

ARRANGEMENT OF SECTIONS

Section

PART ONE—COMMUNICABLE DISEASES

1. Application of this Part to other diseases
2. Declaration of infected area, order for evacuation
3. Stopping of vehicles
4. Sales within an infected area
5. Post mortem examination
6. Marking
7. Disinfection
8. Destruction of buildings
9. Destruction of animals
10. Removal and detention of infected persons or disposal of corpse
11. Isolation of contacts
12. Compensation Board
13. Time for bringing claims
14. Presumption of knowledge of disease
15. Penalty
16. Regulations
17. Regulations as to diseases of a communicable nature
18. Non-communicable diseases
19. Interpretation

PART TWO—VACCINATION

20. Public vaccinators
21. Public vaccination
22. Compulsory vaccination
23. Vaccination of adults
24. Vaccination of children
25. Power of entry for vaccination
26. Examination and vaccination at point of entry
27. Notification of arrival of immigrant
28. Certificate of vaccination
29. Prohibition of the practice of inoculation
30. Penalties
31. Regulations by the Minister
32. Interpretation
33. Savings in respect of certificates of medical practitioners

PART THREE —QUARANTINE

34. Declaration of place as quarantine area
35. Appointment of officers
36. Provision of sanitary stations, anchorages
37. Penalty
38. Regulations in respect of disease
39. Legal proceedings

PART FOUR —VECTOR CONTROL

40. Destruction of vectors including mosquitoes
41. Protection of water receptacles
42. Recovery of cost
43. Method of recovery
44. Penalty for refusal to comply with an order and obstruction
45. Penalty for breach
46. Payments to local authority
47. Regulations
48. Application of this Part to vessels
49. Interpretation

PART FIVE— ENVIRONMENTAL SANITATION

50. Hindering disposal of dead body
51. Sale or serving of unwholesome food
52. Sale of food under insanitary conditions
53. Food unfit for consumption
54. Prohibition of business in noxious or offensive trade
55. Explanation as to carrying on of noxious trade
56. Public nuisance
57. Arrest of offenders

PART SIX—TOBACCO CONTROL MEASURES

Tobacco control measures

58. Prohibition of smoking in public places
59. Advertising in relation to tobacco and tobacco products
60. Tobacco sponsorship

61. Promotion of tobacco and tobacco products
62. Packaging and labelling
63. Health warning on package
64. Point of sale health warning
65. Minimum age restrictions
66. Public education against tobacco use
67. Treatment of tobacco addiction
68. Sale of tobacco products

Administrative and miscellaneous provisions

69. Appointment of inspectors and analysts
70. Functions of an inspector or analyst
71. Powers of an inspector or analyst
72. Obstruction of inspector or analyst
73. Testing of tobacco and tobacco products
74. Power of the Authority to prosecute
75. Collaboration with relevant bodies
76. Regulations
77. Offences
78. Interpretation
79. Transitional provisions

PART SEVEN—FOOD AND DRUGS

Food and Drugs Authority

80. Establishment of Food and Drugs Authority
81. Object of the Authority
82. Functions of the Authority
83. Governing body of the Authority
84. Tenure of office of members
85. Meetings of the Board
86. Disclosure of interest
87. Establishment of committees
88. Allowances
89. Appointment of Chief Executive Officer
90. Functions of the Chief Executive Officer
91. Divisions of the Authority

Act 851

Public Health Act, 2012

- 92. Appointment of Deputy Chief Executive Officers
- 93. Appointment of other staff

Financial provisions

- 94. Funds of the Authority
- 95. Accounts and audit
- 96. Annual report and other reports

Foods

- 97. Registration of food
- 98. Cancellation or suspension of registration
- 99. Importation and exportation of food
- 100. Prohibited acts
- 101. Food for sale to meet prescribed standards
- 102. Food offered as a prize, reward or donation
- 103. Deception of consumers
- 104. Standards for food
- 105. Prohibition against sale of poor quality food
- 106. Manufacture of food under supervision
- 107. Mandatory fortification of food
- 108. Regulation of slaughter houses
- 109. Transportation of meat for sale
- 110. Penalty and defence

*Drugs, herbal medicinal products, cosmetics, medical devices
and household chemical substances*

- 111. Prohibited sale of drugs, herbal medicinal products, cosmetics, medical devices and other household chemical substances
- 112. Standards
- 113. Deception of consumers
- 114. Prohibited advertisement
- 115. Control of manufacturing
- 116. Restriction on importation and manufacture
- 117. Application for registration
- 118. Registration of drugs, herbal medicinal products, medical devices or household chemical substances

- 119. Cancellation or suspension of registration
- 120. Certificate on imported drugs
- 121. Drugs not to be distributed as samples
- 122. Importation of drugs and other products.
- 123. Counterfeit drugs, herbal medicinal products, medical devices and household chemical substances
- 124. Registration of homoeopathic drugs
- 125. Safety monitoring
- 126. Regulation of narcotic and psychotropic substances
- 127. Food and Drugs Laboratory
- 128. Registers
- 129. Penalties

General provisions

- 130. Registration of premises
- 131. Licences and permits
- 132. Closure of premises and safe disposal of unwholesome regulated products
- 133. Reporting of certain diseases
- 134. Notification of food borne diseases
- 135. Powers of authorised officers
- 136. Forfeiture and disposal of seized articles
- 137. Public analysts
- 138. Quarterly reports of analyst
- 139. Power of Authority to obtain particulars of certain ingredients
- 140. Power of Authority to prosecute
- 141. Power of Court to suspend or cancel licence
- 142. Penalties
- 143. Certificate of analysis and presumptions
- 144. Presumption as to adulteration
- 145. Defence in proceedings for sale of food
- 146. Compensation
- 147. Regulations
- 148. Guidelines and Codes of practice
- 149. Interpretation

PART EIGHT—CLINICAL TRIALS

- 150. Establishment of the Clinical Trials Technical Advisory Committee
- 151. Objects of the Committee
- 152. Functions of the Committee
- 153. Composition of the Committee
- 154. Application of provisions
- 155. Clinical trials
- 156. Authority to investigate
- 157. Conditions to conduct clinical trials
- 158. Informed consent for clinical trials
- 159. Supply of information prior to clinical trial
- 160. Powers to stop or suspend clinical trials
- 161. Monitoring of clinical trials
- 162. Reports on clinical trials
- 163. Renewal of clinical trial certificate
- 164. Application of clinical trial provisions
- 165. Penalty
- 166. Interpretation

PART NINE—MISCELLANEOUS PROVISIONS

- 167. Patient's Charter
- 168. International Health Regulations
- 169. Declaration of public health emergency
- 170. Emergency powers in respect of public health matters
- 171. Health information, reporting and notification
- 172. Immunity and Indemnity
- 173. Collaboration
- 174. Application
- 175. Repeals and savings

SCHEDULES

FIRST SCHEDULE

Certificate of vaccination

SECOND SCHEDULE

Messages(Rotational) to be printed on tobacco packs

THIRD SCHEDULE

World Health Organisation WHO Framework Convention on Tobacco Control

FOURTH SCHEDULE

List of publication for standards for drugs

FIFTH SCHEDULE

Diseases for which advertisement for treatment, prevention or cure are prohibited

SIXTH SCHEDULE

Patient's Charter

SEVENTH SCHEDULE

World Health Organization Regulations

Act 851



THE EIGHTH HUNDRED AND FIFTY-ONE

ACT

OF THE PARLIAMENT OF THE REPUBLIC OF GHANA
ENTITLED

PUBLIC HEALTH ACT, 2012

AN ACT to revise and consolidate the law relating to public health to prevent disease, promote, safeguard, maintain and protect the health of humans and animals and to provide for related matters.

DATE OF ASSENT: 9th October, 2012.

PASSED by Parliament and assented to by the President:

PART ONE—COMMUNICABLE DISEASES

Application of this Part to other diseases

1. (1) The Minister shall, by executive instrument, declare that a disease is communicable, infectious or contagious in nature.

(2) Where an instrument is published declaring a disease as communicable, infectious or contagious the provisions of this Part shall apply.

(3) For the purposes of this Part, and of any other enactment, "communicable disease" includes a disease of a communicable, infectious or contagious nature which is declared by the Minister as a communicable disease.

Declaration of infected area, order for evacuation

2. (1) The Minister

(a) shall, by executive instrument, declare a clearly defined area in which a communicable disease has occurred as an infected area, and

(b) may by the same or a subsequent instrument order the evacuation of the whole or a part of the infected area.

(2) The order for evacuation may apply to all persons or to a person or a class of persons specified in the instrument.

(3) A person shall not reside, enter or carry on business within an infected area or a part of an infected area in contravention of an order for evacuation, except under an order in writing to that effect signed by a medical officer and on the conditions specified by the medical officer.

(4) Subsection (3) does not apply to a person passing along a thoroughfare which is allowed to remain open to the public.

(5) A person who contravenes subsection (3) commits an offence and is liable,

(a) for a first offence, to a fine of not more than fifty penalty units or to a term of imprisonment of not more than three months, or to both; and

(b) for a second or subsequent offence, to a term of imprisonment of not more than six months, or to both the fine and the imprisonment.

Stopping of vehicles

3. (1) A medical officer, a veterinary officer, an environmental health officer, a police officer, or any other person designated by the Minister, may for the purpose of medical examination,

(a) stop a vehicle travelling in, or suspected to be travelling in or travelling to or from an infected area, and

(b) detain any of the persons travelling or being conveyed in or on the vehicle.

(2) A person suffering or suspected to be suffering from a communicable disease, or a corpse, or an article suspected to be capable of spreading infection may be removed from the vehicle and dealt with as prescribed by the Regulations made by the Minister.

(3) The driver of a vehicle who refuses or fails to stop when asked to do so by any of the persons mentioned in subsection (1), commits an offence and is liable on summary conviction to a fine of not more than fifty penalty units or to a term of imprisonment of not more than three months, or to both.

Sales within an infected area

4. (1) A person licensed to sell in a store situated in an infected area or a part of an infected area which is included in an order for evacuation, is entitled

- (a) to a transfer of the licence to a store situated in a place to which the order for evacuation does not extend, and
- (b) to a refund of the whole or a part of the fee paid for the licence, or as may be awarded by a Compensation Board established under section 12.

(2) Subsection (1) applies to a food vendor or a person who sells water or beverages.

Post mortem examination

5. Where a medical officer, a veterinary officer or an authorised health officer suspects that a person has died of a communicable disease whether in an infected area or not, the medical officer, veterinary officer or the authorised health officer shall order that the body of the deceased person be conveyed to a specified place for an examination that the medical officer, veterinary officer or the authorised health officer considers necessary.

Marking

6. (1) A medical officer, veterinary officer or any other authorised health officer may place, or cause to be placed, on a house, structure or at an area where a case of a communicable disease has occurred, whether in an infected area or not, a marking denoting the occurrence of the disease as prescribed by Regulations.

(2) The mark shall be kept affixed for a period that the medical officer or veterinary officer or any other authorised health officer considers necessary.

(3) A person who unlawfully removes or obliterates the mark commits an offence and is liable on summary conviction to a fine of not more than one hundred penalty units or to a term of imprisonment of not more than six months or to both.

Disinfection

7. A medical officer, veterinary officer or an authorised health officer may order the disinfection

- (a) of a house, structure or an area in which a case or suspected case of a communicable disease has occurred, whether in an infected area or not, and
- (b) of property belonging to a person residing or being in that house, structure or area.

Destruction of buildings

8. (1) A District Assembly shall by an order of the Court cause the destruction of a house or structure whether in an infected area or not, where a case of a communicable disease has occurred and of anything in that house or building, or elsewhere which a medical officer, veterinary officer or an authorised health officer considers necessary in the interest of public health.

(2) The order shall be carried out in the manner and by the person directed by the District Assembly.

(3) A claim for compensation in respect of the destruction of a house, building, or any other thing under this section shall be determined by a Compensation Board.

Destruction of animals

9. (1) A veterinary officer, or an authorised health officer may order the destruction of an animal whether or not the animal is in an infected area if the officer is satisfied that the animal is likely to be an agent in the transmission of a communicable disease.

(2) A veterinary officer, or an authorised health officer may dispose of the carcass of an animal destroyed in the manner specified by the officer.

(3) A claim for compensation for an animal destroyed shall be determined by the Compensation Board.

Removal and detention of infected persons or disposal of corpse

10. (1) A medical officer or an authorised health officer may

- (a) cause a person suffering or suspected to be suffering from a communicable disease, whether in an infected area or not, to be removed to a health facility or designated place; and
- (b) detain that person until the medical officer or health officer determines that that person is safe to be discharged.

- (2) A medical officer or an authorised health officer may
- (a) determine the manner in which the remains of a deceased person is to be disposed of; or
 - (b) authorise the disposal of the remains of a deceased person in a specified manner

whether or not the deceased person is in an infected area if the medical officer or authorised health officer is satisfied or has reason to believe that the remains of the deceased person is likely to be an agent in the transmission of a communicable disease.

Isolation of contacts

11. (1) A medical officer may order a person living in the same house or compound, or a person who has come into contact with another person suffering or suspected to be suffering from a communicable disease, whether in an infected area or not, to be isolated in a designated place provided by the Government until that person is considered safe to be discharged.

(2) A person authorised by the medical officer to carry out an order under subsection (1) may use reasonable force to compel that person to obey the order.

Compensation Board

12. (1) The District Chief Executive shall establish a Compensation Board when necessary.

(2) The Compensation Board shall hear and determine claims for a refund of sales licence fees under section 4 and damages or compensation for destruction of property under sections 8 and 9 or a provision of the Regulations and a similar claim in respect of measures taken before the commencement of this Act.

(3) The Compensation Board shall consist of five persons including a public officer, a real estate valuer, a legal practitioner and a person who is not a public officer.

(4) The members of the Board are entitled to allowances determined by the District Chief Executive.

(5) In appointing a Compensation Board, the District Chief Executive shall

- (a) define the local limits of the jurisdiction of the board; and
- (b) appoint a secretary to the board;

and where a person appointed is unable or unwilling to act or dies, the District Chief Executive may appoint another person as a member.

(6) An appointment made under this section shall be published within seven days in the *Gazette*.

(7) A compensation board shall have the powers of the High Court to summon witnesses, and to call for the production of books, plans or documents, and to examine witnesses and parties on oath.

(8) A person summoned to attend and give evidence or to produce books, plans or documents

- (a) shall obey the summons served on that person in the same manner as a witness is bound to obey subpoenas from the High Court, and
- (b) is entitled to the same expenses as a witness summoned to attend the High Court on a criminal trial, but the Board may disallow the whole or a part of the expenses.

(9) Where the members of a Compensation Board are equally divided, the matter shall be referred to a Justice of the High Court, whose decision becomes the award of the Board.

(10) The award of the Compensation Board shall be in writing signed by the members or by the Justice and the amount awarded shall be paid out of the Consolidated Fund.

(11) For the purposes of the Courts Act, 1993 (Act 459), a Compensation Board is an inferior Court and is subject to the supervisory jurisdiction of the High Court.

Time for bringing claims

13. (1) A person may make a claim for damages or compensation within three months after the occurrence of any of the matters specified in section 12(2).

(2) Without limiting section 12(1) the District Chief Executive shall establish a Compensation Board within three months after a claim for damages or compensation has been made.

(3) The Compensation Board shall determine a claim brought before it within three months of receipt of the claim.

(4) A claim may be sent in the first instance to the Minister who shall refer the claim to the relevant District Chief Executive who shall establish the Compensation Board.

(5) A claim shall not be entertained unless notice has been received by the Compensation Board or the Minister within the time specified in subsection (1).

(6) A Compensation Board shall inform a claimant of its decision within fourteen days after the determination of the matter.

Presumption of knowledge of disease

14. (1) A person in charge of, or attending to, or living with a person or animal suffering from a communicable disease and has reasonable cause to believe that that person or animal is suffering from a communicable disease shall report to the appropriate health authority of the existence of the disease in that person or animal.

(2) Subsection (1) does not apply where it is proved to the satisfaction of a Magistrate that that person did not have that knowledge and could not with reasonable diligence have obtained that knowledge.

Penalty

15. A person who, without lawful authority or excuse, the proof of which lies on that person,

- (a) contravenes a provision of this Part for which a punishment is not provided, or does anything which, under this Part or under the Regulations that person ought not to do, or
- (b) obstructs or impedes or aids or incites any other person to obstruct or impede a medical officer, veterinary officer, police officer, health officer, or any other person lawfully acting in the execution of a provision of this Part,

commits an offence and is liable on summary conviction to a fine of not more than fifty penalty units or to a term of imprisonment of not more than three months, or to both.

Regulations

16. The Minister may, by legislative instrument, make Regulations

- (a) prescribing the mode of burial or disposal of the body of a person who dies from a communicable disease;

- (b)* for the purposes of establishing a cordon around an infected house, structure or area or part of an infected area where a communicable disease has occurred or is suspected to have occurred, or for preventing persons departing from or going to that area or that part;
- (c)* for the purposes of prohibiting building on, or habitation of, or tillage of or any other usage of the soil in an area, or in a part of the area in which a communicable disease has occurred, or in which the body of a person who has died of a communicable disease, or is suspected to have died of a communicable disease, has been buried, disposed of or destroyed;
- (d)* for closing, destroying, disinfecting, cleaning, or otherwise rendering harmless the houses, buildings, places of convenience, wells, cesspits, dustbins, dumping grounds, and places deemed to be injurious or dangerous to public health;
- (e)* for the removal of persons from an infected area the evacuation of which has been ordered by the Minister;
- (f)* prescribing the form and mode of service or delivery of a notice and any other document under this Part;
- (g)* for isolating persons suffering or suspected to be suffering from a communicable disease, or brought into contact with a person suffering or suspected to be suffering from a communicable disease;
- (h)* for the appointment of inspectors and any other officers necessary for the performance of their functions under this Part;
- (i)* prescribing the procedure to be observed in the proceedings of the Compensation Board, the content of the form for summoning witnesses and any other documents to be used in connection with those proceedings;
- (j)* for preventing, in a place where a communicable disease exists or is suspected to exist, the holding of a public meeting, the performance of a recreational activity, funeral or any other customary activity likely to spread the communicable disease;
- (k)* for the publication of an order within an infected area in an appropriate manner;
- (l)* for the disposal or destruction of refuse or sewage;

- (m) for the purpose of prohibiting the removal of property from an infected house, structure or area;
- (n) prescribing the reporting of cases of sickness or deaths;
- (o) for the erection of temporary shelter, structure, mortuary and similar facilities;
- (p) for inspecting and granting a health certificate to a person travelling from a place where a communicable disease has occurred and for disinfecting the clothing and personal effects of that person;
- (q) for the destruction or disposal of rats, bats, mice, cockroaches and any other kind of vermin, and of mosquitoes and other insects and for the closing of holes made by rats and mice and for the rendering of floors, houses and structure vermin-proof;
- (r) for marking of a house, structure or an area in which a communicable disease has occurred;
- (s) prescribing the mode of the destruction or disposal of the carcass of an animal which dies from a communicable disease; and
- (t) generally for carrying into effect the provisions of this Part.

Regulations as to diseases of a communicable nature

17. The Minister may, by legislative instrument, make Regulations for the control of a disease of a communicable nature and in particular with respect to

- (a) the conditions precedent to the compulsory removal to a health facility, sanatorium, or any other suitable place, of a persons or animal suffering from that disease;
- (b) the detection, investigation, notification and reporting by the appropriate health authority of cases of that disease,
- (c) the supply of medical, veterinary and any other assistance and facilities for the treatment of a person or animal suffering from, and for the detection of, that disease;
- (d) the establishment of the appropriate facility for the proper management of a communicable disease by the responsible authority;
- (e) the appropriate measures to be taken by an infected person or owner of an infected animal to prevent the spread of a communicable disease; and
- (f) any other matters related to a communicable disease.

Non-communicable diseases

18. The Ministry of Health, the Veterinary Services Department and other relevant organisations shall educate the public on non-communicable diseases and provide facilities for screening, early detection and management of non-communicable diseases and for the promotion of public health.

Interpretation

19. In this Part, unless the context otherwise requires,

“animal” includes cattle, sheep, goats, rabbits and any other ruminating domestic animal, horses, mules, asses, swine, dogs, cats, monkeys, captured wild reptiles fish, rodents, mammals, birds, ostrich and poultry comprising domestic fowls, ducks, geese, pigeons, guinea fowl and the eggs of poultry;

“authorised health officer” means a person authorised by the Minister to perform a function under this Part;

“communicable disease” means an illness caused by a specific infectious agent or its toxic products which arises through transmission of that agent or its products from an infected person, animal, or inanimate reservoir to a susceptible host, either directly or indirectly through an intermediate plant or animal host, vector, or the inanimate environment;

“Compensation Board” means a Board established under section 12;

“disease of a contagious nature” means a communicable disease transmissible by physical contact with a person suffering from the disease or with their secretions or objects touched by them;

“environmental health officer” means a health professional who is involved in health promotion, education and who controls activities that have adverse consequences on the environment, public health and safety;

“food vendor” means a person who sells food to the public;

“infectious disease” means a clinically evident illness resulting from the presence of disease causing agents liable to spread

quickly;

“medical officer” means a dental or medical practitioner registered under the appropriate law;

“Minister” means the Minister responsible for Health;

“non-communicable diseases” include cancers, diabetes, cardiovascular diseases, hypertension, malnutrition, obesity, conditions arising from road traffic accidents, environmental and work place hazards;

“police officer “ means a member of the Police Service;

“property” means any material possession including animals;

“Regulations” means the Regulations made under this Part;

“sanatorium” means a convalescent home; and

“vermin” means various small animals or insects, such as mice, or cockroches that are destructiive, annoying or injurious to health

PART TWO—VACCINATION

Public vaccinators

20. (1) For the purposes of this Part, a medical or veterinary officer in any of the public services is a public vaccinator.

(2) The Minister may appoint any other registered medical or veterinary practitioner and any other person certified by a Senior Medical or Veterinary Officer to have the necessary competence, skill and knowledge to be an assistant public vaccinator.

(3) An assistant public vaccinator shall perform the functions of a public vaccinator in accordance with the Regulations made under this Part.

Public vaccination

21. (1) A public vaccinator shall vaccinate, free of charge, persons who present themselves or are presented for the purpose, or persons who are or become liable to be vaccinated.

(2) Subsection (1) does not apply where, vaccination would be injurious to health, or where there is satisfactory evidence that a person is already successfully vaccinated or otherwise has natural immunity to the disease.

Compulsory vaccination

22. (1) The Minister may by executive instrument, generally or with reference to a particular district, area, or place or with respect to a particular class or classes of persons, order the persons to whom the instrument applies who do not produce satisfactory evidence of successful vaccination, to be vaccinated by a public vaccinator, unless in the opinion of the public vaccinator the vaccination would be injurious to health.

(2) The instrument may prescribe at what age a person is liable to a penalty for non-compliance with the terms of the instrument and who is liable where the person who fails to be vaccinated has not attained that age.

(3) An instrument under this section may be made subject to the appropriate qualifications and exceptions, and sections 23, 24 and 25 shall be read subject to those qualifications and exceptions.

Vaccination of adults

23. An adult to whom an instrument made under section 31 applies shall

- (a) attend for examination and if necessary, for vaccination, within the period and at the time and place appointed by the Regulations made under section 31, and
- (b) subsequently attend at the times and at the place that the public vaccinator may direct for the purpose of examination as to whether or not the vaccination has been successful, and if necessary, for re-vaccination.

Vaccination of children

24. The parents of a child to whom an instrument made under section 22 applies shall

- (a) within the stipulated time after the birth of the child, within the period appointed under section 23 bring the child to a public vaccinator at the time and place appointed for examination and if necessary for vaccination, and
- (b) subsequently produce the child at the times and places that the public vaccinator shall direct, for the purpose of examination as to whether or not the vaccination has been successful, and if necessary, for re-vaccination.

Power of entry for vaccination

25. (1) A public vaccinator may

- (a) enter a house, a yard or compound or a building or structure in an area prescribed by the instrument and inspect a person found in that place on any day, or as agreed between the public vaccinator and the community leaders between the hours of six in the morning and six in the evening, and
- (b) vaccinate that person unless satisfied that that person is already successfully vaccinated or otherwise has natural immunity to the disease, or unless the vaccination would be injurious to health.

(2) Subsection (1) does not apply during an epidemic.

Examination and vaccination at point of entry

26. A public vaccinator may examine and vaccinate a person who arrives in the country but cannot produce satisfactory evidence of successful vaccination.

Notification of arrival of immigrant

27. (1) An employer of an immigrant in Ghana shall give notice of the arrival and the place of entry of the immigrant to the appropriate authority before the entry of the immigrant.

(2) The notice of arrival of the immigrant shall include the necessary public health documentation as determined by the Minister in an executive instrument.

Certificate of vaccination

28. A public vaccinator who has vaccinated an adult or a child, and has ascertained that the vaccination has been successful, shall record the vaccination in the appropriate form and shall issue a certificate in the Form set out in the First Schedule where an application for the certificate is made by the adult or the parent of the child.

Prohibition of the practice of inoculation

29. (1) The practice of inoculation is unlawful.

(2) A person who engages in an inoculation practice, or is present at the performance of an operation of inoculation, commits an offence and is liable on summary conviction to a fine of not more than two hundred penalty units or to a term of imprisonment of not more than six months or to both.

Penalties

30. A person who

- (a) fails to comply with a provision of this Part, or a legislative instrument made under this Part,
- (b) deceives or misleads by a false statement or otherwise in respect of a provision of this Part, or
- (c) obstructs a public vaccinator in the performance of functions,

commits an offence and is liable on summary conviction to a fine of not more than fifty penalty units or to a term of imprisonment of not more than three months or to both and when the obstruction continues after conviction, to a fine of not more than ten penalty units for each day during which the failure continues.

Regulations by the Minister

31. The Minister may by legislative instrument, make Regulations to provide for

- (a) the times and places of attendance for the purposes of vaccination;
- (b) the evidence of attendance for the purposes of vaccination;
- (c) the supply of vaccines to public vaccinators;
- (d) the methods of vaccination by public vaccinators;
- (e) the follow-up of persons for adverse reaction and the appropriate management;
- (f) the functions of assistant public vaccinators and the limitations and conditions under which those functions are to be performed;
- (g) the payment of fees under this Part; and
- (h) any other matters necessary for the purpose of vaccination.

Interpretation

32. In this Part, unless the context otherwise requires,

- “child” means a person who is under eighteen years of age;
- “inoculation” means to treat a person or animal with a small quantity of the agent of a disease in the form of a vaccine or serum usually by scarification to provide immunity against the disease;
- “Minister” means the Minister responsible for Health;
- “parent” includes the father or mother of a child, and a person who cares for or has custody of a child;
- “prescribed area” means a district, an area, or a place in respect of which an order made under section 22 is in force;
- “public health documentation” means records on the relevant medical examinations, treatments and vaccinations required of an immigrant;
- “Regulations” means Regulations made under this Part; and
- “successful vaccination” means vaccination which is sufficient to protect against the relevant disease.

Savings in respect of certificates of medical practitioners

33. Subject to this Part, a public vaccinator shall not vaccinate a person who produces to the public vaccinator,

- (a) a certificate signed by a registered medical practitioner to the effect that the person named has within the preceding seven years been successfully vaccinated, or

- (b) a certificate signed within the preceding four months by that medical practitioner to the effect that the person named in the certificate is medically unfit to undergo vaccination.

PART THREE—QUARANTINE

Declaration of place as quarantine area

34. The Minister responsible for Health may, by executive instrument,
- (a) declare a place to be an area for purposes of quarantine within the meaning of Regulations made under section 38.
 - (b) provide for any matter necessary for the purpose of quarantine.

Appointment of officers

35. The Minister may, by executive instrument, appoint persons to be officers to enforce and carry out the provisions of this Part.

Provision of sanitary stations, anchorages

36. (1) A District Assembly shall provide appropriate equipment, houses, structures and sanitary stations for the purposes of this Part.
- (2) The Minister may by executive instrument declare an area as a sanitary station or sanitary anchorage for the purposes of this Part.

Penalty

37. A person who contravenes a provision of a legislative instrument or an executive instrument made under this Part commits an offence and is liable on summary conviction to a fine of not more than two hundred penalty units or to a term of imprisonment of not more than one year or to both.

Regulations in respect of disease

38. (1) The Minister may, by legislative instrument, make Regulations for the purpose of preventing the introduction of a disease into the country from an infected place, or for the purpose of preventing the transmission of a disease from the country into any other country or from one part of the country to another.
- (2) The Regulations shall apply to the whole of the country or to a part specified in the Regulations.
- (3) The Regulations may prescribe the person responsible for the payment of expenses for carrying out a provision of the Regulations or of an instrument made under this Part.

Legal proceedings

39. Proceedings for recovering a penalty or imposing a term of imprisonment for the breach of or for recovering the expenses incurred, or charged by the Government in carrying out a provision of a legislative instrument or an executive instrument made under this Part may be commenced before a Magistrate.

PART FOUR—VECTOR CONTROL

Destruction of vectors including mosquitoes

40. (1) A District Assembly shall whenever necessary establish a vector control team for the purpose of the control of vectors of public health importance in the District.

(2) A vector control team includes

- (a) a medical officer;
- (b) a veterinary officer; and
- (c) an environmental health officer.

(3) A vector control team shall be part of the sub-committee responsible for health in the District.

(4) The team may

- (a) enter any premises between the hours of six in the morning and six in the evening for the purposes of vector control; and
- (b) take immediate steps or order the owner of the premises to take the necessary action to destroy vectors including mosquitoes found on the premises and render the habitat permanently unfit for the breeding of the vectors.

Protection of water receptacles

41. (1) An owner of premises or a person in occupation of premises shall not

- (a) allow on the premises the presence of a receptacle for water containing mosquito larvae, or water to be kept uncovered in a receptacle that has not been emptied and cleaned to the satisfaction of the sanitary authority;
- (b) allow on the premises a preventable condition which may be favourable to the breeding of mosquitoes and other vectors.

(2) Subsection (1) does not apply where the receptacle is properly protected to the satisfaction of the sanitary authority from access to mosquitoes or other vector.

Recovery of cost

42. A District Assembly shall recover from the owner of premises the expenses incurred in carrying out measures in respect of premises under this Part.

Method of recovery

43. Where an owner of premises fails or refuses to pay expenses incurred by the sanitary authority in carrying out a provision of this Part the sanitary authority shall recover the incurred expenses in a summary manner before a District Magistrate.

Penalty for refusal to comply with an order and obstruction

44. A person who

- (a) refuses to comply with an order made under this Part or under a provision of the Regulations or
- (b) obstructs an officer empowered to carry out a provision of this Part or an act authorised by this Part or the Regulations

commits an offence and is liable on summary conviction to a fine of not more than one hundred penalty units or to a term of imprisonment of not more than six months or to both.

Penalty for breach

45. (1) A person who contravenes section 41 commits an offence and is liable on summary conviction to a fine of not more than twenty penalty units or to a term of imprisonment of not more than one month.

(2) In the case of an offence continuing for a period exceeding one day after due notice has been given, the offence is punishable as if a fresh contravention of the law had taken place during each day of its continuance.

Payments to local authority

46. (1) The amounts of money recovered under this Part shall be paid to the District Assembly of the place where the offence was committed.

(2) The amount of moneys recovered shall in addition to other resources provided by the District Assembly be used for public health management in the District.

Regulations

47. The Minister may, by legislative instrument, make Regulations for the effective implementation of the provisions of this Part.

Application of this Part to vessels

48. This Part applies to vessels in the same manner as it applies to premises, with the modifications that are appropriate and necessary.

Interpretation

49. In this Part, unless the context otherwise requires,
- “environmental health officer” means a health professional who is involved in health promotion, education and controls activities that have negative consequences on the environment, public health and safety;
 - “medical officer” means a medical officer registered under the relevant law;
 - “Minister” means the Minister responsible for Health;
 - “owner” includes an occupier, and in respect of
 - (a) premises, the person receiving the rent of the premises in connection with which the word is used, whether personally or who would receive the rent if the premises were let to a tenant;
 - (b) a vessel, the person in actual or constructive possession of the vessel;
 - “premises” includes messuages, buildings, lands, easements, and hereditaments of any tenure, whether open or closed, whether built on or not, whether maintained or not under a statutory authority;
 - “sanitary authority” includes a District Assembly, a Metropolitan Assembly, a Municipal Assembly or a committee of the Assembly, and any other local government authority;
 - “vector” means an intermediate host of a disease causing agent; and
 - “vessel” includes any vehicle whether motorised or not, an aircraft, a ship, tug boat, lighter boat, boat, barge, canoe or other floating craft used or capable of being used for transport.

PART FIVE—ENVIRONMENTAL SANITATION

Hindering disposal of dead body

50. (1) A person commits an offence if that person
- (a) unlawfully hinders the disposal of a dead body, or
 - (b) without lawful authority disinters, dissects or mutilates a dead body, or
 - (c) being under a duty to cause a dead body to be disposed of, fails to discharge that duty.

(2) A person who contravenes subsection (1) is liable on summary conviction to a fine of not more than fifty penalty units or to a term of imprisonment of not more than three months.

Sale or serving of unwholesome food

51. A person commits an offence if that person sells, serves or offers for sale food that is unwholesome or unfit for human or animal consumption and is liable on summary conviction to a fine of not more than one thousand penalty units or to a term of imprisonment of not more than four years or to both.

Sale of food under insanitary conditions

52. (1) A person shall not sell, prepare, package, convey, store or display for sale, food under insanitary conditions to the public.

(2) A person who contravenes subsection (1) commits an offence and is liable on summary conviction to a fine of not more than one thousand penalty units or to a term of imprisonment of not more than four years or to both.

Food unfit for consumption

53. (1) A person shall not

- (a) sell, offer or expose for sale, or have in possession for sale, or
- (b) deposit with or consign to a person for the purpose of sale, food intended for but unfit for human or animal consumption.

(2) Where an offence is committed by a person under subsection (1) (a), that person as well as a person instructed by that person commit an offence and are liable on summary conviction to a fine of not more than one thousand penalty units or to a term of imprisonment of not more than four years or to both.

Prohibition of business in noxious or offensive trade

54. A person who without lawful authority or excuse, the proof of which lies on that person,

(a) carries on a business in noxious trade or offensive matter at a place or causes or permits a business in noxious or offensive matter to continue to be collected at any place, or keeps animals at a place,

(i) to impair or endanger the health of the public inhabiting or using the neighbourhood of that place, or

(ii) to cause damage to the lands, crops, cattle, or goods of the public, or

(iii) to cause material interruption to the public in their lawful businesses or occupations, or

(iv) to materially affect the value of their respective properties,

(b) pollutes or fouls the water of a well, tank, spring, reservoir, or place used or intended to be used for the supply of water for human or animal consumption,

commits an offence and is liable on summary conviction,

(c) for a first offence, to a fine of not more than seven hundred and fifty penalty units or to a term of imprisonment of not more than three years or to both, and

(d) for each day that the offence continues or the offence is repeated, to a penalty of both the fine and the imprisonment provided for in paragraph (c).

Explanation as to carrying on of noxious trade

55. For the purposes of this Part,

(a) "noxious trade" means the carrying out of an offensive or noisy business at a place or causing or permitting offensive or noisy business to continue at a place;

(b) "business" includes a trade, manufacture, work or occupation carried on for gain or charity, or a continued or frequent repetition of an act or a series of acts of any kind where the prejudice or danger caused by the act or omission extends to persons inhabiting or occupying not less than three houses under separate tenancies or any other place of accommodation.

Public nuisance

56. A person who

- (a) within the area of authority of a District Assembly or any other public place or space causes or permits to be placed a carrion, filth, dirt, refuse, or rubbish, or any other offensive or otherwise unwholesome matter, on a street, yard, an enclosure, or open space except at the places set apart by the local authority or the environmental health officer for that purpose, or
- (b) causes or contributes to the creation of a nuisance in a public place which is part of or which adjoins a dwelling-house, or
- (c) in a public place or space, after being warned to desist, makes a loud or an unseemly noise to the annoyance or disturbance of any other person as determined by the Environmental Protection Agency,

commits an offence and is liable on summary conviction to a fine of not more than two hundred and fifty penalty units, or to a term of imprisonment of not more than three years or to both.

Arrest of offenders

57. A person who commits an offence punishable under section 54 may be arrested without a warrant

- (a) by a police officer or health officer or by the owner or occupier of the property on which or with respect to which the offence is committed, or
- (b) by an employee or person authorised by the occupier or owner,

and delivered into the custody of a police officer, who shall, within forty-eight hours, put that person before a Court.

PART SIX —TOBACCO CONTROL MEASURES

Prohibition of smoking in public places

58. (1) A person shall not smoke tobacco or a tobacco product or hold a lighted tobacco product in an enclosed or indoor area of a work place, or in any other public place except in a designated area.

(2) For the purpose of this Part, a work place and a public place include

- (a) offices and office buildings;
- (b) factories, health and educational institutions;
- (c) premises in which children are cared for;
- (d) a means of transportation used for commercial, public or professional purposes by more than one person;
- (e) public transportation terminals;
- (f) wholesale and retail establishments including shopping malls and markets;
- (g) entertainment facilities and facilities rented out for events;
- (h) sports stadia and other sports arenas, whether fully enclosed or not, and any enclosed recreational facilities;
- (i) bars, restaurants and pools whether open or enclosed;
- (j) places of collective use;
- (k) a facility that employs personnel whether paid or not; and
- (l) any other facilities accessible to the public.

(3) A person who is in control of or responsible for a public place or work place shall

- (a) post signs at that workplace that clearly indicate that the establishment is a non-smoking area;
- (b) not display an ashtray in that public place or workplace;
- (c) discontinue service to a customer who is smoking in that place;
- (d) ask a customer or employee who smokes in that place to stop smoking or leave that place immediately;
- (e) issue warnings or take other appropriate disciplinary action against an employee who smokes in that place; and
- (f) arrest or cause to be arrested any person who refuses to stop smoking and refuses to leave that place.

(4) The appropriate authority shall post signs at a work place or a public place to clearly indicate that the place is a non-smoking area.

(5) A person shall not obstruct a person who is in control of or responsible for a public place or workplace in the discharge of duties under this Part.

(6) Despite subsection (4) an appropriate authority may provide a designated area for the smoking of tobacco or a tobacco product.

Advertising in relation to tobacco and tobacco products

59. (1) A person shall not advertise either directly or indirectly

- (a) tobacco, or
- (b) a tobacco product.

(2) Without limiting subsection (1) a person shall not

- (a) use a tobacco trademark, brand logo or brand name of a tobacco product; or
- (b) advertise tobacco, a tobacco product or a tobacco related product on a billboard, wall mural, public transport, transport stop or station including an airport and sea port in any advertisement of a product, or in the organisation of an activity or event.

Tobacco sponsorship

60. (1) A person shall not initiate or engage in any form of tobacco sponsorship.

(2) In furtherance of subsection (1), a person concerned with tobacco or a tobacco product shall not

- (a) organise or promote an organised activity in the country,
- (b) make a financial contribution to an organised activity in the country or make a financial contribution to a person in respect of
 - (i) the organisation or promotion of an organised activity in the country by that person, or
 - (ii) the participation by that person in an organised activity in the country.

(3) For the purpose of subsection (2), "organised activity" includes the use of the name of a tobacco product, trade mark, brand logo, brand name or company name on a tobacco product or in relation to an activity.

Promotion of tobacco and tobacco products

61. (1) A person shall not promote tobacco or a tobacco product by retail sale through the mail or any other means of communication.

(2) A person shall not sell, display for sale, supply or advertise a non-tobacco product or service that contains, either on the product, or in an advertisement of the product, a writing, a picture, an image, graphics, message, or other matter that is commonly identified or associated with or is likely or intended to be identified or associated with a tobacco product, brand, or manufacturer.

Packaging and labelling

62. (1) A person shall not package, label or offer for sale a product that looks like or is likely to be identified or associated with tobacco or a tobacco product.

(2) A person shall not package and label a tobacco product in a manner that seeks to promote the tobacco product in a false, misleading or deceptive way or is likely to create an erroneous impression about its characteristics, health effect, hazard or emissions.

(3) The packaging and labelling of tobacco and tobacco products includes the use of a term, description, trademark, figurative or any other expression that directly or indirectly creates the impression that a particular tobacco product is less harmful than another tobacco product.

(4) A term includes the use of the expression "light", "ultra-light", "mild" and "low tar" and any other expression which creates the impression that the product is less harmful or has beneficial effects.

(5) A unit packet or package of tobacco products for retail or wholesale in the country shall carry the statement "for sale in Ghana only" and also state the country of origin.

Health warning on package

63. (1) A person who manufactures, imports or sells a tobacco product in the country shall ensure that the product carries a health warning on the package as determined by the Food and Drugs Authority.

(2) The package of a tobacco product shall bear two warnings issued by the Food and Drugs Authority.

- (3) The first warning shall
 - (a) be printed largely, clearly, and legibly and permanently attached to the most visible outermost surface of the packet which shall be the front of the package for rectangular packages, and
 - (b) not be less than fifty per cent of the principal display panels
- (4) The secondary warning shall be
 - (a) on the next most visible principal display area which shall be at the back of the rectangular package as specified in the Second Schedule; and
 - (b) included on the package of the tobacco product and cover an area of at least fifty per cent of the total area of the outer surface of the package.
- (5) The contents of the warning may be changed by the Food and Drugs Authority within the periods determined administratively by the Authority provided that a health warning shall not be changed within one year.
- (6) The Food and Drugs Authority shall ensure that the contents and warnings specified in the Second Schedule are randomly displayed on a rotational basis within a reasonable period to be determined by the Authority.

Point of sale health warning

64. A person who sells or offers for sale tobacco or a tobacco product shall conspicuously display at the point of sale a health warning determined by the Food and Drugs Authority.

Minimum age restrictions

- 65.** (1) A person shall not
- (a) sell or offer for sale tobacco or a tobacco product to a child;
 - (b) send a child to sell or buy tobacco or a tobacco product;
 - (c) request a child to light tobacco or a tobacco product;
 - (d) expose a child to tobacco or a tobacco product.
- (2) Where a person who sells or offers for sale tobacco or a tobacco product is in doubt about the age of a purchaser of tobacco or tobacco product, that person shall demand a valid picture identification document from the purchaser as a proof of age and shall not sell to the purchaser unless the document offers adequate evidence of age.

- (3) A valid picture identification document includes
- (a) a passport;
 - (b) a drivers' licence;
 - (c) a voters' identity card;
 - (d) a national identity card; and
 - (e) any other documentation that may be prescribed by the Minister.

(4) It is not a defence for an accused person charged with an offence under this section to prove that the person concerned did not appear to be less than eighteen years of age.

Public education against tobacco use

66. (1) The Minister shall ensure that the Ministry embarks on public education on the effects of tobacco use.

(2) The Minister shall ensure that each health facility has a unit or department that provides education against smoking.

(3) The Minister in collaboration with the Minister responsible for Education, Youth and Sports, the National Commission for Civic Education and other related agencies shall incorporate education against smoking in their programmes.

(4) The Minister responsible for education shall incorporate education on tobacco in the school health programme and other relevant programmes to provide formal education on the dangers of smoking to discourage the youth from tobacco use.

Treatment of tobacco addiction

67. (1) The Minister shall ensure that every region and district has a place for the treatment of persons addicted to tobacco who wish to quit tobacco use.

(2) The treatment of addiction may include the use of a non-tobacco product packaged as a tobacco or tobacco product.

Sale of tobacco products

68. (1) Despite any provision of this Part , a person shall not sell or offer for sale tobacco or a tobacco product

- (a) in a health institution including a hospital, pharmacy, or health clinic,
- (b) in an educational institution, other than a tertiary institution;

(c) in an amusement park, a cinema and sports stadium; and
(d) at other places that may be prescribed by Regulations.

(2) A person shall not sell or offer for sale a tobacco product through a vending machine or a self-service mechanism.

(3) A person shall not sell or offer for sale a tobacco product through the post, the internet or any other medium of communication.

Administrative and miscellaneous provisions

Appointment of inspectors and analysts

69. (1) The Food and Drugs Authority may appoint a person or designate a class of persons as inspectors or analysts to perform the functions of an inspector or analyst under this Act.

(2) The Food and Drugs Authority shall issue a certificate of appointment to the person or class of persons appointed as an inspector or analyst.

(3) An inspector shall not enter a place of residence except with the consent of the occupant or under the authority of a warrant issued under the relevant provisions of the Criminal and other Offences (Procedure) Act, 1960 (Act 30).

Functions of an inspector or analyst

70. (1) An inspector or analyst may, subject to section 69 (3) enter and inspect a place where

- (a) a tobacco or a tobacco product is manufactured, tested, stored, packaged, labelled or sold,
- (b) a thing used in the manufacture, storage, packaging, promotion, sale or testing of tobacco or a tobacco product is to be found,
- (c) information related to the manufacture, storage, packaging, labelling, promotion and sale of tobacco or tobacco product is to be found, or
- (d) there are reasonable grounds to believe that this Part is not being complied with.

(2) An inspector or analyst entering a place for inspection shall provide proof of identity on request.

Powers of an inspector or analyst

71. (1) An inspector or an analyst shall

- (a) examine, open and test equipment, a plant, machinery and accessories, tools, materials, packages or a thing that the inspector or analyst reasonably believes is used or capable of being used for the manufacture, packaging, labelling, storage, distribution, advertising or promotion of a tobacco product;
- (b) examine an operation or a process carried out on any premises used for the production of tobacco and tobacco products;
- (c) examine and make copies of relevant records from a book, document, note, or file including an electronic file which the inspector or analyst reasonably believes might contain information relevant to determine whether a person has complied with the provisions of this Part;
- (d) interview the owner of premises, a person involved in or using a premise for the manufacture, wholesale, import, export, transport, packaging marketing, sale or distribution of a tobacco or tobacco products;
- (e) take reasonable samples of a tobacco or tobacco products or components of tobacco products and analyse them;
- (f) stop, search and detain an aircraft, a ship, vehicle or any other means of transport or storage in which the inspector or analyst reasonably believes tobacco products are contained or conveyed and take samples of the tobacco products and examine them in collaboration with the security agencies;
or
- (g) seize and detain, or order the storage without removal or alteration of a tobacco or tobacco product

if the inspector or analyst reasonably believes that a person has not complied with a provision of this Part after giving written notice to that

person, owner or person in possession of the tobacco product or any other person on the premises where the tobacco product is found.

(2) An inspector may seize or cause to be seized tobacco or a tobacco product or any other thing where the inspector believes on reasonable grounds that a provision of this Part has been contravened in the course of inspection.

Obstruction of inspector or analyst

72. A person shall not

- (a) obstruct an inspector or analyst in the performance of a function under this Part,
- (b) refuse to provide information or documents to which the inspector or analyst is entitled to under this Part, or
- (c) destroy that information or document.

Testing of tobacco and tobacco products

73. (1) The Food and Drugs Authority shall request a manufacturer or importer of tobacco or a tobacco product to bear the cost incurred for testing the tobacco product.

(2) Where a tobacco product does not meet the regulatory requirements of the Food and Drugs Authority the tobacco product, shall be confiscated and destroyed by the Food and Drugs Authority or subject to any other means of disposal that the Food and Drugs Authority considers reasonable.

(3) The cost for the destruction of confiscated tobacco or a tobacco product shall be paid by the manufacturer or importer to the Food and Drugs Authority.

Power of the Authority to prosecute

74. The Food and Drugs Authority may prosecute a person who contravenes a provision of this Part subject to section 56 of the Criminal and Other Offences (Procedure) Act, 1960 (Act 30).

Collaboration with relevant bodies

75. The Food and Drugs Authority shall collaborate with the Customs Division of the Ghana Revenue Authority to check the illicit trade in tobacco and tobacco products and the manufacture of counterfeit tobacco products.

Regulations

76. The Minister, may in consultation with the Food and Drugs Authority by legislative instrument, make Regulations to provide for

- (a) the text and form in which information required on the packet of a tobacco product may be given;
- (b) the manner or method to determine the quantities of hazardous constituents in tobacco products;
- (c) the returns, reports and other information to be submitted to the Food and Drugs Authority by manufacturers and importers of tobacco products;
- (d) the registration of tobacco products;
- (e) the registration and licensing of participants in tobacco and tobacco-related trade;
- (f) to make further provisions in respect of the Third Schedule;
- (g) the imposition of spot fines;
- (h) amending the Schedule to this Part; and
- (i) any other matter required to be prescribed or necessary for the effective implementation of the objects of this Part.

Offences

77. (1) A person who

- (a) smokes in a public place contrary to section 58;
- (b) advertises tobacco or tobacco products contrary to section 59;
- (c) initiates or engages in tobacco sponsorship contrary to section 60;
- (d) promotes tobacco or a tobacco product contrary to section 61;
- (e) packages, labels or offers for sale tobacco or a tobacco product contrary to conditions specified under section 62;
- (f) sells or offers for sale a tobacco product without a conspicuous health warning contrary to section 63;
- (g) sells or offers for sale tobacco or a tobacco product to a child or exposes a child to tobacco or a tobacco product contrary to section 65;

- (h) sells or offers for sale tobacco or tobacco products in a health institution or other institution specified under section 68;
- (i) obstructs an inspector from performing the functions under this Part; or
- (j) contravenes any other provision of this Part

commits an offence and is liable on summary conviction to a fine of not more than seven hundred and fifty penalty units or to a term of imprisonment of not more than three years or to both and in the case of a continuing offence to a further fine of ten penalty units for each day during which the offence continues.

(2) Where an offence under this Part is committed by a body of persons or an organisation

- (a) in the case of a body corporate other than a partnership each director, or secretary of that body is guilty of the offence; and
- (b) in the case of a partnership, each partner is guilty of the offence.

(3) Despite subsection (2) a person shall not be convicted of an offence if the person proves that the offence was committed without that person's knowledge or consent, or that the person took the necessary steps having regard to the circumstances to prevent the commission of the offence.

(4) The Minister may in consultation with the Minister responsible for Finance retain thirty per cent of the fines imposed and other proceeds for the performance of functions of the Food and Drugs Authority under this Part.

Interpretation

78. In this Part, unless the context otherwise requires

"advertisement" includes a statement, communication, representation or reference distributed to members of the public or brought to the notice of members of the public

- (a) which encourages or is likely to encourage the use of tobacco or a tobacco product, or
- (b) which is intended to promote or is likely to promote the sale of tobacco or a tobacco product or encourage its use, or

- (c) which draws attention to the nature of tobacco or a tobacco product or encourages or is likely to encourage its use, or which draws attention to the nature, properties advantages or its uses, and a drawn, still or moving picture, sign, symbol, or any other visual image or audible message designed for the sale of, or which publicises tobacco or a tobacco product or encourages or is likely to encourage its use;
- “appropriate authority” means a person in charge of a place specified under section 58 (2) of this Part;
- “child” means a person below the age of eighteen years;
- “constituents” means nicotine, tar and any other component of a tobacco product or of tobacco smoke which the Minister may by an executive instrument declare to be a constituent for the purposes of this Part;
- “designated area” means an area set aside for smoking in a workplace or a public place specified under section 58 (2) and designed in a manner to prevent smoke from spreading to a non-smoking area;
- “entertainment facilities” includes a cinema, concert halls, theatres, video houses, disco halls and other halls or places of performance;
- “indoor or enclosed” , means a space covered by a roof or enclosed by two or more walls or partition regardless of the material used for the roof, walls or partition and regardless of whether the structure is temporary or permanent;
- “Minister” means the Minister responsible for Health;
- “Ministry” means the Ministry of Health;
- “office and office buildings” includes public areas, corridors, lounges, eating areas reception areas, elevators, escalators, foyers, staircases, restrooms, amenity areas, laundry room, individual offices, outbuildings such as sheds and huts and vehicles among others used in the course of work;

- “package” includes a packing, carton, wrapping or any other container in which tobacco or a tobacco product is generally sold by retail;
- “place of collective use” means a place ordinarily used by two or more persons at least one of whom is a non-smoker;
- “premises” includes any building or land, ship, aircraft caravan but does not include a building or place used exclusively as a dwelling a place;
- “prescribe” means prescribed by Regulations;
- “promotional event” means an event or activity organised by or on behalf of a participant with the aim of promoting a brand of tobacco product, which event or activity would not occur but for the support given to it by or on behalf of the participant;
- “public place” includes a building, or a facility specified under section 58 (2) which is accessible to the general public regardless of ownership or right of access;
- “public transportation” includes transportation used for commercial, public or professional purposes by more than one person and public transportation terminals;
- “public transportation terminal” includes platforms, bus stops or other common waiting areas whether indoors or outdoors;
- “Regulations” means Regulations made under this Part;
- “security agencies” includes the Ghana Police Service and the Customs Division of the Ghana Revenue Authority;
- “smoke” includes being in possession or control of a lit tobacco product regardless of whether the smoke is being actively inhaled or exhaled;
- “sponsorship” means any form of contribution to an event, activity or individual with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly;
- “tobacco product” means a product entirely or partly made of

tobacco leaf as raw material which has been treated or manufactured to be smoked, sucked, chewed or sniffed or handled;

“trade mark” includes

- (a) a mark whether registered or registrable for trade purposes or a recognised version of the trade mark,
- (b) certification trade mark or collective trade mark,
- (c) a trade mark as defined by the Trade Marks Act 2004 (Act 664); and

“work place” includes

- (a) an area whether permanent or temporary in which a person performs a duty of employment or work regardless of whether the work is done for compensation or on voluntary basis; and
- (b) common areas and any other area generally used or frequented during the course of employment.

Transitional provisions

79. (1) On the commencement of this Act where an advertisement to which this Part applies has been placed, that advertisement shall be removed within six months after the commencement of this Act.

(2) A tobacco product manufactured and packaged before the commencement of this Act which is prohibited under this Part shall be marketed within three months after the commencement of this Act.

PART SEVEN— FOOD AND DRUGS

Food and Drugs Authority

Establishment of Food and Drugs Authority

80. (1) There is hereby established a body corporate to be known as the Food and Drugs Authority.

(2) Where there is hindrance to the acquisition of property, the property may be acquired for the Authority under the State Property and Contracts Act, 1960 (CA. 6) or the State Lands Act, (Act, 125) and the costs shall be borne by the Authority.

Object of the Authority

81. The object of the Authority is to provide and enforce standards for the sale of food, herbal medicinal products, cosmetics, drugs, medical devices and household chemical substances.

Functions of the Authority

82. To achieve its object, the Authority shall

- (a) ensure adequate and effective standards for food, drugs, cosmetics, household chemicals and medical devices;
- (b) monitor through the District Assemblies and any other agency of State compliance with the provisions of this Part;
- (c) advise the Minister on measures for the protection of the health of consumers;
- (d) advise the Minister on the preparation of effective Regulations for the implementation of this Part;
- (e) approve the initiation and conduct of clinical trials in the country; and
- (f) perform any other functions that are ancillary to attaining the objects of the Authority.

Governing body of the Authority

83. (1) The governing body of the Authority is a Board consisting of

- (a) a chairperson,
- (b) one representative of the Standards Authority,
- (c) one medical practitioner who is a specialist in active practice nominated by the Minister,

- (d) one representative each of
 - (i) one pharmacist nominated by the Pharmacy Council,
 - (ii) the Centre for Scientific Research into Plant Medicine,
 - (iii) the Attorney-General not below the level of Principal State Attorney,
 - (iv) the Veterinary Services Department,
 - (v) the Food Research Institute,
 - (vi) one traditional medicine practitioner nominated by the Traditional Medicine Practice Council
- (e) the Chief Executive Officer of the Authority, and
- (f) one other person who is a woman.

(2) The members of the Board shall be appointed by the President in accordance with article 70 of the Constitution.

(3) The Board shall ensure the proper and effective performance of the functions of the Authority.

Tenure of office of members

84. (1) A member of the Board shall hold office for a period not exceeding three years and is eligible for re-appointment but a member shall not be appointed for more than two terms.

(2) Subsection (1) does not apply to the Chief Executive Officer.

(3) A member of the Board may at any time resign from office in writing addressed to the President through the Minister.

(4) A member of the Board, other than the Chief Executive Officer, who is absent from three consecutive meetings of the Board without sufficient cause ceases to be a member of the Board.

(5) The President may by letter addressed to a member revoke the appointment of that member.

(6) Where a member of the Board is, for a sufficient reason, unable to act as a member, the Minister shall determine whether the inability would result in the declaration of a vacancy.

(7) Where there is a vacancy

- (a) under subsection (3), (4), or section 86(2),
- (b) as a result of a declaration under subsection (6), or

(c) by reason of the death of a member, the Minister shall notify the President of the vacancy, and the President shall in accordance with article 70 of the Constitution appoint a person to fill the vacancy.

Meetings of the Board

85. (1) The Board shall meet at least once every three months for the despatch of business at the times and in the places determined by the chairperson.

(2) The chairperson shall at the request in writing of not less than one-third of the membership of the Board convene an extraordinary meeting of the Board at the place and time determined by the chairperson.

(3) The quorum at a meeting of the Board is seven members of the Board or a greater number determined by the Board in respect of an important matter.

(4) The chairperson shall preside at the meetings of the Board and in the absence of the chairperson, a member of the Board elected by the members present from among their number shall preside.

(5) Matters before the Board shall be decided by a majority of the members present and voting and in the event of an equality of votes, the person presiding shall have a casting vote.

(6) The Board may co-opt a person to attend a Board meeting, but that person shall not vote on a matter for decision at the meeting.

Disclosure of interest

86. (1) A member of the Board who has an interest in a matter for consideration

(a) shall disclose the nature of the interest and the disclosure shall form part of the record of the consideration of the matter; and

(b) shall not participate in the deliberations of the Board in respect of that matter.

(2) A member ceases to be a member of the Board if that member has an interest in a matter before the Board and

(a) fails to disclose that interest, or

(b) participates in the deliberations of the matter.

Establishment of committees

87. (1) The Board may establish committees consisting of members of the Board or non-members or both to perform a function.

(2) A committee of the Board may be chaired by a member of the Board.

(3) Section 86 applies to members of committees of the Board.

Allowances

88. Members of the Board and members of a committee of the Board shall be paid the allowances approved by the Minister in consultation with the Minister responsible for Finance.

Appointment of Chief Executive Officer

89. (1) The President shall in accordance with article 195 of the Constitution appoint for the Authority a Chief Executive Officer.

(2) The Chief Executive Officer shall hold office on the terms and conditions specified in the letter of appointment .

(3) A person is not qualified to be appointed the Chief Executive Officer of the Authority unless that person has considerable knowledge in health or allied sciences and experience in organisation and management.

Functions of the Chief Executive Officer

90. (1) The Chief Executive Officer is responsible for the day to day administration of the Authority.

(2) The Chief Executive Officer may delegate a function to a Deputy Chief Executive Officer or an officer of the Authority but shall not be relieved of the ultimate responsibility for the performance of the delegated function.

Divisions of the Authority

91. (1) The Authority shall have two Divisions which are

(a) the Food Division, and

(b) the Drugs, Cosmetics, Medical Devices and Household Chemical Substances Division.

(2) Despite subsection (1), the Authority may create other new Divisions or restructure existing Divisions.

Appointment of Deputy Chief Executive Officers

92. (1) The Authority shall have a Deputy Chief Executive Officer to head each division of the Authority.

(2) The Deputy Chief Executive Officers shall hold office on the terms and conditions specified in their letters of appointment

(3) The Deputy Chief Executive Officers are responsible to the Chief Executive Officer in the performance of their functions.

Appointment of other staff

93. (1) The Authority shall have other staff that are necessary for the proper and effective performance of the functions of the Authority.

(2) Other public officers may be seconded to the Authority or may otherwise give assistance to it.

(3) The Authority may engage the services of consultants.

Financial provisions

Funds of the Authority

94. (1) The funds of the Authority include

(a) moneys approved by Parliament,

(b) donations, gifts and grants,

(c) loans contracted and guaranteed by the Government, subject to article 181 of the Constitution, and

(d) any other moneys that are approved by the Minister responsible for Finance.

(2) The Authority shall retain a percentage of money that accrues to the Authority in the performance of its functions as provided by law.

Accounts and audit

95. (1) The Authority shall keep books of accounts and proper records in relation to them in the form approved by the Auditor-General.

(2) The Authority shall submit the accounts of the Authority to the Auditor-General for audit within three months after the end of the financial year.

(3) The Auditor-General shall, not later than three months after the receipt of the accounts, audit the accounts and forward a copy of the audit report to the Minister.

Annual report and other reports

96. (1) The Authority shall within one month after receipt of the audit report, submit an annual report to the Minister covering the activities and the operations of the Authority for the year to which the report relates.

(2) The annual report shall include the report of the Auditor-General.

(3) The Minister shall, within one month after the receipt of the annual report, submit the report to Parliament with a statement that the Minister considers necessary.

(4) The Authority shall also, submit to the Minister any other reports which the Minister may require in writing.

Foods

Registration of food

97. (1) A person shall not manufacture, import, export, distribute, sell or supply food or expose food for sale unless the Authority has registered the food.

(2) Subsection (1) does not prevent the importation of samples for purposes of registration of the food.

(3) An application for the registration of a food shall be made to the Authority in the prescribed manner together with the prescribed application fees.

(4) The Authority shall register the food if it is satisfied that the food complies with the prescribed standards, and the manufacturing operations for the food complies with the prescribed current codes of good manufacturing practices.

(5) The Authority may charge fees to cover the cost of carrying out good manufacturing practice inspection or laboratory investigations in respect of the registration of a food.

(6) An application under subsection (3) may be withdrawn at any time by the applicant before registration, but the withdrawal does not entitle the applicant to a refund of the application fees and the samples submitted.

Cancellation or suspension of registration

98. (1) The Authority shall suspend or cancel a licence issued under this Part if information submitted in respect of the registration changes or it is found to have been inaccurate.

(2) An applicant may at any time after suspension or cancellation of a registration re-submit new information on the food.

(3) A person responsible for the registration of the food who fails to inform the Authority of a change in the information submitted for its registration commits an offence.

(4) The Authority shall cancel an approval in respect of a registered food if it is not made available on the market after three years of registration.

Importation and exportation of food

99 (1) A person shall not carry on the business of an exporter or importer of food unless that person is registered by the Authority under this Part as an exporter or importer and has complied with the Regulations and Guidelines.

(2) The Authority shall keep and maintain in the prescribed manner a register containing

- (a) the name of each registered exporter or importer of food;
- (b) the date of registration;
- (c) the kind of food in respect of which the exporter or importer is registered as an exporter or importer;
- (d) the chemical composition, microbiological and physical status of the food the importer imports or the exporter exports;
- (e) the certificate of analysis issued by the manufacturer and attested to by an authority of the importing or exporting country; and
- (f) any other particulars determined by the Authority.

(3) The Chief Executive Officer shall as soon as is practicable proceed to consider the application and grant registration, if on receipt of an application for registration it is satisfied that

- (a) the composition of the food proposed to be exported or imported is not of a standard below the specifications prescribed under this Part or the Regulations; and

- (b) the food or its products and the practices related to the food or its products do not contravene a provision of this Part, the Regulations or Guidelines.

Prohibited acts

100. (1) A person shall not advertise a food as a preventive or cure for a disease, disorder or an abnormal physical state.

(2) A person shall not advertise food unless the advertisement has been approved by the Authority.

(3) A person commits an offence if that person sells or offers for sale a food that

- (a) has in or on it a poisonous or harmful substance;
- (b) is unwholesome or unfit for human or animal consumption;
- (c) consists in whole or in part of a filthy, putrid, rotten, decomposed or diseased animal or vegetable substance;
- (d) is adulterated;
- (e) is injurious to health; or
- (f) is not of the nature, substance, quality or prescribed standards.

(4) For the purposes of subsection (3) food is adulterated if

- (a) a constituent of the food has in whole or in part been omitted or abstracted,
- (b) a damage to or the poor quality of the food has been concealed in any manner,
- (c) a substance of the food has been substituted wholly or in part,
- (d) a substance has been added to, or mixed or packed with, the food to increase its bulk or weight or reduce its quality or strength or to make it appear better or of greater value than it is;
- (e) it contains an additive not expressly permitted by the national standards, the Codex or the Regulations; or is in excess of the quantity permitted;
- (f) a constituent of the food exceeds the amount stated on the label or permitted in the Regulations;
- (g) its nature, substance and quality has been affected to its detriment.

(5) A person shall not sell, prepare, package, convey, store or display for sale food under insanitary conditions.

(6) Food shall be stored and conveyed in a manner that preserves its safety, composition, quality and purity and minimizes the dissipation of its nutritive properties from climatic and any other deteriorating conditions.

(7) A person shall not

(a) sell, or offer or expose for sale, or have in possession for sale, or

(b) deposit with or consign to a person for the purpose of sale, a food intended for but unfit for human or animal consumption.

(8) Where an offence is committed by a person under subsection 7 (a) that person as well as a person who instructed that person commit an offence.

(9) Where a person is charged with an offence under subsection 7 (b), it is a defence for that person to prove that

(a) notice was given to the person to whom the food was sold, deposited or consigned;

(b) the food in question was not intended for human or animal consumption; or

(c) at the time when the person delivered or dispatched the food to that person,

(i) it was fit for human or animal consumption, or

(ii) that person did not know or could not with reasonable diligence have ascertained that the food was unfit for human or animal consumption.

Food for sale to meet prescribed standards

101. A person commits an offence if that person sells or offers for sale food that is not of the nature, substance, quality or prescribed standard.

Food offered as a prize, reward or donation

102. (1) Section 101 applies to a food intended for human consumption which is

(a) offered as a prize, grant, donation or a reward in connection with an entertainment to which the public is admitted whether on payment of money or not, or

(b) offered as a prize, grant, donation or reward or given away for advertisement purposes or in furtherance of a trade or business, as if the food were exposed for sale by the organisers of the entertainment or the person offering or giving away the food.

(2) In this section "entertainment" includes a public or social gathering, amusement, exhibition, performance, sport or game.

Deception of consumers

103. (1) A person who manufactures, labels, packages, sells or advertises a food in a manner that is false, misleading, deceptive or misbranded as regards its character, nature, value additives, substance, quality, quantity, composition, merit or safety commits an offence.

(2) For the purposes of subsection (1), food is misbranded

- (a) if it is an imitation of, or resembles any other food or food product in a manner likely to be confused with that food or food product under the name of which it is sold and is not plainly and conspicuously labelled so as to indicate its true character;
- (b) if its labelling or advertising is false, deceptive, misleading or in violation of this Part, the Regulations or Guidelines;
- (c) if it is offered for sale under the name of another food;
- (d) if false claims are made for it on the label or otherwise;
- (e) if the packaging containing it or the label on it, bears the name of a fictitious individual or company as the manufacturer or producer of the product, or it is falsely stated to be the product of a place or country; or
- (f) if it purports to be, or is represented as being, for special dietary uses, unless its label bears the prescribed nutritional information concerning its dietary properties.

Standards for food

104. Where a standard for food is prescribed under an enactment, a person who manufactures, labels, packages, sells or advertises food in a manner that the food is likely to be mistaken for food of the prescribed standard commits an offence.

Prohibition against sale of poor quality food

105. (1) A person shall not sell to the prejudice of a purchaser, food that is not of the nature, substance, safety or quality of the article demanded by the purchaser.

(2) It is not a defence to an offence to plead that the purchaser was not prejudiced because the food was bought for analysis or for a purpose other than for consumption.

Manufacture of food under supervision

106. A person shall not manufacture a food for sale unless the food is manufactured under the supervision of a person with appropriate knowledge and qualification who can ensure the purity, quality and wholesomeness of the food.

Mandatory fortification of food

107. (1) A person shall not import, manufacture, package, label, advertise, store, deliver, distribute, trade, sell or export food for human or animal consumption that is not fortified in accordance with this Part, the Regulations or Guidelines.

(2) Food is fortified where it has additives such as potassium iodate, protein, essential amino acids, vitamins, minerals, essential fatty acids or any other nutritional substance added to it to enhance its nutritional value.

(3) The Food and Drugs Authority shall prescribe and implement the standards for the fortification of food.

(4) A person shall not label, package for sale or advertise food in a manner that is likely to be mistaken for food of the prescribed standard.

(5) This section does not apply to salt for industrial purposes.

(6) Salt for industrial purposes shall

(a) be labelled clearly to that effect,

(b) be stored and displayed separately from salt intended for human or animal consumption, and

(c) not be transported unless covered by a permit issued by the Authority.

Regulation of slaughter houses

108. (1) A person shall not use any premises for the slaughter of animals or cause or permit an animal to be slaughtered with intent to

supply, sell, offer the meat for sale or expose the meat for sale for human or animal consumption, unless the premises are registered by the District Assembly.

(2) A person shall not commit public nuisance by slaughtering an animal or dressing the carcass of an animal for human consumption or animal consumption in a place other than a slaughter house where there is a slaughter house designated for the area.

(3) Despite subsection (2), a District Assembly may for good cause, by a permit signed by the District Chief Executive, permit the slaughter of an animal in a place which is not a slaughter house.

(4) The Veterinary Services Department shall in collaboration with the Authority carry out meat inspection in slaughter houses.

(5) The Minister may, acting in accordance with the advice of the Authority, and in consultation with the Veterinary Service Department by legislative instrument make Regulations relating to the sale of meat for human or animal consumption.

(6) Regulations under subsection (5) shall

- (a) prescribe the methods, instruments or appliances which may be used to carry out the slaughtering;
- (b) provide for and regulate the inspection of slaughter and butchery facilities to determine whether or not they are suitable for the intended purposes;
- (c) provide for the disposal, treatment or processing of waste matters, refuse and the by-products resulting from the slaughtering of animals in slaughterhouses;
- (d) prescribe the places and the circumstances in which an animal may be slaughtered in a place, other than a slaughter house, and the actions to be taken in the event of that slaughter;
- (e) regulate the treatment and disposal of an animal, the carcass or viscera or a part of any of them, in relation to which a breach of this Act has been committed and the offender convicted;

(f) provide for any other matter in relation to slaughter and slaughter facilities which are necessary for the proper maintenance of quality standards in respect of meat intended for human or animal consumption.

(7) Regulations for carrying out meat inspection shall be in accordance with the standards of the Codex Alimentarius Commission of the Food and Agriculture Organisation and the World Health Organisation.

(8) Regulations made under this section shall not deny a religious community reasonable facilities for obtaining food or the flesh of animals slaughtered by the method specially required by the religion.

Transportation of meat for sale

109. (1) Subject to subsection (2), a person shall not convey or cause to be conveyed for commercial purposes meat or a meat product from a slaughter house, facility or cold store in a vehicle unless the Authority has in writing approved the use of that vehicle for the conveyance of the meat or meat product.

(2) Subsection (1) does not apply to the transport of meat products in a hermetically sealed container or in any other containers of a type approved by the Authority.

(3) The Authority or an inspector designated for that purpose may refuse to approve a vehicle which

(a) does not have its tray or load-carrying part covered,

(b) does not have proper provisions for preventing contamination, or

(c) is considered for any other reason to be unsuitable for the carriage of meat or meat products.

(4) Where the Authority considers that a vehicle has ceased to be suitable for carrying meat or meat products, it shall revoke the approval of that vehicle.

(5) A person who contravenes a provision of this section commits an offence and is liable on summary conviction to a fine of not less than fifty penalty units and not more than two thousand penalty units or to a term of imprisonment of not less than three months and not more than four years or to both.

Penalty and defence

110. (1) A person who contravenes section 97 to 108 commits an offence and is liable on summary conviction to a fine of not less than one thousand penalty units and not more than seven thousand five hundred penalty units or to a term of imprisonment of not less than four years and not more than fifteen years or to both.

(2) In proceedings for an offence under a provision of a section referred to in subsection (1), in respect of food containing an extraneous matter, unless the presence of the extraneous matter has rendered the food injurious to health, it is a defence for the accused to prove that the presence of that matter was an unavoidable consequence and forms part of the process of preparation or collection of that food.

Drugs, herbal medicinal products, cosmetics, medical devices and household chemical substances

Prohibited sale of drugs, herbal medicinal products, cosmetics, medical devices and other household chemical substances

111. A person commits an offence if that person sells a drug, herbal medicinal product, cosmetic, medical device or household chemical substance which

- (a) has in or on it a substance that may cause injury to the health of the user when the article is used
 - (i) according to the directions on the label accompanying the article; or
 - (ii) for a purpose and by a method of use that is customary or usual;
- (b) consists in whole or in part of a filthy, rotten, decomposed or diseased substance or of a foreign matter likely to cause injury;
- (c) is adulterated; or
- (d) is prepared, preserved, packed or stored under insanitary conditions.

Standards

112. (1) Where a standard is prescribed for a drug, herbal medicinal product, cosmetic, medical device or household chemical substance, a person who manufactures, labels, packages, sells or advertises any other substance in a manner that it is likely to be mistaken for that drug, product, cosmetic, medical device or household chemical substance commits an offence

unless the substance is the drug, herbal medicinal product, cosmetic, medical device or household chemical substance in question and complies with the prescribed standard.

(2) Where a standard has not been prescribed for a drug, herbal medicinal product, cosmetic, medical device or household chemical substance but a standard for the drug, herbal medicinal product, cosmetic, medical device or household chemical substance is contained in a publication specified in the Fourth Schedule, a person who labels, packages, sells or advertises any other substance or article in a manner that it is likely to be mistaken for the drug, herbal medicinal product, cosmetic, medical device or household chemical substance commits an offence.

(3) A person who manufactures, labels, packages, sells or advertises a drug, herbal medicinal product, cosmetic, medical device or household chemical substance for which a standard has not been prescribed, or for which a standard is not contained in a publication specified in the Fourth Schedule commits an offence unless the drug, herbal medicinal product, cosmetic, medical device or household chemical substance

- (a) is in accordance with the professed standard under which it is labelled, sold or advertised, and
- (b) does not resemble, a drug, herbal medicinal product, cosmetic, medical device or household chemical substance for which a standard has been prescribed or which is contained in a publication specified in the Fourth Schedule.

Deception of consumers

113. (1) A person commits an offence if that person labels, packages, sells or advertises a drug, a herbal medicinal product, cosmetic, medical device or household chemical substance

- (a) in contravention of Regulations or Guidelines made under this Part, or
- (b) in a manner, that is false, misleading or deceptive or misbranded as regards its character, constitution, value, potency, quality, composition, merits or safety.

(2) For the purposes of subsection (1), a drug or herbal medicinal product is misbranded

- (a) if it is so coloured, coated, powdered or polished in a manner that changes the product or if it is made to appear to be of a better or greater therapeutic value than it really is, or

- (b) if it is not labeled in the prescribed manner, or
- (c) if its label or container or anything accompanying the drug or herbal medicinal product bears a statement, design or device which makes a false claim for the drug or herbal medicinal product, or which is false or misleading.

Prohibited advertisement

114. (1) A person shall not advertise a drug, a herbal medicinal product, cosmetic, medical device or household chemical substance to the general public as a treatment, preventive or cure for a disease, disorder or an abnormal physical state, unless the advertisement has been approved by the Authority.

(2) Despite subsection (1) a person shall not advertise a drug, a herbal medicinal product, medical device or cosmetic for the treatment or cure for diseases specified in the Fifth Schedule.

Control of manufacturing

115. (1) A person shall not manufacture a drug, herbal medicinal product, cosmetic, medical device or household chemical substance for sale unless

(a) the manufacturing operation is carried on, or is supervised by a pharmacist or a qualified person approved by the Authority as having specialist knowledge in the article to be manufactured, and

(b) the conditions under which the manufacture is to be carried on are as specified in the Guidelines of the Authority to ensure that the article will be of good quality and safe to use.

(2) An application for approval under subsection (1) shall be made to the Authority and may be granted by the Authority subject to the conditions determined by the Authority.

Restriction on importation and manufacture

116. The Minister may, by executive instrument, prohibit the importation, manufacture, exportation, advertisement or sale of a drug, herbal medicine, cosmetic or medical device or household chemical substance as specified in the instrument.

Application for registration

117. (1) An application for the registration of a drug, herbal medicinal product, cosmetic medical device or household chemical substance shall be made to the Authority in the prescribed manner and be accompanied with the prescribed fees.

(2) The Authority shall register the drug, herbal medicinal product, medical device, cosmetic or household chemical substance if the Authority is satisfied that the drug, herbal medicinal product, medical device, cosmetic or household chemical substance complies with the prescribed standards and that the manufacturing operations for the article comply with the prescribed current code of good manufacturing practice.

(3) The Authority may charge an applicant the costs that the Authority may incur for the purposes of carrying out good manufacturing practice and inspection for laboratory investigations prior to registration of the drug, herbal medicinal product, cosmetic, medical device or household chemical substance.

(4) An application under subsection (1) may at any time be withdrawn by the applicant but the withdrawal does not entitle the applicant to the refund of the application fees.

Registration of drugs, herbal medicinal products, medical devices or household chemical substances

118. (1) A person shall not manufacture, prepare, import, export, distribute, sell, supply or exhibit for sale a drug, herbal medicinal product, cosmetic, medical device or household chemical substance unless the article has been registered by the Authority.

(2) Subsection (1) does not apply to an import permit issued by the Authority for the importation of any of the articles mentioned in that subsection which is imported for personal use.

(3) Subsection (1) does not prevent the importation of a sample for purposes of registration of the drug, herbal medicinal product, cosmetic, medical device or household chemical substance.

(4) The Authority may approve the registration of a drug, herbal medicinal product, medical device or household chemical substance subject to the conditions that it may impose where

- (a) a person makes an application for the registration of the drug, herbal medicinal product, medical device or household chemical substance, and
- (b) the Authority conducts the necessary investigation and is satisfied that it is suitable for the purpose for which it is intended and that it complies with the prescribed requirements.

(5) Where the Authority

(a) refuses to approve the registration of a drug, herbal medicinal product, cosmetic, medical device or household chemical substance, or

(b) approves registration of the products subject to the conditions specified under subsection (4)

the Chief Executive Officer shall inform the applicant in writing of the decision and the reasons for the decision within thirty day of the refusal or approval.

(6) Without limiting subsection (4),

(a) where the applicant is not satisfied with the decision of the Authority, the applicant may make representations to the Authority within sixty days after the date of the notification; and

(b) where the Authority is satisfied with the representations submitted, it may approve the registration of the drug, cosmetic, herbal medicinal product, medical device, household chemical substance or if it is still not satisfied it shall reject the application.

(7) Where the Authority approves the registration of a drug, cosmetic, herbal medicinal product, medical device or household chemical substance the Chief Executive Officer shall

(a) enter in the register the prescribed particulars of the drug, herbal medicinal product, cosmetic, medical device or household chemical substance and the relevant conditions or particulars,

(b) allocate a registration number to the medicine, herbal medicinal product, cosmetic, medical device or household chemical substance for a period of not more than five years, and

(c) issue to the applicant a certificate of registration in the prescribed form showing the registration number of the drug, herbal medicinal product, cosmetic, medical device or house chemical substance and the conditions subject to which it is registered.

(8) Despite the proposed name of the applicant, the Authority may reject a name on the grounds that

(a) it constitutes a safety hazard,

- (b) it is misleading,
- (c) it is established or based on international non-proprietary names, or
- (d) it stems from a related substance or for any other sufficient reason determined by the Authority

and register the product under a name approved by the Authority.

Cancellation or suspension of registration

119. (1) The Authority shall suspend or cancel a licence issued under this Part if an information submitted in respect of the registration changes or it is found to have been inaccurate.

(2) An applicant may at anytime after suspension or cancellation of a registration re-submit new information on the drug, herbal medicinal product, cosmetic, medical device or household chemical substance.

(3) A person responsible for the registration of a drug , herbal medicinal product, cosmetic, medical device or household chemical substance who fails to inform the Authority of a change in the information submitted for its registration commits an offence.

(4) The Authority shall cancel an approval in respect of a registered product if the product is not made available on the market after one year of registration.

Certificate on imported drugs

120. Where a drug, herbal medicinal product, cosmetic, medical device or household chemical substance is imported as a finished product, an application for its registration shall be accompanied by a certificate of analysis or certificate of pharmaceutical product for drugs issued by the competent regulatory authority of the exporting country.

Drugs not to be distributed as samples

121. (1) A person who, without permission from the Authority, distributes a drug or herbal medicinal product as samples commits an offence.

(2) Subsection (1) does not apply to the distribution of samples of drugs or herbal medicinal product to physicians, surgeons, dentists, veterinary surgeons, pharmacists, midwives, nurses or medical assistants.

Importation of drugs and other products

122. (1) A person who has not been issued with a licence or permit under this Part, shall not import a drug, herbal medicinal product, medical device, cosmetic or household chemical substance.

(2) Subject to subsection (1), the Authority may, in the public interest, authorise parallel importation of drugs or herbal medicinal products.

(3) A person shall not import a drug or herbal medicinal product which has a shelf life of less than sixty per cent or a drug or a herbal medicinal product with a shelf life of less or equal to twenty four months whose remaining shelf life is less than eighty per cent.

(4) In this section, "parallel importation" means importing a drug without authorisation of the drug registration holder from another country where it is legitimately placed.

Counterfeit drugs, herbal medicinal products, medical devices and household chemical substances

123. (1) A person shall not manufacture, import, export, supply, possess or offer for sale a counterfeit drug, herbal medicinal product, cosmetic, medical device or household chemical substance.

(2) For the purposes of this Part, a drug, herbal medicinal product, medical device, cosmetic or household chemical substance is counterfeit if

- (a) the product or article is one which is deliberately or fraudulently mislabelled with respect to its identity or source;
- (b) it is manufactured under a name which belongs to another drug;
- (c) it is an imitation of or is a substitute for another drug, herbal medicinal product, medical device, cosmetic or household chemical substance or if
 - (i) it resembles another drug, herbal medicinal product, medical device, cosmetic or household chemical substance,
 - (ii) it is likely to deceive, or
 - (iii) it bears on its label or container the name of another drug, herbal medicinal product, medical device, cosmetic or household chemical substance unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity

- with any other drug, herbal medicinal product, medical device, cosmetic or household chemical substance;
- (d) the label or container bears the name of an individual or a company which is fictitious or does not exist and purports to be the manufacturer of the drug, herbal medicinal product, cosmetic, medical device or household chemical substance;
 - (e) it has been substituted wholly or in part by any other drug or substance;
 - (f) it purports to be a product of a manufacturer of whom it is not truly a product; or
 - (g) it is a drug which or the container or labelling of which, without authorisation, bears
 - (i) the trademark, trade name or any other identifying mark, imprint, or device, or
 - (ii) the likeness of a drug manufacturer of drugs, processor, packer or distributor, other than the person who in fact manufactured, processed, packed, or distributed the drug or article and which thereby falsely purports or is represented to be the product of or to have been packed or distributed by the other drug manufacturer, processor, packer or distributor.

Registration of homeopathic drug

124. (1) A person shall not manufacture, prepare, supply, sell, distribute, export or import a homeopathic drug, unless the homeopathic drug has been registered with the Authority.

(2) The Authority may issue Guidelines for the registration of homeopathic drugs.

Safety monitoring

125. (1) A local representative for a regulated product shall be appointed by the relevant body.

(2) The local representative

- (a) shall monitor the safety of the product granted marketing approval, and
- (b) shall report an adverse effect or event to the Authority during the period under which the product is registered.

(3) The Authority shall continually monitor the safety of the products regulated under this Act by analysis of the adverse effect or event reports and by any other means and take appropriate regulatory action when necessary.

Regulation of narcotic and psychotropic substances

126. The Authority shall regulate narcotic drugs, psychotropic substances for legal or medical use and precursor chemicals in accordance with the international conventions and any other relevant guidelines and protocols to which Ghana subscribes, including

- (a) the Single Convention on Narcotic Drugs of 1961 (1961 Convention) as amended by the 1972 Protocol,
- (b) the Convention on Psychotropic Substances of 1971 adopted in 1988, and
- (c) the United Nations Convention against Illicit Drugs Trafficking and Psychotropic substances, 1988.

Food and Drugs Laboratory

127. (1) The Authority shall have a laboratory to be known as the Food and Drugs Laboratory.

(2) The Laboratory shall perform functions related to the quality of products regulated under this Part and shall in particular

- (a) analyse
 - (i) drugs,
 - (ii) medical devices,
 - (iii) herbal medicinal products,
 - (iv) cosmetics,
 - (v) raw materials,
 - (vi) medicine adjuvants,
 - (vii) packaging materials,
 - (viii) medicine delivery systems,
 - (ix) systemic diagnostic agents, and
 - (x) any other product that the Authority considers a product of drugs for the purposes of this Part;
- (b) analyse
 - (i) foods,
 - (ii) food packaging materials, and
 - (iii) raw materials used in the manufacture of food;
- (c) conduct research and training; and

- (d) perform any other functions in relation to the Laboratory as determined by the Authority.
- (3) The Authority shall issue guidelines to provide for
 - (a) the procedure for the submission to the Laboratory of samples of articles of food, drugs, herbal medicinal products, medical devices and provisions for analysis or tests and the forms of the Laboratory's report, and
 - (b) any other matters that are necessary or expedient to enable the Laboratory to perform its functions.
- (4) The Minister may appoint a laboratory or a qualified person to authenticate the analytical results in case of a dispute regarding analytical results.
- (5) The Authority may use the services of an approved laboratory for the testing of products regulated by the Authority.

Registers

128. The Authority shall keep separate registers for the registration of food, human drugs, animal drugs, herbal medicinal products, homeopathic drugs, cosmetics, medical devices and household chemical substances.

Penalties

129. A person who contravenes sections 111 to 124 commits an offence and is liable on summary conviction to a fine of not less than seven thousand five hundred penalty units and not more than fifteen thousand penalty units or to a term of imprisonment of not less than fifteen years and not more than twenty-five years or to both.

General provisions

Registration of premises

130. (1) A person shall not manufacture for sale, sell, supply or store products regulated under this Part except in premises registered for that purpose under this Part.

(2) An application for the registration or renewal of the registration of premises shall be made to the Authority in the prescribed form and shall be accompanied with the prescribed fees.

(3) A registration may be renewed for a period of not more than five years.

(4) A change of a registered premise shall be notified to the Authority.

Licences and permits

- 131.** (1) The Authority shall issue a licence for
- (a) manufacturing premises,
 - (b) storage facilities,
 - (c) importers or exporters, and
- any other licence or permit determined by the Authority for the purposes of this Part on an application made in the prescribed form.
- (2) An application for a licence or permit under this Part shall be made to the Authority and shall be accompanied by the prescribed fees.
- (3) A licence or a permit may be renewed for a period of not more than five years.

Closure of premises and safe disposal of unwholesome regulated products

- 132.** (1) The Authority shall, order the closure of any premises where articles regulated by this Part are manufactured, stored, prepared or sold, if the Authority has reason to believe that the articles are exposed to the risk of contamination or deterioration, and the Authority may make a further order appropriate in the circumstances.
- (2) The Authority shall supervise the safe disposal of an unwholesome regulated product at a fee determined by the Authority.
- (3) A person shall not dispose of an unwholesome regulated product without the supervision of the Authority.
- (4) A person who contravenes subsection (3) shall pay a fine of not more than five thousand penalty units to the Authority.

Reporting of certain diseases

- 133.** (1) An employer or occupier shall not allow a person who works in direct contact with food in food processing and handling operations and who
- (a) suffers from a septic sore, diarrhoea, chronic cough, hepatitis or septic sore throat,
 - (b) suffers from or is a carrier of typhoid or paratyphoid, a salmonella infection, dysentery or staphylococcal infection liable to cause food borne diseases, or
 - (c) any other infectious or contagious disease

to handle food and shall require the person to take the necessary measures including seeking medical attention and reporting the matter to the employer or occupier.

(2) The employer or occupier shall

(a) arrange for the employee who suffers from the condition specified in subsection (1) to be attended to by a medical practitioner, and

(b) keep a record related to that incidence.

(3) The employer shall, without delay, notify the Authority of the actions taken under this section.

Notification of food borne diseases

134. (1) Where a medical officer or any other person becomes aware or suspects that a patient under the care of the medical officer or under the care of that other person suffers from a food borne disease, the medical officer or that other person shall, without delay, send to the medical officer of health of the area in which the patient ordinarily resides, a report stating

(a) the name, age and sex of the patient and the address of the residence of that patient, and

(b) the particulars of the food borne disease from which the patient is or is suspected to be suffering.

(2) The medical officer of health shall immediately take the necessary measures to investigate and prevent the spread or re-occurrence of food borne disease within the area of jurisdiction and report the actions and measures taken to the Authority in the prescribed manner on receipt of the report.

(3) Subject to subsection (2), the Authority shall collaborate with other relevant agencies to determine the manner in which food borne incidences shall be reported.

Powers of authorised officers

135. (1) An authorised officer may, at a reasonable hour, for the proper performance of a function under this Part

(a) enter any premises where the officer believes an article to which this Part applies is prepared, preserved, packed, stored or conveyed and examine the article and take samples and

examine anything that the officer believes is used or is capable of being used for the preparation, preservation, packaging, storing or conveying of the article;

- (b) open and examine a receptacle or package which the officer believes contains an article to which this Part applies;
- (c) examine the books, documents, or any other records found in a place mentioned in paragraph (a) which the officer believes contains an information relevant to the enforcement of this Part and make copies of them or take extracts from them; and
- (d) seize and detain for the period that the officer considers necessary an article by means of or in relation to which it is believed a provision of this Part has been contravened.

(2) An authorised officer acting under this section shall produce the authority to act if required.

(3) Where the owner or a responsible person in occupation of premises is present and refuses to open a container or door on being asked to do so, an authorised officer may by a warrant break open the container or door of the premises where food or drugs may be kept for storage or sale.

(4) A person who obstructs or impedes an authorised officer in the course of the officer's duties or by a gratuity, bribe, promise or any other inducement prevents or attempts to prevent the due execution by the authorised officer of duties under this Part or of the Regulations commits an offence.

(5) An authorised officer

- (a) may at a reasonable time, examine food intended for human or animal consumption which has been distributed, sold or is offered or exposed for sale or is in the possession of or has been deposited with or consigned to a person for the purpose of distribution or sale or manufacture for sale, if it appears to the authorised officer to be unfit for human or animal consumption, and
- (b) may seize and remove it in order to have it dealt with in a manner provided by this Part or the Regulations.

(6) An authorised officer who seizes food under subsection (1) shall inform the person in whose possession the food was found of the intention to have it disposed of in the prescribed manner.

(7) An authorised officer may seize and cause to be disposed of in a manner prescribed by Guidelines the carcass or a part of the carcass of an animal received into a butchery facility or cold store for the purpose of selling for human or animal consumption, which on examination is found to be diseased or unfit for human or animal consumption and compensation shall not be paid to the owner of the carcass or a part of the carcass.

(8) Where in pursuance of a provision of this section a carcass or a part of it is seized by an authorised officer, the officer shall record or cause to be recorded

- (a) a description or any other particulars as will suffice to identify the carcass or part of it, and
- (b) the grounds on which the seizure was effected before causing it to be disposed of.

(9) For the purposes of this section, the authorised officer may deal with poultry, game and fish in the same manner as if the poultry, game and fish were carcasses or animals for slaughter.

Forfeiture and disposal of seized articles

136. (1) Where a person is convicted of an offence under this Part, the Court may order that an article by means of or in relation to which the offence was committed or a thing of a similar nature belonging to or in the possession of the convicted person or found with the article be forfeited and on the order being made the article or thing may be disposed of as directed by the Court.

(2) A person who removes, alters or interferes with an article or a thing seized under this Part without the authority of an authorised officer commits an offence.

Public analysts

137. (1) The Minister may, on the advice of the Board and subject to article 195 of the Constitution, appoint on the terms determined by the Minister, a public analyst for each district qualified to undertake the analysis required under this Part.

(2) An authorised officer may submit an article seized by the officer or a sample of it to a public analyst for analysis or examination.

(3) A public analyst shall as soon as practicable analyse or examine a sample sent to the analyst in pursuance of this Part and shall give the authorized officer a certificate specifying the result of the analysis or examination.

(4) The certificate shall be in the form prescribed by the Minister after consultation with the Authority.

(5) A person shall not be appointed a public analyst for the area where that person is engaged directly or indirectly in a trade or business connected with the sale of drug, herbal medicinal product, cosmetics, medical devices or household chemical substances.

Quarterly reports of analysts

138. A public analyst shall

- (a) submit a quarterly report to the Authority on the number of articles which have been analysed by the analyst under this Part and the finding of the analysis; and
- (b) forward copies of the report to the Metropolitan, Municipal and District Assemblies.

Power of Authority to obtain particulars of certain ingredients

139. (1) The Authority may direct a person who at the date of the directive or at a subsequent time carries on a business which includes the production, importation or use of articles to which this Part applies, to furnish the Authority, within a period specified in the directive, specified particulars on the composition and use of the substance sold or for sale in the course of that business or used in the preparation of products regulated by the Authority.

(2) Directives made under subsection (1) may require the following particulars to be furnished in respect of the substance:

- (a) particulars on the composition and chemical formula of the substance;
- (b) particulars of the investigations carried out by or to the knowledge of the persons carrying on the business, to determine whether and to what extent the substance used is injurious to or in any other way affect health; and

(c) particulars of the investigations or inquiries carried out by or to the knowledge of the person carrying on the business for the purpose of determining the cumulative effect on the health of a person consuming the substance in ordinary quantities.

(3) Particulars furnished in accordance with directives under this section and information on the particulars shall not, without the previous consent in writing of the persons carrying on the business, be disclosed except for the purposes of prosecution of for an offence under this Part.

(4) A person who discloses any particulars or an information in contravention of subsection (3), commits an offence.

Power of Authority to prosecute

140. The Authority may prosecute a person who contravenes a provision of this Part subject to section 56 of the Criminal and Other Offences (Procedure) Act, 1960 (Act 30).

Power of Court to suspend or cancel licence

141. (1) On conviction of a person for an offence under this Part, the Regulations or Guidelines, the Court may suspend or cancel a licence issued to that person in addition to or in place of any other penalty which it may impose.

(2) The registrar of the Court shall inform the Authority of the conviction or the suspension or cancellation of the licence within fourteen days of the conviction.

Penalties

142. (1) A person who commits an offence under this Part or the Regulations for which a penalty is not provided is liable on summary conviction

(a) in the case of a first offence, to a fine of not less than one thousand penalty units or to a term of imprisonment of not less than six months, or to both

(b) in the case of a subsequent offence, to a fine of not less than five hundred penalty units or to a term of imprisonment of not less than two years or to both.

(2) A person holding a mining lease for salt shall have the mining lease suspended if that person is convicted twice under this Part or the Regulations.

Certificate of analysis and presumptions

- 143.** In proceedings under this Part or the Regulations,
- (a) a certificate of analysis signed by a public analyst shall be accepted as prima facie evidence of the facts stated in it;
 - (b) evidence that a package containing an article to which this Part or the Regulations apply bears a name, address or registered mark of the person by whom it was manufactured or packed is prima facie evidence that the article was manufactured or packed by that person;
 - (c) a substance commonly used for human or animal consumption shall, if sold, or offered or exposed for sale, be presumed until the contrary is proved, to have been sold or to be intended for sale for human or animal consumption;
 - (d) a substance commonly used for human or animal consumption which is found on premises used for the preparation or sale of that substance and a substance commonly used in the manufacture of products for animal consumption which is found on premises used for the preparation or sale of those products, shall be presumed until the contrary is proved, to be intended for sale or for manufacturing the products for sale for human or animal consumption.

Presumption as to adulteration

144. Where a person is prosecuted under this Part or the Regulations and it is established that

- (a) the article has been declared to be adulterated if a prescribed substance has been added to it; and
- (b) the person is in possession of or has on the premises of that person, the specified substance

the burden of proving that the article was not adulterated by the addition of substance lies on the accused.

Defence in proceedings for sale of food

145. (1) Subject to subsection (2), it is a defence in proceedings for an offence relating to the sale of an article in breach of a provision of this

Part or of the Regulations to prove that

- (a) the accused sold the article in the same package and in the same condition as it was when it was bought, and
- (b) the accused could not with reasonable diligence have ascertained that the sale of the article would be in breach of this Part or of the Regulations.

(2) An accused person who desires to rely on subsection (1) shall give notice of that intention at least ten days before the date of the trial and shall disclose to the prosecution the name of the person from whom the article was bought and the date of the purchase.

Compensation

146. (1) Where at the trial of a person for an offence under this Part or the Regulations, the Court on the application of an interested person

- (a) determines that at the date of a closure order the use of the premises did not involve imminent risk of danger to health, and
- (b) is satisfied that loss has been occasioned by the closure order the Court may order the Authority to pay compensation to that person of an amount specified by the Court.

(2) For the purposes of subsection (1), interested person includes

- (a) the person accused of an offence under this Part or the Regulations, and
- (b) any other person who at the time when the closure order was made was carrying on business at those premises.

Regulations

147. (1) The Minister in consultation with the Food and Drugs Authority may, by legislative instrument, make Regulations

- (a) prescribing the fees to be paid for a service performed by the Authority;
- (b) amending the Schedules to this Part; and
- (c) generally for giving full effect to this Part.

(2) Despite the provisions of any other enactment to the contrary, Regulations made under this section may contain the penalties determined by the Authority in consultation with the Minister.

(3) The Minister may, after consultation with the Authority, declare by an executive instrument that a particular substance or thing is a food for the purpose of this Part.

Guidelines and Codes of practice

148. (1) The Authority may issue guidelines and codes of practice in connection with food and drugs and any other products or devices regulated by the Authority to persons in the food and drugs industry and the persons shall comply with the guidelines and codes of practice.

(2) Without limiting subsection (1) the Authority may issue guidelines in respect of the following:

- (a) specifying what constitutes adulteration of a product regulated under this Part;
- (b) governing
 - (i) the treatment, processing and manufacture of food,
 - (ii) the packaging, labelling, advertising and selling of food,
 - (iii) the size, dimensions, fill and specifications of packages of food,
 - (iv) the use of a substance as an ingredient in a food,
 - (v) the protection of the consumer or purchaser of food from being deceived or misled as to its quality, character, composition, fill, merit or safety or to prevent injury to the health of a consumer or purchaser, and
 - (vi) the registration of an article to which this Part applies if the Authority is satisfied that the article complies with the required standard for that article, and the manufacturing operations of that article comply with the code of good manufacturing practices,
- (c) for the regulation of importation or exportation of food, drugs, herbal medicines, cosmetics, medical devices or household chemical substances in order to ensure compliance with this Part;
- (d) specifying the type and level of food additives and recipients;
- (e) identifying a standard for food products to prevent injury to the health of the consumer or purchaser of the food;

- (f) for the destruction of an adulterated food or drug;
 - (g) prescribing methods of manufacture, processing, sale, storage and transportation of food, drugs, cosmetics, medical devices or chemical substances;
 - (h) the procedure for the clearance of drugs, herbal medicines, medical devices, household chemical substances or products regulated under this Part and any other from the ports;
 - (i) prohibiting the manufacture, importation, exportation or sale of specified drugs, herbal medicinal products, medical devices, cosmetics or household chemical substances;
 - (j) prescribing forms and particulars to be provided in forms;
 - (k) the food and drugs laboratory specifying its functions and rules for the operation of the laboratory;
 - (l) on pharmacovigilance and safety monitoring of drugs placed on the market within the country as well as post authorisation safety studies and adverse drugs reaction reporting to relevant stakeholders;
 - (m) for the monitoring of the safety of products regulated under this Part and the seizure and disposal of products regulated under this Part; and
 - (n) for the allocation and reporting of narcotics and psychotropic substances.
- (3) The guidelines may contain provisions
- (a) prohibiting, restricting or regulating the sale or storage, possession or exposure for sale of a specific food in a place in the Republic by a specified person or category of persons;
 - (b) imposing requirements in respect of the construction and layout of premises used in, at or from, which food for human or animal consumption is manufactured, stored, sold, offered or exposed for distribution or sale, equipment, maintenance, cleanliness, ventilation and extraction of fumes or heat, lighting and water supply in respect of the premises;
 - (c) imposing requirements for the provision, maintenance, cleanliness of sanitary and washing facilities in connection with those premises, the disposal of refuse and the maintenance and cleanliness of apparatus, equipment, furnishings

and utensils used in those premises, and in particular, the Guidelines may impose requirements that a sanitary convenience situated in the premises is supplied with water through a suitable flushing appliance;

- (d) prohibiting or restricting spitting on the premises or in any other way, littering the premises where food for human or animal consumption is manufactured or stored, or sold, offered or exposed for distribution or sale;
- (e) imposing requirements as to the clothing to be worn by persons engaged to work in those premises;
- (f) requiring the periodic medical examination of persons engaged in those premises or a category of them, the immunisation of those persons against a special disease, and prohibiting the employment or continued employment of any of them found to be suffering from a specified disease;
- (g) regulating the selling of salt which is not fortified with potassium iodate for persons allergic to potassium iodate;
- (h) in respect of the contamination of food or water for human or animal consumption by household chemical substances;
- (i) in respect of the disposal of household chemical substances likely to cause injury or be dangerous to the health of a person; and
- (j) regulating generally the treatment and disposal of food which is unfit for human or animal consumption or food which is condemned by an inspector under this Part.

(4) A person who fails to comply with subsection (1) or (2) shall pay an administrative penalty of not more than two thousand five hundred penalty units to the Authority.

(5) A person who fails to pay a penalty imposed under subsection (4) commits an offence and is liable on summary conviction to a term of imprisonment of not more than five years in addition to payment of the penalty imposed.

Interpretation

- 149.** In this part, unless the context otherwise requires,
- “Authority” means the Food and Drugs Authority established under section 80;
 - “advertisement” includes a representation by any means for the purpose of promoting, directly or indirectly, the sale or disposal of a product regulated under this Part;

"article" includes

- (a) products regulated under this Part,
- (b) a thing used for the manufacture, preparation, packaging or storage of a product regulated under this Part, and
- (c) a labelling or an advertising material on food, drug, herbal medicine, cosmetic, medical device or household chemical substance;

"authorised officer" means a medical officer of health, a health inspector or a person authorised in writing by the Chief Executive Officer, the Minister or a District Assembly, or any other person authorised by the Authority to perform a function under this Part;

"Board" means the governing body of the Authority;

"certificate" means a document issued by the Authority under this Part;

"Codex" means the standards, codes of practice, guidelines and recommendations issued by the Codex Alimentarius Commission;

"container" in relation to products regulated under this Part includes a bottle, jar, box, packet, sachet or any other receptacle which contains or is to contain in it a product regulated under this Part which is not a capsule or any other article in which the product is or is to be administered or eaten, and where the receptacle is or is to be contained in another receptacle, the former but not the latter receptacle;

"cosmetic" includes a substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair, eye or teeth and deodorants and perfumes;

"Court" means a court of competent jurisdiction;

"drugs" includes

- (a) a substance referred to in a publication mentioned in the Fourth Schedule,
- (b) a substance or mixture of substances prepared, sold or represented for use in
 - (i) the diagnosis, treatment, mitigation or prevention of disease, disorder of abnormal

- physical state or the symptoms of it, in man or animal, or
- (ii) restoring, correcting or modifying organic functions in man or animal, and
- (c) nutritional supplements;
- "device" means an instrument or apparatus including components, parts and accessories of it manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or the symptom of it in man or animal;
- "export" means take out of the Republic;
- "food" includes water, a food product, a live animal or a live plant, and
- (a) a substance or a thing of a kind used, capable of being used or represented as being for use, for human or animal consumption whether it is live, raw, prepared or partly prepared,
- (b) a substance or a thing of a kind used, capable of being used or represented as being for use, as an ingredient or additive in a substance or a thing referred to in paragraph (a),
- (c) a substance used in preparing a substance or a thing referred to in paragraph (a),
- (d) chewing gum or an ingredient or additive in chewing gum or a substance used in preparing chewing gum, and
- (e) a substance or a thing declared by the Minister to be a food under section 146 (3);
- "health inspector" means a person lawfully appointed to be a health inspector or a sanitary inspector;
- "herbal medicinal product" includes plant-derived material preparations with therapeutic or any other human health benefits which contain raw or processed ingredients from one or more plants and materials or organic or animal origin;
- "homeopathic" includes
- (a) a substance that can be attenuated to render it stronger as the potency increases and at same time that the original substance is diluted, and

- (b) a substance that can cause certain symptoms in a healthy person and can be used to relieve those symptoms in any other person suffering from those symptoms;
- “homeopathy” means an alternative system of medicine based on the concept that diseases can be cured when a patient is treated with minute quantities of a substance that produces symptoms of the disease on a healthy person;
- “household chemical substance” means a substance or mixture of substances packaged for use in a domestic or office setting as
- (a) a germicide,
 - (b) an antiseptic,
 - (c) a disinfectant,
 - (d) a pesticide,
 - (e) an insecticide,
 - (f) a rodenticide,
 - (g) a vermicide, or
 - (h) a detergent;
- or any other substance or mixture of substances declared by the Minister, after consultation with the Authority, to be a chemical substance;
- “import” means bring into the Republic;
- “industrial purposes” means the use otherwise than for human or animal consumption;
- “insanitary conditions” means the conditions or circumstances which might contaminate a product regulated under this Act with dirt or filth or might render the article injurious or dangerous to health;
- “label” includes a legend, tag, brand, work or mark, pictorial or any other descriptive matter written, printed, stenciled, marked, embossed or impressed on or attached to a product regulated under this Part;
- “manufacture” includes the operations involved in the production, preparation, processing, compounding, formulating, filling,

- refining transformation, packing, packaging, re-packaging and labelling of products regulated under this Part;
- “medical device” means an instrument, apparatus, implement, a medical equipment, machine, contrivance, implant, in vitro reagent or any other similar or related article, including a component, part or an accessory which is
- (a) recognised in the official natural formulary or pharmacopoeia or a supplement to them, or
 - (b) intended for use in the diagnosis of a disease or any other condition, or in the cure, mitigation, treatment or prevention of disease in humans and animals, or
 - (c) intended to affect the structure or a function of the body of the human being or other animal and which does not achieve any of its principal intended purposes through chemical action within the body of the human being or any other animal and which is not dependent on being metabolised for the achievement of any of its principal intended purposes;
- “Minister” means the Minister responsible for Health;
- “naturopathy” means a system of the treatment of a disease by seeking to assist natural recovery;
- “package” means in relation to a product regulated under this Part, a box, packet or any other article in which one or more primary containers of products regulated under this Part is or are to be enclosed in one or more other boxes, packets or articles in question, the collective number of them;
- “person” includes a media house for purposes of advertisements;
- “premises” includes land, buildings, structures, basements, and vessels and in relation to a building, includes a part of a building and the cartilage, forecourt, yard or place of storage used in connection with the building or part of the building and in relation to a vessel, includes a ship, boat, an aircraft, a carriage or receptacle of any kind whether open or closed;
- “products regulated under this Part” means food, drugs, cosmetics, household chemical substances, food supplements, tobacco, herbal medicines and medical devices;

- “public analyst” means a person appointed by the Minister to act as an analyst for the purposes of this Part;
- “Regulations” means the Regulations made under this Part;
- “sell” or “sale” includes sell or sale by wholesale or retail, import, offer, advertise, keep, expose, display, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale, or prepare or possess for sale and barter or exchange, supply or dispose of to a person whether for a consideration or otherwise;
- “selling” includes offering for sale, exposing for sale and having in possession for sale or distribution;
- “slaughter facility” means a slaughterhouse, slaughter slab, abattoir and premises or a place habitually used for the slaughter of animals for human or animal consumption;
- “substance” means a natural or artificial substance whether in solid or liquid form or in the form of a gas, vapour or radiation;
- and
- “unfit product” means a product regulated under this Part which contravenes a provision of this Part.

PART EIGHT— CLINICAL TRIALS

Clinical Trials Technical Advisory Committee

Establishment of the Clinical Trials Technical Advisory Committee

150. There is hereby established a Clinical Trials Technical Advisory Committee which shall operate under the Food and Drugs Authority.

Object of the Committee

151. The object of the Committee is to provide the Authority with ongoing and timely medical and scientific advice on current and emerging issues related to clinical trials.

Functions of the Committee

152. The Committee shall

- (a) regularly review and advise the Authority on the clinical trials system in the country and make recommendations regarding its maintenance and improvement;
- (b) perform causality assessment and issue reports on adverse event in relation to clinical trials;
- (c) make recommendations to the Authority regarding actions the Authority may take to resolve issues or concerns related to the conduct of clinical trials including the need to halt or suspend a clinical trial;
- (d) recommend publication of case reports, as well as its risk or benefit evaluations in medical and scientific journals with prior consent of the sponsor;
- (e) recommend educational programmes and topics for investigators aimed at enhancing reporting of adverse effect or event and improving compliance with Good Clinical Practice as recommended by the International Conference on Harmonization Guidelines and Helsinki Declaration;
- (f) advise the Authority periodically on the review of guidelines for clinical trials and Good Clinical Practice issued by the Authority;
- (g) advise the Authority on clinical end points in the review of protocols submitted to the Authority;
- (h) recommend to the Authority approval of clinical trials;
- (i) evaluate final reports of clinical trials that have been approved by the Authority;

- (j) advise the Authority on matters relating to inspections conducted by the Authority on Good Clinical Practice and Good Laboratory Practice; and
- (k) perform any other functions that are ancillary to the attainment of the object of the Committee.

Composition of the Committee

153. (1) The Committee consists of the following:

- (a) a clinical pharmacologist,
- (b) a social scientist,
- (c) an internal medicine practitioner,
- (d) a clinical pharmacist,
- (e) an epidemiologist,
- (f) a pharmacologist,
- (g) a biostatistician,
- (h) a paediatrician,
- (i) a geriatrician,
- (j) a clinical pathologist,
- (k) a surgical specialist,
- (l) a medical herbalist; and
- (m) a toxicologist

(2) The members of the Committee shall nominate one of their member as the chairperson.

Application of provisions

154. The provisions of sections 84 to 86 and 88 on tenure of office, meetings, disclosure of interest and allowances apply to this Part with the necessary modification.

Clinical trials

155. (1) A person shall not, in the course of a business carried on by that person,

- (a) sell, supply or donate a drug, herbal medicinal product, cosmetic or medical device for the purpose of a clinical trial, or
- (b) procure, import, manufacture or assemble a drug, herbal medicinal product, cosmetic, medical device for sale or supply for the purpose of a clinical trial,

unless that person is a holder of an approved valid certificate issued by the Authority.

(2) A person shall not conduct a clinical trial of a drug, herbal medicinal product, cosmetic, medical device or procedure without an approved valid certificate issued by the Authority.

(3) A person who desires to conduct a clinical trial of a medicine, herbal medicinal product, cosmetic, medical device or procedure shall submit to the Authority an application in the prescribed form duly signed and accompanied with

(a) the prescribed fee,

(b) an ethical clearance issued by an approved institute for medical research where applicable, and the relevant information as provided under the guidelines for conducting clinical trials, and

(c) an international registration number in respect of the product.

(4) Where a clinical trial is to be conducted in a hospital, veterinary institution or designated institution, the application referred to in subsection (3) shall be signed by the principal investigator for the trial.

(5) For the purposes of this section a designated institution includes a medical or veterinary institution or any other institution approved by the Authority.

Authority to investigate

156. (1) On the receipt of an application, the Authority shall conduct investigations to authenticate the safety, efficacy, purity and quality of the drug, herbal medicinal product, medical device or cosmetic and if it is satisfied that the drug, product or device is reasonably safe, efficacious and of acceptable quality and the application including documents, dossiers and laboratory investigations are complete, the Authority shall within one hundred and eighty days approve the drug, herbal medicinal product, cosmetic or medical device for the purposes of the clinical trial.

(2) Subject to subsection (1), the Authority shall issue a clinical trial certificate for the clinical trial in respect of the approved products or procedure or reject the application.

(3) An applicant who is aggrieved by a decision of the Authority as regards the grant of an authorisation for the conduct of a clinical trial may make a representation to the Minister within sixty days.

(4) Where a representation is not submitted by the applicant within the sixty days the decision of the Authority in respect of the application shall stand.

Conditions to conduct clinical trials

157. A clinical trial of a drug, herbal medicinal product, cosmetic or medical device authorised by the Authority is subject to the specific and general conditions imposed by the Authority and the safety of the persons or animals taking part in the trial.

Informed consent for clinical trials

158. Where the Authority grants authorisation for the conduct of a clinical trial of a drug, herbal medicinal product, cosmetic or medical device or procedure the trial shall not take place until

- (a) in the case of the treatment of adult persons, the voluntary written informed consent of the person taking part in the clinical trial has been freely obtained by the person conducting the trial and for a person who cannot read and write in a language that must person under stands;
- (b) in the case of the treatment of a child or persons under legal disability, the voluntary written informed consent of their parents or legal guardians has been freely obtained by the person conducting the trial;
- (c) in the case of animals, the voluntary written informed consent of the owners of the animals taking part in the clinical trial has been freely obtained by the person conducting the trial; and
- (d) insurance coverage is provided for prospective participants.

Supply of information prior to clinical trial

159. Where a clinical trial of a drug, herbal medicinal product, cosmetic or medical device is authorised under this Part, the person conducting the trial shall, before commencing the trial

- (a) inform the persons taking part in the trial or persons whose animals will take part in the trial about
 - (i) the aims and objectives of the clinical trial and the way in which it will be conducted, and
 - (ii) the possible risks, discomforts and any other adverse effects that may result,

- (b) ensure that a person or an animal taking part in the trial does not sustain an injury during the trial from the amounts which are prescribed by the Authority; and
- (c) sign an indemnity in the form determined by the Authority indemnifying the Authority from liability in respect of an injury or an adverse event which may be sustained by a person or an animal, directly or indirectly, as a result of the conduct of the trial and which occurs or reveals itself at the time of trial or subsequently.

Powers to stop or suspend clinical trials

160. (1) If at any stage during the authorised clinical trial of a medicine, herbal medicinal product, cosmetic or medical device the Authority is satisfied that considering the initial risks, discomforts or any other adverse event caused to a person or an animal taking part in the trial, it is in the public interest to stop or suspend the trial, the Authority shall order the person conducting the clinical trial to stop or suspend the trial immediately.

(2) Without limiting subsection (1), the Authority may for any other reasonable cause suspend, vary or stop a clinical trial.

(3) The Authority shall notify the person conducting the trial of its decision immediately and the reasons for the decision.

Monitoring of clinical trials

161. The Authority shall monitor a clinical trial from the beginning to the end in order to ensure adequate protection of the general public against the risks or adverse events from the authorised clinical trial to satisfy itself that the specific and general conditions subject to which the trial was authorised are being strictly adhered to by the person conducting the trial and that the trial will achieve its aims and objectives.

Reports on clinical trials

162. (1) A person conducting a clinical trial shall submit to the Authority the reports that the Authority may require.

(2) In addition to the report, the person who is conducting the trial shall immediately report to the Authority any adverse event observed during the trial.

Renewal of clinical trial certificate

163. (1) Subject to this section, a clinical trial certificate unless previously renewed or revoked, shall expire at the end of the authorised period of the trial.

(2) A certificate may be renewed by the Authority for a further period on the application of the holder.

Application of clinical trial provisions

164. The provisions of this Part apply to human and animal participant studies and includes

- (a) social and behavioural research,
- (b) genetic research, and
- (c) research on human or animal biological samples.

Penalty

165. A person who contravenes this Part commits an offence and is liable on summary conviction to a fine of not less than fifteen thousand penalty units or to a term of imprisonment of not less than twenty-five years or to both.

Interpretation

166. In this Part, unless the context otherwise requires,

“adult” means a person who is eighteen years of age or over that age;

“adverse event” means an undesirable experience occurring following the administration of a medicare and the event does not necessarily have a causal relationship with treatment;

“child” means a person who is below eighteen years of age; and

“clinical trial” means an investigation consisting of a particular description by, or under the direction of a medical practitioner, dentist or veterinary surgeon to the patient or animal where there is evidence that a medicine, medical device or procedure or herbal medicine of that description has effects which may be beneficial to and safe to the patient or animal, and the medicine, medical device or procedure or herbal medicine is for the purpose of ascertaining beneficial or harmful effects.

PART NINE—MISCELLANEOUS PROVISIONS

Patient’s Charter

167. The principles contained in the Sixth Schedule shall apply to all persons who relate to patients or clients.

International Health Regulations

168. (1) The provisions of the World Health Organisation, International Health Regulations specified in the Seventh Schedule shall apply in addition to the Regulations made under this Part in so far as a provision of the Seventh Schedule is not inconsistent with a provision of any of those Regulations.

(2) The Minister shall give effect to the International Health Regulations to provide a public health response to the international spread of disease.

(3) The Minister may by legislative instrument modify the provisions of the Seventh Schedule to suit the purpose of the Republic.

Declaration of public health emergency

169. (1) The Minister shall declare a public health emergency by Executive Instrument where there is a situation that poses an immediate risk to health, life property or the environment.

(2) To meet the criteria for a public health emergency, the incident should

- (a) immediately threaten life, health, property or the environment;
- (b) have already caused loss of life, health detriments, property damage or environmental damage; OR
- (c) have a high probability of escalating to cause immediate danger to life, health, property and the environment.

Emergency powers in respect of public health matters

170. (1) The Minister shall direct a public health official to respond immediately to a public health emergency and may order an individual to take preventive measures or be quarantined.

(2) A public health official may be authorised to act outside the area of authority of the public health officer.

Health information, reporting and notification

171. (1) The Minister may by legislative instrument provide for details in respect of notification and reporting of public health events.

(2) For purposes of subsection (1) “public health events” includes infections, exposures to environmental toxins, poisoning and other matters of public health importance.

Immunity and Indemnity

172. A public health official or a designated officer who acts in good faith under Parts One to Five of this Act is immuned from prosecution and indemnified from acts performed by that official.

Collaboration

173. (1) The Ministry of Health shall collaborate with relevant bodies in carrying out the provisions of this Act.

(2) Where there is a public health emergency the Ministry shall co-operate with the National Disaster Management Organisation and other relevant public agencies.

(3) The Minister may in collaboration with relevant bodies, by legislative instrument provide for public health matters in respect of

- (a) environmental sanitation, waste management and pollution;
- (b) mortuaries and funerals homes;
- (c) housing;
- (d) road construction;
- (e) water;
- (f) harmful use of alcohol;
- (g) restaurants and food distribution;
- (h) occupational health;
- (i) health impact assessment;
- (j) regulation of zoonotic diseases;
- (k) mining operations;
- (l) swimming pools;
- (m) oil and gas;
- (n) plastic waste;
- (o) agro or bio chemicals; and
- (p) any other matters of public health importance.

Application

174. (1) This Act binds the Republic.

(2) The provisions of Part 1 to 5 on communicable diseases, vaccination, quarantine, vector control and environmental sanitation shall apply to animals with the necessary modification.

Repeals and savings

175. (1) The following enactments are hereby repealed.

- (a) Infectious Diseases Act, 1908 (Cap 78);
- (b) Mosquitoes Act, 1911 (Cap 75);
- (c) Quarantine Act, 1915 (Cap 77);
- (d) The Food and Drugs Act, 1992 (PNDCL 305B).

(2) Sections 285-288 of the Criminal Offences Act, 1960 (Act 29) are hereby repealed.

(3) Despite the repeal of the enactments under subsection (1), any licence, authorisation, Regulation, notice, order, direction, appointment or any other act lawfully made or done under the repealed enactment and in force immediately before the commencement of this Act shall be considered to have been made or done under this Act and shall continue to have effect until reviewed, cancelled or terminated.

SCHEDULES

FIRST SCHEDULE

(Section 28)

CERTIFICATE OF VACCINATION

Certificate of successful vaccination

I, the undersigned, hereby certify thata man, woman, boy, girl of the apparent age of about.....years, a resident of in thewas successfully vaccinated by me at..... in the District of..... on the day of

.....

Signature
Public Vaccinator

SECOND SCHEDULE

(Section 63)

**MESSAGES (ROTATIONAL) TO BE PRINTED ON
TOBACCO PACKS**

1. Smoking causes cancer
2. Smoking causes heart disease
3. Smoking causes fatal diseases
4. Smoking kills
5. Smoking is highly addictive, don't start
6. Smokers die younger
7. Smoking damages the health of those around you
8. If you give up smoking, you reduce the risk, of serious disease
9. Smoking is dangerous to your health
10. Smoking causes addiction
11. Protect children; don't let them breath your smoke
12. Smoking causes cancer, chronic bronchitis and other chest diseases; or
13. Any other messages from the Food and Drugs Authority

THIRD SCHEDULE

(Section 76)

**WORLD HEALTH ORGANIZATION 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 1: INTRODUCTION

Article I

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;
- (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

11: 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 multicultural 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 text, 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 5 0% or more of the principal display areas but shall be no less than 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 on tobacco 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 13

Tobacco 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 2 1.
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 the development 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) co-operate with competent international and regional inter-governmental organizations and other bodies, including governmental and non-governmental agencies, in regional and global tobacco surveillance and exchange of information on the indicators specified in paragraph 3(a) of this Article; and
 - (c) co-operate 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, socio-economic, 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 co-operate 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) co-operate 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 inter-governmental organizations and non-governmental 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 co-ordination 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 and development 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 economics 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 with economies 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 I 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 I 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.

Annex 1:

WHA 56.1 WHO Framework Convention on Tobacco Control

The Fifty-sixth World Health Assembly,

Recalling resolutions WHA49.17 and WHA52.18 calling for the development of a WHO framework convention on tobacco control in accordance with Article 19 of the Constitution of WHO;

Determined to protect present and future generations from tobacco consumption and exposure to tobacco smoke;

Noting with profound concern the escalation in smoking and other forms of tobacco use worldwide;

Acknowledging with appreciation the report of the Chair of the Intergovernmental Negotiating Body on the outcome of the work of the Intergovernmental Negotiating Body; ²

Convinced that this convention is a groundbreaking step in advancing national, regional and international action and global cooperation to protect human health against the devastating impact of tobacco consumption and exposure to tobacco smoke, and mindful that special consideration should be given to the particular situation of developing countries and countries with economies in transition;

Emphasizing the need for expeditious entry into force and effective implementation of the convention,

1. ADOPTS the Convention attached to this resolution;
2. NOTES, in accordance with Article 34 of the Convention, that the Convention shall be open for signature at WHO 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;
3. CALLS UPON all States and regional economic integration organizations entitled to do so, to consider signing, ratifying, accepting, approving, formally confirming or acceding to the Convention at the earliest opportunity, with a view to bringing the Convention into force as soon as possible;

4. URGES all States and regional economic integration organizations, pending entry into force of the Convention, to take all appropriate measures to curb tobacco consumption and exposure to tobacco smoke,
5. URGES all Member States, regional economic integration organizations, observers and other interested parties to support the preparatory activities referred to in this resolution and effectively to encourage prompt entry into force and implementation of the Convention;
6. CALLS UPON the United Nations and invites other relevant international organizations to continue to provide support for strengthening national and international tobacco control programmes;
7. DECIDES to establish, in accordance with Rule 42 of the Rules of Procedure of the World Health Assembly, an open-ended intergovernmental working group that shall be open to all States and regional economic integration organizations referred to in Article 34 of the Convention in order to consider and prepare proposals on those issues identified in the Convention for consideration and adoption, as appropriate, by the first session of the Conference of the Parties; such issues should include:
 - (1) rules of procedure for the Conference of the Parties (Article 23.3), including criteria for participation of observers at sessions of the Conference of the Parties (Article 23.6);
 - (2) options for the designation of a permanent secretariat and arrangements for its functioning (Article 24. 1);
 - (3) financial rules for the Conference of the Parties and its subsidiary bodies, and financial provisions governing the functioning of the secretariat (Article 23.4);
 - (4) a draft budget for the first financial period (Article 23.4);
 - (5) a review of existing and potential sources and mechanisms of assistance to Parties in meeting their obligations under the Convention (Article 26.5);

8. FURTHER DECIDES that the Open-ended Intergovernmental Working Group shall also oversee preparations for the first session of the Conference of the Parties and report directly to it;
9. RESOLVES that decisions that had been taken by the Intergovernmental Negotiating Body on the WHO framework convention on tobacco control concerning the participation of nongovernmental organizations shall apply to the activities of the Open-ended Intergovernmental Working Group;
10. REQUESTS the Director-General:
 - (1) to provide secretariat functions under the Convention until such time as a permanent secretariat is designated and established;
 - (2) to take appropriate steps to provide support to Member States, in particular developing countries and countries with economies in transition, in preparation for entry into force of the Convention;
 - (3) to convene, as frequently as necessary, between 16 June 2003 and the first session of the Conference of the Parties, meetings of the Open-ended Intergovernmental Working Group;
 - (4) to continue to ensure that WHO plays a key role in providing technical advice, direction and support for global tobacco control;
 - (5) to keep the Health Assembly informed of progress made toward entry into force of the Convention and of preparations under way for the first session of the Conference of the Parties.

Annex 2: History of the WHO FCTC process

The idea of an international instrument for tobacco was initiated with the adoption of Resolution WHA 48.11 in May 1995, requesting the Director-General to report to the Fortyninth Session of the World Health Assembly on the feasibility of developing an international instrument such as guidelines, a declaration, or an international convention on tobacco control.

As a result of Resolution WHA48.1 1, WHO was requested to draft a feasibility study which was presented by the Director-General to the Ninety-seventh Session of the WHO Executive Board ("The Feasibility of an International Instrument for Tobacco Control" (EB97/INF.DOC.4)). During that same session, the Executive Board adopted Resolution EB97R8, "International framework convention for tobacco control."

Later that year, the Forty-ninth Session of the WHA adopted Resolution WHA49.17, "International framework convention for tobacco control", requesting the Director-General to initiate the development of a Framework Convention on Tobacco Control. As a result of this resolution, WHO's first treaty-making enterprise was formally launched.

In 1998 newly-elected WHO Director-General, Dr Gro Harlem Brundtland made global tobacco control a priority through the establishment of a Cabinet Project, the Tobacco Free Initiative, to focus international attention, resources and action upon the global tobacco epidemic. New multisectoral partnerships reflecting the nature of the action were developed. More importantly, Dr Brundtland worked with Member States to secure a negotiating mandate for the Framework Convention on Tobacco Control and set about the task of mobilizing public and political opinion in favour of global rules for tobacco control.

In May 1999 the Fifty-second World Health Assembly paved the way for multilateral negotiations on the WHO Framework Convention on Tobacco Control and possible related protocols. Resolution WHA52.18 established two bodies to draft the framework convention, to complete negotiations and to submit the final text for consideration by the Fifty-sixth World Health Assembly. These two bodies included a technical working group to prepare the proposed draft elements of the Framework Convention; and an intergovernmental negotiating body to draft and negotiate the proposed Framework Convention and possible related protocols. Both bodies were open to all Member States and regional economic integration organizations to which their Member States had transferred competence over matters related to tobacco control.

The working group held two sessions in Geneva (25-29 October 1999 and 27-29 March 2000). Its output was a document with provisional texts

of proposed draft elements for the Framework Convention, submitted to the Fifty-third World Health Assembly with the comments of the working group'. In Resolution WHA53.16, the Health Assembly called upon the Intergovernmental Negotiating Body to commence negotiations with an initial focus on the draft Framework Convention without prejudice to future discussions on possible protocols, to report progress to the Fifty-fourth World Health Assembly, and to examine the question of extended participation by nongovernmental organizations as observers.

The first session of the Intergovernmental Negotiating Body (Geneva, 16-21 October 2000) was preceded by a public hearing on issues surrounding the Framework Convention. The Director-General convened this hearing in order to provide a forum for the public health community, the tobacco industry and farmers' groups to submit their case; records of the proceedings were made available to the Negotiating Body and, through the WHO web site, to the public. At the first session, Ambassador Celso Amorim of Brazil was elected as Chair, and a bureau was established with Vice-Chairs from Australia, India, Islamic Republic of Iran, South Africa, Turkey and the United States of America. The provisional texts of the proposed draft elements for a WHO Framework Convention on Tobacco Control 2, which had been prepared by the working group, were accepted as a sound basis for initiating negotiations. Subsequently, Ambassador Amorim prepared a Chair's text of the Framework Convention on Tobacco Control 3 ; this first draft was released in January 2001 as a basis for further negotiations at the second session.

A report on participation of nongovernmental organizations in the work of the Negotiating Body was presented to the Executive Board at its 107th session in January 2001. In accordance with the provisions of decision EB 107(2) of the Executive Board, the Chairman of the Board acting jointly with the Chairman of the Standing Committee on Non-Governmental Organizations admitted two nongovernmental organizations, the International Nongovernmental Coalition Against Tobacco and Infact, into official relations with WHO as of 26 April 2001'.

In further preparation for the second session of the Negotiating Body, regional intersessional consultations were convened in most regions and subregions. Additional regional and subregional intersessional consultations took place in preparation for each of the subsequent sessions of the Negotiating Body.

At the second session of the Negotiating Body (Geneva, 30 April - 5 May 2001), responsibility for consideration of the proposed draft elements was divided between three working groups. The principal output was the set of three CoChairs' working papers, an inventory of textual proposals made at the session merged with the Chair's original text. These working papers became the rolling draft text of the Framework Convention.

At the third session (Geneva, 22-28 November 2001), two working groups issued revised texts and Working Group One later drafted a text. These documents were used to further negotiations during the fourth session.

Having taken over as Permanent Representative of Brazil in Geneva in replacement of Ambassador Amorim, Ambassador Seixas Corra was elected as Chair of the Intergovernmental Negotiating Body on the WHO Framework Convention on Tobacco Control during its fourth session (Geneva, 18-23 March 2002).

It was agreed that Ambassador Seixas Corra should prepare a new Chair's text, which would form the basis of negotiations during the fifth session of the Negotiating Body (14-25 October 2002). The text was released in July 2002. An international technical conference on illicit trade in tobacco products was hosted by the United States of America at the United Nations Headquarters in New York (30 July - 1 August 2002).

The first four sessions of the Negotiating Body had considered numerous textual alternatives. Concerted deliberations at the fifth session narrowed the options, resulting in more focused negotiations. After a first reading, in plenary, of the new Chair's text, six issues were identified and discussed in open-ended informal meetings: advertising, promotion and sponsorship; financial resources; illicit trade in tobacco products; liability and compensation; packaging and labelling; and trade and health. Informal groups also held discussions on legal, institutional and

procedural issues and use of terms. Substantial advances in the negotiations were made and consensus was reached in several areas. On the basis of the outputs of the informal sessions and the intersessional consultations with various delegations and groups of delegations, Ambassador Seixas Corrêa issued a revised Chair's text of a Framework Convention on Tobacco Control on 15 January 2003.

The sixth and final session of the Negotiating Body ran from 17 February - 1 March 2003. The negotiations were intense and broad ranging. Two important issues, advertising, promotion and sponsorship and financial resources, were discussed in two informal groups. At the final plenary meeting, the Negotiating Body agreed to transmit the text to the Fifty-sixth World Health Assembly for consideration for adoption in accordance with Article 19 of the Constitution. It also agreed that the discussion of protocols should be postponed until that Health Assembly, at which there would be time for consideration of the matter. At its final plenary meeting, the Negotiating Body agreed that the Chair of the Negotiating Body should draft a resolution recommending adoption of the WHO Framework Convention on Tobacco Control by the Health Assembly⁶. The final draft of the WHO Framework Convention on Tobacco Control⁷ was thus submitted to the Health Assembly for consideration for adoption, pursuant to Resolution WHA52.18.

On 21 May 2003, the 56th World Health Assembly, unanimously adopted the WHO Framework Convention on Tobacco Control. The Convention was opened for signature, for a period of one year, from 16 June 2003 to 22 June 2003 at WHO headquarters in Geneva and thereafter at United Nations Headquarters in New York, from 30 June 2003 to 29 June 2004.

The WHO Framework Convention on Tobacco Control is a landmark for the future of global public health and has major implications for WHO's health goals. The conclusion of the negotiating process and the unanimous adoption of the WHO Framework Convention on Tobacco Control, in full accordance with Health Assembly resolutions, represents a milestone for the promotion of public health and provides new legal dimensions for international health cooperation.

- 1 Document A53112.
- 2 Document AIFCTCIINB1/2.
- 3 Document AIFCTCIINB2/2.
- 4 Document EBI07119.
- 5 Document AIFCTCIINB2/6 Add. 1.
- 6 This draft resolution is contained in document A56/8/REV. 1.
- 7 See document A56/8, Annex.
- 8 WHO Document WHA56.1

FOURTH SCHEDULE

(Section 112)

Standards for drugs

List of publications:

- (a) the British Pharmacopoeia;
- (b) the Extra Pharmacopoeia;
- (c) the United States Pharmacopoeia;
- (d) the International Pharmacopoeia
- (e) the standards, codes of practice, guidelines and recommendations issued by the Codex Alimentarius Commission, and
- (f) any other work of reference adopted and approved by the Authority

FIFTH SCHEDULE

(Section 114)

Diseases for which advertisement for treatment, prevention or cure are prohibited:

- (a) Sexually transmitted diseases, other forms of genito-urinary diseases. Acquired Immune Deficiency Syndrome (AIDS) or diseases connected with the human reproductive functions.
- (b) Any of the following:

Alcoholism
Amenorrhoea
Appendicitis
Arteriosclerosis
Asthma
Bladder Stones
Blindness
Cancer
Convulsion
Deafness
Diabetes
Diphtheria
Diseases of the reproductive organ
Dropsy
Epilepsy or fits
Erysipelas
Fibroid
Gallstones
Goitre
Heart disease
Hernia or rupture
Hypertension
Infertility
Kidney failure
Kidney stones
Leprosy
Leukemia
Locomotortazy
Systemic Lupus Erythematosis
Mental disorders
Nephritis or Bright's disease
Obesity
Paralysis
Pleurisy
Pneumonia
Poliomyeltis

Prostate diseases
Scarlet fever
Septicaemia
Sexual impotence
Smallpox
Tetanus or lock-jaw
Trachoma
Tuberculosis

SIXTH SCHEDULE

(Section 167)

PATIENT'S CHARTER

The Health Service is for all people living in Ghana irrespective of age, sex, ethnic background or religion.

The Service requires collaboration between health workers, patients, clients and society. Thus the attainment of optimal health care is dependent on team work.

Health facilities must therefore provide for and respect the rights and responsibilities of patients, clients, families, health workers and other health care providers. They must be sensitive to the patient's socio-cultural and religious backgrounds, age, gender and any other differences as well as the needs of patients with disabilities.

The Health Service expects health care institutions to adopt the Patient's Charter to ensure that Service personnel as well as patients, clients and their families understand their rights and responsibilities.

This Charter is made to protect the rights of the patient in the Health Service. It addresses:

- (a) the right of the individual to an easily accessible, equitable and comprehensive health care of the highest quality within the resources of the country;
- (b) respect for the patient as an individual with a right of choice in respect of health care plans;

- (c) the right to protection from discrimination based on culture, ethnicity, language, religion, gender, age and type of illness or disability; and
- (d) the responsibility of the patient or client for personal and communal health through preventive, promotive and simple curative strategies.

THE PATIENT'S RIGHTS

1. The patient has the right to quality basic health care irrespective of the patient's geographical location.
2. The patient is entitled to full information on the patient's condition and management and the possible risks involved except in emergency situations when the patient is unable to make a decision and the need for treatment is urgent.
3. The patient is entitled to know of the alternative treatments and other health care providers within the Service if these may contribute to improved outcomes.
4. The patient has the right to know the identity of the caregivers and any other persons who may handle the patient including students, trainees and ancillary workers.
5. The patient has the right to consent or decide to participate in a proposed research study involving the patient after a full explanation has been given; and the patient may withdraw at any stage of the research project.
6. A patient who declines to participate in or withdraws from a research project is entitled to the most effective care available.
7. The patient has the right to privacy during consultation, examination and treatment and in cases where it is necessary to use the notes of the patient's case for teaching and conferences, the consent of the patient must be sought.
8. The patient is entitled to confidentiality of information obtained about the patient and that information shall not be disclosed to

third party without the consent of the patient or the person entitled to act on the consent of the patient or the person entitled to act on behalf of the patient except where the information is required by law or is in the public interest.

9. The patient is entitled to the relevant information regarding policies and regulation of the health facilities that the patient attends.
10. Procedures for complaints, disputes and conflict resolution shall be explained to patients or their accredited representatives.
11. Hospital charges, mode of payment and the forms of anticipated expenditure shall be explained to the patient prior to treatment
12. Exemption facilities shall be made known to the patient.
13. The patient is entitled to personal safety and reasonable security of property within the confines of the institution.
14. The patient has the right to a second medical opinion if the patient so desires.

THE PATIENT'S RESPONSIBILITIES

The patient should understand the responsibilities of the patient as regard the patient's own health and therefore co-operate fully with the health care providers. The patient is responsible for,

- (a) providing full and accurate medical history for diagnosis, treatment, counseling and rehabilitation purposes;
- (b) requesting additional information or clarification regarding the patient's health or treatment, which may not have been well understood;
- (c) complying with the prescribed treatment, reporting adverse effects and adhering to follow up requests;
- (d) informing the healthcare providers of any anticipated problems in following prescribed treatment or advice;
- (e) obtaining the necessary information, which has a bearing on the management and treatment including the financial implications;

- (f) acquiring knowledge on preventive, promotive and simple curative practices and where necessary for seeking early professional help;
- (g) maintaining safe and hygienic environment in order to promote good health;
- (h) respecting the rights of other patients or clients and Health Service personnel.
- (i) protecting the property of the health facility.

NB: These rights and responsibilities shall be exercised by accredited and recognized representatives on behalf of minors and patients who are unable for whatever reason to make informed decisions by themselves.

In all health care activities the patient's dignity and interest must be paramount.

SEVENTH SCHEDULE

(Section 168)

WORLD HEALTH ORGANISATION REGULATIONS

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 remains 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;
- "crevif" 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 insect vectors of human diseases present in baggage, cargo, containers, conveyances, goods and postal parcels;
- "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 load cargo or stores; permission for an aircraft, after landing, to embark or disembark, discharge or load cargo or stores; and permission

- for a ground transport vehicle, upon arrival, to embark or disembark, 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 co-ordinated 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 Authority 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. VMO 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 HIR 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 Verifications

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 Co-operation of WHO with intergovernmental organizations and international bodies

1. WHO shall co-operate and co-ordinate 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 VMO 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 time frame 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 or 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 3 1, 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 I 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 a conveniently 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 travellers

Article 30 Travellers under public health observation

Subject to Article 43 or as authorized in applicable international agreements, a suspect traveller 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 travellers 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 transshipment 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.

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. State 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 traveller 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. 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 travellers 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 MMO 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 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

- I. 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 Sanita 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, signe in Washington;
 - (i) Protocol of 23 April 1946 to prolong the International Sanitary Convention for Aeria 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 198 1.
- 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 I 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 I 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 I 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 the 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 I

A. CORE CAPACITY REQUIREMENTS FOR SURVEILLANCE AND RESPONSE

1. States Parties shall utilize existing national structures and resources to meet their core capacity requirements under these Regulations, including with regard to:
 - (a) their surveillance, reporting, notification, verification, response and collaboration activities; and
 - (b) their activities concerning designated airports, ports and ground crossings.
2. Each State Party shall assess, within two years following the entry into force of these Regulations for that State Party, the ability of existing national structures and resources to meet the minimum requirements described in this Annex. As a result of such assessment, States Parties shall develop and implement plans of action to ensure that these core capacities are present and functioning throughout their territories as set out in paragraph 1 of Article 5 and paragraph 1 of Article 13.
3. States Parties and WHO shall support assessments, planning and implementation processes under this Annex.
4. At the local community level and/or primary public health response level

The capacities:

- (a) to detect events involving disease or death above expected levels for the particular time and place in all areas within the territory of the State Party; and
- (b) to report all available essential information immediately to the appropriate level of healthcare response. At the community level, reporting shall be to local community health-care institutions or the appropriate health personnel. At the primary public health response level, reporting shall be to the intermediate or national response level, depending on organizational structures. For the purposes of this

Annex, essential information includes the following: clinical descriptions, laboratory results, sources and type of risk, numbers of, human cases and deaths, conditions affecting the spread of the disease and the health measures employed; and

(c) to implement preliminary control measures immediately.

5. At the intermediate public health response levels

The capacities:

(a) to confirm the status of reported events and to support or implement additional control measures; and

(b) to assess reported events immediately and, if found urgent, to report all essential information to the national level. For the purposes of this Annex, the criteria for urgent events include serious public health impact and/or unusual or unexpected nature with high potential for spread.

6. At the national level

Assessment and notification. The capacities:

(a) to assess all reports of urgent events within 48 hours; and

(b) to notify WHO immediately through the National IHR Focal Point when the assessment indicates the event is notifiable pursuant to paragraph 1 of Article 6 and Annex 2 and to inform WHO as required pursuant to Article 7 and paragraph 2 of Article 9.

Public health response. The capacities:

(a) to determine rapidly the control measures required to prevent domestic and international spread;

(b) to provide support through specialized staff, laboratory analysis of samples (domestically or through collaborating centres) and logistical assistance (e.g. equipment, supplies and transport);

(c) to provide on-site assistance as required to supplement local investigations;

(d) to provide a direct operational link with senior health and other officials to approve rapidly and implement containment and control measures;

(e) to provide direct liaison with other relevant government ministries;

- (f) to provide, by the most efficient means of communication available, links with hospitals, clinics, airports, ports, ground crossings, laboratories and other key operational areas for the dissemination of information and recommendations received from WHO regarding events in the State Party's own territory and in the territories of other States Parties;
- (g) to establish, operate and maintain a national public health emergency response plan, including the creation of multidisciplinary/multicultural teams to respond to events that may constitute a public health emergency of international concern; and
- (h) to provide the foregoing on a 24-hour basis.

B. CORE CAPACITY REQUIREMENTS FOR DESIGNATED AIRPORTS, PORTS AND GROUND CROSSINGS

1. At all times

The capacities:

- (a) to provide access to (i) an appropriate medical service including diagnostic facilities located so as to allow the prompt assessment and care of ill travellers, and (ii) adequate staff, equipment and premises;
- (b) to provide access to equipment and personnel for the transport of ill travellers to an appropriate medical facility;
- (c) to provide trained personnel for the inspection of conveyances;
- (d) to ensure a safe environment for travellers using point of entry facilities, including potable water supplies, eating establishments, flight catering facilities, public washrooms, appropriate solid and liquid waste disposal services and other potential risk areas, by conducting inspection programmes, as appropriate; and
- (e) to provide as far as practicable a programme and trained personnel for the control of vectors and reservoirs in and near points of entry.

2. For responding to events that may constitute a public health emergency of international concern

The capacities:

- (a) to provide appropriate public health emergency response by establishing and maintaining a public health emergency contingency plan, including the nomination of a coordinator and contact points for relevant point of entry, public health and other agencies and services;
- (b) to provide assessment of and care for affected travellers or animals by establishing arrangements with local medical and veterinary facilities for their isolation, treatment and other support services that may be required;
- (c) to provide appropriate space, separate from other travellers, to interview suspect or affected persons;
- (d) to provide for the assessment and, if required, quarantine of suspect travellers, preferably in facilities away from the point of entry;
- (e) to apply recommended measures to disinsect, derat, disinfect, decontaminate or otherwise treat baggage, cargo, containers, conveyances, goods or postal parcels including, when appropriate, at locations specially designated and equipped for this purpose;
- (f) to apply entry or exit controls for arriving and departing travellers; and
- (g) to provide access to specially designated equipment, and to trained personnel with appropriate personal protection, for the transfer of travellers who may carry infection or contamination.

Date of *Gazette* notification: 16th October, 2012.