclosure to relevant governmental authorities of expenditures by the tobacco industry on advertising,
promotion and sponsorship not yet prohibited. Those authorities may decide to make those figures available, subject to national law, to the public and to the Conference of the Parties, pursuant to Article 21;
(e) undertake a comprehensive ban or, in the case of a Party that is not in a position to undertake a comprehensive ban due to its constitution or constitutional principles, restrict tobacco advertising, promotion and sponsorship on radio, television, print media and, as appropriate, other media, such as the internet, within a period of five years; and
(f) prohibit, or in the case of a Party that is not in a position to prohibit due to its constitution or constitutional principles restrict, tobacco sponsorship of international events, activities and/or participants therein.
5. Parties are encouraged to implement measures beyond the obligations set out in paragraph 4.
6. Parties shall cooperate in the development of technologies and other means necessary to facilitate the elimination of cross-border advertising.
7. Parties which have a ban on certain forms of tobacco advertising, promotion and sponsorship have the sovereign right to ban those forms of cross-border tobacco advertising, promotion and sponsorship entering their territory and to impose equal penalties as those applicable to domestic advertising, promotion and sponsorship originating from their territory in accordance with their national law. This paragraph does not endorse or approve of any particular penalty.
8. Parties shall consider the elaboration of a protocol setting out appropriate measures that require international collaboration for a comprehensive ban on cross-border advertising, promotion and sponsorship.

Article 14 Demand reduction measures concerning tobacco dependence and cessation

1. Each Party shall develop and disseminate appropriate, comprehensive and integrated guidelines based on scientific evidence and best practices, taking into account national circumstances and priorities, and shall take effective measures to promote cessation of tobacco use and adequate treatment for tobacco dependence.

2. Towards this end, each Party shall endeavour to:

(a) design and implement effective programmes aimed at promoting the cessation of tobacco use, in such locations as educational institutions, health care facilities, workplaces and sporting environments;

(b) include diagnosis and treatment of tobacco dependence and counselling services on cessation of tobacco use in national health and education programmes, plans and strategies, with the participation of health workers, community workers and social workers as appropriate;

(c) establish in health care facilities and rehabilitation centres programmes for diagnosing, counselling, preventing and treating tobacco dependence; and

(d) collaborate with other Parties to facilitate accessibility and affordability for treatment of tobacco dependence including pharmaceutical products pursuant to Article 22. Such products and their constituents may include medicines, products used to administer medicines and diagnostics when appropriate.

PART IV: MEASURES RELATING TO THE REDUCTION OF THE SUPPLY OF TOBACCO

Article 15 Illicit trade in tobacco products

1. The Parties recognize that the elimination of all forms of illicit trade in tobacco products, including smuggling, illicit manufacturing and counterfeiting, and thedevelopment and implementation of related national law, in addition to subregional, regional and global agreements, are essential components of tobacco control.

2. Each Party shall adopt and implement effective legislative, executive, administrative or other measures to ensure that all unit packets and packages of tobacco products and any outside packaging of such products are marked to assist Parties in determining the origin of tobacco products, and in accordance with national law and relevant bilateral or multilateral agreements, assist Parties in determining the point of diversion and monitor, document and control the movement of tobacco products and their legal status. In addition, each Party shall:

(a) require that unit packets and packages of tobacco products for retail and wholesale use that are sold on its domestic market carry the statement: *"Sales only allowed in (insert name of the country, subnational, regional or federal unit)"* or carry any other effective marking indicating the final destination or which would assist authorities in determining whether the product is legally for sale on the domestic market; and

(b) consider, as appropriate, developing a practical tracking and tracing regime that would further secure the distribution system and assist in the investigation of illicit trade.

3. Each Party shall require that the packaging information or marking specified in paragraph 2 of this Article shall be presented in legible form and/or appear in its principal language or languages.

4. With a view to eliminating illicit trade in tobacco products, each Party shall:

(a) monitor and collect data on cross-border trade in tobacco products, including illicit trade, and exchange information among customs, tax and other authorities, as appropriate, and in accordance with national law and relevant applicable bilateral or multilateral agreements;

(b) enact or strengthen legislation, with appropriate penalties and remedies, against illicit trade in tobacco products, including counterfeit and contraband cigarettes;

(c) take appropriate steps to ensure that all confiscated manufacturing equipment, counterfeit and contraband cigarettes and other tobacco products are destroyed, using environmentally-friendly methods where feasible, or disposed of in accordance with national law;

(d) adopt and implement measures to monitor, document and control the storage and distribution of tobacco products held or moving under suspension of taxes or duties within its jurisdiction; and

(e) adopt measures as appropriate to enable the confiscation of proceeds derived from the illicit trade in

tobacco products.
5. Information collected pursuant to subparagraphs 4(a) and 4(d) of this Article shall, as appropriate, be provided in aggregate form by the Parties in their periodic reports to the Conference of the Parties, in accordance with Article 21.
6. The Parties shall, as appropriate and in accordance with national law, promote cooperation between national agencies, as well as relevant regional and international intergovernmental organizations as it relates to investigations, prosecutions and proceedings, with a view to eliminating illicit trade in tobacco products. Special emphasis shall be placed on cooperation at regional and subregional levels to combat illicit trade of tobacco products.
7. Each Party shall endeavour to adopt and implement further measures including licensing, where appropriate, to control or regulate the production and distribution of tobacco products in order to prevent illicit trade.

Article 16 Sales to and by minors
1. Each Party shall adopt and implement effective legislative, executive, administrative or other measures at the appropriate government level to prohibit the sales of tobacco products to persons under the age set by domestic law, national law or eighteen. These measures may include:
(a) requiring that all sellers of tobacco products place a clear and prominent indicator inside their point of sale about the prohibition of tobacco sales to minors and, in case of doubt, request that each tobacco purchaser provide appropriate evidence of having reached full legal age;
(b) banning the sale of tobacco products in any manner by which they are directly accessible, such as store shelves;
(c) prohibiting the manufacture and sale of sweets, snacks, toys or any other objects in the form of tobacco products which appeal to minors; and
(d) ensuring that tobacco vending machines under its jurisdiction are not accessible to minors and do not promote the sale of tobacco products to minors.
2. Each Party shall prohibit or promote the prohibition of the distribution of free tobacco products to the public and especially minors.
3. Each Party shall endeavour to prohibit the sale of cigarettes individually or in small packets which increase the affordability of such products to minors.
4. The Parties recognize that in order to increase their effectiveness, measures to prevent tobacco product sales to minors should, where appropriate, be implemented in conjunction with other provisions contained in this Convention.
5. When signing, ratifying, accepting, approving or acceding to the Convention or at any time thereafter, a Party may, by means of a binding written declaration, indicate its commitment to prohibit the introduction of tobacco vending machines within its jurisdiction or, as appropriate, to a total ban on tobacco vending machines. The declaration made pursuant to this Article shall be circulated by the Depositary to all Parties to the Convention.
6. Each Party shall adopt and implement effective legislative, executive, administrative or other measures, including penalties against sellers and distributors, in order to ensure compliance with the obligations contained in paragraphs 1-5 of this Article.
7. Each Party should, as appropriate, adopt and implement effective legislative, executive, administrative or other measures to prohibit the sales of tobacco products by persons under the age set by domestic law, national law or eighteen.

Article 17 Provision of support for economically viable alternative activities
Parties shall, in cooperation with each other and with competent international and regional intergovernmental organizations, promote, as appropriate, economically viable alternatives for tobacco workers, growers and, as the case may be, individual sellers.

PART V: PROTECTION OF THE ENVIRONMENT

Article 18 Protection of the environment and the health of persons
In carrying out their obligations under this Convention, the Parties agree to have due regard to the protection of the environment and the health of persons in relation to the environment in respect of tobacco cultivation and manufacture within their respective territories.

PART VI: QUESTIONS RELATED TO LIABILITY

Article 19 Liability
1. For the purpose of tobacco control, the Parties shall consider taking legislative action or promoting their existing laws, where necessary, to deal with criminal and civil liability, including compensation where appropriate.
2. Parties shall cooperate with each other in exchanging information through the Conference of the Parties in accordance with Article 21 including:
(a) information on the health effects of the consumption of tobacco products and exposure to tobacco smoke in accordance with Article 20.3(a); and
(b) information on legislation and regulations in force as well as pertinent jurisprudence.
3. The Parties shall, as appropriate and mutually agreed, within the limits of national legislation, policies, legal practices and applicable existing treaty arrangements, afford one another assistance in legal proceedings relating to civil and criminal liability consistent with this Convention.
4. The Convention shall in no way affect or limit any rights of access of the Parties to each other's courts where such rights exist.
5. The Conference of the Parties may consider, if possible, at an early stage, taking account of the work being done in relevant international fora, issues related to liability including appropriate international approaches to these issues and appropriate means to support, upon request, the Parties in their legislative and other activities in accordance with this Article.

PART VII: SCIENTIFIC AND TECHNICAL COOPERATION AND COMMUNICATION OF INFORMATION

Article 20 Research, surveillance and exchange of information
1. The Parties undertake to develop and promote national research and to coordinate research programmes at the regional and international levels in the field of tobacco control. Towards this end, each Party shall:
(a) initiate and cooperate in, directly or through competent international and regional intergovernmental organizations and other bodies, the conduct of research and scientific assessments, and in so doing promote and encourage research that addresses the determinants and consequences of tobacco consumption and exposure to tobacco smoke as well as research for identification of alternative crops; and
(b) promote and strengthen, with the support of competent international and regional intergovernmental organizations and other bodies, training and support for all those engaged in tobacco control activities, including research, implementation and evaluation.
2. The Parties shall establish, as appropriate, programmes for national, regional and global surveillance of the magnitude, patterns, determinants and consequences of tobacco consumption and exposure to tobacco smoke. Towards this end, the Parties should integrate tobacco surveillance programmes into national, regional and global health surveillance programmes so that data are comparable and can be analysed at the regional and international levels, as appropriate.
3. Parties recognize the importance of financial and technical assistance from international and regional intergovernmental organizations and other bodies. Each Party shall endeavour to:
(a) establish progressively a national system for the epidemiological surveillance of tobacco consumption and related social, economic and health indicators;
(b) cooperate with competent international and regional intergovernmental organizations and other bodies, including governmental and nongovernmental agencies, in regional and global tobacco surveillance and exchange of information on the indicators specified in paragraph 3(a) of this Article; and
(c) cooperate with the World Health Organization in the development of general guidelines or procedures

for defining the collection, analysis and dissemination of tobacco-related surveillance data.
4. The Parties shall, subject to national law, promote and facilitate the exchange of publicly available scientific, technical, socioeconomic, commercial and legal information, as well as information regarding practices of the tobacco industry and the cultivation of tobacco, which is relevant to this Convention, and in so doing shall take into account and address the special needs of developing country Parties and Parties with economies in transition. Each Party shall endeavour to:
(a) progressively establish and maintain an updated database of laws and regulations on tobacco control and, as appropriate, information about their enforcement, as well as pertinent jurisprudence, and cooperate in the development of programmes for regional and global tobacco control;
(b) progressively establish and maintain updated data from national surveillance programmes in accordance with paragraph 3(a) of this Article; and
(c) cooperate with competent international organizations to progressively establish and maintain a global system to regularly collect and disseminate information on tobacco production, manufacture and the activities of the tobacco industry which have an impact on the Convention or national tobacco control activities.
5. Parties should cooperate in regional and international intergovernmental organizations and financial and development institutions of which they are members, to promote and encourage provision of technical and financial resources to the Secretariat to assist developing country Parties and Parties with economies in transition to meet their commitments on research, surveillance and exchange of information.

Article 21 Reporting and exchange of information
1. Each Party shall submit to the Conference of the Parties, through the Secretariat, periodic reports on its implementation of this Convention, which should include the following:
(a) information on legislative, executive, administrative or other measures taken to implement the Convention;
(b) information, as appropriate, on any constraints or barriers encountered in its implementation of the Convention, and on the measures taken to overcome these barriers;
(c) information, as appropriate, on financial and technical assistance provided or received for tobacco control activities;
(d) information on surveillance and research as specified in Article 20; and
(e) information specified in Articles 6.3, 13.2, 13.3, 13.4(d), 15.5 and 19.2.
2. The frequency and format of such reports by all Parties shall be determined by the Conference of the Parties. Each Party shall make its initial report within two years of the entry into force of the Convention for that Party.
3. The Conference of the Parties, pursuant to Articles 22 and 26, shall consider arrangements to assist developing country Parties and Parties with economies in transition, at their request, in meeting their obligations under this Article.
4. The reporting and exchange of information under the Convention shall be subject to national law regarding confidentiality and privacy. The Parties shall protect, as mutually agreed, any confidential information that is exchanged.

Article 22 Cooperation in the scientific, technical, and legal fields and provision of related expertise
1. The Parties shall cooperate directly or through competent international bodies to strengthen their capacity to fulfill the obligations arising from this Convention, taking into account the needs of developing country Parties and Parties with economies in transition. Such cooperation shall promote the transfer of technical, scientific and legal expertise and technology, as mutually agreed, to establish and strengthen national tobacco control strategies, plans and programmes aiming at, *inter alia*:
(a) facilitation of the development, transfer and acquisition of technology, knowledge, skills, capacity and expertise related to tobacco control;
(b) provision of technical, scientific, legal and other expertise to establish and strengthen national tobacco control strategies, plans and programmes, aiming at implementation of the Convention through, *inter alia*:

(i) assisting, upon request, in the development of a strong legislative foundation as well as technical programmes, including those on prevention of initiation, promotion of cessation and protection from exposure to tobacco smoke;
(ii) assisting, as appropriate, tobacco workers in the development of appropriate economically and legally viable alternative livelihoods in an economically viable manner; and
(iii) assisting, as appropriate, tobacco growers in shifting agricultural production to alternative crops in an economically viable manner;
(c) support for appropriate training or sensitization programmes for appropriate personnel in accordance with Article 12;
(d) provision, as appropriate, of the necessary material, equipment and supplies, as well as logistical support, for tobacco control strategies, plans and programmes;
(e) identification of methods for tobacco control, including comprehensive treatment of nicotine addiction; and
(f) promotion, as appropriate, of research to increase the affordability of comprehensive treatment of nicotine addiction.
2. The Conference of the Parties shall promote and facilitate transfer of technical, scientific and legal expertise and technology with the financial support secured in accordance with Article 26.

PART VIII: INSTITUTIONAL ARRANGEMENTS AND FINANCIAL RESOURCES

Article 23 Conference of the Parties
1. A Conference of the Parties is hereby established. The first session of the Conference shall be convened by the World Health Organization not later than one year after the entry into force of this Convention. The Conference will determine the venue and timing of subsequent regular sessions at its first session.
2. Extraordinary sessions of the Conference of the Parties shall be held at such other times as may be deemed necessary by the Conference, or at the written request of any Party, provided that, within six months of the request being communicated to them by the Secretariat of the Convention, it is supported by at least one-third of the Parties.
3. The Conference of the Parties shall adopt by consensus its Rules of Procedure at its first session.
4. The Conference of the Parties shall by consensus adopt financial rules for itself as well as governing the funding of any subsidiary bodies it may establish as well as financial provisions governing the functioning of the Secretariat. At each ordinary session, it shall adopt a budget for the financial period until the next ordinary session.
5. The Conference of the Parties shall keep under regular review the implementation of the Convention and take the decisions necessary to promote its effective implementation and may adopt protocols, annexes and amendments to the Convention, in accordance with Articles 28, 29 and 33. Towards this end, it shall:
(a) promote and facilitate the exchange of information pursuant to Articles 20 and 21;
(b) promote and guide the development and periodic refinement of comparable methodologies for research and the collection of data, in addition to those provided for in Article 20, relevant to the implementation of the Convention;
(c) promote, as appropriate, the development, implementation and evaluation of strategies, plans, and programmes, as well as policies, legislation and other measures;
(d) consider reports submitted by the Parties in accordance with Article 21 and adopt regular reports on the implementation of the Convention;
(e) promote and facilitate the mobilization of financial resources for the implementation of the Convention in accordance with Article 26;
(f) establish such subsidiary bodies as are necessary to achieve the objective of the Convention;
(g) request, where appropriate, the services and cooperation of, and information provided by, competent and relevant organizations and bodies of the United Nations system and other international and regional intergovernmental organizations and nongovernmental organizations and bodies as a means of strengthening the implementation of the Convention; and

(h) consider other action, as appropriate, for the achievement of the objective of the Convention in the light of experience gained in its implementation.
6. The Conference of the Parties shall establish the criteria for the participation of observers at its proceedings.

Article 24 Secretariat
1. The Conference of the Parties shall designate a permanent secretariat and make arrangements for its functioning. The Conference of the Parties shall endeavour to do so at its first session.
2. Until such time as a permanent secretariat is designated and established, secretariat functions under this Convention shall be provided by the World Health Organization.
3. Secretariat functions shall be:
(a) to make arrangements for sessions of the Conference of the Parties and any subsidiary bodies and to provide them with services as required;
(b) to transmit reports received by it pursuant to the Convention;
(c) to provide support to the Parties, particularly developing country Parties and Parties with economies in transition, on request, in the compilation and communication of information required in accordance with the provisions of the Convention;
(d) to prepare reports on its activities under the Convention under the guidance of the Conference of the Parties and submit them to the Conference of the Parties;
(e) to ensure, under the guidance of the Conference of the Parties, the necessary coordination with the competent international and regional intergovernmental organizations and other bodies;
(f) to enter, under the guidance of the Conference of the Parties, into such administrative or contractual arrangements as may be required for the effective discharge of its functions; and
(g) to perform other secretariat functions specified by the Convention and by any of its protocols and such other functions as may be determined by the Conference of the Parties.

Article 25 Relations between the Conference of the Parties and intergovernmental organizations
In order to provide technical and financial cooperation for achieving the objective of this Convention, the Conference of the Parties may request the cooperation of competent international and regional intergovernmental organizations including financial anddevelopment institutions.

Article 26 Financial resources
1. The Parties recognize the important role that financial resources play in achieving the objective of this Convention.
2. Each Party shall provide financial support in respect of its national activities intended to achieve the objective of the Convention, in accordance with its national plans, priorities and programmes.
3. Parties shall promote, as appropriate, the utilization of bilateral, regional, subregional and other multilateral channels to provide funding for the development and strengthening of multisectoral comprehensive tobacco control programmes of developing country Parties and Parties with economies in transition. Accordingly, economically viable alternatives to tobacco production, including crop diversification should be addressed and supported in the context of nationally developed strategies of sustainable development.
4. Parties represented in relevant regional and international intergovernmental organizations, and financial and development institutions shall encourage these entities to provide financial assistance for developing country Parties and for Parties with economies in transition to assist them in meeting their obligations under the Convention, without limiting the rights of participation within these organizations.
5. The Parties agree that:
(a) to assist Parties in meeting their obligations under the Convention, all relevant potential and existing resources, financial, technical, or otherwise, both public and private that are available for tobacco control activities, should be mobilized and utilized for the benefit of all Parties, especially developing countries and countries with economies in transition;

(b) the Secretariat shall advise developing country Parties and Parties with economies in transition, upon request, on available sources of funding to facilitate the implementation of their obligations under the Convention;
(c) the Conference of the Parties in its first session shall review existing and potential sources and mechanisms of assistance based on a study conducted by the Secretariat and other relevant information, and consider their adequacy; and
(d) the results of this review shall be taken into account by the Conference of the Parties in determining the necessity to enhance existing mechanisms or to establish a voluntary global fund or other appropriate financial mechanisms to channel additional financial resources, as needed, to developing country Parties and Parties witheconomies in transition to assist them in meeting the objectives of the Convention.

PART IX: SETTLEMENT OF DISPUTES

Article 27 Settlement of disputes
1. In the event of a dispute between two or more Parties concerning the interpretation or application of this Convention, the Parties concerned shall seek through diplomatic channels a settlement of the dispute through negotiation or any other peaceful means of their own choice, including good offices, mediation, or conciliation. Failure to reach agreement by good offices, mediation or conciliation shall not absolve parties to the dispute from the responsibility of continuing to seek to resolve it.
2. When ratifying, accepting, approving, formally confirming or acceding to the Convention, or at any time thereafter, a State or regional economic integration organization may declare in writing to the Depositary that, for a dispute not resolved in accordance with paragraph 1 of this Article, it accepts, as compulsory, ad hoc arbitration in accordance with procedures to be adopted by consensus by the Conference of the Parties.
3. The provisions of this Article shall apply with respect to any protocol as between the parties to the protocol, unless otherwise provided therein.

PART X: DEVELOPMENT OF THE CONVENTION

Article 28 Amendments to this Convention
1. Any Party may propose amendments to this Convention. Such amendments will be considered by the Conference of the Parties.
2. Amendments to the Convention shall be adopted by the Conference of the Parties. The text of any proposed amendment to the Convention shall be communicated to the Parties by the Secretariat at least six months before the session at which it is proposed for adoption. The Secretariat shall also communicate proposed amendments to the signatories of the Convention and, for information, to the Depositary.
3. The Parties shall make every effort to reach agreement by consensus on any proposed amendment to the Convention. If all efforts at consensus have been exhausted, and no agreement reached, the amendment shall as a last resort be adopted by a three-quarters majority vote of the Parties present and voting at the session. For purposes of this Article, Parties present and voting means Parties present and casting an affirmative or negative vote. Any adopted amendment shall be communicated by the Secretariat to the Depositary, who shall circulate it to all Parties for acceptance.
4. Instruments of acceptance in respect of an amendment shall be deposited with the Depositary. An amendment adopted in accordance with paragraph 3 of this Article shall enter into force for those Parties having accepted it on the ninetieth day after the date of receipt by the Depositary of an instrument of acceptance by at least two-thirds of the Parties to the Convention.
5. The amendment shall enter into force for any other Party on the ninetieth day after the date on which that Party deposits with the Depositary its instrument of acceptance of the said amendment.

Article 29 Adoption and amendment of annexes to this Convention
1. Annexes to this Convention and amendments thereto shall be proposed, adopted and shall enter into force in accordance with the procedure set forth in Article 28.
2. Annexes to the Convention shall form an integral part thereof and, unless otherwise expressly provided,

a reference to the Convention constitutes at the same time a reference to any annexes thereto.
3. Annexes shall be restricted to lists, forms and any other descriptive material relating to procedural, scientific, technical or administrative matters.

PART XI: FINAL PROVISIONS

Article 30 Reservations
No reservations may be made to this Convention.

Article 31 Withdrawal
1. At any time after two years from the date on which this Convention has entered into force for a Party, that Party may withdraw from the Convention by giving written notification to the Depositary.
2. Any such withdrawal shall take effect upon expiry of one year from the date of receipt by the Depositary of the notification of withdrawal, or on such later date as may be specified in the notification of withdrawal.
3. Any Party that withdraws from the Convention shall be considered as also having withdrawn from any protocol to which it is a Party.

Article 32 Right to vote
1. Each Party to this Convention shall have one vote, except as provided for in paragraph 2 of this Article.
2. Regional economic integration organizations, in matters within their competence, shall exercise their right to vote with a number of votes equal to the number of their Member States that are Parties to the Convention. Such an organization shall not exercise its right to vote if any of its Member States exercises its right, and vice versa.

Article 33 Protocols
1. Any Party may propose protocols. Such proposals will be considered by the Conference of the Parties.
2. The Conference of the Parties may adopt protocols to this Convention. In adopting these protocols every effort shall be made to reach consensus. If all efforts at consensus have been exhausted, and no agreement reached, the protocol shall as a last resort be adopted by a three-quarters majority vote of the Parties present and voting at the session. For the purposes of this Article, Parties present and voting means Parties present and casting an affirmative or negative vote.
3. The text of any proposed protocol shall be communicated to the Parties by the Secretariat at least six months before the session at which it is proposed for adoption.
4. Only Parties to the Convention may be parties to a protocol.
5. Any protocol to the Convention shall be binding only on the parties to the protocol in question. Only Parties to a protocol may take decisions on matters exclusively relating to the protocol in question.
6. The requirements for entry into force of any protocol shall be established by that instrument.

Article 34 Signature
This Convention shall be open for signature by all Members of the World Health Organization and by any States that are not Members of the World Health Organization but are members of the United Nations and by regional economic integration organizations at the World Health Organization headquarters in Geneva from 16 June 2003 to 22 June 2003, and thereafter at United Nations Headquarters in New York, from 30 June 2003 to 29 June 2004.

Article 35 Ratification, acceptance, approval, formal confirmation or accession
1. This Convention shall be subject to ratification, acceptance, approval or accession by States and to formal confirmation or accession by regional economic integration organizations. It shall be open for accession from the day after the date on which the Convention is closed for signature. Instruments of ratification, acceptance, approval, formal confirmation or accession shall be deposited with the Depositary.
2. Any regional economic integration organization which becomes a Party to the Convention without any of its Member States being a Party shall be bound by all the obligations under the Convention. In the case

of those organizations, one or more of whose Member States is a Party to the Convention, the organization and its Member States shall decide on their respective responsibilities for the performance of their obligations under the Convention. In such cases, the organization and the Member States shall not be entitled to exercise rights under the Convention concurrently.
3. Regional economic integration organizations shall, in their instruments relating to formal confirmation or in their instruments of accession, declare the extent of their competence with respect to the matters governed by the Convention. These organizations shall also inform the Depositary, who shall in turn inform the Parties, of any substantial modification in the extent of their competence.

Article 36 Entry into force
1. This Convention shall enter into force on the ninetieth day following the date of deposit of the fortieth instrument of ratification, acceptance, approval, formal confirmation or accession with the Depositary.
2. For each State that ratifies, accepts or approves the Convention or accedes thereto after the conditions set out in paragraph 1 of this Article for entry into force have been fulfilled, the Convention shall enter into force on the ninetieth day following the date of deposit of its instrument of ratification, acceptance, approval or accession.
3. For each regional economic integration organization depositing an instrument of formal confirmation or an instrument of accession after the conditions set out in paragraph 1 of this Article for entry into force have been fulfilled, the Convention shall enter into force on the ninetieth day following the date of its depositing of the instrument of formal confirmation or of accession.
4. For the purposes of this Article, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by States Members of the organization.

Article 37 Depositary
The Secretary-General of the United Nations shall be the Depositary of this Convention and amendments thereto and of protocols and annexes adopted in accordance with Articles 28, 29 and 33.

Article 38 Authentic texts
The original of this Convention, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations. IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Convention. DONE at GENEVA this twenty-first day of May two thousand and three.