CHAPTER 244

THE PHARMACY AND POISONS ACT

SUBSIDIARY LEGISLATION

List of Subsidiary Legislation

THE PHARMACY AND POISONS (SALE OF MEPACRINE) RULES

[Legal Notice 114 of 1960]

1. These Rules may be cited as the Pharmacy and Poisons (Sale of Mepacrine) Rules.

2. Any person who sells mepacrinc tablets containing less than 95.0 per cent or more than 105.0 per cent of 100 milligrams of Mepa-crine Hydrochloride as described in the British Pharmacopoeia, 1958, shall be guilty of an offence and liable to a fine not exceeding five hundred shillings or to imprisonment for a term not exceeding one month, or to both such fine and imprisonment, and in addition to any penalty imposed under this ordinance the court may order any article in respect of which such offence has been committed or which has been used for the commission of such offence to be forfeited.

THE POISONS LIST (CONFIRMATION) ORDER

ARRANGEMENT OF PARAGRAPHS

THE POISONS LIST (CONFIRMATION) ORDER

[Legal Notice 168 of 1961, Legal Notice 250 of 1961, Legal Notice 423 of 1961, Legal Notice 146 of 1963, Legal Notice 93 of 1964, Legal Notice 150 of 1968, Legal Notice 15 of 2002]

1. Citation

This Order may be cited as the Poisons List Confirmation Order.

2. Poisons List confirmed

The Poisons List prepared by the Pharmacy and Poisons Board and set out in the Schedule to this Order is confirmed as the list of substances which are to be treated as poisons for the purposes of the Act.

SCHEDULE

[para. 2]

POISONS LIST

[L.N. 150/1968, L.N. 15/2002, s. 2.]

Part I

1. Acetanilide; alkyl acetanilides.

2. Acetohexamide.

3. Acetylcarbromal.

4. Acetyldihydrocodeine; its salts.

5. Acocanthera, glycosides of.

6. Adenium, glycosides of.

7. Alkali fluorides other than those specified in Part II of this list.

8. Alkaloids, the following; their salts, simple or complex; their quaternary compounds

Aconite, alkaloids of.

Atropine.

Belladonna, alkaloids of.

Brucine.

Calabar bean, alkaloids of.

Coca, alkaloids of.

Cocaine.

Codeine.

Colchicum, alkaloids of.

Coniine.

Contarnine.

Curare, alkaloids of; curare bases.

Ecgonine; its esters.

Emeline.

Ephedra, alkaloids of.

Ergot, alkaloids of, homologues and hydrogenated.

Gelsemium, alkaloids of.

Homatropine.

Hyoscine.

Hyoscyamine.

Jaborandi, alkaloids of.

Lobelia, alkaloids of.

Morphine.

Papaverine.

Pomegranate, alkaloids of.

Quebracho, alkaloids of, other than the alkaloids of red quebracho.

Rauwolfia, alkaloids of; their derivatives.

Sabadilla, alkaloids of.

Solanaceous alkaloids not otherwise included in this List.

Stavesacre, alkaloids of.

Strychnine.

Thebaine.

Veratrum, alkaloids of.

Yohimba, alkaloids of.

9. Allyl isopropylacetyl urea.

10. Allylprodine; its salts.

11. Alphameprodine; its salts.

12. Alphaprodine; its salts.

13. Amidopyrine; its salts; amidopyrine sulphonates; their salts.

14. Amino-alcohols esterfield with banzoic acid, phenylacetic acid, phenylpropionic acid, cinnamic acid or the derivatives of these acids, their salts.

15. p-Aminobenzenesulphonamide;

its salts, derivatives of p-amino-benzenesulphonamide having any of the hydrogen atoms of the p-amino group or of the sulphonamide group substituted by another radical; their salts.

16. p-Aminobenzoic acid, esters of; their salts.

17. B-Aminopropy1benzene and B-aminoisopropylbenzene and any compound

structurally derived from either of those substances by substitution in the chain or by ring closure therein (or by both such substitution and such closure), except ephedrine, Nmethylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, and prenylamine; any substance falling within this item.

18. p-Amino-salicylic acid; its salts; any preparation of p-Amino salicylic acid; its salts.

19. Amitriptyline; its salts.

20. Amyl nitrite.

21. Androgenic, oestrogenic and progestational substances, the following Benzoestrol.

Derivatives of stilbene, dibenzyl or naphthalene with oestrogenic activity; their esters.

Steroid compounds with androgenic or oestrogenic or progestational activity; their esters.

22. Anileridine; its salts.

23. Antibiotics, that is to say any substances produced by a living organism and which have a suppressive or destructive action on other organisms; their synthetic equivalents; their salts; preparations of such substances and their salts.

24. Anti-histamine substances, the following; their salts; their molecular compounds

Antazoline.

Bromodiphenhydramine.

Buclizine.

Carbinoxamine.

Chlorcyclizine.

Chlorpheniramine.

Cinnarizine.

Clemizole.

Cyclizine.

Cyproheptadine.

3-Di-n-butylaminomethyl-4, 5, 6-tryhydroxyphthalide.

Diphenhydramine.

Diphenylpyraline.

Doxylamine.

Isothipendyl.

Mebhydrolin.

Meclozine.

Phenindamine.

Pheniramine.

Phenyltoloxamine.

Promethazine.

Pyrrobutamine.

Thenalidine.

Tolpropamine.

Triprolidine.

Substances being tetra-substituted N derivatives of ethylene-diamine or

propylenediamine.

25. Antimony, chlorides of; oxides of antimony; sulphides of antimony; antimonates; antimonites; organic compounds of antimony.

26. Apomorphine; its salts.

27. Arsenical substances, the following, except those specified in Part II of this List; halides of arsenic; oxides of arsenic; arsenates; arsenites; organic compounds of arsenic.

28. Azacyclonol; its salts.

29. Barbituric acid; its salts; derivatives of barbituric acid; their salts; compounds of barbituric acid, their salts, their derivates, their salts, with any other substances.

30. Barium, salts of, other than barium sulphate and the salts of barium specified in Part II of this List.

31. Benactyzine; its salts.

32. Benzethidine; its salts.

33. Benzhexol; its salts.

34. Benzoylmorphine, its salts.

35. Benztropine and its homologues; their salts.

36. Benzylmorphine; its salts.

37. Betameprodine; its salts.

38. Betaprodine; its salts.

39. Bromvaletone.

40. Busulphan; its salts.

41. Butylchloral hydrate.

42. Cannabis (the dried flowering or fruiting tops of Cannabis saliva Linn); the resin of cannabis; extracts of cannabis; tinctures of cannabis; cannabin tannate.

43. Cantharidin; cantharidates.

44. Captodiame; it salts.

45. Carbachol.

46. Carbromal.

47. Carisoprodol.

48. Carperidine; its salts.

49. Chloral; its addition and its condensation products; their molecular compounds.

50. Chlordiazepoxide; its salts.

51. Chlormethiazole; its salts.

52. Chloroform.

53. Chlorothiazide and other derivatives of benzo-1, 2, 4-thiadiazine-7-sulphonamide 1, 1-dioxide, whether hydrogenated or not.

54. Chlorphenoxamine.

55. Chlorphentermine; its salts.

56. Chlorpropamide; its salts.

57. Chlorprothixene, and other derivatives of 9-methylenethiaxanthen and their salts.

58. Chlorthalidone.

59. Clonitazene; its salts.

60. Clorexolone.

61. Creosote obtained from wood.

62. Croton, oil of.

63. Cyclarbamate.

64. Cycrimine; its salts.

65. Oehydroemetine; its salts.

66. Oemecarium bromide.

67. Oesipramine; its salts.

68. Desomorphine; its salts.

69. Dextromethorphan; its salts.

70. Dextromoramide; its salts.

71. Dextrorphan; its salts.

72. Diacetylmorphine; its salts.

73. Diacetylnalorphine; its salts.

74. 4-4-Oiamidino-diazoaminobenzene; its salts.

75. Oiampromide, its salts and other compounds containing the chemical structure of 1:4 benzodiazepine substituted to any degree; their salts.

76. Oiazepam.

77. Diethylcarbamazine.

78. Digitalis, glycosides of; other active principles of digitalis.

79. Dihydrocodeine; its salts.

80. Dihydrocodeinone; its salts; its esters; their salts.

81. Dihydromorphine; its salts, its esters; their salts.

82. Dimenoxadole; its salts.

83. Oimepheptanol; its salts.

84. Oinitrocresols (DNC); their compounds with a metal or a base.

85. Oinitronaphthols; dinitrophenols; dinitrothymols.

86. Dinosam; its compounds with a metal or a base.

87. Dinoseb; its compounds with a metal or a base.

88. Dioxaphetyl butyrate; its salts.

89. Diphenoxylate; its salts.

90. Dipipanone; its salts.

91. Disulfiram.

92. Dithienylallylamines; dithienylalkylallylamines; their salts.

93. Dyflos.

94. Ecothiopate iodide.

95. Ectylurea.

96. Elaterin.

97. Emylcamate.

98. Ergot (the sclerotia of any species of Claviceps); extracts of ergot; tinctures of ergot.

99. Erythrityl tetranitrate.

100. Ethchlorvynol.

101. Ethinamate.

102. Ethionamide.

103. Ethoheptazine; its salts.

104. Ethylmorphine; its salts.

105. Etonitazene; its salts.

106. Etoxeridine; its salts.

107. Fentanyl; its salts.

108. Fluoroacetamide.

109. Fluoroacetanilide.

110. Furethidine; its salts.

111. Gallamine; its salts, its quaternary compounds.

112. Glutethimide; its salts.

113. Glyceryl trinitrate.

114. Guanidines, the followingpolymethylene diguanidines; di-p-anisyl-p-phenetylguanidine.

115. Haloperidol, and other 4-substituted derivatives of N-(3-P. fluorobenzoylpropyl} piperidine.

116. Hexapropymate.

117. Hormones; natural and synthetic; any preparations, admixture, extract or other substance containing any proportion of any substance having the action of any hormone.

118. Hydrazines, benzyl, phenethyl and phenoxyethyl; their a-methyl derivatives; acyl derivatives of any of the foregoing substances comprised in this item; salts of any compounds comprised in this item.

119. Hydrocyanic acid; cyanides; double cyanides of mercury and zinc.

120. Hydromorphinol; its salts.

121. Hydromorphone; its salts; its esters; their salts.

122. Hydroxy-N-N-dimethyltryptamines, esters or ethers of these; salts of any of the foregoing.

123. Hydroxypethidine; its salts.

124. Hydroxyzine; its salts.

125. Imipramine; its salts.

126. Indomethacin; its salts.

127. Insulin.

128. Isomethadone (isoamidone); its salts.

129. Isoniazid; its salts, derivatives; their salts.

130. Ketobemidone; its salts.

131 . Laudexium; its salts.

132. Lead acetates; compounds of lead with acids from fixed oils.

133. Levomethorphan; its salts.

134. Levomoramide; its salts.

135. Levophenacylmorphan; its salts.

136. Levorphanol; its salts.

137. Mannity1 hexanitrate.

138. Mannomustine; its salts.

139. Mephenesin; its esters.

140. Meprobamate.

141. Mercaptopurine; its salts; derivatives of mercaptopurine; their salts.

142. Mercury, oxides of; nitrates of mercury; mercuric ammonium chlorides; potassio-mercuric iodides; organic compounds of mercury which contain a methyl (CH3) group directly linked to the mercury atom; mercuric oxycyanides; mercuric thiocyanate.

143. Metaxalone.

144. Metazocine; its salts.

145. Metformin; its salts.

146. Methadone (amidone); its salts.

147. Methadyl acetate; its salts.

148. Methaqualone; its salts.

149. Methixene; its salts.

150. Methocarbamol.

151. Methoxsalen.

152. Methyldesorphine; its salts.

153. Methyldihydromorphine; its salts.

154. Methylpentynol; its esters and other derivatives.

155. 1-Methyl-4-phenylpiperidine-4-carboxylic acid.

156. Methyprylone.

157. Metopon; its salts.

158. Monofturoacetic acid; its salts.

159. Morpheridine; its salts.

160. Mustine and any other N-substituted derivatives of di-(2-chloroethyly) amine; their salts.

161. Myrophine; its salts.

162. Nalorphine; its salts.

163. Nicocodine; its salts.

164. Nicotine; its salts.

165. m-Nitrophenol; O-nitrophenol; p-nitrophenol.

166. Noracymehadol; its salts.

167. Norcodeine; its salts.

168. Norlevorphanol; its salts.

169. Normethadone; its salts.

170. Normorphine; its salts.

171. Norpipanone.

172. Nortryptyline; its salts.

173. Nux Vomica.

174. Opium.

175. Orphenadrine; its salts.

176. Orthocaine; its salts.

177. Ouabain.

178. Oxalic acid.

179. Oxazepam.

180. Oxethazaine.

181. Oxycinchoninic acid, derivatives of; their salts; their esters.

182. Oxycodone; its salts, its esters; their salts.

183. Oxymorphone; its salts.

184. Oxyphenbutazone.

185. Paramethadione.

186. Pargyline; its salts.

187. Pemoline; its salts.

188. Phenacemide.

189. Phenadoxone; its salts.

190. Phenamidine; its salts.

191. Phenaglycodol.

192. Phenampromide; its salts.

193. Phenanthridinium and its derivatives.

194. Phenazocine; its salts.

195. Phenbutrazate.

196. Phencyclidine; its salts.

197. Phenetidylphenacetin.

198. Phenformin; its salts.

199. Phenols (any member of the series of phenols of which the first member is phenol and of which the molecular composition varies from member to member by one atom of carbon and two atoms of hydrogen) except in substances containing less than sixty percent, weight in weight, of phenols; compounds of phenol with a metal, except in substances containing less than the equivalent of sixty percent; weight in weight, of phenols.

200. Phenomorphan; its salts.

201. Phenoperidine; its salts.

202. Phenothiazine, derivatives of; their salts; except dimethoxanate, its salts and promethazine, its salts and its molecular compounds.

203. Phenylbutazone.

204. Phenylcinchonicic acid; salicylcinchoninic acid; their salts.

206. Pholcodine; its salts.

207. Phosphorus, yellow, except as provided in Part II of this List. Phosphorous compounds, the following-

Amiton, azinphos-ethyl, azinphos-methyl, demeton-O, demeton-S, demeton-0, methyl, demeton-S-methyl, diethyl 4-methyl-7-coumarinyl phosphorothionate, diethyl pnitrophenyl phosphate, dimefox, disulfoton, ethion, ethyl p-nitrophenyl phenylphosphonothionate, mazidox, mecarbam, mevinphos, mipafox, oxydemeton-tmethyl, parathion, phenkapton, phorate, phosphamidon, schradan, sulfotep, TEPP (HETP), thionazin, triphosphoric pentadimethylamide, vamidothion.

208. Picric acid.

209. Picrotoxin.

210. Piminodine; its salts.

211. Pituitary gland, the active principles of.

212. Polymethylenebistrimethylammonium salts.

213. Procyclidine; its salts.

214. Proheptazine; its salts.

215. Promoxolan.

216. Propoxyphene; its salts.

217. Propylhexedrine; its salts.

218. Prothionanide.

219. Prothipendyl; its salts.

220. Quinapyramine and analogous substances; their salts.

221. Quinuronium; its salts.

222. Quinethazone.

223. Racemethorphan; its salts.

224. Racemoramide; its salts.

225. Racemorphan; its salts.

226. Savin, oil of.

227. Strophanthus: glycosides of strophanthus.

228. Styramate.

229. Sulphinpyrazone.

230. Sulphonal; alkyl sulphonals.

231. Sulphones; their salts, their derivatives.

232. Suprarenal gland medulla, the active principles of; their salts.

233. Syrosingopine.

234. Tetrabenazine; its salts.

235. Thalidomide; its salts.

236. Thallium, salts of.

237. Thebacon; its salts; its esters; their salts.

238. Thiacetazone; its salts; its derivatives.

239. Thyroid gland, the active principles of; their salts.

40. Tolbutamide.

241. Toxaphene.

242. Tretamine; its salts.

243. Triaziquone.

244. Tribromethyl alcohol.

245. 2,2,2-Trichloroethyl alcohol, esters of; their salts.

246. Trimeperidine; its salts.

247. Trimipramine; its salts.

248. Troxidone.

249. Zoxazolamine.

Part II - GROUP A

1. Ammonia.

2. Barium carbonate, if in the form of preparations for the destruction of rats and mice.

3. Barium silicofluoride.

4. Barium sulphide when contained in depilatories.

5. Formaldehyde.

6. Formic Acid.

7. Hydrochloric acid.

8. Hydrofluoric acid; potassium fluoride; sodium fluoride; sodium silicofluoride.

9. Metallic oxalates, other than potassium quadroxalate, if in the form of photographic solutions.

10. Nitric acid.

11. Phenols as defined in Part I of this list in substances containing less than sixty per cent., weight in weight, of phenols; compounds of phenol with a metal in substances containing less than the equivalent of sixty per cent., weight in weight, of phenols.

12. Phenylene diamines; toluene diamines; other alkylated-benzenediamines; their salts.

12A. Phosphorous compounds, the following-

Endosulfan, ethion, mecarbam, phenkapton.

13. Phosphorous, yellow, when contained in rat poison.

14. Potassium hydroxide.

15. Potassium quadroxalatc.

16. Sodium hydroxide.

17. Sodium nitrite.

18. Sulphuric acid.

19. Zinc Phosphide.

GROUP B

1. Aconite, alkaloids of, in preparations containing less than 0.02 per cent of the alkaloids of aconite.

2. Arsenic in preparations containing less than the equivalent of 0.01 per cent of arsenic trioxide, and dentifices containing less than 0.5 per cent of acetarsol.

3. Belladonna, alkaloids of, in preparations containing less than 0.15 per cent of the alkaloids of belladonna calculated as hyoscyamine.

4. Chloral hydrate in preparations intended-

(a) for internal consumption containing less than 2.3 per cent chloral hydrate; and.

(b) for external application containing less than 10.1 per cent chloral hydrate.

5. Codeine, when contained in any substance in a proportion of less than 1.5 per cent and also when contained in Compound Tablets of Codeine B.P., or tablets of a similar composition each containing not more than 116th grain of Codeine.

6. Coniine in preparations containing less than 0.02 per cent.

7. Ethylmorphine in preparations containing less than 0.2 per cent.

8. Hyoscyamine in preparations containing less than 0.15 per cent.

9. Lobelia, alkaloids of, in preparations containing less than 0.25 per cent.

10. Mercuric ammonium chloride when contained in an ointment not exceeding 15 per cent.

11. Mercury oxide when contained in yellow oxide of Mercury Ointment.

12. Morphine in preparations containing less than 0.2 per cent of anyhydrous morphine.

13. Morpholinylethylmorphine in preparations containing less than 1 per cent.

14. Nux vomica, in preparations containing less than 0.2 per cent of alkaloids calculated as strychnine.

15. Opium when in preparations for external use containing less than 2 per cent (opium).

16. Stramonium, in preparations containing less than 0.15 per cent of alkaloids calculated as hyoscyamine.

17. Strychnine in preparations containing less than 0.2 per cent of strychnine.

18. Deltamethrine.

THE PHARMACY AND POISONS (PROHIBITED MEDICINES) ORDER

[Legal Notice 36 of 1963]

1. This Order may be cited as the Pharmacy and Poisons (Prohibited Medicines) Order.

2. The manufacture, sale, advertisement or possession of the proprietory medicine and the poison set out in the Schedule to this Order is prohibited.

SCHEDULE

1. Nu-cell.

2. Part I poison known as Thalidomide which is marketed under the names Distaval or Contergan, or Softenon and which is an ingredient of Asmaval, Tensival, Valgis and Valgraine.

THE PHARMACY AND POISONS (CONTROL OF DRUGS) RULES

[Legal Notice 180 of 1969, Legal Notice 247 of 1969, Legal Notice 228 of 1974]

1. These Rules may be cited as the Pharmacy and Poisons (Control of Drugs) Rules.

2. In these Rules "drug" means any medicine, medicinal preparation or therapeutic substance which is contained in an ampule or capsule in any form in which such drug may be used for injection.

3. No person other than those authorized to import, possess, distribute, sell or purchase Part 1 poisons under the Act shall import, possess, distribute, sell or purchase any drug.

4. Any person who is authorized to import, possess, distribute, sell or purchase any drugs shall do so subject to the conditions governing the importation, possession, distribution, sale and purchase of Part 1 poisons under the Act.

5. Any person who fails to comply with paragraphs 3 and 4 of these Rules shall be guilty of an offence and shall be liable to a fine not exceeding two thousand shillings or to a term of imprisonment not exceeding two months or both such fine and such imprisonment.

THE PHARMACY AND POISONS (REGISTRATION OF DRUGS) RULES

ARRANGEMENT OF RULES

Rule

THE PHARMACY AND POISONS (REGISTRATION OF DRUGS) RULES

[Legal Notice 147 of 1981, Legal Notice 142 of 1991, Legal Notice 192 of 2010]

1. Citation and commencement

These Rules may be cited as the Pharmacy and Poisons (Registration of Drugs) Rules, 1981, and shall come into operation on the 1st April, 1982.

2. Interpretation

In these Rules, "drug" means any substance or mixture of substances, which can be used for any of the following purposes—

(a) treating, preventing or alleviating symptoms of disease;

(b) diagnosing disease or ascertaining the existence, degree or extent of a physiological condition; or

(c) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily and whether by way of terminating, reducing, postponing or increasing or accelerating the operation of that function, in human beings and animals and includes a substance which can be used as a contraceptive or for the purpose of inducing anaesthesia; but does not include a product prepared by a pharmacist in his pharmacy and dispensed by him without promotion; blood, blood plasma and blood preparations containing cellular elements of blood or substances such as dental fillings and plates or surgical preparations such as catgut and plaster of Paris bandages.

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

"import" includes parallel importation; and

"parallel importation" means the importation into Kenya of patented drugs under section 58(2) of the Industrial Property Act (Cap. 237).

[L.N. 19/2010, s. 3.]

3. Control of the manufacture, etc. of drugs

No person shall import, manufacture for sale or sell any drug in Kenya unless that drug has been registered and listed in accordance with the provisions of these Rules.

[L.N. 19/2010, s. 4.]

4. Application for registration of drug

(1) An application for registration of a drug shall be in Form 1 set out in the Schedule.

(1A) An application for registration of parallel imported drugs, poisons, listing of herbal, complementary medicines and cosmetics shall be in form 1 in the Schedule.

(2) In addition to the information required to be furnished in the prescribed form the applicant shall furnish such further information and material as may be required by the Board for the proper evaluation of the drug in respect of which the application is made.

(3) An application for renewal of registration of a drug under rule 7, shall be in Form 1A set out in the Schedule; and

[L.N. 142/1991, s. 2., L.N. 192/2010, s. 5.]

5. Fees

(1) An application made under rule 4 shall be accompanied by the following fees—

(a) five thousand shillings if the drug required to be registered has been manufactured outside Kenya; and

(b) one thousand shillings if the drug required to be registered has been manufactured in Kenya.

(2) If the registration is being renewed the applicant shall pay the following fees—

(a) one thousand shillings in respect of a drug manufactured outside Kenya; and

(b) five hundred shillings in respect of a drug manufactured in Kenya.

(3) A fee of five hundred shillings shall be paid for a duplicate copy of the certificate of registration if the original is defaced, damaged or lost and such copy shall bear the words "DUPLICATE COPY".

6. Issue of certificate of registration

(1) The Board shall consider the application made under rule 4, and, if it is satisfied of the safety, efficacy, quality and economic value of the drug, shall register the drug and issue a certificate of registration which shall be in Form 2 set out in the Schedule.

(1A) The Board shall consider the application made under subrule 4(1)(a) and may, if it is satisfied of the safety, quality, efficacy and economic value of the drugs, register the same, and issue a certificate of registration which shall begin Form 2.

(2) The Board may, while considering a drug for registration under paragraph (1), approve the details as supplied by the applicant or approve it with such amendments as it may deem appropriate in respect of the following particulars—

(a) the name under which the drug may be sold;

(b) the labelling;

(c) the statement of the representations to be made for the promotion of the drug in respect of—

(i) the claim to be made for the drug;

(ii) the route of administration;

(iii) the dosage;

(iv) the contra-indications, the side effects and precautions, if any; and

(v) the package size.

(3) If the Board is not satisfied as to the safety, efficacy, quality or economic value of the drug, it may, after providing an opportunity to the applicant to be heard, reject the application for the registration of the drug and inform the applicant the reasons for rejection in writing.

[L.N. 192/2010, s. 6.]

7. Duration, etc. of certificate of registration

(1) A certificate of registration issued under these Rules shall, unless earlier suspended or revoked, be in force for a period of five years from the date of issue and may thereafter be renewed for periods not exceeding five years at any one time.

(2) If an application for renewal is made before the expiration of the period of validity of a certificate of registration the certificate shall remain in force until the application is approved; except that where the application for renewal is made after the expiration of the period of validity of the certificate of registration the application shall be considered as a fresh application and the provisions of rule 6 shall apply accordingly.

8. Suspension or revocation of certificate of registration

(1) The Board may suspend or revoke a certificate of registration issued under these Rules for such period as the Board may determine.

(2) The powers conferred by paragraph (1) shall not be exercised by the Board in respect of any certificate of registration except on one or more of the following grounds—

(a) that the matters stated in the application on which the certificate of registration was granted were false or incomplete in a material particular;

(b) that any of the provisions of the certificate of of registration has to a material extent been contravened by the holder of the certificate; or

(c) that the premises on which, or on part of which, drugs are manufactured, assembled or stored by or on behalf of the holder of the certificate of registration are unsuitable for the manufacturing, assembling or storage of drugs;

(d) that new information has been discovered by the Board which renders the drug unsafe or dangerous.

9. Conditions for registration of a new drug

(1) The Board shall, before registering a new drug for which the research work has been conducted in any other country and its efficacy, safety, and quality established in that country, require an investigation on the pharmaceutical, pharmacological and other aspects of the drug to be conducted and clinical trials to be made which are necessary to establish its quality and where applicable the biological availability and its safety and efficacy to be established under local conditions.

(1A) Any person wishing to carry out a clinical trial in the country shall apply to the Board for approval before engaging in such study involving investigational products.

(1B) An application under paragraph (1A) shall be accompanied by the fees set out in Part B of the Second Schedule.

(2) Notwithstanding paragraph (1), the Board may register a new drug and require the investigations and clinical trials specified in paragraph (1) to be conducted after its registration.

(3) The Board may, if in its opinion it is necessary to do so in the interest of public health, register a new drug for a period of two years.

[L.N. 192/2010, s. 7.]

9A. Register

(1) The Board shall maintain a register containing a record of all the drugs registered.

(2) There shall be payable by entities whose drugs are registered a retention fee in the amount specified in Part A of the Second Schedule.

[L.N. 192/2010, s. 8.]

10. Inspection of premises

The Board may, before issuing a certificate of registration under these Rules, cause the premises in which the manufacturing of the drug is proposed to be conducted to be inspected by inspectors appointed for that purpose, and the inspectors shall have powers to enter the premises and inspect the plant and the process of manufacture intended to be employed is the manufacturing of the drug and make a report to the Board.

11. Offences and penalties

Any person who contravenes any of the provisions of these Rules shall be guilty of an offence and shall be liable to a fine not exceeding six thousand shillings or to a term of imprisonment not exceeding six months or to both such fine and such imprisonment.

FIRST SCHEDULE

[r. 4.]

FORMS

Form 1

APPLICATION FOR REGISTRATION OF A DRUG

(*to be submitted in sextuplicate*)
CONFIDENTIAL
Part 1

The Registrar,

Pharmacy and Poisons Board,

P.O. Box 30016,

NAIROBI.

1. Name of Applicant……

Business Address…….

Telephone Number…….

2. Name of product to be registered……

Type of formulation to be registered…….

Presentation of the product…….

3. Identification (physical appearance of the product)…….

4. Therapeutic classification……..

(a) Name and business address of manufacturer……

(b) Country of origin……..

6. Registration Number of the product in country of origin and all other countries where it is marketed…….

7. Is the product authorized to be on the market in the country of origin? If yes, attach a legal certificate of free sale from the registering Authority……

If no, state the reasons below:—

……

Part II

8. Pharmaceutical Formula of the Product

CONSTITUENT			
Chemical Name	Approved Name (if any)	Quantity	Active or non-Active

Part III

9. The names and structural formula of the active ingredients are as follows:

Approved or Chemical Name	Structural Formula

Part IV

10. Specifications for all the active and non-active raw materials used in the manufacturing process are as follows—

Part V

11. Analytical control procedures which are performed on all active and non-active materials before they are used in the manufacturing process are as follows—

Part VI

12. Analytic control procedures and the frequency with which they are performed during the manufacturing process are as follows—

Part VII

13. Full specifications of lima manufactured product are as follows-

Part VIII

14. The analytic control procedures which are performed on the final manufactured product are as follows—

Part IX

15. The inferred shelf-life of the product is as follows—

Part X

16. Summaries of the method of manufacture and packaging are as follows—

Part XI

17. A summary of the experimental details and results of the tests performed on the drug to confirm its pharmacological effects—

Part XII

18. Summary of the experiments and results performed on the drug to confirm its physiological availability—

Part XIII

19. Particulars of clinical tests conducted with reference to the efficacy of the use of the drug, with a summary of the nature of the tests, by whom conducted and where, results etc., and with special reference to comparative of controlled clinical tests, double blind tests, etc.—

The undersigned declares that all the information contained herein is correct to the best of his knowledge and belief.

....
Date of application Signature of applicant

Note:

1. A separate application is required for each drug.

2. A dosage form in a specified strength shall be considered as a drug.

3. Application fees are not refundable.

Form 1A (r. 4(3))

APPLICATION FOR RE-REGISTRATION OF A DRUG
CONFIDENTIAL
(to be submitted in sextriplicate)

The Registrar,

Pharmacy and Poisons Board,

P.O. Box 30016,

Nairobi.

1. Name of Applicant (manufacturer) .....

Registered physical business address

(See note (1) .....

.....

.....

Telephone No. (Office) .....

2. Name of product to be re-registered .....

.....

Type of formulation *(see note 2)* .....

.....

Presentation of the product .....

3. Identification physical appearance of the product) .....

.....

(a) Therapeutic classification(s) .....

.....

.....

(b) Specific indication(s) .....

.....

.....

(c) Category (*see note 3*)

.....

.....

5. Name and business address of manufacturer

.....

.....

6. Registration number of the product in Kenya

.....

.....

Date of first registration .....

7. Has the product been discontinued in any country?

.....

.....

If yes, Why?

.....

.....

8. Have you changed the pharmaceutical formula?

If yes, state changes and provide the new formula

.....

.....

9. Have you changed the manufacturing procedures?

If yes, state the new changes

.....

.....

10. Have you made any other changes in quality control of finished

productis, analytical procedures and packaging specifications?

If yes, state new specifications

.....

.....

11. Provide recent (5-10 years) pharmacological, physiological, Clinical toxilocogical and bio availability data *(see note 4)*

.....

.....

12. We the undersigned (hereby declare that all the information contained (herein is correct to the best of our knowledge:

	Name	***Signature***	***Qualifications***	***date***
(a) Quality Control Manager	.....	.....	.....	.....
(b) Production Manager	.....	.....	.....	.....
(c) Registration Officer *(see note 5)*	.....	.....	.....	.....

Notes-

(1) for foreign manufacturers give your local agents contacts;

(2) tablet, capsule injections;

(3) prescription only medicine (POM), over the counter medicine (OTC), pharmacy medicine (P), general sales (GS);

(4) for veterinary products, provide residue levels in milk and meat;

(5) for (c) local manufacturers, local agents—the company pharmacist is to sign;

(6) a separate application is required for each drug;

(7) re-application fee is not refundable;

(8) a dosage form in a specific strength shall be considered as a drug;

(9) applicants are notified that any false information given in the application may lead to fines and refusal of subsequent registration of products;

(10) each reapplication must be accompanied by six samples of the smallest commercial pack.

Date ....

Signature of Applicant

FORM 2 (r. 6)

THE PHARMACY AND POISONS (REGISTRATION OF DRUGS) RULES, 1981

REGISTRATION OF DRUGS CERTIFICATE

Number……

It is hereby certified that the medicine (drug) as described hereunder, has been registered subject to the conditions indicated here-under—

1. Approved name……

2. Trade name under which marketed……

3. Registration No. ……

4. Active ingredients and quantities per unit……..

5. Form of preparations……

6. Condition under which medicine is registered……

7. Name and business address of manufacturer……..

8. Registered in the name of…….

Business address…….

9. Date of registration……

10. Expiry date of registration……..

....

Date Registrar, Pharmacy and Poisons Board

SECOND SCHEDULE

[r. 5(2)(b), 9(1B)]

FEES

[L.N. 192/1991, s. 9.]

A	***Fees (USD)***
Imported product(s)	300
Locally Manufactured products(s)	300
Late application for retention penalty	100
Appeal for rejected application of registration	300
B	
Application for clinical trials	1000

THE PHARMACY AND POISONS (CONDUCT OF INQUIRIES) RULES

[Legal Notice 52 of 1985]

1. These Rules may be cited as the Pharmacy and Poisons (Conduct of Inquiries) Rules.

2. In these Rules, unless the context otherwise requires—

"chairman" means the chairman of the Board;

"charge" means a charge or charges specified in a notice of inquiry;

"complainant" means a person or body of persons who makes a complaint to the Board;

"inquiry" means an inquiry held by the Board under these Rules.

3. An inquiry into the conduct of a registered pharmacist may be instituted by the Board on its own initiative or upon a complaint addressed to the Board by or on behalf of any person alleging professional misconduct on the part of the registered pharmacist.

4. A person who lodges a complaint of professional misconduct against a registered pharmacist shall furnish an affidavit detailing the specific acts complained of to the registrar and the complainant must be prepared to give evidence before the Board in the event of an inquiry being held.

5. (1) The registrar shall, in accordance with the circumstances and if necessary in consultation with the chairman, on receipt of a complaint under these Rules—

(a) seek further information from the complainant; or

(b) advise the registered pharmacist of the nature of the complaint against him and ask him for an explanation warning him that the explanation may be used in evidence if an inquiry into his conduct is held in accordance with these Rules; or

(c) place the matter before the Board with the relevant documents.

(2) The Board may, after giving the matter due consideration—

(a) cause further investigation of the complaint to be made; or

(b) seek legal advice or such other assistance as it may deem necessary; or

(c) if it is of the opinion that the complaint, even if substantiated, would not be held to constitute professional misconduct or if, for any other reason it considers that an inquiry should not be held, take such action as it deems fit; or

(d) if it is the opinion that the evidence furnished in support of the complaint discloses prima facie evidence of professional misconduct, hold an inquiry in accordance with these Rules.

6. (1) The registrar shall, if an inquiry is to be held—

(a) submit to the Board all documents and other material having bearing on the inquiry; and

(b) send to the registered pharmacist against whom the complaint relates a notice of inquiry which shall—

(i) state the nature of the charge preferred against him giving full particulars of such a charge, including copies of any relevant documents;

(ii) specify the date, time and venue of the inquiry;

(iii) inform the registered pharmacist that he may submit further statements to the Board prior to the inquiry, which statements may be used as evidence; and that he shall be afforded the opportunity, by himself or through his legal representative, of answering the charge or being heard in his defence.

(2) The notice of inquiry sent to a registered pharmacist under paragraph (1) shall be in the form set out in the Schedule and shall be sent by registered post to his last known address as notified to the registrar or by other means approved by the Board.

7. (1) The Board may make such order as to costs as it deems fit; and such costs shall be recoverable as a civil debt.

(2) In cases where a complainant or the registered pharmacist against whom the complaint is made requests that witnesses be summoned to give evidence, the Board may require the complainant or the registered pharmacist to deposit a sum of money sufficient to cover the costs of bringing the witness to the place where the inquiry is being held.

8. A person who fails when summoned by the Board to attend as a witness or to produce any books or documents which he is required to produce shall be guilty of an offence and liable to a fine not exceeding two thousand shillings or in default, to imprisonment for not more than three months.

9. In a case where the registered pharmacist against whom a complaint has been made appears personally or is represented by an advocate, the following procedure shall be followed—

(a) the registrar shall read the notice of the inquiry addressed to the registered pharmacist;

(b) the complainant shall be invited to adduce evidence in support of the complaint;

(c) the registered pharmacist shall then be asked to state his case, either personally or through his legal representative and to produce evidence in support of his case, or in the event of deciding to produce a written statement in his defence, that statement shall be read;

(d) at the conclusion of the case of the accused person, the Board shall, if he has adduced evidence, hear the complainant or his legal representative on the case generally but the Board shall not at this stage hear further evidence unless there are, in the opinion of the Board, special reasons for hearing such further evidence;

(e) if the registered pharmacist does not adduce any evidence, the complainant shall not be heard in reply;

(f) when a witness appears before the Board he shall be examined by the person at whose request he was summoned, then cross-examined by the person against whom the complaint is made or his representative and finally reexamined by the person who requested that he should be summoned to give evidence at the inquiry.

10. In a case where the registered pharmacist is not present, the following procedure shall be followed—

(a) the registrar shall read the notice of inquiry addressed to the registered pharmacist under rule 5;

(b) the complainant shall then be asked to state his case and to produce his evidence in support of it.

11. In a case in which neither the complainant nor the registered pharmacist appears, the Board shall consider and decide what further action, if any, may be taken.

12. (1) Members of the Board may, with the permission of the chairman, put such questions to witnesses as they deem necessary.

(2) All oral evidence shall be taken on oath and the Board may decline to admit the evidence of any witness or deponent to a document who is not present for, or declines to submit to, cross-examination.

(3) Upon the conclusion of the case, the Board shall deliberate upon the evidence in camera, and the judgment and verdict shall be communicated in open meeting or at a later date, in writing, as the Board may direct.

13. Any decision of the Board in regard to any point arising in connection with, or in the course of, an inquiry may be arrived at in camera but shall be communicated to the persons concerned in open meeting.

14. The Board may, upon a finding of guilty as charged, administer one or other of the following penalties—

(a) a reprimand or a caution or reprimand and a caution; or

(b) the penalties specified in section 12 of the Act.

15. The Board may at any stage during an inquiry under these Rules adjourn its proceedings as it thinks fit.

16. Any party to the proceedings shall, on application, be furnished with a transcript of the shorthand notes or a certified copy of the proceedings or determination or finding of the Board on the payment of a fee of five shillings for every page of the shorthand notes or certified proceedings or determination or finding of the Board.

17. Meeting of the Board for purposes of an inquiry under these Rules, except so far as the chairman may otherwise direct, shall be held at the offices of the Board and may be held as regularly as circumstances require.

SCHEDULE

[r. 6(2).]

FORM OF SUMMONS TO ATTEND AN INQUIRY UNDER THE PHARMACY AND POISONS (CONDUCT OF INQUIRIES) RULES

Dear Sir/Madam,

Disciplinary Inquiry

I have been directed to inform you that the following charge which has been preferred against you will be considered at a meeting of the Pharmacy and Poisons Board, to be held at....., on..... at.....

That you, being a registered pharmacist.....

and that in relation to the facts alleged you have been guilty of professional misconduct.

You are requested to appear before the Board to establish any defence which may wish to offer, but if you should decide not to do so, the Board may consider and deal with the charge in your absence.

If you wish your letter of ....., or any other letter you may address to me to constitute your defence, please advise me of this in writing not later than 14 days before the date set down for the inquiry.

.....
Register

THE PHARMACY AND POISONS (PROHIBITED MEDICINES) ORDER

[Legal Notice 526 of 1997]

1. This Order may be cited as the Pharmacy and Poisons (Prohibited Medicines) Order.

2. The manufacture, sale, advertisement or possession of the proprietory medicine set out in the Schedule to this Order is prohibited.

SCHEDULE

Pearl Omega

THE PHARMACY AND POISONS (PROHIBITED MEDICINES) ORDER

[Legal Notice 128 of 1998]

1. This order may be cited as the Pharmacy and Poisons (Prohibited Medicines) Order.

2. The manufacture, sale, advertisement or possession of the proprietary medicine specified in the Schedule is prohibited.

SCHEDULE

Polyatomic Oxygen (Ozone)

THE PHARMACY AND POISONS RULES

ARRANGEMENT OF RULES

Rule

THE PHARMACY AND POISONS RULES

[Legal Notice 186 of 1957, Legal Notice 332 of 1958, Legal Notice 426 of 1958, Legal Notice 498 of 1958, Legal Notice 550 of 1959, Legal Notice 587 of 1961, Legal Notice 631 of 1963, Legal Notice 365 of 1964, Legal Notice 92 of 1964, Legal Notice 115 of 1968, Legal Notice 125 of 1969, Legal Notice 248 of 1969, Legal Notice 41 of 1971, Legal Notice 51 of 1985, Legal Notice 61 of 2002, Legal Notice 98 of 2022]

1. Citation

These Rules may be cited as the Pharmacy and Poisons Rules.

2. Interpretation

(1) In these Rules, unless the context otherwise requires—

"animal" includes bird;

"antimonial poisons" means chlorides of antimony, oxides of antimony, sulphides of antimony, antimonates, antimonites, and organic compounds of antimony;

"arsenical poisons" means halides of arsenic, oxides of arsenic, sulphides of arsenic, arsenates, arsenites, copper acetoarsenites, sodium thioarsenates, and organic compounds of arsenic;

"British Pharmaceutical Codex", "British Pharmacopoeia" and "British Veterinary Codex" include supplements;

"food" includes drink;

"medicine for the internal treatment of ailments" includes any medicine to be administered by parenteral injection but does not include any mouth-wash, eye drops, eye lotion, ear drops, douche or similar article;

"poison" means a poison included in Part I or Part II of the Poisons List as the case may be;

"Poisons List" means the Poisons List for which provision is made in section 25 of the Act;

"sell" includes an agreement to sell and an offer to sell or any other act whatsoever by which willingness to enter into any transaction of sale is expressed, and an offer to sell includes the exposing of goods for sale.

(2) A reference to the percentage of a poison contained in a substance shall, unless otherwise expressly provided, be construed so that a reference to a substance containing 1 per cent of a poison means—

(a) in the case of a solid, that one gramme of the poison is contained in every hundred millilitres of the substance or preparation;

(b) in the case of a liquid, that one millilitre of the poison, or, if the poison itself is a solid, one gramme of the poison, is contained in every hundred millilitres of the substance or preparation, and so in proportion for any greater or lesser percentage.

(3) For the purposes of these Rules—

(a) a poison shall not be taken to be sold, issued or supplied otherwise than in accordance with a prescription or other order by reason only that the prescription or order specifies a quantity of the poison in terms of the imperial system and the quantity sold, issued or supplied is the equivalent of that amount in the metric system, or by reason only that the prescription or order specifies a quantity of the poison in terms of the metric system and the quantity sold, issued or supplied is the equivalent of that amount in the imperial system; and

(b) the quantity of a poison in the imperial system which is the equivalent of a particular quantity in the metric system, and the quantity of a poison in the metric system which is the equivalent of a similar quantity in the

imperial system, shall be deemed to be that set out as such in the Tables of Equivalents contained in the British Pharmacopoeia, the British Pharmaceutical Codex or the British Veterinary Codex.

3. Importation of drugs and Part I poison

(1) Any person, other than a person issued with an import licence in form 17 set out in Schedule VIII, who imports any drug or Part I poison from any place outside Kenya shall be guilty of an offence.

(2) The Board may issue an import licence authorizing the importation of any drug cosmetics, herbals, medical devices, technologies upon payment of two per cent Freight on Board value or Part I poison to the following persons—

(a) an authorized seller of poisons;

(b) persons licensed under the provisions of sections 27 and 28 of the Act, in accordance with the terms of such licence;

(c) the Government or a local authority and its institutions for public purposes;

(d) a person requiring to import poisons for industrial purposes;

(e) any bona fide tourist or visitor having in his possession, on his arrival in Kenya, any drug or poison for the medical treatment or any other lawful use by himself or any other member of his party;

(f) any duly qualified medical practitioner, dentist or veterinary surgeon who satisfies the Board that he is urgently in need of a drug or poison which he is unable to obtain in Kenya;

(g) a hospital at and of which a medical practitioner registered under the Medical Practitioners and Dentists Act (Cap. 253), is resident and in direct control.

(3) A person requiring to import Part I poison under the provisions of paragraph (2)(d) shall indicate in his application for an import licence the purpose for which the poison is required and, if the importer is not the person who will use the poison, the name or names of the person or persons to whom the poison will be sold.

(4) The Board may, without assigning any reason therefor, refuse an application for a licence to import any drug or Part I poison; and any person aggrieved by the decision of the Board may appeal to the Minister whose decision shall be final.

(5) A person issued with an import licence under these Rules shall comply with the rules and regulations of the Central Bank of Kenya which may be in force from time to time.

(6) A person, issued with an import licence under these Rules who imports any drug or Part I poison from any place outside Kenya shall keep a full, accurate and separate record of such importation.

(7) A person referred to in paragraph (2) and a licensed seller of Part II poison shall not import Part II poison without an import licence issued under these Rules.

[Corr. No. 52/1984, L.N. 120/1984, L.N. 191/2010, r. 3.]

3A. Restriction on the importation or manufacture of specified drugs

(1) No person, shall, without the approval of the Registrar, in writing import or manufacture any of the following drugs—

(a) amphetamine;

(b) amoberbital;

(c) amferpramone;

(d) barbital;

(e) dexamphetamnie;

(f) cyclovarbital;

(g) ethinamate

(h) lysergide, or its salts;

(i) glutethimide;
(j) methamphetamine;
(k) methyphenidate;
(l) meprobamate;
(m) methaqualone, or its salts;
(n) methylphenobarbital;
(o) methylprylon;
(p) psilocin;
(q) psilocybine;
(r) phencyclidine;
(s) phenmetrazine;
(t) phenobarbital;
(u) pentobarbital;
(v) pipradrol;
(w) secobarbital;
(x) medroxyprogeshrone and its salt; and
(y) foreign traditional medicine of any description.

(2) A person who contravenes paragraph (1) shall be guilty of an offence.

[L.N. 125/1969, L.N. 191/2010, r. 2.]

4. Exportation of drugs and poisons

(1) A person, other than a person, issued with an export licence in form 23 set out in Schedule VIII, who exports any drug or poison to a destination outside Kenya shall be guilty of an offence.

(2) The Board may issue an export licence authorizing the exportation of any drug or poison to an authorized seller of poisons or other person licensed to deal in poisons under section 27 or section 28 of the Act.

(3) The Board may, without assigning any reason therefor, reject an application for a licence to export drugs or poisons to any destination outside Kenya; and a person who is aggrieved by the decision of the Board may appeal to the Minister whose decision shall be final.

(4) A person issued with an export licence under these Rules shall comply with the rules and regulations of the Central Bank of Kenya which are in force from time to time.

(5) Every authorized seller of poison and any other person licensed to deal in poisons under section 27 or section 28 of the Act who exports any drugs or poisons to a destination outside Kenya shall—

(a) keep a full and accurate record of those exports; and
(b) if the drug or poison is sent by post, send the export by registered or parcel post; and
(c) comply with the requirement of rule 15 relating to the transportation of poisons.

(6) A person who fails to comply with the provisions of paragraph (5) shall be guilty of an offence.

5. Exemptions

(1) A person who imports a Part I poison for industrial purposes in accordance with the provision of rule 3 may, notwithstanding the provisions of section 26 of the Act—

(a) lawfully possess the Part I poison in the quantity authorised to be imported;

(b) sell the poison so imported to the person named in the application as the purchaser, and the purchaser may, notwithstanding the provisions of section 26 of the Act, lawfully possess the poison.

(2) An authorised seller of poisons shall not be required to comply with the provisions of section 29(2) and section 30 of the Act in the case of—

(a) substances specified in Schedule I if the sale is effected by, or under the supervision of, a registered pharmacist; and

(b) machine-spread plaster;

(c) surgical dressings;

(d) articles containing barium carbonate and prepared for the destruction of rats and mice;

(e) corn paints in which the only poison is a poison included in the Poisons List under the heading of "Cannabis".

(3) Nothing in Part III of the Act or in these Rules shall apply to—

(a) an article in Group I of Schedule II;

(b) a poison specified in the first column of Group II of Schedule II to these Rules if contained in or in the form of any of the articles or substances specified in the second column.

(4) The requirements of subrule (c) of section 34(1) of the Act shall not apply to any substance specified in Schedule III.

6. Poisons to be supplied only upon prescription

(1) Subject to subrule (2), no person shall sell by retail a Part I poison specified in Schedule IV except on and in accordance with a prescription given by a duly qualified medical practitioner, dentist or veterinary surgeon in the form provided by this rule.

(2) Where an authorised seller of poisons has reasonable cause to believe that a person ordering a Part I poison is a duly qualified medical practitioner, dentist or veterinary surgeon and who is by reason of some emergency unable to furnish such a prescription immediately, he may, notwithstanding that no such prescription has been given, if the person undertakes to furnish him with such a prescription within the twenty-four hours next following, deliver the poison ordered in accordance with the directions of the person, so, however, that notwithstanding anything in the directions, the supply shall not be repeated unless the prescription has been given.

(3) A person by whom any such undertaking has been given who fails to deliver to the seller a prescription in accordance with the undertaking, or who, for the purpose of obtaining delivery of a poison under subrule (2), makes a statement which is to his knowledge false, shall be guilty of an offence.

(4) The provisions of this rule shall not apply to—

(a) a sale referred to in section 29(1) of the Act;

(b) the sale by an authorised seller of poisons of a substance specified in Group II of Schedule IV to a farmer or other person concerned with the welfare of animals as a regular part of the exercise of his trade, business or profession who is in possession of a permit issued by a duly qualified veterinary surgeon;

(c) the sale of strychnine, in quantities not exceeding four ounces at any one time to persons authorised by the District Commissioner to obtain this substance for the purposes of poisoning vermin.

(5) For the purposes of this rule a prescription shall—

(a) be in writing and be signed by the person giving it with his usual signature and be dated by him;

(b) specify the address of the person giving it;

(c) specify the name and address of the person for whose treatment it is given or, if the prescription is given by a veterinary surgeon, of the person to whom the medicine is to be delivered;

(d) have written thereon, if given by a dentist, the words "for dental treatment only" or, if given by a veterinary surgeon, the words "for animal treatment only";

(e) specify the total amount of the medicine to be supplied and, except in the case of a preparation which is to be used for external treatment only, the dose to be taken.

(6) The person dispensing the prescription shall comply with the following requirements —

(a) the prescription shall not be dispensed more than once unless the prescriber has directed thereon either that it may be dispensed a stated number of times or that it may be dispensed at stated intervals;

(b) if the prescription contains a direction that it may be dispensed a stated number of times or at stated intervals it shall not be dispensed otherwise than in accordance with the direction;

(c) a prescription which contains a direction that it may be dispensed a stated number of times but no direction as to the intervals at which it may be dispensed shall not be dispensed more often than once in three days, and a prescription which contains a direction that it is to be dispensed at stated intervals but no direction as to the number of times that it may be dispensed shall not be dispensed more often than three times;

(d) at the time of dispensing or, where a poison has been delivered in accordance with subrule (2), on the subsequent receipt of the prescription there shall be noted on the prescription above the signature of the prescriber the name and address of the seller and the date on which the prescription was dispensed;

(e) except in the case of a prescription which may be dispensed again, the prescription shall, for a period of two years, be retained and kept on the premises on which it was dispensed so as to be readily available for inspection.

(7) For the purposes of subrule (4)(b) a permit—

(a) shall be in the form set out in Schedule IX; and

(b) shall be produced on every occasion when supplies are required; and

(c) on every occasion the supplier shall endorse the permit with his name and address and the date.

(8) A person who fails to comply with the provisions of subrule (6) shall be guilty of an offence.

7. Restriction of sales by licensed sellers of Part II poisons

(1) No person may, by virtue of being a licensed seller of Part II poisons, sell or offer for sale a poison otherwise than in accordance with the provisions of his licence.

(2) A licensed seller of Part II poisons shall not sell a poison, other than ammonia, hydrochloric acid, nitric acid, potassium quadroxalate and sulphuric acid, except in a closed container as closed by the manufacturer or other person from whom the poison was obtained.

(3) A person who fails to comply with the provisions of subrule (2) shall be guilty of an offence.

8. Restriction of sales by person licensed to deal in poisons for mining, agricultural or horticultural purposes

(1) No person may, by virtue of being licensed to deal in poisons for mining, agricultural or horticultural purposes, sell or offer for sale a poison otherwise than in accordance with the provisions of his licence.

(2) A person licensed to deal in poisons for mining, agricultural and horticultural purposes shall not sell—

(a) a poison, other than ammonia, hydrochloric acid, nitric acid, potassium quadroxalate and sulphuric acid, except in a closed container as closed by the manufacturer or other person from whom the poison was obtained;

(b) a Part I poison unless—

(i) the purchaser thereof is a person engaged in the trade, business or profession of mining, agriculture or horticulture and requires the poison for the purposes of his trade, business or profession; and

(ii) the sale is made by one of the persons named in the application for the licence to sell the poisons; and

(iii) the poison, if it be one of the substances referred to in Schedule V, shall, in addition to any other requirements of the Act and these Rules, be labelled in the manner described in that Schedule; and

(iv) the requirements of section 30 of the Act are complied with.

(3) A person who fails to comply with the provisions of subrule (2) shall be guilty of an offence.

9. Labelling of containers

(1) A container of poison required to be labelled in accordance with section 34 of the Act shall be labelled clearly and distinctly in the English language with the required particulars and in the following manner—

(a) the name of the poison shall be the term by which the poison is specified in the Poisons List:

Provided that—

(i) where the term describes a group of poisons and not the poison specifically, the name of the poison shall be—

(A) if the poison is the subject of a monograph in either the British Pharmacopoeia or the *British Pharmaceutical Codex* or the *British Veterinary Codex* one or other of the names, synonyms or abbreviated names set out at the head of the monograph; and

(B) in any other case, the accepted scientific name or name descriptive of the true nature and origin of the poison, and in such cases the appropriate name of the poison shall be written in English or in Latin;

(ii) in the case of a preparation in the *British Pharmacopoeia* or the *British Pharmaceutical Codex* or the *British Veterinary Codex* or a dilution or admixture of such a preparation, or a surgical dressing for which a standard is described in the British Pharmaceutical Codex it shall be sufficient to state the name, synonym or abbreviated name used to describe the preparation or surgical dressing in the British Pharmacopoeia or the British Pharmaceutical Codex or the British Veterinary Codex with the addition of the letters B.P or B.P.C or B.Vet.C., as the case may be;

(b) the particulars as to the proportion which a poison contained in a preparation bears to the total ingredients shall be expressed as the percentage which the poison bears to the total ingredients:

Provided that—

(i) in the case of a preparation containing a poison specified in the first column of Schedule VI, it shall be sufficient to state on the label the

particulars specified in the second column of that Schedule against the description of the poison;

(ii) in the case of a preparation or surgical dressing which is named in accordance with the provisions of proviso (ii) to subrule (1)(a), it shall not be necessary to state on the label the proportion of the poison contained in the preparation, and in the case of any dilution or admixture of such a preparation, it shall be sufficient to state the proportion which the preparation bears to the total ingredients of the dilution or admixture;

(iii) where the poison is in tablets, pills, cachets, capsules, lozenges or similar articles, or in ampoules, it shall be sufficient to state on the container thereof the number of the articles, and the amount of the poison or the amount of the preparation contained in each tablet, pill, catchet, capsule, lozenge or other similar article;

(c) the word "Poison" or the alternative indication of character specified in rule 10, as the case may be, shall—

(i) in the case of a poison not specified in Schedule I or in Group B of Part II of the Poisons List, either be printed in red letters on a contrasting background or in letters of some other colour set against a red background;

(ii) in all cases be easily legible and either on a separate label or surrounded by a line within which there must be no other words.

(2) Where a proportion is stated as a percentage, the statement shall indicate whether the percentage is calculated on the basis of weight in weight, weight in volume or volume in volume.

(3) Directions for the use of a poison shall be given in the English language, in addition to any other language.

(4) Where poison is contained in an ampoule, cachet or other similar article the box or receptacle containing the ampoules, catchets or other articles only need be labelled in pursuance of the provisions of section 34 of the Act and these Rules.

(5) Where the container of a poison or the container of an ampoule, cachet or other similar article is labelled in accordance with the provisions of the Act and these Rules, an outer cover or wrapper to that container used only for the purpose of delivery or transport need not be similarly labelled if it complies with the provisions of rule 15.

(6) A person who sells a poison not labelled in accordance with the provisions of these Rules shall be guilty of an offence.

10. Indication of character of poison

(1) A poison specified in Schedule V shall be labelled with the words and in the manner specified in that behalf in Schedule V.

(2) The words specified in Schedule V shall not be modified in meaning by the addition of other words or marks and shall—

(a) in the case of a poison not specified in Schedule I or in Group B of Part II of the Poisons List, be printed in red letters on a contrasting background or in some other colour on a red background;

(b) in all cases be easily legible on a separate label or surrounded by a line within which there must be no other words.

11. Directions as to use

(1) No person shall sell liquid poison in bottles of more than 120 fluid ounces capacity unless the bottle is labelled with the words "NOT TO BE TAKEN".

(2) No person shall sell embrocation, liniment, lotion, liquid or antiseptic, or other liquid medicine for external application, which contains poison, unless the container is labelled with the name of the article and the words "FOR EXTERNAL USE ONLY".

(3) No person shall sell hydrocyanic acid or cyanide unless the container is labelled with the words "WARNING. This container holds a poisonous substance and should be opened and used by persons having expert knowledge of the precautions to be taken in its use."

(4) A person who fails to comply with any provision of this rule shall be guilty of an offence.

12. Containers for poisons

(1) No person shall keep, sell or consign for transport a poison unless—

(a) it is contained in a container impervious to the poison and sufficiently strong to prevent leakage arising from the ordinary risks of handling and transport; and

(b) in the case of a liquid contained in a bottle of capacity of not more than 120 fluid ounces, not being a medicine made up ready for the internal treatment of human ailments, the outer surface of the bottle is fluted vertically with ribs or grooves recognisable by touch.

(2) The provisions of subrule (1)(b) shall not apply to the sale or the keeping of poisons for the purposes of education, research or analysis by a person or institution concerned with scientific education, research or chemical analysis.

13. Safe custody of poisons

(1) No person engaged in a trade, business or profession shall knowingly have in his possession or under his control a poison, unless the following conditions are complied with at all times when the poison is not in actual use—

(a) the poison shall be kept under lock and key—

(i) in a separate room or compartment specially reserved for keeping poisons and partitioned off from the rest of the premises; or

(ii) in a cupboard, box or other receptacle specially reserved for keeping poisons, clearly marked with the words "Poisons Only", and kept in a place apart from anything containing food or drink;

(b) the poison shall be kept in a place ordinarily accessible only to persons lawfully having access thereto;

(c) the key of the room, compartment, cupboard, box or other receptacle in which poisons are kept shall be retained under the control of the person in charge of the poison.

(2) The provisions of subrule (1) of this rule shall not apply to the possession of—

(a) a substance specified in Schedule I;

(b) a substance specified in Group B of Part II of the Poisons List;

(c) medicines prescribed for the personal use of the person having possession or control thereof.

(3) A person in possession of a container or other receptacle which has been used for containing a poison and which is no longer required for that purpose shall by destruction or other means render that container or receptacle innocuous.

(4) Poisons for the treatment of human ailments shall be kept entirely separate from other poisons.

(5) A person who fails to comply with any provisions of this rule shall be guilty of an offence.

13A. Pharmaceutical representative's permit

(1) A representative of a person engaged in the sale and supply of pharmaceuticals containing a poison may, in the course of business, give free samples of such products to persons who may lawfully possess Part I poisons if he—

(a) is in possession of a permit issued by the Board in that behalf; and

(b) enters the following particulars, at the time of issue, in a book used regularly for the purpose—

(i) the date on which the poison was issued;

(ii) the name and quantity of the poison given; and

(iii) the name and address and signature of the person to whom the poison was given.

(2) Every application for a permit under paragraph (1) of this rule shall be made to the Board in form 18 in Schedule VIII and shall be accompanied by a fee of twenty-five shillings in respect of the issue of the permit.

(3) Every permit under paragraph (1) of this rule—

(a) shall be in form 19 in Schedule VIII to these Rules;

(b) shall expire on the 31st December of the year of issue or on the earlier termination of the employment by the person concerned of the person in respect of whom the permit is issued.

[L.N. 41/1971.]

14. Special provisions with respect to hospitals

(1) All poisons not in actual use in any hospital, infirmary, dispensary, clinic, nursing home or other similar institution at which human ailments are treated shall be kept under the control of the person in charge of the institution or some fit and proper person specially detailed for that purpose and shall only be issued for use as required.

(2) In any such institution, at which medicines are dispensed in a dispensing or pharmaceutical department in charge of a person appointed for that purpose, no medicine containing a poison shall, except in a case of emergency, be supplied from that department for use in the wards, operating theatres or other sections of the institution except upon a written order signed by a duly qualified medical or dental practitioner or by a sister or nurse in charge of a ward, theatre or other section of the institution; and the person supplying the medicine shall label the container with the words describing its contents and, in the case of medicines containing poisons other than poisons specified in Schedule I to these Rules or in Group B of Part II of the Poisons List, in addition thereto, an indication that the poison is to be stored in a cupboard reserved solely for the storage of poisons.

(3) Any poison, other than a poison specified in Schedule I or in Group B of Part II of the Poisons List, issued for use in any ward, theatre or other section of the institution shall, at all times when not actually in use, be stored in a cupboard reserved solely for the storage of poisons.

(4) The person in charge of the institution shall, not less than once in every three months, carry out, or arrange and be responsible for the carrying out by a medical practitioner, a pharmacist or some other person appointed for the purpose by the person in charge, of an inspection of—

(i) all stores, cupboards and other places where poisons are kept in the institution;

(ii) the methods by which poisons are issued, dispensed and used in the institution; and

(iii) all books and other records whatsoever kept in the institution for the purpose of recording the purchase, issue and use of poisons.

(5) The person carrying out the inspection shall submit copies of his report in form 20 in Schedule VIII to these Rules—

(i) to the person in charge of the institution, if that person has not himself carried out the inspection; and

(ii) to the registrar.

(6) A person who fails to comply with any provision of this rule shall be guilty of an offence.

[L.N. 41/1971.]

15. Transport of poisons

(1) No person shall consign for transport a poison specified in Schedule VII unless the outside of the package is labelled conspicuously with the name or description of the poison and a notice indicating that it is to be kept separate from food and from empty food containers.

(2) No person shall knowingly transport a poison specified in Schedule VII in a vehicle in which food is being transported unless the food is carried in a part of the vehicle effectively separated from that containing the poison, or is otherwise adequately protected from the risk of contamination.

(3) A person who fails to comply with any provision of this rule shall be guilty of an offence.

16. Manufacture of drugs

(1) No person shall manufacture for sale any drug which is or may be used for the treatment of any human or animal ailment unless he is in possession of a licence for that purpose issued by the Board.

(2) Every application for a licence under paragraph (1) of this rule shall be made to the Board in Form 21 in Schedule VIII to these Rules and shall be accompanied by a fee of one hundred shillings in respect of the issue of the licence, which shall be refundable if the licence is not granted.

(3) Upon an application for a licence under this rule, the Board may, in its absolute discretion, refuse to grant the licence, or may grant the licence either unconditionally or subject to conditions as it may think fit.

(4) A licence under this rule shall be in Form 22 in Schedule VIII to these Rules.

(5) In an establishment in which drugs are manufactured, whether for sale or otherwise, for the purpose of the treatment of any human or animal ailment, such manufacture shall be carried out by, or under the supervision of—

(a) a registered pharmacist; or

(b) a person having a Fellowship or Associateship of the Royal Institute of Chemistry or an equivalent qualification recognized by the Board.

(6) The Board may, by notice in the *Gazette*, exempt any establishment or class of establishment from any or all of the provisions of this rule.

(7) A person who contravenes any of the provisions of this rule, or who fails to comply with any condition of a licence issued thereunder, shall be guilty of an offence.

[L.N. 41/1971.]

17. Restriction on sale of mepacrine and bisulphate tablets

(1) A person who sells mepacrine tablets containing less than 95.0 per cent or more than 105.0 per cent of 100 milligrams of Mepacrine Hydrochloride as described in the *British Pharmacopoeia* shall be guilty of an offence and liable to a fine not exceeding five hundred shillings or to imprisonment for a term not exceeding one month or to both, and in addition to any penalty imposed under these Rules the Court may order any article in respect of which the offence has been committed or which has been used for the commission of the offence to be forfeited.

(2) A person who sells quinine bisulphate tablets containing less than 95.0 per cent or more than 105.0 per cent of 5 grains of Quinine Bisulphate as described in the British Pharmacopoeia and containing any colouring matter shall be guilty of an offence and liable to a fine not exceeding five hundred shillings and to imprisonment for a term not exceeding one month or to both such fine and such imprisonment, and in addition to any penalty imposed

under these Rules the court may order any article in respect of which such offence has been committed or which has been used for the commission of the offence to be forfeited.

18. The Poisons Book

(1) The Poisons Book shall be in the form set out in Schedule VIII.

(2) In the case of a person licensed under the provisions of section 27 of the Act as a wholesale dealer in poisons or an authorised seller of poisons having a wholesale section distinct and separate from any retail shop in which complete and detailed records of the receipts and disposals of all poisons are regularly maintained, the Board may, upon such conditions as it may deem fit to impose, relieve that person of the necessity to record sales by way of wholesale in the Poisons Book.

19. Fees

The following fees shall be paid in connection with matters arising under the Act—

		Annual Amount (KSh,)
(a)	For a certificate of registration as a pharmacist/ Pharmaceutical Technologist	5,000
(b)	For the restoration of name to the register	5,000
(c)	Professional Practice	5,000
(d)	For the registration of premises	10,000
(e)	For a wholesale dealer's license per annum	30,000
(f)	For a license to deal in mining, agricultural and horticultural Poisons per annum	5,000
(g)	For a license to sell Part II poisons per annum	5,000
(h)	For a license to manufacture drugs per product	5,000
(i)	Advertisement per product	5,000
(j)	Pharmaceutical representative permit	5,000
(k)	For application approval for import permit 2% value Freight on Board	
(l)	Good Manufacturing Practice Audit per site—	
	(i) Foreign manufacturing site.....	USD4,000
	(ii) Local manufacturing site	USD 1,000
(m)	Training and Assessment/Evaluation fees for pharmacists and pharmaceutical technologists	
	Kenyan Citizen	*Foreigners*
Stage/Level I	9,500/=	22,000/=
Stage/Level II	7,000/=	20,000/=

(n)	New application, inspection and course approval fees for pharmacy training institutions	KSh.
	(i) Degree programmes	400,000
	(ii)Diploma programme	210,000
(o)	Renewal of Annual course approval fees (sect 8)	KSh.
	(i) Degree programmes	60,000
	(ii) Diploma programme	30,000
(p)	Indexing of students in the pharmacy training institutions in Kenya	KSh.
	(i) Degree programmes	1,000
	(ii) Diploma programme	1,000

[L.N. 191/2010, s. 4.]

20. Forms

The forms to be used under the Act and these Rules shall be those set out in Schedule VIII.

21. Preservation of books

All books and other prescribed records for the purposes of Part III of the Act shall be preserved on the premises on which the sales recorded therein were made for a period of two years from the date on which the last entry was made therein.

SCHEDULE I

[r. 5]

SUBSTANCES EXEMPTED FROM THE PROVISIONS OF SECTION 29(2) AND SECTION 30(1)(A) AND (B) OF THE ACT

GROUP I

A substance containing any of the poisons specified in the first column below if the poison content is less than the percentage specified in the second column.

Poison	*Percentage of poison content below which substance is exempted*
1. Alkaloids, including their salts simple or complex-	
2. Aconite, alkaloids of	0.02 percent
3. Apomorphine	0.20 percent
4. Atropine	0.15 percent
5. Belladonna, alkaloids of	0.15 percent, calculated as hyoscyamine
6. Brucine	0.20 percent
7. Coca, alkaloids of	0.10 percent

8. Cocaine	0.10 percent
9. Codeine	1.50 percent
10. Colchicum, alkaloids of	0.50 percent, calculated as colchincine
11. Coniine	0.10 percent
12. Cotarnine	0.20 percent
13. Ecgonine and its esters	0.10 percent
14. Emetine	1.00 percent
15. Ethylmorphine	0.20 percent
16. Gelsemium, alkaloids of	0.10 percent
17. Homatropine	0.15 percent
18. Hyoscine	0.15 percent
19. Hyoscyamine	0.15 percent
20. Jaborandi, alkaloids of	0.50 percent
21. Lobelia, alkaloids of	0.50 percent
22. Morphine	0.20 percent, calculated as anhydrous morphine
23. Morpholinylethylmorphine	1.50 percent
24. Papaverine	1.00 percent
25. Pomegranate, alkaloids of	0.50 percent
26. Sabadilla, alkaloids of	1.00 percent
27. Solanaceous alkaloids, not otherwise included in this Schedule	0.15 percent, calculated as hyoscyamine
28. Stavesacre, alkaloids of	0.20 percent
29. Strychnine	0.20 percent
30. Thabaine	1.00 percent
31. Veratrum, alkaloids of	1.00 percent
32. Adrenalin, its salts, in preparations for external use only	0.10 percent
33. Amino-alcohols, esterified with benzoic acids, phenylacetic acid, phenylpropionic acid, cinnamic acid or the deriatives of these acids	10.00 per cent of esterified amino-alcohols
34. Antimonial poisons	Equivalent of of 1.00 per cent of antimony trioxide
35. Arsenical poisons	Equivalent of 0.01 per cent of arsenic trioxide and dentifrices containing less than 0.30 per cent of acetarsol.
36. Butyl chloral hydrate	10.00 percent
37. Cantharidin	0.01 percent
38. Cantharidates	Equivalent of 0.01 per cent of cantharidin
39. Chloral formamide	10.00 percent
40. Cholral hydrate	10.00 percent
41. Digitalis, glycosides and other active principles of	One unit of activity (as defined in the British Pharmacopola) in two grams of the substance.
42. Dinitrocresols (DNC), their compounds with a metal or a base	Equivalent of 5.00 per cent of dinitrocresols

43. Hydrocyanic acid	0.15 per cent weight in weight of hydrocyanic acid (HCN)
44. Insulin	Not exceeding 80 units in 1 mil
45. Cyanides	Equivalent of 0.10 per cent weight in weight of hydrocyanic acid (HCN).
46. Mercuric chloride	1.00 percent
47. Mercuric iodide	2.00 percent
48. Nitrates of mercury	Equivalent of 3.00 per cent weight in weight of mercury (Hg).
49. Potassio-mercuric iodides	Equivalent of 1.00 per cent of mercuric iodide.
50. Organic compounds of mercury	Equivalent of 0.20 per cent weight in weight of mercury (Hg).
51. Nux vomica	0.20 per cent of strychnine
52. Opium	0.20 per cent of morphine calculated as anhydrous morphine
53. Para-amino-benzoic acid, esters of; their salts	1.00 percent
54. Para-aminobenzenesulphonamide; its salts; derivatives of para-aminobenzenesulphonamide having any of the hydrogen atoms of the para-substituted group or of the sulphonamide group substituted by another radical; their salts; when incorporated in a base for external application only	50 percent

GROUP II

Antibiotics, the following—

Bacitracin Gramicidin Neomycin Polymyxins

when incorporated in a base for treatment of the skin.

Chloramphenicol

when incorporated in a special base for the treatment of the feet of animals.

Anti-histamine substances, the following; their salts; their molecular compounds—

Antazoline.

Bromodiphenhydramine.

Buclizine.

Carbinoxamine.

Chlorcyclizine.

Chlorpheniramine.

Cinnarizine.

Clemizole.

Cyclizine.

Cyproheptadine.

3-Di- n-butylaminomethyl-4, 5, 6-trihydroxypthalide. Diphenhydramine.

Diphenylpyraline.

Doxylamine.

Isothipendyl.

Mebhydrolin.

Meclozine.

Phenindamine.

Pheniramine.

Phenyltoloxamine.

Promethazine.

Pyrrobutamine.

Thenalidine.

Tolpropamine.

Triprolidine.

Substances being tetra-substituted N derivatives of ethylenediamine or propylenediamine.

SCHEDULE II

[r. 5]

[L.N. 92/1964, L.N. 125/1969.]

ARTICLES EXEMPTED FROM PART III OF THE ACT AND THESE RULES

GROUP I

Adhesives, anti-fouling compositions; builders' materials; ceramics; distempers; electrical valves; enamels; explosives; fillers; fireworks; fluorescent lamps; glazes; glue; inks; lacquer solvents; loading materials; matches; medicated soaps; motor fuels and lubricants; paints other than pharmaceutical paints; photographic paper; pigment; plastics; propellants; rubber; varnishes; tyrothricin, framycetin.

GROUP II

Poison	*Substance or article in which exempted*
1. Acetanilide; alkyl acetanilides	Substances not being preparation for the treatment of human ailments
2. Brucine	Surgical spirit containing not more than 0.015 per cent of brucine.
3. Emetine	Ipecachuana, extracts and tinctures of ipecachuana; substances containing less than 0.05 per cent of emetine.

4. Ephedra, alkaloids of	Substances containing less than 1 per cent of the alkaloids of ephedra.
5. Formic acid	Substitutes containing not less than 5 per cent weight in weight formic acid (HCOOH)
6. Jaborandi, alkaloids of	Substances containing less than 0.025 per cent of the alkaloids of jaborandi.
7. Lobelia, alkaloids of	Preparations for the relief of asthma in the form of cigarettes, smoking mixtures or fumigants, substances containing less than 0.1 per cent of the alkaloids of lobelia.
8. Nicotine	Tobacco.
9. Pomegranate, alkaloids of	Pomegranate bark
10. Solanaceous alkaloids	Stramonium contained in preparations for the relief of asthma in the form of cigarettes, smoking mixtures or fumigants.
11. Staversacre, alkaloids of	Soaps, ointments; lotions for external use.
12. Ammonia	Substances not being solution of ammonia or preparations containing solutions of ammonia substances containing less than 5 per cent weight in weight of ammonia (NH3); refrigerators; smelling bottles.
13. Antibiotics as defined in the Poisons List	Preparations or concentrates for animal feeding.
14. Antihistamine substances as defined in the Poisons List	Preparations intended for external application only.
15. Antimony, chlorides of	Polishes.
16. Arsenical poisons	Pyrites ores or sulphuric acid containing arsenical poisons as naturaimpurities.
17. Barium, salts of	Witherite other than finely ground witherite.
18. Beta-aminopropylbenzene; its salts; its N-alkyl derivatives; their salts, beta-aminoisopropylbenzene; its salts; its Nalkyl derivatives; their salts	Appliances for inhalation in which the poison is

	absorbed in inert solid material.
18A. Carbarsone	Poultry feeding stuffs containing not more than 0.0375 per cent Carbarsone.
19. Chloroform	Substances containing less than 10 per cent of chloroform.
20. Creosote obtained from wood	Substances containing less than 50 per cent of creosote obtained from wood.
21. Formaldehyde	Substances containing less than 5 per cent weight in weight of formaldehyde (HCHO); photographic glazing or hardening solutions/
22. Hormones as defined in the Poisons List	Cosmetic preparations for external application and plant hormones.
23. Hydrochloric acid	Substances containing less than 9 per cent weight in weight of hydrochloric acid (HCL).
24. Lead acetate	Substances containing less than 4 per cent
25. Lead, compounds of	Machine-spread plasters
26. Mercuric chloride	Batteries
27. Mercuric chloride, mercuric iodide; orgnanic compounds of mercury	Dressings on seeds or bulbs
28. Mercury, nitrates of	Ointments containing less than the equivalent of 3 per cent weight in weight of mercury (Hg).
29. Nitric acid	Substances containing less than 9 per cent weight in weight of nitric acid (HNO3)
30. Nitrobenzene	Substances containing less than 0.1 per cent of nitrobenzene, soaps containing less than 1 per cent of nitrobenzene, polishes.
31. Oxalic acid; metallic oxalates	Laundry blue; polishes
32. Oxycinchoninic acid; derivatives of their salts; their esters	Preparations for external applications only containing not more than

	the equivalent of 3 per cent oxycinchoninic acid.
33. Paranitrobenzylcyanide	Photographic solutions containing less than the equivalent of 0.1 per cent of HCN.
34. Paranitrophenol	Preparations for use in agriculture and horticulture containing not more than 0.5 per cent of paranitrophenol as a preservative.
34A. Phenylcinchonininic acid	Preparations for external application only containing not more than the equivalent of 10.1% of phenylcinchoninic acid.
35. Phenols	Carvacrol; creosote obtained from coal tar; essential oils in which phenols occur naturally, medicines containing less than 1 per cent of phenols; nasal sprays, mouth washes, pastilles, lozenges, capsules,
36. Phenylene diamines; toluene diamines; other alkylatedbenzene diamines; their salts	Substances other than preparations for the dyeing of hair
37. Phenylmercuric salts	Toilet, cosmetic and therapeutic preparation containing
38. Picric acid	Substances containing less than 5 per cent of picric acid
39. Potassium hydroxide	Substances containing less than 12 per cent of potassium hydroxide accumulators; batteries.
40. Procaine	Combined with antibiotics when contained in preparations or concentrates for animal feeding.
41. Sodium ehtyl mercurithiosalicylate	Therapeutic substances containing less than 0.1 per cent of sodium ethyl mercurithiosalicylate as a preservative.
42. Sodium fluoride	Substances containing less than 3 per cent of

	sodium fluoride as a preservative.
43. Sodium hydroxide	Substances containing less than 12 per cent of sodium hydroxide
44. Sodium silicofluoride	Substances containing less than 3 per cent of sodium silicofluoride as a preservative.
44A. Sulphone	Substances containing a mixture of dapsone and pyrimethamine, recommended for use as an antimalarial.
45. Sulphuric acid	Substances containing less than 9 per cent weight in weight of sulphuric acid (H2SO4): accumulators, batteries; fire extinguishers.

SCHEDULE III

[r. 5]

SUBSTANCES EXEMPT FROM CERTAIN LABELLING REQUIREMENTS

[L.N. 248/1969.]

1. Antibiotics.

2. Hormones; natural and synthetic; any preparations, admixture, extract or other substance containing any proportion of any substance having the action of any hormone.

3. Isoniazid; its salts, derivatives of isoniazid; their salts.

4. Para-amino-salicylic acid; its salts; any preparation of para-amino-salicylic acid; its salts.

5. Sulphones; their salts; their derivatives.

6. Thiacetazone; its salts; its derivatives.

7. Drugs as defined in the Pharmacy and Poisons (Control of Drugs) Rules, 1969, which are not specifically named in the Schedule to the Poisons List Confirmation Order.

SCHEDULE IV

GROUP I

Substances required to be sold by retail only upon a prescription given by a duly qualified medical practitioner, dentist or veterinary surgeon.

1. Acetanilide; alkyl acetanilides.

2A. Acetohexamide.

3. Acetylcarbromal.

4. Allylisopropylacetylurea.

5. Amidopyrine; amidopyrine sulphonates; their salts.

6. Amitryptyline; its salts.

7. Antibiotics.

8. Antimony, organic compounds of, for injection.

9. Arsenic, organic compounds of, for injection.

10. Azacyclonal; its salts.

11. Barbituric acid; its salts, derivatives of barbituric acid; their salts; compounds of barbituric acid, its salts, its derivatives, their salts, with any other substance.

12. Benactyzine; its salts.

13. Benztropine and its homologues; their salts.

14. Benzhexol; its salts.

15. Bromvaletone.

16. Busulphan; its salts.

17. B-Aminopropylbenzene and B-aminoisopropylbenzene and any compound structurally derived from either of those substances by substitution in the side chain or by ring closure therein (or by both such substitution and such closure), except ephedrine Nmethylephedrine, N-diethylamioethylephedrine, phenylpropanolamine and prenylamine; any salt of any substance falling within this item.

18. Captodiame; its salts.

19. Carbromal.

20. Carisoprodol.

21. Chlordiazepoxide; its salts.

22. Chlormethiazole; its salts.

23. Chlorothiazide and other derivatives of benzo-1, 2, 4-thiadiazine-7-sulphonamide 1, 1-dioxide, whether hydrogenated or not.

24. Chlorphenoxamine.

25. Chlorphentermine.

26. Chlorpropamide; its salts.

27. Chlorprothixene, and other derivatives of 9-methylenethiaxanthen; and their salts.

28. Chlorthalidone, and other derivatives of O-Chlorobenzene sulphonamide.

29. Chlorexolone.

30. Curare; alkaloids of; curare bases and salts.

31. Cyclarbamate.

32. Cycrimine; its salts.

33. Demecarium bromide.

34. Desipramine; its salts.

35. /4; 4-diamidino-diazoamino-benzene; its salts.

36. Diazepam, and other compounds containing the chemical structure of 1:4 benzodiazepine substituted to any degree; their salts.

37. Dinitrocresols (DNC); their compounds with a metal or a base, except preparations for use in agriculture or horticulture.

38. Dinitronapthols; dinitrophenols; dinitrothymols.

39. Disulfiram.

40. Dithienylallylamines; dithienylalkylallylamines; their salts except diethylthiambutene, dimethylthiambutene and ethylmethylthiambutene.

41. Ectylurea.

42. Emylcamate.

43. Ergot; alkaloids of; homologues of; their salts.

44. Ethchlorvynol.

45. Ethinamate.

46. Ethionamide.

47. Ethoheptazine; its salts.

48. Gallamine; its salts; its quaternary compounds.

49. Haloperidol, and other 4 substituted derivatives of N-(3-p. fluorobenzoylpropyl) piperidine.

50. Hexapropymate.

51. Hormones, adrenal cortical, natural and synthetic; any preparations, admixture, extract or other substance containing any proportion of any substance having the action of any adrenal cortical Hormone.

52. Hormones, sex, natural and synthetic and analogous substance, except when in the form of avian implants.

53. Hydrazines, benzyl phenethyl or phenoxyethyl; their a-methyl derivatives; acyl derivatives of any of the foregoing substances comprised in this item; salts of any compounds comprised in this item.

54. 4-Hydroxymethyl-2, 2-diisopropyl-1, 3-dioxolan.

55. Hydroxy N-N-dimethyl tryptamines, esters or ethers of these; salts of any of the foregoing (Psilocin and Psilocybe).

56. Hydroxyzine; its salts.

57. Imipramine; its salts.

58. Indomethacin; its salts.

59. Isoniazid; its salts, derivatives of isoniazid; their salts.

60. Mannomustine; its salts.

61. Mephenesin; its esters.

62. Meprobamate.

63. Mercaptopurine; its salts, derivatives and their salts.

64. Metaxolone.

65. Metformin; its salts.

66. Methaqualone; its salts.

67. Methixene; its salts.

68. Methocarbamol.

69. Methoxsalen.

70. Methylpentynol; its esters and other derivatives.

71. Mustine and any other N-substituted derivatives of di-(2 Chloroethyl) amine; their salts.

72. Nortryptyline; its salts.

73. Orphenadrine; its salts.

74. Oxethazaine.

75. Oxyphenbutazone.

76. Para-aminobenzenesulphonamide; its salts; derivatives of para-aminobenzenesulphonamide having any of the hydrogen atoms of the para-amino group or of the sulphonamide group substituted by another radical; their salts, except when contained in ointments or surgical dressings or in preparations for the prevention and treatment of diseases in poultry.

77. Para-amino-salicylic acid; its salts; any preparation of para-aminosalicylic acid, its salts.

78. Paramethadione.

79. Pargyline; its salts.

80. Pemoline; its salts.

81. Phenacemide.

82. Phenaglycodol.

83. Phenanthridinium and its derivatives.

84. Phenbutrazate.

85. Phenetidylphenacetin.

86. Phenformin; its salts.

87. Phenothiazine, derivatives of; their salts; except dimethoxanate, its salts and promethazine, its salts and its molecular compounds.

88. Phenylbutazone; its salts.

89. Phenylcinchoninic acid; salicylcinchoninic acid; their salts, their esters.

90. Phenylhydantoin; its alkyl and aryl derivatives; their salts.

91. Pituitary gland, the active principles of; except when contained in preparation intended for external application only or, except in the case of lysinevasopressin or oxytocin, in inhalants.

92. Polymethylenebistrimethylammonium salts.

93. Procyclidine; its salts.

94. Promoxolan.

95. Propylhexedrine; its salts; except when contained in inhalers.

96. Prothionamide.

97. Prothipendyl.

98. Quinapyramine and analogous substances; their salts.

99. Quinethazone.

100. Rauwolfia, alkaloids of; derivatives of; their salts.

101. Strychnine except in preparations included in Part II of the Poisons List.

102. Styramate.

103. Sulphinpyrazone.

104. Sulphonal; alkyl sulphonals.

105. Sulphones; their derivatives; their salts.

106. Suprarenal gland medulla, the active principles of; their salts; except when contained in preparations intended for external application only or in inhalants, rectal preparations or preparations intended for use in the eye.

107. Syrosingopine.

108. Tetrabenazine; its salts.

109. Thalidomide; its salts.

110. Thiacetazone; its salts; its derivatives.

111. Thyroid gland, the active principles of; their salts.

112. Tolbutamide.

113. Tretamine; its salts.

114. Triazi quone.

115. Tribromethyl alcohol.

116. Trimipramine.

117. Troxidone.

118. Zoxazolamine; its salts.

GROUP II

SUBSTANCES TO WHICH RULE 6(3)(B) APPLIES

1. Antibiotics.

2. Arsenic, organic compounds of, for injection.

3. 4:4-diamidino-diazoaminobenzene; its salts.

4. Phenanthridinium and its derivatives.

5. Para-aminobenzenesulphonamide; its salts; derivatives of paraaminobenzene-sulphonamide having any of the hydrogen atoms of the parasubstituted group or any of the sulphonamide group substituted by another radical; their salts.

6. Quinapyramine; its salts.

SCHEDULE V

[r. 8 and 10.]

INDICATION OF CHARACTER OF POISON

1. To be labelled with the words **"Caution. It is dangerous to take this preparation except under medical supervision"**—

Medicines made up ready for the internal treatment of human ailments if the poison is one of the following—

Beta-aminopropylbenzene; its salts; its N-alkyl derivatives; their salts.

Beta-aminoisopropylbenzene; its salts; its N-alkyl derivatives; their salts.

Insulin.

Phenylethylhydantoin; its salts; its acyl derivatives; their salts.

Pituitary gland, the active principles of.

Thyroid gland, the active principles of; their salts.

2. To be labelled with the words **"Caution. It is dangerous to exceed the stated dose"**—

Medicines (other than medicines mentioned in paragraph 1 of this Schedule) made up ready for the internal treatment of human ailments except in the case of a substance included in the First Schedule.

3. To be labelled with the words **"Poison. For animal treatment only"**—

Medicines made up ready for the treatment of animals.

4. To be labelled with the words **"Caution. This preparation may cause serious inflammation of the skin in certain persons and should be used only in accordance with expert advice"**—

Preparations for the dyeing of hair containing phenylene diamines, toluene diamines or other alkylated-benzene diamines or their salts.

5. To be labelled with the words **"Caution. This substance is caustic"**—

Potassium hydroxide, sodium hydroxide, and articles containing either of those substances.

6. To be labelled with the words **"Caution. This substance is poisonous. The inhalation of its vapour, mist, spray or dust may have harmful consequences. It may also be dangerous to let it come into contact with the skin or clothing"**—

Dinitrocresols (DNC), their compounds with a metal or a base, except preparations for the treatment of human ailments and except winter washes containing not more than the equivalent of five per cent of dinitrocresols.

Dinosam, its compounds with a metal or a base.

Dinoseb, its compounds with a metal or a base.

Fluoroacetamide; Fluoroacetanilide.

Phosphorus compounds, the following—

Diethyl thiophosphate of ethyl-mercapto-ethanol, dimefox, ethyl-para-nitrophenyl-benzene thiophosphonate, hexaethyl tetraphosphate (HETP), 4-methyl hydroxy-coumarin-diethyl thiophosphate, mipafox, parintrophenyl-diethyl phosphate, parathion, schradan, tetraethyl pyrophosphate (TEPP),

triphosphoric pentadimethylamide, di-isopropyl fluorophenate, demeton, mazidox, methyl demeton, sulphotepp, amiton, demeton-O, demeton-S, demeton-O-methyl, demeton-S-methyl, diethyl 4-methyl-7-coumarinyl phosphorothionate, diethyl p-nitrophenyl phosphate, ethyl p-nitrophenyl phenyl-phosphonothionate.

7. To be labelled with the words **"Caution. This preparation should be administered only under medical supervision. The vapour is dangerous"**— medicines made up ready for the internal or external treatment of human ailments and containing di-isopropyl fluorophosphonate.

8. To be labelled with the words **"Caution. This may cause drowsiness"**—

Anti-histamine substances, the following; their salts; their molecular compounds—

Antazoline.

Bromodiphenhydramine.

Buclizine.

Chlorcyclizine.

(p-Chlorophenylpyrid-2-ylmethyl) 2-dimethylaminoethyl ether 1-(4-p-Chlorophenyl-3-phenyl-but-2-enyl)-pyrrolidine.

Chlorpheniramine.

Clemizole.

Cyclizine.

3-Di-n-butylaminomethyl-4:5:6-trihydroxyphthalide.

1-Dimethylamino-3-phenyl-3-(2-pyridyl)-propane.

Diphenhydramine.

Diphenylpyraline.

Doxylamine.

Isothipendyl.

Mebhydrolin.

Meclozine.

Phenindamine.

Promethazine.

Thenalidine.

Triprolidine.

Substances being tetra-substituted N derivatives of ethylenediamine or propylenediamine.

SCHEDULE VI

[r. 9(1)(b).]

STATEMENT OF PARTICULARS PERMITTED IN CERTAIN CASES AS TO PROPORTION OF POISON

Name of poison	Particulars
1. Alkaloids.	
2. Aconite, alkaloids of	The proportion of any one alkaloid of aconite that the preparation would be calculated to contain on the assumption that all the alkaloids of aconite in the preparation were that alkaloid.
3. Belladonna, alkaloids of	The same as above, with the substitution for the reference to aconite of a reference to belladonna, calabar bean or such other of the said poisons as the case may require.
4. Calabar bean, alkaloids of	
5. Coca, alkaloids of	
6. Ephedra, alkaloids of	
7. Ergot, alkaloids of	
8. Gelsemium, alkaloids of	
9. Jaborandi, alkaloids of	
10. Lobelia, alkaloids of	
11. Pomegranate, alkaloids of	
12. Quebracho, alkaloids of, other than the alkaloids of red quebracho	
13. Sabadilla, alkaloids of	
14. Solanaceous alkaloids not otherwise included in the Poisons List	
15. Stavesacre, alkaloids of	
16. Veratrum, alkaloids of	
17. Yohimba, alkaloids of	

18. Colchicum, alkaloids of	
19. Antimonial poisons	The proportion of antimony trioxide (Sb2 O3) or antimony pentoxide (Sb2 O5) that the preparation would be calculated to contain on the assumption that the antimony (Sb) in the poison had been wholly converted into antimony trioxide or antimony pentoxide as the case may be.
20. Arsenical poisons	The proportion of arsenic trioxide (As2 O3) or arsenic pentoxide (As2 O5) that the preparation would be calculated to contain on the assumption that the arsenic (As) in the poison had been wholly converted into arsenic trioxide or arsenic pentoxide as the case may be.
21. Barium, salts of	The proportion of one particular barium salt which the preparation would be calculated to contain on the assumption that the barium (Ba) in the poison had been wholly converted into that salt.
22. Digitalis, glycosides of; other active principles of digitalis	The number of units of activity as defined in the *British Pharmacopoeia* contained in a specified quantity of the preparation.
23. Hydrocyanic acid; cyanides, double cyanides of mercury and zinc	The proportion of hydrocyanic acid (HCN) that the preparation would be calculated to contain on the assumption that the cyanides in the poison had been wholly converted into hydrocyanic acid.
24. Insulin	The number of units of activity as defined in the *British*

	Pharmacopoeia contained in a specified quantity of the preparation.
25. Lead, compounds of, with acids from fixed oils	The proportion of lead oxide (Pbo) that the preparation would be calculated to contain on the assumption that the lead in the poison had been wholly converted into lead ozide.
26. Mercury, organic compounds of	The proportion of organically combined mercury (Hg) contained in the preparation.
27. Nux vomica	The proportion of strychnine contained in the preparation.
28. Opium	The proportion of morphine contained in the preparation.
29. Phenols	The proportion of phenols (added together) contained in the preparation.
30. Compounds of a phenols with a metal	The proportion of phenols (added together) that the preparation would be calculated to contain on the assumption that the compounds of phenols with a metal had been wholly converted into the corresponding phenols.
31. Pituitary gland, the active principles of	Either— (a) the number of units of activity as defined in the *British Pharmacopoeia* contained in a specified quantity of the preparation; or (b) the proportion of pituitary gland, or of anterior or of posterior lobe of the gland, as the case may be, contained in the preparation; or (c) the amount of pituitary gland or of anterior or of posterior lobe of the gland, as the case may be, from

	which a specified quantity of the preparation was obtained, together with an indication whether the amount relates to fresh or to dried gland substance.
32. Potassium hydroxide	The proportion of potassium monoxide (K_2O) which the preparation would be calculated to contain on the assumption that the potassium hydroxide in the preparation had been wholly converted into potassium monoxide.
33. Sodium hydroxide	The proportion of sodium monoxide (Na_2O) which the preparation would be calculated to contain on the assumption that the sodium hydroxide in the preparation had been wholly converted into sodium monoxide.
34. Strophanthus, glycosides of	The amount of Standard Tincture of Strophanthus as defined in the *British Pharmacopoeia* which possesses the same activity as a specified quantity of the preparation when assayed by the method described in the said Pharmacopoeia.
35. Suprarenal gland, the active principles of their salts	Either— (a) the proportion of suprarenal gland or of the cortex or of the medulla of the gland, as the case may be, contained in the preparation; or (b) the amount of suprarenal gland or of the cortex or of the medulla of the gland, as the case may be, from which a specified quantity of the preparation was obtained, together with an indication

	whether the amount relates to fresh or to dried gland substance.
36. Thyroid gland, the active principles of their salts	Either— (a) the proportion of thyroid gland contained in the preparation; or (b) the amount of thyroid gland from which a specified quantity of the preparation was obtained, together with an indication whether the amount relates to fresh or to dried gland.

SCHEDULE VII

[r. 15.]

POISONS REQUIRED TO BE SPECIALLY LABELLED FOR TRANSPORT

1. Arsenical poisons.

2. Barium, salts of.

3. Dinitrocresols (DNC), their compounds with a metal or a base when contained in preparations for use in agriculture or horticulture, except winter washes containing not more than the equivalent of 5 per cent of dinitrocresols.

4. Dinitrophenols when contained in preparations for use in agriculture or horticulture.

5. Dinosam, its compounds with a metal or a base, when contained in preparations for use in agriculture or horticulture.

6. Dinoseb, its compounds with a metal or base, when contained in preparations for use in agriculture or horticulture.

6A. Endosulfan.

7. Fluoroacetamide; Fluoroacetanilide.

8. Hydrocyanic acid; cyanides.

9. Nicotine.

10. Phosphorus compounds, the following—

Diethyl thiophosphate of ethyl-mercapto-ethanol, dimefox, ethyl-paranitro-phenyl-benzene thiophosphonate, hexaethyl tetraphosphate (HETP), 4-methyl-hydroxy-coumarin-diethyl thiophosphate, mipafox, paranitrophenyl-diethyl phosphate, parathion, schradan, tetraethyl

pyrophosphate (TEPP), triphosphoric pentadimethylamide, di-isopropyl-fluorophenate, demeton, mazidox, methyl demeton, sulphotepp, amiton,demeton-O, demeton-S, demeton-O-methyl, demeton-S-methyl, diethyl 4-methyl-7-coumarinyl phosphorothionate, diethyl p-nitrophenyl phosphate, ethyl p-nitrophenyl phenylphosphonothionate, ethion, mecarbam, phenkapton.

11. Strychnine.

12. Thallium, salts of.

SCHEDULE VIII

[L.N. 365/1964, L.N. 41/1971, r. 20, L.N. 61/2002, s. 2, L.N. 91/2004, s. 2.]

CROSSHEADING

1. Application for registration as a pharmacist (section 7).

2. Register of pharmacists (section 6).

3. Certificate of registration as a pharmacist (section 9).

4. Application for registration of premises (section 23).

5. Register of premises (section 23).

6. Application for wholesale dealer's licence (section 27).

7. Wholesale dealer's licence (section 27).

8. Register of wholesale dealer's licences (section 27).

9. Application for licence to deal in poisons for mining, agricultural and horticultural purposes (section 28).

10. Licence to deal in poisons for mining, agricultural and horticultural purposes (section 28).

11. Register of dealers in mining, agricultural and horticultural poisons (section 28).

12. Certificate for purchase of poison (section 29).

13. Application for licence to sell Part II poisons (section 32).

14. Licence to sell Part II poisons (section 32).

15. Register of licences issued to sellers of Part II poisons (section 32).

16. Poisons Book (section 30).

17. Permit to import Part I poisons (rule 3).

18. Application for pharmaceutical representative's permit (rule 13A).

19. Pharmaceutical representative's permit (rule 13A).

20. Institution inspection report (rule 14).

21. Application for licence to manufacture drugs for sale (rule 16).

22. Licence to manufacture drugs for sale (rule 16).

23. Application for licence for the exportation of drugs and poisons.

24. Annual professional practise licence as a pharmacist (section 9A).

25. Roll of Pharmaceutical Technologists (section 6(2)).

26. Application for enrolment as a pharmaceutical technologist (section 7(2)).

27. Application for annual practice licence for a pharmacist (section 9A).

28. Certificate of enrolment as a pharmaceutical technologist (section 9(2)).

29. Application for licence as a pharmaceutical technologist (section 20(1A)).

30. Application for registration of premises for a pharmaceutical technologist (section 20(1A)).

31. Certificate for registration of premises for a pharmaceutical technologist (section 20(1A)).

32. Annual licence to practice as a pharmaceutical technologist (section 20(2A).

33. Certificate of registration of premises for pharmacist (section 23(c)).

FORM 1

APPLICATION FOR REGISTRATION AS A PHARMACIST

The Registrar, Pharmacy and Poisons Board,

Afya House, P.O. Box 30016, Nairobi.

I, ... of ..... hereby make application for registration as a pharmacist.

I hereby declare that to the best of my knowledge and belief I am not aware of any circumstances which would disqualify me for registration.

My qualifications are .....

.....

I enclose the following certificates/diplomas—

.....

.....

Date .....

Signature

FORM 2

REGISTER OF PHARMACISTS

REGISTRATION No.	Date	Name of Applicant	Address	Qualification	Date of Qualification	Registration Fee

FORM 3

CERTIFICATE OF REGISTRATION AS A PHARMACIST

.....

is hereby registered as a pharmacist in accordance with the provisions of Part II of the Pharmacy and Poisons Act.

Given at Nairobi on the ....., 20 .....

.....

Registrar, Pharmacy and Poisons Board

FORM 4

APPLICATION FOR REGISTRATION OF PREMISES

The Registrar, Pharmacy and Poisons Board,

Afya House, P.O. Box 30016, Nairobi.

In accordance with the provisions of section 23 of the Pharmacy and Poisons Act, I/We ..... wishing to carry on the business of a pharmacist, do hereby apply for registration of premises situated at ..... in the town of .....

The business, in so far as concerns the retail sale of drugs, will be under the control of ..... a pharmacist registered in accordance with Part II of the Act.

Date .....

Signature of Applicant

N.B.—Any change of pharmacist under whose control the business is carried on must be notified to the Registrar within seven days.

Fee: Sh. 100.

FORM 5

REGISTER OF PREMISES

REGISTRATION No.	Date	Name(s) of owner(s) of the business	Address of premises where business of a pharmacist is carried on (give name of minor settlement/ town)	Name of pharmacist under whose control the business of a pharmacist is carried on

FORM 6

APPLICATION FOR WHOLESALE DEALER'S LICENCE

The Registrar, Pharmacy and Poisons Board,

Medical Headquarters, P.O. Box 30016, Nairobi.

I/We ..... of .....

wishing to carry on business as a wholesale dealer in poisons at ..... in the town of ..... hereby apply for the issue/renewal of a wholesale dealer's licence.

The registered pharmacist in control of the distribution of poisons is ....., resident in .....

Date .....

Signature of Applicant

N.B.—Any change of registered pharmacist under whose control the distribution of poisons is effected must be notified to the Registrar within seven days.

FORM 7

WHOLESALE DEALER'S LICENCE

Messrs ..... of ....., carrying on business at ..... are hereby authorised to sell poisons by way of wholesale dealing.

Date .....

.....

Registrar, Pharmacy and Poisons Board

Note.—This licence expires on the 31st day of December, 20.....

Fee: Sh. 400

FORM 8

REGISTER OF WHOLESALE DEALERS

REGISTRATION No.	Date	Name(s) of owner(s) of the business	Address of premises where business is carried on	Name of pharmacist in control of the distribution of poisons

FORM 9

APPLICATION FOR LICENCE TO DEAL IN POISONS FOR MINING, AGRICULTURAL AND HORTICULTURAL PURPOSES

The Registrar, Pharmacy and Poisons Board,

Medical Headquarters, P.O. Box 30016, Nairobi.

I/We ..... of ..... carrying on a regular business in *mining/agricultural/and/or horticultural accessories at ..... in the town of ..... , hereby apply for the issue/renewal of a licence to deal in the following poisons .....

.....

I/We hereby nominate the following person(s) .....

.....

.....

who may sell in accordance with the provisions of rule 10 of the Pharmacy and Poisons Rules.

Date .....

.....

Signature of Applicant

* Delete as necessary.

Note.—Not more than two persons may be nominated.

FORM 10

LICENCE TO DEAL IN MINING, AGRICULTURAL OR HORTICULTURAL POISONS

Messrs. ..... of .....

carrying on business at ..... are hereby licensed to deal in the following poisons .....

.....

.....

.....

The following person(s) are hereby authorised to sell these poisons in accordance with the provisions of rule 10 of the Pharmacy and Poisons Rules.

.....

.....

Date .....

.....

Registrar, Pharmacy and Poisons Board

N.B.—Any change in persons authorised to sell must be notified to the Registrar within seven days.

Note.—This licence expires on the 31st day of December, 20.....

Fee: Sh. 50.

FORM 11

REGISTER OF DEALERS IN MINING, AGRICULTURAL AND HORTICULTURAL POISONS

REGISTRATION No.	Date	Name of owner(s) of the business	Address of premises where business is carried on	Name(s) of person(s) authorised to sell poisons

FORM 12

CERTIFICATE FOR PURCHASE OF POISON

For the purposes of paragraph (b) of subsection (2) of section 29 of the Pharmacy and Poisons Act, I, the undersigned, hereby certify from my knowledge of (a) ..... of (b) ....., that he is a person to whom (c) ..... may properly be supplied.

I further certify that (d) ..... is the signature of the said (a) .....

Date .....

.....

Signature and designation of officer giving

certificate

(a) Insert full name of intending purchaser.

(b) Insert full postal address.

(c) Insert name of poison.

(d) Intending purchaser to sign his name here.

FORM 13

APPLICATION FOR LICENCE TO SELL PART II POISONS

To the Civil Secretary,

.....

I/We ..... , being engaged in the business of ....., hereby apply to sell poisons by wholesale/retail in Group A/ Group B of Part II of the Poisons List or specified poisons, on the following premises .....

.....

I/We hereby nominate the following person(s) .....

..... who will sell such poisons in accordance with the provisions of the Pharmacy and Poisons Act and the Pharmacy and Poisons Rules.

Date .....

Signature of Applicant

FORM 14

LICENCE TO SELL PART II POISONS

....., of ....., carrying on the business ..... at ....., is hereby licensed to sell the following

Part II Poisons .....

Insert here either .....

Group A, ...

Group B, or

.....

specified poisons .....

as the case may .....

be and whether .....

by wholesale or .....

retail sale. .....

.....

The following person(s) are hereby authorised to sell these poisons in accordance with the provisions of the Pharmacy and Poisons Act and the Pharmacy and Poisons Rules.

.....

.....

Date .....

.....

Civil Secretary

N.B.—Any change of persons authorised to sell must be notified to the Civil Secretary within seven days.

Note.—This licence expires on 31st December, 20 .....

Fee: Sh. 40.

FORM 15

REGISTER OF LICENCES ISSUED TO SELLERS OF PART II POISONS

REGISTRATION No.	Date	Name of licensee	Address of premises where business is carried on	Class of licence	Name(s) of person(s) authorised to sell poisons

FORM 16

POISONS BOOK

Date of sale	Name and quantity of poison supplied	PURCHASER'S Name	Address	Business trade or occupation	Purpose for which stated to be required	Date of certificate (if any)	Name and address of person giving certificate (if any)	Signature of purchaser, or where a signed order is permitted the date of the signed order

FORM 17

MINISTRY OF HEALTH AND CENTRAL BANK OF KENYA

FOR EXCHANGE CONTROL USE No.

APPLICATION FOR IMPORT AND/OR FOREIGN EXCHANGE ALLOCATION

IMPORTER'S FULL NAME AND ADDRESS:

NOTE.—Applicant to attach sellers Proforma Invoice.
Proforma Invoice No.
Date: .....
Reference: .....

IMPORTER'S BANK AND BRANCH:

TOTAL AMOUNT IN FOREIGN CURRENCY: In Figures:
In Words: Exchange rates: Kenya Currency equivalent Sh.

SELLER'S FULL NAME AND ADDRESS:

APPLICABLE SCHEDULE:
COUNTRY OF ORIGIN:

Date of Shipment:

Terms of Payment (State commission rate if applicable):

Mode of Transport Port of Loading

F.O.B. Freight Insurance

Port of Discharge:

S.I.T.C. Code	Generic Name	Trade Name	Package Size	Quantity	Reg. No.	Unit price

Signature of Applicant: ..... Date: .....

FOR OFFICIAL USE OF MINISTRY OF HEALTH

....

Valid up to Replacement

.....

Extended to

FOR USE OF CENTRAL BANK OF KENYA

.....

Replacement

.....

Exchange Control Authorization Stamp and Signature

SPECIAL INSTRUCTIONS:

Approved subject to clean report of finding by general superintendence company limited as to:

quality and quantity inspection and Price comparison:

To be contacted at:

FOR USE BY REMITTING BANK

PAYMENTS MADE

Date	Foreign Currency Remitted	Exchange Rate	Kenya Currency Equivalent	Branch Stamp and Authorized Signature

FORM 18

APPLICATION FOR PHARMACEUTICAL REPRESENTATIVE'S PERMIT

I/We ....., of (postal add....., being engaged in the sale and supply of pharmaceutical goods, hereby make application that our representative Mr. ..... be permitted to possess pharmaceutical goods containing Part I poisons as scheduled below, for the purpose of giving free samples to persons who may lawfully possess such goods.

SCHEDULE

.....

.....

.....

Date .....

.....

(Signature of Applicant)

FORM 19

PHARMACEUTICAL REPRESENTATIVE'S PERMIT

Mr. ..... as representative

of ..... is hereby permitted to possess and supply free samples of pharmaceutical goods containing Part I Poisons, as scheduled below, to persons who are authorized to use them in their trade, business or profession as laid down in the Pharmacy and Poisons Act, subject to maintenance of records as required by rule 13A(1)(b) of the Pharmacy and Poisons Rules.

SCHEDULE

.....

.....

.....

Date .....

.....

The Pharmacy and Poisons Board,

P.O. Box 30016,

Nairobi.

Note.—This permit expires on 31st December, 20..... , or upon the person named ceasing to be employed as a pharmaceutical representative of the firm stated above.

FEE: Sh. 25.

FORM 20

INSTITUTION INSPECTION REPORT

I, the undersigned of (postal address) ....., have today carried out an inspection of ..... as required by rule 14 of the Pharmacy and Poisons Rules.

The following defects are reported—

1. Storage .....

.....

.....

2. Methods of Handling .....

.....

.....

3. Records .....

.....

.....

I have the following recommendations to make—

.....

.....

.....

The previous inspection was carried out on .....

Signature .....

Designation .....

Date .....

To: 1. ..... (person in charge of the Institution).

2. The Registrar, Pharmacy and Poisons Board.

FORM 21

APPLICATION FOR A LICENCE TO MANUFACTURE DRUGS FOR SALE

The Registrar, The Pharmacy and Poisons Board .....

.....

I/We ....., of (postal address) ....., having premises situated at ..... and being engaged in the business of ..... hereby apply to manufacture for sale the following drug(s) medicine(s) .....

This/These drug(s)/medicine(s) has/have the following composition .....

The manufacture of the above drug(s)/medicine(s) will be carried out under the direct personal supervision of ..... who has the following qualifications .....

The manufacture of the above drug(s)/medicine(s) will be carried out at .....

Date .....

.....

(Signature of Applicant)

Note.—Any change of the person under whose direct personal supervision the manufacture is carried out, whether temporary or permanent, must be notified

to the Registrar..... of (postal address) ..... and having premises situated at ..... is hereby licensed to manufacture for sale the following drug(s)/medicine(s)..... under the direct personal supervision of .....

Note—The licence expires on 31st December, 20 .....

Registration No. .....

Date .....

.....

Registrar,

Pharmacy and Poisons Board,

P.O. Box 30016,

Nairobi.

Any change of the person under whose direct personal supervision the manufacture is carried on, whether temporary or permanent, must be notified to the Registrar immediately.

FORM 23

MINISTRY OF HEALTH

APPLICATION FOR LICENCE FOR THE EXPORTATION OF DRUGS AND POISONS

EXPORTER'S NAME AND ADDRESS CODE No.

CONSIGNEE'S NAME AND ADDRESS:

INVOICE No.:

CD3 No.

Country of origin: Destination of goods:

DATE OF SHIPMENT: Terms of delivery and payments:

Mode of transport: Port of loading F.O.B. Value:

Port of discharge:

Generic Name	Trade Name	Pack Size	Unit Price	Quantity	Batch No.	Country of Manufacture

I declare that the particulars which I have given are true and accurate to the best of my knowledge and belief.

Date ..... Signed .....

Applicant

This document will be effective as an Export Licence only when it has been validated by the Chief Pharmacist.

FOR OFFICIAL USE ONLY: EXPORT LICENCE: NUMBER .....

Export of goods described above is approved, subject to .....

Date .....

.....

for Chief Pharmacist

This licence is not transferable.

FORM TO BE FULLY COMPLETED IN TRIPLICATE (PREFERABLY TYPEWRITTEN) BY APPLICANT:

PHARMACY AND POISONS ACT (CAP. 244) RULE .....

FORM 24

[L.N. 61/2002, s. 2.]

ANNUAL PROFESSIONAL PRACTICE LICENCE AS A PHARMACIST

Serial No.....

Prof./Dr. .....

(Full names in block letters)

is hereby licensed by the Pharmacy and Poisons Board to render pharmaceutical services in Kenya.

Dated the ..... day of ..... 20 .....

Registrar, Pharmacy and Poisons Board

Licence No. .....

This Licence expires on 31st December, 20 .....

Fee: KSh. 2,500

FORM 25

ROLL OF PHARMACEUTICAL TECHNOLOGISTS

TRAINING INSTITUTION
DATE OF QUALIFICATION
QUALIFICATION
ADDRESS
ID No.
NAME OF APPLICANT
ENROLMENT

FORM 26

APPLICATION FOR ENROLMENT AS A PHARMACEUTICAL TECHNOLOGIST

The Registrar,

Pharmacy and Poisons Board,

P.O. Box 27663-00506,

Nairobi

I .....

of P.O. Box .....

..... ID No. ..... do hereby apply to be enrolled as a Pharmaceutical Technologist in accordance with the Pharmacy and Poisons Act.

Qualification .....

Institution .....

.....

Date of Qualification .....

Period of Internship: From ..... to .....

(Attach proof of Internship*)

.....

Signature of Applicant

* Applicants are advised to attach genuine evidence from recognized institution of attachment. Any false information given may lead to prosecution.

FORM 27

APPLICATION FOR ANNUAL PRACTICE LICENCE FOR A PHARMACIST

The Registrar,

Pharmacy and Poisons Board,

P.O. Box 27663-00506,

Nairobi

I .....

of P.O. Box .....

.....

Registration No. ..... do hereby apply for a Practice licence as a pharmacist.

.....

Date

.....

.....

Signature of Applicant

FORM 28

SERIAL No. .....

CERTIFICATE OF ENROLMENT AS A PHARMACEUTICAL TECHNOLOGIST

The Registrar,

Pharmacy and Poisons Board,

P.O. Box 27663-00506,

Nairobi

.....

(Name and Address)

ID/No. .....

Having duly satisfied the Pharmacy and Poisons Board is hereby enrolled as a Pharmaceutical Technologist in accordance with the Pharmacy and Poisons Act.

Given on the ..... day of ..... in the year 20 .....

Enrolment No. .....

.....

(Registrar, Pharmacy and Poisons Board)

Fee: KSh. 500

FORM 29

APPLICATION FOR LICENCE AS PHARMACEUTICAL TECHNOLOGIST

The Registrar,

Pharmacy and Poisons Board,

P.O. Box 27663-00506,

Nairobi

Dear Sir/Madam

I, ...

of P.O. Box .....

ID/No. ..... do hereby apply for a licence as a pharmaceutical technologist.

Enrolment No. ..... Date of enrolment .....

Name of premises .....

Plot No. ..... Road .....

Town .....

.....

Signature of Applicant

.....

.....

Date

FORM 30

APPLICATION FOR REGISTRATION OF PREMISES FOR A PHARMACEUTICAL TECHNOLOGIST

The Registrar,

Pharmacy and Poisons Board,

P.O. Box 27663–00506,

Nairobi

I/We .....

.....

wishing to carry on the business of a Pharmaceutical Technologist, do hereby apply for registration of premises situated at ..... in the township of .....

The business in so far as concerns the retail sale of drugs will be under the control of ..... a Pharmaceutical Technologist enrolled in accordance with Part II of the Act.

Date ....

Signature of the Applicant

Note.—Any change of premises of a Pharmaceutical Technologist under whose control the business is carried on must be notified to the Registrar within seven days.

FORM 31

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

PREMISES REGISTRATION CERTIFICATE FOR PHARMACEUTICAL TECHNOLOGIST'S PRACTICE

SERIAL No. .....

Name of Premises .....

Registration No. of premises .....

Location of premises .....

Town ..... Street .....

Plot No. .....

Name of pharmaceutical technologist .....

ID No. ..... Enrolment No. .....

Has met the necessary conditions for the business of a pharmaceutical technologist to be carried therein.

.....

(Registrar, Pharmacy and Poisons Board)

.....

Date

Note: (a) This registration expires on 31st December, 20 .....

(b) No change of premises is permitted without the authority of the Board.

(c) This registration shall become void upon expiration of 30 days from any change of ownership of the business.

Fee: KSh. 5,000

FORM 32

SERIAL NO. .....

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

ANNUAL LICENCE TO PRACTICE AS A PHARMACEUTICAL TECHNOLOGIST

.....

(Name and Address)

is hereby licensed to practice as a pharmaceutical technologist in accordance with the Pharmacy and Poisons Act.

Name of Premises .....

Plot No. ..... Road .....

Town .....

Given at Nairobi on the ..... day o..... of the year 20 .....

.....

(Registrar, Pharmacy and Poisons Board)

.....

Date

This licence expires on the 31st December, 20 .....

Fee: KSh. 2,500

FORM 33

SERIAL No. .....

CERTIFICATE FOR REGISTRATION OF PREMISES

Messrs. .....

of .....

Plot No. ..... is registered to carry on business of a pharmacist as provided for by section 23.

Date .....

.....

Registrar, Pharmacy and Poisons Board.

Note: (a) This registration expires on 31st December, 20 .....

(b) No change of premises is permitted without the authority of the Board.

(c) This registration shall become void upon expiration of 30 days from any change of ownership of the business.

Fee: KSh. 5,000

SCHEDULE IX

[Rule 6.]

PERMIT AUTHORISING FARMERS AND OTHER PERSONS TO BE IN POSSESSION OF SUBSTANCES SPECIFIED IN GROUP II OF SCHEDULE IV TO THE RULES

For the purposes of rule 6 of the Pharmacy and Poisons Rules, I, the undersigned, of .....hereby authorise ..... of ..... to purchase and possess the following substances in Group II of Schedule IV to the Rules—

.....

.....

.....

.....

.....

.....

1. If any quantity is specified against any or all of the items listed above the permit holder may not purchase or possess more than that quantity at any time.

2. This permit is valid for a period of six months from date of issue.

3. This permit must be produced to the authorised seller of poisons on each occasion when supplies are purchased.

Date .....

.....

Signature

THE PHARMACY AND POISONS (PARALLEL IMPORTED MEDICINAL SUBSTANCES) RULES

ARRANGEMENT OF RULES

THE PHARMACY AND POISONS (PARALLEL IMPORTED MEDICINAL SUBSTANCES) RULES

[Legal Notice 126 of 2019]

PART I – PRELIMINARY

1. Citation

These Rules may be cited as the Pharmacy and Poisons (Parallel Imported Medicinal Substances) Rules.

2. Application

These Rules shall apply to medicinal substances which are parallel imported and distributed on the Kenyan market except—

(a) a medicinal substance prepared by a pharmacist in the pharmacy and dispensed without promotion, blood, blood plasma and blood preparations containing cellular elements of blood, or substances such as dental fillings and plates, or surgical preparations such as catgut and plaster of Paris bandages;

(b) non-registered patented medicinal substance for compassionate use;

(c) an orphan medicinal substance; or

(d) non-registered medicinal substance for named patient use and hospitals.

3. Interpretation

In these Rules, unless the context otherwise requires—

"Act" means the Pharmacy and Poisons Act (Cap 244);

"Appeals Committee" means the Parallel Importation Appeals Committee established under rule 48;

"authorized officer" means the registrar, pharmaceutical analyst, pharmaceutical inspector, a medical officer, an inspector of medicinal substances, an administrative officer or a police officer in the rank of Superintendent and above;

"branded generic medicinal substance" means a medicinal substance usually intended to be interchangeable with the originator brand product, manufactured without a licence from the originator manufacturer and marketed after the expiry of patent or other exclusivity rights;

"certificate" means the certificate of parallel importation issued under rule 6;

"country of origin" means a country from which the parallel imported medicinal substance is imported;

"licence" means a licence granted under rule 14 to allow the licensee to carry on parallel importation of a medicinal substance;

"licensee" means a person licensed to engage in parallel importation of a medicinal substance under these rules;

"marketing authorization" means the certificate of registration issued by the competent medicinal substance regulatory authority in the country of origin for the purpose of marketing or free distribution of a medicinal substance after evaluation for safety, efficacy and quality;

"marketing authorization holder" means a person who holds a marketing authorization;

"notification" means the process of entering actual movement and state of each unit of a medicinal substance into the tracing system established under rule 43;

"parallel importation" means the importation into Kenya, by a licensed importer of medicinal substance other than the marketing authorization holder or his or her technical

representative of the following medicinal substances which require marketing authorization in Kenya—

(a) patented medicinal substances under section 58(2) of the Industrial Property Act (Cap. 509);

(b) non-patented medicinal substances; or

(c) branded generic medicinal substances;

"parallel imported medicinal substance" means a medicinal substance imported into Kenya under these Rules;

"pharmacovigilance" means the detection, assessment, understanding and prevention of adverse effects or any other medicinal substance-related problem; and

"risk management plan" means a detailed description of a plan that contains—

(a) a description and analysis of the safety profile of the medicinal substance including a summary of the safety concerns; and

(b) a set of medicinal substance vigilance and risk minimization activities designed to identify, characterize and manage risks relating to the medicinal substance including the assessment of the effectiveness of these activities and interventions.

PART II – CERTIFICATE OF PARALLEL IMPORTATION AND PARALLEL IMPORT LICENCE

4. Qualification to parallel medicinal substances

A person shall not parallel import a medicinal substance into Kenya unless—

(a) the person is incorporated as a limited liability company under the Companies Act (Cap. 486);

(b) the person has been granted a certificate of parallel importation;

(c) the person is licensed to parallel import the medicinal substance;

(d) the medicinal substance has a valid registration in Kenya under the Pharmacy and Poisons (Registration of Drugs) Rules (L.N. 147/1981); and

(e) the medicinal substance has a valid market authorization in the country of origin.

5. Application for a certificate of parallel importation

(1) A person who wishes to undertake parallel importation shall apply, to the Board, for a certificate of parallel importation in the Form 1 set out in the First Schedule.

(2) The application form shall be accompanied by—

(a) a certified copy of the applicant's certificate of incorporation;

(b) a certified copy of the applicant's memorandum and articles of association or its equivalent under the Companies Act (Cap. 486);

(c) the applicant's company profile as may be appropriate for parallel importation of medicinal substances;

(d) a copy of certificate of registration, issued under section 9 of the Act, to the registered pharmacist who shall be at the premises;

(e) a copy of certificate of registration of premises issued under section 23 of the Act;

(f) a copy of wholesale dealer's licence issued under section 27 of the Act;

(g) a copy of manufacturer's licence issued under section 35A of the Act, where applicable;

(h) a copy of certificate of membership of Pharmaceutical Society of Kenya;

(i) such other information as the Board may require from time to time; and

(j) the application fee prescribed in the Second Schedule.

6. Issuance of certificate of parallel importation

The Board shall consider an application made under rule 5 and where satisfied that all the necessary requirements have been met, issue a certificate of parallel importation to the applicant, within a reasonable time of the applicant lodging the application.

7. Certificate of parallel importation not transferable

A certificate of parallel importation issued under rule 6 shall not be transferred, assigned or encumbered in any way.

8. Validity of certificate of parallel importation

The certificate of parallel importation granted under rule 6 shall expire on 31st December of every year.

9. Rejection of an application for a certificate of parallel importation

(1) The Board may, within fourteen days of receipt of an application under rule 5, consider and reject an application which in the opinion of the Board—

(a) is substantially defective; or

(b) has not met the requirements of rule 4.

(2) The Board shall communicate the rejection of an application to the applicant within fourteen days of the Board's decision and shall state the reason for the rejection.

10. Application for renewal of certificate of parallel importation

(1) The holder of certificate of parallel importation may apply to the Board for renewal of the certificate at least three months before the expiry of the certificate.

(2) The application referred to under paragraph (1) shall—

(a) be in Form 1 set out in the First Schedule; and

(b) be accompanied by the renewal fees prescribed in the Second Schedule.

(3) The Board may renew a certificate where—

(a) it is satisfied that the licensee has been operating in compliance with these Rules; and

(b) the certificate holder has fulfilled its tax obligations and submitted a current certified copy of a tax compliance certificate or its equivalent as issued by the Kenya Revenue Authority.

(4) Where the holder of a certificate submits an application for renewal of a certificate under paragraph (1), the certificate shall be deemed to be valid until the application for renewal is determined.

(5) A holder of a certificate of parallel importation who does not wish to renew a certificate shall inform the Board and specify the parallel imported medicinal substances within its possession and how it intends to dispose of the substances.

(6) The certificate of parallel importation of a holder who fails to apply for renewal of the certificate within the period prescribed in paragraph (1) shall, at the expiry of its validity, be deemed to have lapsed and the holder shall not parallel import or sell such medicinal substances or purport to do anything in relation to the medicinal substances in Kenya.

(7) A person who contravenes paragraph (6) commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding ten years, or to both.

11. Application for parallel import licence

(1) The holder of a certificate of parallel importation shall apply to the Board for a license to parallel import a medicinal substance in Form 2 set out in the First Schedule.

(2) An application made under paragraph (1) shall be accompanied by—

(a) copies of the package insert and patient information leaflet translated into English or Kiswahili, where available;

(b) an appropriately labelled sample of the medicinal substance to be imported;

(c) information on the exporter, stating whether it is a manufacturer, packer, re-packer or wholesaler;

(d) a statement of justification for importation of the medicinal substance including but not limited to the economic advantage of reduced price;

(e) evidence that the medicinal substance is covered by an existing market authorization in the country of origin;

(f) an undertaking that the applicant will ensure the continued safety, efficacy and quality of the medicinal substance as determined by the Board in Form 3 set out in the First Schedule;

(g) a written confirmation of the lowest price at which the medicine is currently sold by the marketing authorization holder of the certificate of registration in Kenya dated not more than one month before the date of submission of the application for a parallel import licence;

(h) such other information as may be required by the Board from time to time; and

(i) the application fee prescribed in the Second Schedule.

(3) The marketing authorization holder shall not prevent the importation of a parallel imported medicine into Kenya or its sale on account of holding a certificate of registration or on account of the existence of a patent on such medicine.

12. Additional requirements by the Board

(1) The Board may, when considering an application made under rule 11, make inquiries and request for such additional evidence and documents as the Board may consider necessary.

(2) The Board shall, within seven working days, specify to the applicant such additional evidence and documents as it may require under paragraph (1).

(3) The Board shall reject an application where an applicant fails to provide additional evidence and documents under paragraph (2).

13. Board inquiries in country of origin

The Board may, where it considers it necessary—

(a) make inquiries to the authorities in the country of origin of a medicinal substance to ensure that the medicinal substance in question has a valid marketing authorization in the country of origin;

(b) verify manufacturer details, the marketing authorization holder, the complete composition, the shelf life and the storage conditions; or

(c) carry out audits on the importers.

14. Issuance of licence

(1) The Board may, if satisfied that an applicant has met all the requirements, issue a parallel import licence to the applicant, within a reasonable time of the applicant lodging the application.

(2) The licensee may, upon receipt of a licence, proceed with the importation of the medicinal substance after the medicinal substance has been licensed.

15. Licence not transferable

A licence issued under rule 14(1) shall not be transferred, assigned or encumbered in any way.

16. Validity of licence

The licence issued under rule 14(1) shall expire on 31st December of every year.

17. Rejection of an application for a parallel import licence

(1) The Board may, within fourteen days of the applicant lodging the application under rule 11, reject an application which in the opinion of the Board—

(a) is substantially defective; or

(b) has not complied with the requirements under rule 11.

(2) The rejection referred to under paragraph (1) shall be communicated to the applicant within fourteen days of the Board's decision and shall state the reason for the rejection.

18. General conditions of parallel import licence

A licensee shall—

(a) take measures to ensure the safe use of the medicinal substance and include them in the licensee's risk management plan;

(b) comply with obligations on the recording or reporting of suspected adverse reactions to the Board;

(c) comply with any other conditions or restrictions with regard to the safe and effective use of the medicinal substance; and

(d) establish an adequate pharmacovigilance system.

19. Application for renewal of a parallel import licence

(1) A licensee shall apply to the Board for renewal of a licence to parallel import medicinal substances at least three months before the expiry of the licence.

(2) An application under paragraph (1) shall—

(a) be in Form 2 set out in the First Schedule; and

(b) be accompanied with the renewal fees prescribed in the Second Schedule.

(3) The Board may renew a licence where—

(a) it is satisfied that the licensee has been operating in compliance with these Rules; and

(b) the licensee has fulfilled its tax obligations and submitted a current certified copy of a tax compliance certificate or its equivalent as issued by the Kenya Revenue Authority.

(4) Where the licensee submits an application for renewal of a licence under paragraph (1), the licence shall be deemed to continue in force until the application for renewal is determined.

(5) A licensee who does not wish to renew a licence shall inform the Board and specify the parallel imported medicinal substances within its possession and how it intends to dispose of the substances.

(6) The licence of a licensee who fails to submit an application for renewal of license within the period prescribed in paragraph (1) shall, at the expiry of its validity, be deemed to have lapsed and the licensee shall not parallel import or sell such medicinal substances or purport to do anything in relation to the medicinal substances.

(7) A person who contravenes paragraph (6) commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

20. Revocation, variation and suspension of parallel import licence

(1) The Board may revoke, vary or suspend a parallel import licence if the Board determines that—

(a) the medicinal substance to which the parallel import licence relates is harmful;

(b) the qualitative or quantitative composition of the medicinal substance is not as described in the application for the parallel import licence or the material supplied with it;

(c) the application or the material supplied with it was incorrect;

(d) there has been a breach of any of the terms of the parallel import licence or a requirement on packaging and leaflets;

(e) a general condition of the parallel import licence has not been fulfilled;

(f) the licensee has not complied with rule 11;

(g) the licensee has ceased to be established in Kenya; or

(h) urgent action to protect public health is necessary, in which case it may suspend the parallel import licence.

(2) A person aggrieved by the decision to vary, revoke or suspend a licence may lodge an appeal to the Appeals Committee within thirty days from the date of the decision.

21. Suspension of use, sale, supply or offer for sale or supply of medicinal substance

(1) The Board may suspend the use, sale, supply or offer for sale or supply within Kenya of a medicinal substance or batches of a medicinal substance to which a parallel import licence relates if the Board determines that—

(a) the medicinal substance to which the parallel import licence relates is harmful;

(b) the positive therapeutic effects of the medicinal substance do not outweigh the risks of the medicinal substance to the health of patients or of the public;

(c) the medicinal substance lacks therapeutic efficacy, given that therapeutic results cannot be obtained from the medicinal substance;

(d) the qualitative or quantitative composition of the medicinal substance is not as described in the application for the parallel import licence or the material supplied with it; or

(e) there has been a breach of any of the terms of the parallel import licence or a requirement on packaging and leaflets.

(2) The Board shall notify a licensee, in writing, of a suspension under this rule for a specified period that is to take effect from the date specified in the notice and shall state reasons for the suspension.

(3) The Board may, in exceptional circumstances and for such a transitional period as the Board may determine, allow the supply of the medicinal substance to patients who are already being treated with a medicinal substance that is the subject of a suspension under this rule.

(4) A parallel importer shall destroy any expired parallel imported medicines remaining in stock after their expiry date, whether during the duration of the permit or after the parallel importation permit has expired.

(5) A person who contravenes paragraph (4) commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

(6) A person aggrieved by a decision made by the Board under this rule may appeal to the Appeals Committee within thirty days from the date of the Board's decision.

22. Recall of a medicinal substance from the market

(1) The Board shall, in writing, require a licensee whose licence has been revoked or suspended under rule 20 to take all reasonably practicable steps to—

(a) inform wholesalers, retailers, medical practitioners, patients and any other person who may be in possession of the medicinal substance to which the parallel import licence relates of—

(i) the revocation or suspension;

(ii) the reasons for the revocation or suspension; and

(iii) any action to be taken to restrict or prevent the further use, sale, supply or offer for sale or supply of the medicinal substance.

(b) recall from the market in Kenya and recover possession of—

(i) the medicinal substance; or

(ii) the batches of the medicinal substance specified in the notice,

within the time and for the period specified in the notice.

(2) The licensee shall as soon as is practicable inform in writing the marketing authorization holder of the recall of the parallel imported medicinal substance.

(3) A person who contravenes paragraphs (1) or (2) commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

PART III – INVENTORY OF PARALLEL IMPORTED MEDICINAL SUBSTANCE

23. Inventory of parallel imported medicinal substances

The Registrar shall keep an inventory containing—

(a) the names of all the holders of certificates of parallel importation;

(b) the names of all licensees;

(c) all parallel imported medicinal substances; and

(d) such other information as may be determined by the Board from time to time.

24. Record-keeping obligations

(1) A licensee shall at all times keep manual or electronic records of the origin, imported quantities and batch numbers of the parallel imported medicinal substances.

(2) The licensee shall share the records kept under paragraph (1) with the Board, when required to.

(3) A person who contravenes paragraphs (1) or (2) commits an offence and is liable, upon conviction, to a fine not exceeding two hundred thousand or to imprisonment for a term not exceeding one year, or to both.

PART IV – PHARMACOVIGILANCE

25. Pharmacovigilance issues

(1) A licensee shall establish a system for handling matters relating to pharmacovigilance including a system for—

(a) identifying and reporting adverse reactions;

(b) a system for safety recalls; and

(c) the implementation of risk management plans and direct healthcare professional communication letters.

(2) For the purposes of this rule—

"direct healthcare professional communication" means a single, additional risk minimisation measure sent by marketing authorization holder to healthcare providers to directly inform healthcare professionals about new and important information about a medicinal substance.

(3) The licensee shall submit periodic safety update reports to the Board twice a year.

(4) A periodic safety update report submitted under paragraph (3) shall contain—

(a) summaries of data relevant to the benefits and risks of the medicinal substance, including results of all studies, with a consideration of their potential impact on the licence for the medicinal substance;

(b) a scientific evaluation of the risk-benefit balance of the medicinal substance; and

(c) data relating to the volume of sales of the medicinal substance and any data the licensee has relating to the volume of prescriptions, including an estimate of the population exposed to the medicinal substance.

(5) A person who contravenes this rule commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

(6) The court may, in addition to the penalty imposed under paragraph (4), order any medicinal substance in respect of which the offence has been committed or which has been used for the commission of such offence to be forfeited.

26. Additional obligations

In addition to the obligations under rules 23 to 25, a licensee shall—

(a) declare information on its supplier, including the name, location and contacts of each of parallel imported medicinal substance;

(b) take full responsibility of quality, efficacy, safety, potency, and security of parallel-imported medicinal substance;

(c) ensure that the storage conditions, Good Distribution Practice and Good Manufacturing Practice are observed during transport and distribution of parallel imported medicinal substances;

(d) have standard operating procedures;

(e) comply with Pharmacy and Poisons Board guidelines on Good Distribution Practice;

(f) recall and destroy parallel imported medicinal substances if the medicinal substances are determined not to comply with quality, safety or efficacy; and

(g) declare the cost benefit of the medicinal substance to the public.

PART V – PRICING OF PARALLEL IMPORTED MEDICINAL SUBSTANCES

27. Principles of pricing of parallel imported medicinal substances

The following principles shall guide all aspects of pricing of parallel imported medicinal substances—

(a) the economic circumstances prevailing in the country;

(b) the price of the locally available medicinal substance;

(c) the cost of importation or packaging, where applicable;

(d) government policy or directives; and

(e) such principles as may be considered necessary.

28. Pricing guidelines

(1) The Board shall develop guidelines on the pricing of parallel imported medicinal substances to give effect to rule 27.

(2) A person who contravenes any provision of the guidelines developed under paragraph (1) commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

PART VI – PACKAGING AND LABELLING OF
PARALLEL IMPORTED MEDICINAL SUBSTANCES

29. Labelling and packaging guidelines

(1) The Board shall make guidelines on the labelling and packaging of parallel imported medicinal substances.

(2) The guidelines shall provide for the following—

(a) the form and content of the package insert;

(b) the form and content of the patient information leaflet;

(c) the labelling of the parallel imported medicinal substance; and

(d) any other information on labelling and packaging that may be deemed necessary.

(3) Where medicine is to be repackaged in Kenya after importation, the repackaging shall be done at a site approved and licensed by the Board for that purpose.

(4) A person who contravenes any provision of the guidelines commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

PART VII – INSPECTIONS

30. Places authorized officers may enter

(1) An authorized officer appointed by the Board shall—

(a) carry out regular inspections of premises; and

(b) inspect consignments of medicinal substances at the port of entry.

(2) An authorized officer may, at any reasonable time, carry out regular inspection of premises and consignments of medicinal substances at the port of entry.

(3) Despite paragraph (2), an authorized officer may enter any place in which the authorized officer believes, on reasonable grounds, that any person or persons is in any way contravening these Rules.

(4) The authorized officer entering any premises under this rule shall, if so required, produce for inspection by the person who is or appears to be in charge of the premises his job identification card.

31. Powers of authorized officers

(1) In order to carry out an inspection in any place pursuant to rule 30, an authorized officer may—

(a) enter and inspect the premises or a port of entry;

(b) take samples of any medicinal substance;

(c) examine any medicinal substance;

(d) require any person in such place to produce for inspection, in the manner and form requested by the officer, the medicinal substance;

(e) open or require any person in the place to open any container or package in the premises;

(f) conduct any test or analysis or take any measurements; or

(g) require any person found in the place to produce for inspection or copying, any written or electronic information that is relevant to the administration or enforcement of these Rules.

(2) The authorized officer shall submit a report to the Board after carrying out an inspection in accordance with paragraph (1).

32. Use of records

When carrying out an inspection in any place, an authorized officer may—

(a) use or cause to be used any computer system in the place to examine data contained in or available to the computer system that is relevant to the administration or enforcement of these Rules;

(b) reproduce the data in the form of a print-out or other intelligible output and take it for examination or copying;

(c) use or cause to be used any copying equipment in the place to make copies of any data, record or document; or

(d) scrutinize any other record system in use in that place.

33. Entry of dwelling place

An authorized officer may not enter a dwelling place except with the consent of the occupant or under the authority of a warrant issued under rule 34.

34. Magistrate court to issue warrant

(1) Upon an *ex parte* application by an authorized officer, a magistrate may, if the magistrate is satisfied by information on oath, issue a warrant authorizing the authorized officer or officers named in the warrant to enter and inspect a dwelling place, subject to any conditions specified in the warrant such as—

(a) the dwelling place is a place referred to in rule 33;

(b) entry to the dwelling place is necessary for the administration or enforcement of these Rule.

(c) the occupant does not consent to the entry, or that entry has been refused or there are reasonable grounds for believing that it will be refused or seeking such consent shall hamper investigations.

(2) The time of such entry shall be between six o'clock in the forenoon and six o'clock in the afternoon of any day of the week.

35. Use of force

An authorized officer executing a warrant issued under rule 34 shall not use force unless the authorized officer is accompanied by a police officer of the rank of an inspector and above and the use of force is specifically authorized in the warrant.

36. Certificate of analysis

An authorized officer who has analysed or examined a medicinal substance or a sample of it, under these Rules, shall issue a certificate and report setting out the results of the analysis or examination.

37. Assistance of an authorized officer

(1) The owner of a place or the person in charge of a place and every person found in a place to be inspected by an authorized officer under these Rules shall—

(a) provide all reasonable assistance to enable the authorized officer to carry out his or her duties under these Rules; and

(b) furnish the authorized officer with such information as the authorized officer may reasonably require for the purpose for which entry into the place has been made.

(2) The authorised officer shall issue an inspection certificate once satisfied with the inspection.

(3) A person who fails to provide assistance or furnish an authorized officer with the required information commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

38. Obstruction

(1) A person shall not obstruct or hinder, or knowingly make a false or misleading statement to an authorized officer who is carrying out duties under these Rules.

(2) A person who obstructs or hinders, or knowingly makes a false or misleading statement to an authorized officer who is carrying out duties under these Rules commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

39. Seizure

(1) An authorized officer may, during an inspection under these Rules, seize any medicinal substance which or in relation to which the authorized officer believes, on reasonable grounds, that these Rules have been contravened and the authorized officer shall make a full inventory of the substances seized.

(2) The authorized officer may direct that any medicinal substance seized be kept or stored in the place where it was seized or that it be moved to another place.

(3) A person shall not remove, alter or interfere in any manner with any medicinal substance seized unless authorized by an authorized officer.

40. Order for restoration

(1) Any person from whom a medicinal substance has been seized under rule 39 may, within thirty days after the date of seizure, apply to the Board for an order of restoration.

(2) The Board may order that the medicinal substance seized under these Rules be restored immediately to the applicant if, on hearing the application, the Board is satisfied that—

(a) the applicant is entitled to possession of the medicinal substance seized; and

(b) the medicinal substance seized will not be required as evidence in any proceedings in respect of an offence under these Rules.

41. Rejection of an application for order of restoration

(1) The Board may, within fourteen days of the applicant lodging the application, reject the application that fails to satisfy the requirements under rule 40(2).

(2) The Board shall communicate the rejection under paragraph (1), in writing, to the applicant and shall state the reason for the rejection.

42. Appeal

(1) A person aggrieved by the decision of the Board under rule 41 may appeal to the Appeals Committee within thirty days of the Board's decision.

(2) The Appeals Committee may order that the medicinal substance be restored immediately to the applicant if, on hearing the application, the Appeals Committee is satisfied that—

(a) the applicant is entitled to possession of the medicinal substance seized; and

(b) the medicinal substance seized will not be required as evidence in any proceedings in respect of an offence under these rules.

(3) A person aggrieved by the decision of the Appeals Committee may appeal to the High Court within thirty days of the Appeals Committee's decision.

(4) The High Court may order that the medicinal substance be restored immediately to the applicant if, on hearing the application, the High Court is satisfied that—

(a) the applicant is entitled to possession of the medicinal substance seized; and

(b) the medicinal substance seized will not be required as evidence in any proceedings in respect of an offence under these rules.

PART VIII – TRACING OF PARALLEL IMPORTED MEDICINAL SUBSTANCES

43. Establishment of a tracing system

The Board shall establish and maintain a system that ensures that a registered parallel imported medicinal substance can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the health facility, institution or private practice where the medicinal substance is used.

44. Data matrix of medicinal substances

(1) The tracing system established rule 43 shall contain data matrix of parallel imported medicinal substances provided by the licensees.

(2) The data matrix, in relation to a medicinal substance, shall consist of—

(a) business name;

(b) name of marketing authorization holder;

(c) name of the local technical representative;

(d) date of manufacture;

(e) the batch number;

(f) the serial number; and

(g) the expiry date.

(3) For the purposes of this rule—

"data matrix" means a two-dimensional code in data matrix type or any other suitable code that provides the individualization of each medicinal substance as a safety feature.

45. Functions of the tracing system

The tracing system established under rule 43 shall be used to—

(a) check the individualization, standards and content of the reported data matrix;

(b) record the appropriate data matrix in the database and reject inappropriate ones;

(c) track the importation, purchase, transfer, consumption, loss and reimbursement of each medicinal substance in the supply chain; and

(d) recall and block transactions unauthorized under these rules and that are not allowed through the system.

46. Duties of a licensee

The licensee shall—

(a) register each of their medicinal substances on the tracing system;

(b) make notification for matters including purchase, sale, return, importation and deactivation steps of the medicinal substances for expiry date, stealing and decomposition;

(c) make notification of all cancelled activities and transactions carried out on the medicinal substances and confirm the convenient ones and refuse the inconvenient ones;

(d) store for a minimum of five years and submit when required by the Board, written documentation of transactions including production and importation documents, bill of sale, receiving note and prescription; and

(e) immediately inform the Board when the licensee identifies a medicinal substance that is subjected to notification to the tracing system but has not been notified to the system.

47. Batch recalls

The licensee shall—

(a) keep documents relating to the sale or supply of medicinal products under the licence which may facilitate the recall from sale of medicinal substances in accordance with paragraph (b);

(b) maintain an emergency plan to ensure effective implementation of the recall of a medicinal substance from the market where recall is ordered by the Board.

PART IX – THE PARALLEL IMPORTATION APPEALS COMMITTEE

48. The Appeals Committee

(1) There shall be an appeals committee to be known as the Parallel Importation Appeals Committee to consider and decide appeals from the decisions of the Board under these Rules consisting of—

(a) the Chairman of the Board who shall be the chairman of the Appeals Committee;

(b) two members of the Board;

(c) one person nominated by the Consumers Federation of Kenya and appointed by the Cabinet Secretary;

(d) one person nominated by the Hospital Pharmacists Association of Kenya and appointed by the Cabinet Secretary;

(e) one person nominated by the Pharmaceutical Society of Kenya and appointed by the Cabinet Secretary;

(f) one person nominated by the Kenya Pharmaceuticals Association and appointed by the Cabinet Secretary; and

(g) one person nominated by the National Quality Control Laboratory and appointed by the Cabinet Secretary.

(2) In appointing the members of the Appeals Committee under paragraph (1)(c) to (g), the Cabinet Secretary shall take into account the gender, regional and other diversities of the people of Kenya.

(3) Any member may at any time, by notice to the Chairperson, resign from office.

(4) Where the office of any members become vacant, whether by death or otherwise, the Chairperson may appoint another person to be a member of the Appeals Committee for the remainder of the term of the member whose vacancy caused the appointment.

(5) The procedures for the conduct of meetings of the Appeals Committee shall be as provided in the Third Schedule.

(6) The Board shall provide secretariat services to the Appeals Committee.

49. Procedure of Appeals

(1) A person aggrieved by a decision of the Board may, within thirty days of receiving the decision, appeal to the Appeals Committee.

(2) Upon receipt of an appeal, the Appeals Committee, shall consider the appeal and may summarily reject the appeal, if it determines that the grounds of appeal are frivolous or vexatious or do not disclose sufficient reason for interfering with the decision of the Board.

(3) The Appeals Committee may, upon hearing an appeal, affirm or reverse the decision of the Board, or make such other order as the Appeals Committee considers necessary and fit.

(4) Any person who is aggrieved by the decision of the Appeals Committee may within thirty days appeal to the High Court.

PART X – MISCELLANEOUS PROVISIONS

50. Transition

A person carrying out any activity involving parallel importation of medicinal substances immediately before the coming into force of these Rules shall, within six months from the date of coming into force, take all necessary measures to ensure full compliance with these Rules.

51. Offences in connection with application of parallel import licence

(1) A person who, in the course of an application for the grant, renewal or variation of a parallel import licence for a relevant medicinal substance—

(a) fails to provide the Board with any information that is relevant to the evaluation of the safety, quality or efficacy of the medicinal substance; or

(b) provides to the Board any information that is relevant to the evaluation of the safety, quality or efficacy of the medicinal substance but that is false or misleading in a material particular,

commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

(2) In addition to the penalty under paragraph (1), the licence of a person convicted of an offence under this rule shall be revoked for a period of not less three years.

52. Provision of false or misleading information

(1) A licensee commits an offence if the licensee provides false or misleading information about a medicinal substance that is supplied pursuant to the obligations in these Rules.

(2) A person who contravenes this rule is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

53. Failure to comply with urgent safety restrictions

A licensee who—

(a) fails to inform the Board that the licensee has taken urgent safety restrictions on the licensee's own initiative; or

(b) fails to implement an urgent safety restriction imposed on the licensee by the Board,

commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

54. The offence of use, sale, supply, e.t.c of a suspended medicinal substance

(1) A person who knowingly, or having reasonable cause to believe, that the use, sale, supply or offer for sale or supply is suspended—

(a) sells, supplies or offers to sell or supply the medicinal substance; or

(b) procures the sale, supplies or offers for sale or supply of the medicinal substance,

commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

(2) In addition to the penalty imposed under paragraph (1), the court may order any medicinal substance in respect of which the offence has been committed or which has been used for the commission of such offence to be forfeited.

55. General offence of breach of provisions in these rules

A person commits an offence if that person—

(a) is the holder of certificate of parallel importation or licensee and fails to comply with any requirement or obligation in these Rules;

(b) contravenes any prohibition in these Rules; or

(c) fails to comply with any requirement imposed on a person by the Board pursuant to these Rules.

FIRST SCHEDULE

FORMS

Form 1 **[rr. 5(1), 10(2)(a)]**

APPLICATION FOR CERTIFICATE OF PARALLEL IMPORTATION OR RENEWAL OF CERTIFICATE OF PARALLEL IMPORTATION

(to be submitted in six copies)

CONFIDENTIAL

The application shall be addressed to the Registrar, Pharmacy and Poisons Board, P.O. Box 27663, Nairobi

Application (Tick as appropriate):

Grant of new certificate	Renewal of certificate	Year

of parallel importation | of parallel importation

Please use Block (Capitals) Letters

1. Name of applicant.....

2. Physical and postal address of the company:

(a) City/Town.....
(b) L.R. No.....
(c) Street.....
(d) Building.....
(e) P.O. Box.....
(f) Telephone Numbers.....
(g) E-mail Address.....

3. Date of incorporation.....

4. Certificate of incorporation No.....

5. CR 12 search.....

6. Number and date of issue of previous certificate of parallel importation.....

7. The number of employees of the company.....

8. Declaration (by Director/Secretary):

I, the undersigned, hereby declare—

(a) THAT the particulars set out herein are true and correct to the best of my knowledge and belief;

(b) THAT if granted certificate of parallel importation, I shall transact parallel importation of medicinal substances in accordance with the provisions of the Pharmacy and Poisons Act (Cap. 244), these rules and any rules, guidelines or directive as may from time to time be issued by the Board.

Name.....

Signature.....

Date.....

Form 2 **(rr. 11(1) & 19(2(a))**

APPLICATION FOR LICENCE OR RENEWAL OF PARALLEL IMPORTED MEDICINAL SUBSTANCE LICENCE/CERTIFICATE

(to be submitted in six copies)

CONFIDENTIAL

The application shall be addressed to the Registrar, Pharmacy and Poisons Board, P.O. Box 27663, Nairobi

Application (Tick as appropriate):

Grant of new licence | Renewal of licence | Year

Please use Block (Capitals) Letters

1. Name of applicant.....

2. Physical and postal address of the company:

(a) City/Town.....
(b) L.R. No.....
(c) Street.....
(d) Building.....
(e) P. O. Box.....
(f) Telephone Numbers.....
(g) E-mail address.....

3. Certificate of Parallel Importation No. .....

4. Number and date of issue of previous licence .....

5. Details of the medicinal substance to be parallel imported:

(a) Trade Name (*Proprietary Product name*).....
(b) International Non-Proprietary Name.....
(c) Strength of the Active Pharmaceutical Ingredient per unit dosage of the product.....
(d) Pharmaceutical dosage form and route of administration.....
(e) Packaging/Pack size of the product.....
(f) Visual description of the product.....
(g) Proposed shelf-life of the product.....

6. Registration number of the medicinal substance in Kenya.....

7. Justification for importation.....

Declaration (by Director/Secretary):

I, the undersigned, hereby declare —

(a) THAT the particulars set out herein are true and correct to the best of my knowledge and belief;

(b) THAT if licensed, I shall transact parallel importation of medicinal substances in accordance with the provisions of the Pharmacy and Poisons Act, Cap. 244, these rules and any rules, guidelines or directive as may from time to time be issued by the Board.

Name.....

Signature.....

Date.....

Form 3 **(r. 11(2)(f))**

LETTER OF UNDERTAKING

(to be submitted in six copies)

CONFIDENTIAL

Registrar,

Pharmacy and Poisons Board,

P.O. Box 27663,

NAIROBI

RE:

We undertake to ensure that all medicinal substances that we parallel import meet the safety, quality and efficacy standards as determined by the Board.

Yours sincerely,

Name and signature of applicant

SECOND SCHEDULE

[r. 10(2(b), 19(2)(b)]

FEES

1. The following are the prescribed fees for the various licences as outlined in the table.

Type	*Fees (Kshs)*
Application for certificate of parallel importation	
Application for renewal of certificate of parallel importation	
Application fee for a new parallel import licence	
Appeal of rejected application for parallel import licence	
Application for renewal of parallel import licence	

2. Any fee payable under paragraph (1) shall be paid by bankers cheque payable to the Board or by any other means prescribed by the Board.

3. The prescribed fees in paragraph (1) may be reviewed by the Board from time to time.

THIRD SCHEDULE

[r. 48(5)]

CONDUCT OF PROCEEDINGS OF THE
PARALLEL IMPORTATION APPEALS COMMITTEE

1. Quorum

(1) The quorum of the Appeals Committee shall be five members, including the Chairperson.

(2) Despite paragraph (1), members shall not be allowed to delegate their responsibility to their subordinate officers.

2. Majority decision

(1) Decisions shall be taken by simple majority.

(2) In case of a tie, the proposal supported by the Chairperson shall prevail, and shall be signed by the members agreeing thereto.

3. Disclosure of interest

If any member of the Appeals Committee has any interest in any particular proceedings before the Appeals Committee, he or she shall inform the Chairperson who may after

considering the interest, appoint another person in his or her place for the purpose of that particular appeal.

4. Venue

The Appeals Committee shall sit at such a place as it may consider most convenient, having regard to all the circumstances of the particular proceedings.

5. Rules

Subject to the provisions of this Schedule, the Appeals Committee shall have power to make the rules governing procedures.

6. Proof of documents

A document purporting to be a copy of an order of the Appeals Committee and certified by the Chairperson to be a true copy thereof shall in any legal proceeding be *prima facie* evidence of that order.

THE PHARMACY AND POISONS (CONDUCT OF CLINICAL TRIALS) RULES

ARRANGEMENT OF RULES

THE PHARMACY AND POISONS (CONDUCT OF CLINICAL TRIALS) RULES

[Legal Notice 95 of 2022]

PART I – PRELIMINARY

1. Citation

These Rules may be cited as the Pharmacy and Poisons (Conduct of Clinical Trials) Rules.

2. Interpretation

In these Rules, unless the context otherwise requires—

"adverse drug reaction" means a noxious or unintended response to a clinical trial study or interventional product related to a dose or to a registered health product which occurs at doses normally used in humans for prophylaxis, diagnosis or therapy of diseases or for modification of physiological function;

"adverse event" means an untoward medical occurrence in a patient or a participant in a clinical investigation study or intervention product, and which does not necessarily have a causal relationship with the treatment;

"applicant" means a person applying to conduct a clinical trial in accordance with rule 4;

"audit" means a systematic examination that is carried out independently of the persons who are directly involved in a clinical trial to determine whether the conduct of that clinical trial complies with the approved study protocol and whether data reported are consistent with the data on record at the site of the trial;

"blinding" means a procedure in which a participant in a study, investigator or data analyst is unaware of the treatment assignment;

"clinical trial report" means a written description of a clinical trial;

"comparator" means a health product or marketed product, active or placebo, used as a reference in a clinical trial;

"contract research organisation" means an organisation that is contracted by the sponsor to perform one or more of the duties and functions of the sponsor in the conduct of the clinical trial;

"data and safety monitoring board" means an independent board that is appointed in accordance with rule 12;

"double blinding" means blinding which applies to a participant in a study, the investigator and data analyst;

"ethical clearance" means the authorisation issued by an ethics committee to conduct a clinical trial;

"ethics committee" means a scientific and ethical review committee of an institution which is accredited by the National Commission for Science, Technology and Innovation in accordance with the Science, Technology and Innovation (Registration and Accreditation of Research Institutions) Rules (L.N. 106/2014);

"expert advisory committee" means an expert advisory committee responsible for clinical trials that is appointed by the Board in accordance with rule 6;

"generic product" means a multisource health product which is intended to be interchangeable with the comparator product which is usually manufactured without a licence from the innovator company and marketed after the expiry of patent or other exclusivity rights;

"good clinical practice" means a standard for the design, conduct, performance and monitoring, auditing, recording, analysis and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of participants in a clinical trial study are protected;

"good manufacturing practice" means that part of quality assurance which ensures that investigational health products are consistently produced and controlled to the quality standards appropriate to their intended use and as may be required by the marketing authorization;

"informed written consent" means authority voluntarily given by a participant to confirm the participant's willingness to participate in a particular clinical trial after having been informed of all aspects of the clinical trial that are relevant to the participant's decision to participate;

"interchangeable health product" means a health product which is therapeutically equivalent to a comparator product and can be interchanged in clinical practice;

"investigational health product" means a medical device, health technology or pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a registered health product or technology, when used or assembled (formulated or packaged) in a way that is different from the registered form, or when used for an unregistered indication, or when used to gain further information about a registered use;

"investigator" means an appropriately qualified person responsible for the conduct of a clinical trial;

"investigator's brochure" means a compilation of the clinical and non-clinical data on the investigational health product that is relevant to the clinical trial;

"legal representative" means a person authorised to give informed written consent on behalf of a prospective participant in a clinical trial for that participant's participation in the clinical trial;

"material transfer agreement" means a written agreement between a provider and recipient of research material that is aimed at protecting the intellectual and other property rights of the provider while permitting research with the material by the recipient to proceed;

"minimum anticipated biological effect level" means an anticipated dose needed to result in a biological effect in a participant of a clinical trial which is recommended as a useful approach to calculate the safe starting dose as the lowest dose that is active;

"monitor" means a person appointed by, and responsible to, the sponsor or contract research organization for the monitoring and reporting of progress of a clinical trial and verification of data therefrom;

"no observed adverse effect level" means the greatest concentration or amount of a substance found by experiment or observation that does not cause any alteration of morphology, functional capacity, growth, development or lifespan of the target organism distinguishable from those observed in normal (control) organisms of the same species and strain under the same defined conditions of exposure;

"participant" means an individual who participates in a clinical trial as a recipient of the investigational product or as part of the control group;

"periodic safety update report" means a report containing update safety data pertaining to a registered health product and a scientific evaluation report regarding the benefits and risks of the health product;

"protocol" means a document that states the background, rationale and objectives of a clinical trial and describes the clinical trial's design, methodology and organisation,

including statistical considerations, and the conditions under which the trial is to be performed and managed;

"quality assurance" means planned and systematic actions that are established to ensure that the trial is performed and the data are generated, recorded and reported in compliance with good clinical practice requirements;

"quality control" means the operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the activities related to the clinical trial have been fulfilled;

"randomisation" means the process of assigning a participant or control group treatment using an element of chance to determine the assignments in order to reduce bias;

"recognition" means the acceptance of the regulatory decision of another regulator or trusted institution that is based on evidence that the regulatory requirements of that other regulator or trusted institution are sufficient to meet the regulatory requirements of the Board;

"reliance" means taking into account and giving significant weight to the assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, by the Board in reaching its own decision and involves remaining independent, responsible and accountable for the decisions taken by the Board;

"serious adverse event" means an untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongs hospitalization, results in persistent or significant disability, or is a congenital anomaly or birth defect;

"single blinding" means blinding which applies to a study participant;

"source data" means information in original records and certified copies of original records of clinical findings, observations or other activities in a clinical trial that is necessary for the reconstruction and evaluation of the trial;

"sponsor" means a person who takes legal responsibility for the initiation, management and financing of a clinical trial;

"suspected unexpected serious adverse reaction" means serious adverse reaction that is not identified in practice, severity or frequency by the reference safety information;

"vulnerable participant" means an individual whose decision to participate in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or by coercion; and

"work sharing" means the sharing of activities to accomplish a particular regulatory task.

3. Scope of application

(1) These Rules shall apply to the conduct of a clinical trial—

(a) to test an unregistered health product;

(b) to test a registered health product where the proposed clinical trial is on the changes relating to the health product including—

(i) the indications and clinical use;

(ii) the target patient population;

(iii) the administration of the health product; or

(iv) the dosage regimen;

(c) to undertake a comparative bioavailability trial;

(d) to generate data on a health product that is registered in Kenya based on recognition, reliance or a work sharing arrangement;

(e) to establish bioequivalence for registration of a generic health product;

(f) to identify adverse reactions;

(g) to generate data on the absorption, distribution, metabolism and excretion of a health product; and

(h) to conduct a post-marketing study of a registered health product including the efficacy studies monitoring resistance.

(2) These Rules shall not apply to a clinical trial—

(a) that covers randomised controlled clinical trials relating to behavioural intervention;

(b) that involves an adult participant in the use of an educational test, survey, interview or observation of public behaviour unless—

(i) the information obtained is recorded in such a manner that the participant can be identified, directly or through identifiers linked to the participant; and

(ii) a disclosure of the responses of the participant outside the clinical trial could reasonably place the participant at risk of criminal or civil liability or be damaging to the financial standing, employability or reputation of the participant; or

(c) that involves the collection or evaluation of existing data, documents, or pathological or diagnostic specimens which are publicly available or if the information is recorded by the investigator in such a manner that the participants thereof cannot be identified, directly or through identifiers linked to the participant.

PART II – APPROVAL TO CONDUCT CLINICAL TRIAL

4. Application for approval to conduct clinical trial

(1) A person shall not conduct a clinical trial of any health product without the written authorisation of the Board.

(2) An application to conduct a clinical trial shall be made by a sponsor or the sponsor's legal representative.

(3) An application under sub-rule (2) shall—

(a) be made in a duly filled and signed application form as set out in the First Schedule;

(b) be accompanied by the documents specified in sub-rule (4); and

(c) be accompanied by the fee specified in the Second Schedule.

(4) An application made under sub-rule (2) shall be accompanied by the following documents—

(a) a cover letter addressed to the Board;

(b) the study protocol duly signed and dated by the sponsor and principal investigator;

(c) the proposed participant information leaflet;

(d) the proposed informed written consent form;

(e) the investigator's brochure;

(f) a good manufacturing practice certificate of the investigational health product from the manufacturer issued by a competent health authority in the manufacturer's jurisdiction of origin;

(g) a certificate of analysis of the investigational health product;

(h) a pictorial sample of the investigational health product;

(i) the *curriculum vitae* of the investigator and study pharmacist;

(j) proof of recent training in good clinical practice for core study staff;

(k) the charter, composition and meeting schedule of the data and safety monitoring board;

(l) a statistical analysis plan;

(m) a detailed budget of the study;

(n) a recommendation from the relevant ethics committee;

(o) a valid indemnity cover for the investigator issued by a regulated insurance agency in Kenya;

(p) a valid insurance certificate for the participants issued by a regulated insurance agency in Kenya;

(q) copies of current practice licences or certificates from the relevant professional body that regulates the conduct of the investigators or study pharmacists;

(r) a copy of the approval letter from a collaborating institution or other regulatory authority, if applicable;

(s) a material transfer agreement, if applicable; and

(t) declarations by the principal investigator and sponsor on—

(i) financial disclosure;

(ii) conflict of interest;

(iii) compliance with good clinical practice;

(iv) compliance with legal requirements; and

(v) submission of correct information.

(5) In this rule, "core study staff" means the persons actively involved in the conduct of the clinical trial.

5. Processing of applications to conduct clinical trials

(1) The Board shall, through the expert advisory committee evaluate an application submitted in accordance with rule 4.

(2) When conducting an evaluation under sub-rule (1), the Board shall consider—

(a) the reliability and robustness of the data generated in the clinical trial;

(b) whether the applicant has complied with the requirements concerning the manufacturing or importation of the investigational health product and any auxiliary health product connected therewith the investigational health medicinal product;

(c) whether the applicant has complied with the labelling requirements set out in the Third Schedule; and

(d) whether the investigator's brochure is adequate.

(3) The Board may approve or reject the application submitted under rule 4 and shall specify the reasons for the rejection in writing.

(4) The reasons for the rejection of an application by the Board under sub-rule (3) may include—

(a) insufficient information provided in the application;

(b) submission of false or falsified information;

(c) lack of a favourable opinion from an ethics committee;

(d) that the investigational health product endangers a participant;

(e) the safety of a participant has not been guaranteed; or

(f) any other reason as may be determined by the Board.

(5) The Board shall communicate the decision made under sub-rule (3) in writing to the applicant within thirty working days after the receipt of the application.

(6) The Board shall publish on its website a list of the approved or rejected applications under sub-rule (3) and update the list at least once in every six months.

6. Expert advisory committees

(1) The Board shall appoint an expert advisory committee for clinical trials which shall assist the Board to efficiently process each application for approval to conduct a clinical trial and study oversight.

(2) The Board shall designate members of the staff of the Board to assist the expert advisory committee in the performance of its functions.

PART III – INVESTIGATORS AND SPONSORS

7. Principal investigators

(1) A person is qualified to be appointed as a principal investigator if that person—

(a) has a degree in medicine, pharmacy, pharmacology, toxicology, biochemistry, dentistry or a related discipline from a university recognised in Kenya;

(b) has a valid practice licence from the relevant regulatory authority;

(c) has a valid professional indemnity cover;

(d) has had formal training in good clinical practice that was undertaken at least two years before the date of an application under rule 4;

(e) has previous experience in at least two clinical trials; and

(f) is a citizen of Kenya or is permanently resident in Kenya.

(2) The responsibilities of the principal investigator shall be—

(a) to thoroughly familiarise himself or herself with the characteristics and appropriate use of the investigational health product;

(b) to comply with ethical, good clinical practice and legal requirements in the conduct of the clinical trial;

(c) to facilitate access by the Board to the clinical trial for the purpose of monitoring and auditing the clinical trial or for inspection;

(d) to ensure that the data from the clinical trial is accurately recorded and submitted to the Board;

(e) to maintain records of the delivery processes and health products used in the clinical trial;

(f) to maintain a record of the persons to whom the investigator has delegated duties;

(g) to be responsible for the investigational medical product at the study site; and

(h) to maintain a list of staff who conduct the clinical trial.

(3) The principal investigator shall be liable for all aspects of the conduct of the clinical trial at a study site.

(4) A principal investigator shall not deviate significantly from, or make major changes to, the protocol of the clinical trial or to the information specified in the participant information booklet without the prior review and approval of the Board.

(5) Sub-rule (4) shall not apply where the deviation or change involves a logistical or administrative aspect of the clinical trial, or is based on issues relating to the immediate safety of a participant.

8. Responsibilities of sponsors

(1) A sponsor shall be responsible for—

(a) implementing and maintaining quality assurance to ensure that a clinical trial is conducted following good clinical practice requirements;

(b) ensuring that the investigational health product provided for the trial has been manufactured following good manufacturing practice; and

(c) ensuring that data is generated, recorded and reported in compliance with good clinical practice requirements and applicable Rules.

(2) A sponsor shall ensure that the clinical trial institution, contract research organisation, investigator, monitor, study pharmacist and participant have sufficient insurance cover for the clinical trial.

(3) A sponsor shall ensure that adequate treatment of a participant in case of injury or disease occurs during the course of the clinical trial.

(4) A sponsor shall provide an up-to-date investigator's brochure and drug safety update report whenever available, and in any case, at least once in year to the Board, unless there are substantial changes to the previous version to the brochure or report.

(5) A sponsor shall appoint qualified and suitable trained individuals to monitor a clinical trial.

(6) A sponsor shall report to the Board any serious adverse events and suspected unexpected serious adverse reactions that occur during the course of the clinical trial.

(7) An immediate notification of the event referred to in sub-rule (6) shall be made in writing and a detailed written report be submitted within fifteen days after the occurrence of the event.

(8) Despite sub-rule (7), the Board may direct the sponsor to provide additional information in any case where the adverse event causes death or threatens the life of a participant.

(9) A sponsor shall inform the Board in writing of a voluntary suspension or termination of the clinical trial within fifteen days after the suspension or termination and the reasons thereof.

(10) At the conclusion of a clinical trial, the sponsor shall submit—

(a) an executive summary of the report of the clinical trial;

(b) an annual study progress report; and

(c) a copy of the clinical trial report.

PART IV – CONDUCT OF CLINICAL TRIALS

9. Adherence to protocols

(1) Each clinical trial shall be conducted in compliance with the protocol approved by the Board.

(2) The sponsor of a clinical trial shall submit the protocol of the trial to the Board, which shall contain—

(a) the general information of the clinical trial;

(b) the background information of the clinical trial including non-clinical data;

(c) the objectives of the clinical trial;

(d) the design of the clinical trial;

(e) the selection, treatment and withdrawal of a participant;

(f) the ethical considerations of the clinical trial;

(g) a post-trial access program;

(h) the mode of the assessment of the efficacy of the investigational health product;

(i) the mode of assessment of the safety of the investigational health product;

(j) the mode for collecting, analysing and reporting the statistics of the clinical trial;

(k) the source data documents of the clinical trial; and

(l) the quality control measures of the clinical trial.

10. Child participants

(1) A sponsor who intends to conduct a clinical trial where the intended participant is a child shall ensure that the information in an approved participant information booklet referred to in rule 4(4)(c) specifies—

(a) the pathophysiology of the disease or subject of the clinical trial;

(b) the methods of diagnosis;

(c) the currently available treatment or prevention strategy in the paediatric population;

(d) the incidence and prevalence of the disease or subject of the clinical trial in the overall population and in the paediatric population; and

(e) the evidence and assumptions on key differences between the disease or subject of the clinical trial in the overall population and the paediatric population.

(2) Where the intended participant is a child, before making an application under rule 4, a sponsor shall ensure that—

(a) the clinical trial has been conducted with a participant who was an adult;

(b) the objective of the clinical trial is to obtain knowledge relevant to the health needs of children;

(c) the legal representative of each participant has been issued with the approved participant information booklet; and

(d) no financial inducement has been offered to the participant or the legal representative of the participant.

(3) When conducting a clinical trial where the participant is a child, an investigator shall ensure that the informed written consent of each legal representative of the participant has been obtained.

(4) The conduct of a clinical trial where a participant is a child shall ensure that the well-being of the participant is not compromised by participating in the clinical trial.

(5) The Board shall consider the following when evaluating an application under rule 4 where a participant is a child—

(a) the prevalence of the condition to be treated among children in the population;

(b) the seriousness of the condition to be treated by the outcome of the clinical trial;

(c) the availability and suitability of an alternative treatment for the condition, including the efficacy and the adverse event profile of that treatment;

(d) whether the investigational health product is novel or one of a class of compounds with known properties;

(e) whether there are unique paediatric indications for the investigational health product;

(f) the need for the development of a paediatric-specific endpoint;

(g) the age ranges of the proposed paediatric patients likely to be treated with the investigative health product;

(h) the unique paediatric or developmental safety concerns of the investigational health product, including any nonclinical safety issues; and

(i) the potential for paediatric formulation development.

(6) An application made under rule 4 where a participant is a child shall specify the following information of the investigational health product—

(a) the genotoxicity;

(b) the reprotoxicity;

(c) the carcinogenicity, if applicable;
(d) the juvenile animal studies, if applicable;
(e) the pharmacokinetics;
(f) the absorption;
(g) the distribution;
(h) the metabolism;
(i) the excretion; and
(j) the pharmacodynamics.

11. Informed written consent

(1) Before the making an application under rule 4, a sponsor shall obtain a recommendation to conduct the clinical trial from the relevant ethics committee.

(2) An investigator shall submit, in writing, an approved participant information booklet to each participant or the participant's legal representative, in English, Kiswahili or the local spoken language of the participant.

(3) If a participant or the participant's legal representative is unable to read the approved participant information booklet submitted under sub-rule (2), the investigator shall explain to the participant or legal representative, and in the presence of impartial witness, the information in the booklet.

(4) A participant information booklet shall contain the following information—
(a) a declaration that a clinical trial involves research activities;
(b) the objective of the clinical trial;
(c) the treatment that will be employed in the clinical trial;
(d) the procedure to be followed in the clinical trial;
(e) the responsibilities of the participant;
(f) the aspects of the clinical trial that are experimental;
(g) the reasonably foreseeable risks to a participant;
(h) the reasonably expected benefits of the clinical trial, if any;
(i) an alternative procedure or treatment available to participants and the important potential benefit and risk of the alternative;
(j) the compensation or treatment available to the participant in the event of injury or adverse event related to the clinical trial;
(k) that the participation in the clinical trial is voluntary and that the participant may decline to participate or withdraw from the trial at any time without penalty or loss of benefits to which the participant is otherwise entitled;
(l) the anticipated payment, if any, to the participant;
(m) the anticipated expenses, if any, of the participant;
(n) the foreseeable circumstances or reasons under which the participation of the participant may be terminated;
(o) the expected duration of a participant's role in the clinical trial; and
(p) the approximate number of participants involved in the clinical trial.

(5) On receipt the approved participant information booklet under sub-rule (2), the participant or participant's legal representative may submit an informed written consent to an investigator.

(6) If the participant or participant's legal representative agrees with the information submitted under sub-rule (3), the investigator shall prepare an informed written consent and the participant or legal representative, and the impartial witnesses, shall sign and date the informed written consent.

(7) A sponsor, investigator, study pharmacist, monitor and any other person connected with the conduct of the clinical trial shall not coerce or unduly influence a participant or participant's legal representative to participate or to continue to participate in the clinical trial if the participant or legal representative has withdrawn his or her informed written consent.

(8) Where new information is available that would require the informed written consent of a participant, an investigator shall prepare a revised participant information booklet, submit the revised booklet for approval in accordance with rule 4 and thereafter submit the revised booklet in accordance with sub-rule (2) or inform the participant of the revised booklet in accordance with sub-rule (3).

(9) The Board may gain access to a participant's original medical records for verification of data, or the conduct of a procedure or treatment used in the clinical trial without violating the confidentiality of the participant to the extent permitted by the participant or participant's legal representative as specified in the informed written consent authorizing such access.

(10) The information of a participant or participant's legal representative shall be kept confidential and not made publicly available or to any other person without the express written consent of the participant or participant's legal representative.

(11) Where the results of a clinical trial are published, the identity of a participant shall not be disclosed.

(12) The participation of a participant in a clinical trial is voluntary and a participant may decline to participate or withdraw the informed written consent issued by the participant at any time without penalty or loss of benefits to which the participant is otherwise entitled.

12. Safety reports

(1) A sponsor shall submit to the Board a report of any suspected unexpected serious adverse reaction or serious adverse event that occurs in a clinical trial.

(2) Where a sponsor conducts a clinical trial on the same health product or active pharmaceutical substance in another country, the sponsor shall submit a report of any suspected unexpected serious adverse reaction or serious adverse event that occurs in that other clinical trial to the Board.

(3) A sponsor shall submit a report of an initially fatal or life threatening suspected unexpected serious adverse reaction or serious adverse event as soon as it occurs but, in any case, not later than seven days after the occurrence of the event.

(4) Subject to sub-rule (3), a sponsor shall submit a report on a suspected unexpected serious adverse reaction which is not fatal or lifethreatening within fifteen days after the occurrence of the event.

(5) A report of the occurrence of a suspected unexpected serious adverse reaction or serious adverse event shall specify—

(a) the suspected unexpected serious adverse reaction or serious adverse event which is related to the clinical trial; and

(b) the suspected unexpected serious adverse reaction or serious adverse event which is not related to the clinical trial.

(6) A sponsor shall submit to the Board, at least once in each year from the date of authorisation of the clinical trial, and throughout the conduct of the clinical trial, or on request by the Board, a safety report on the safety information received during the reporting period.

(7) The safety report submitted under sub-rule (6) shall contain a log of serious adverse events and suspected unexpected serious adverse reactions that occur during the clinical trial and indicate—

(a) the age, date of the informed written consent and identity of the participant who was affected by the serious adverse event or suspected unexpected serious adverse reaction;

(b) the type, date of commencement and end date of the serious adverse event or suspected unexpected serious adverse reaction;

(c) the reason for reporting the occurrence as a serious adverse event or suspected unexpected serious adverse reaction;

(d) how the serious adverse event or suspected unexpected serious adverse reaction relates to the investigational health product; and

(e) the outcome of the serious adverse event or suspected unexpected serious adverse reaction.

(8) A sponsor shall notify the investigators involved in the clinical trial of any serious adverse event or suspected unexpected serious adverse reaction related to the clinical trial within fifteen days after the occurrence of the event.

(9) A sponsor shall submit to the Board a report of any new information or change in nature, severity or frequency of risk factors in respect of the investigational health product or conduct of the clinical trial within fifteen days after the sponsor becomes aware of the information or change.

13. Data and safety monitoring board

(1) The sponsor shall establish a data and safety monitoring board in respect of a clinical trial which shall be responsible for the following—

(a) assessing the progress of the clinical trial;

(b) assessing the safety data of the clinical trial;

(c) assessing the critical efficacy endpoints of the clinical trial; and

(d) recommending to the sponsor whether to continue, modify, or stop the clinical trial.

(2) A sponsor shall appoint a data safety and monitoring board where—

(a) the endpoint of a clinical trial is such that a highly favourable or unfavourable result, or even a finding of futility, at an interim analysis might ethically require termination of the clinical trial before its planned completion;

(b) there are a *priori* justifications for a particular safety concern;

(c) there is prior information suggesting the possibility of toxicity with the treatment offered during the clinical trial;

(d) the clinical trial is being performed in a potentially vulnerable population;

(e) the clinical trial is being performed in a population at an elevated risk of death or other serious outcomes; or

(f) the clinical trial is being conducted for a period exceeding three years and at multiple centres.

(3) The data and safety board shall include the following persons—

(a) a clinician with expertise in the relevant clinical speciality that is the focus of the clinical trial;

(b) a biostatistician who is knowledgeable about statistical methods for a clinical trial and sequential analysis of data generated from a clinical trial;

(c) a toxicologist;

(d) an epidemiologist;

(e) a clinical pharmacologist; and

(f) where a clinical trial involves an unusually high risk or broad public health implication, a medical ethicist who is knowledgeable about the design, conduct and interpretation of clinical trials; and

(g) any other scientist who the sponsor considers to be necessary.

(4) In this paragraph, “medical ethicist” means a medical practitioner or medical professional who specialises in research, moral, legal and ethical issues that arise in health care settings.

14. Investigational health product

(1) An investigational health product shall be manufactured in accordance with the requirements of good manufacturing practices.

(2) The import, export, storage and destruction of the investigational health product shall comply with the applicable regulatory requirements to ensure integrity and accountability of the products.

(3) An application for import or export of the investigational health product shall be made to the Board and a respective permit obtained.

(4) The Board may revoke or suspend a permit issued under sub-rule (3) for the following reasons—

(a) the investigational health product was manufactured in conditions that were or are not consistent with good manufacturing practices;

(b) the discontinuation of the clinical trial; or

(c) false information provided by the sponsor.

(5) The Board may authorise the disposal of an investigational health product upon written request by the sponsor or the sponsor's legal representative in accordance with the Board's procedures on safe management of pharmaceutical waste.

(6) A sponsor shall submit a certificate of analysis for an investigational health product and for a comparator product when making an application under rule 4.

(7) A sponsor shall specify the following information when making an application under rule 4—

(a) the name and source of the investigational health product;

(b) the method of manufacturing the investigational health product;

(c) the physicochemical properties and structure elucidation of the investigational health product;

(d) the impurities of the investigational health product;

(e) the specifications, test methods and batch analyses of the investigational health product;

(f) the stability and packaging of the investigational health product; and

(g) the proposed dosage form of the investigational health product.

(8) Where the pharmaceutical or chemical properties of an investigational health product have been altered compared to those in use during animal testing or a previous clinical trial, the sponsor shall describe and justify the alteration.

(9) A sponsor shall immediately notify the Board in writing where a pharmaceutical or chemical alteration that may affect the quality, safety or efficacy of the investigational health product occurs in an investigational health product that is used in an ongoing clinical trial.

(10) In this paragraph, "comparator product" means a product of established quality, safety and efficacy that may be used as a reference in a clinical trial or bioequivalence study.

15. Pharmacy at site for clinical trial

(1) A sponsor shall ensure that a site at which a clinical trial is being undertaken has a designated pharmacy.

(2) The pharmacy designated under sub-rule (1) shall, at a minimum, have—

(a) facilities and equipment that reflect the types of procedures and treatments of the clinical trial that shall be undertaken by the investigator;

(b) a biosafety level cabinet, if necessary;

(c) a controlled environment that prevents microbiological contamination and regulates the temperature;

(d) a designated storage area, with a quarantine area;

(e) documented procedures that comply with good pharmacy practice; and

(f) a rigorous quality management system.

(3) The designated storage area referred to in sub-rule (2)(d) shall—

(a) have adequate space for the separate storage of different health products;

(b) be temperature-controlled and, if appropriate, humidity monitored, with alarm controls;

(c) be shielded from direct sunlight; and

(d) be mapped to identify and avoid using hot and cold spots, if necessary.

16. Clinical trial laboratories

A sponsor shall ensure that any laboratory that is used in support of a clinical trial is of a suitable size, construction and location to meet the requirements of the clinical trial and that—

(a) the design of the laboratory provides an adequate degree of separation of different activities of the laboratory;

(b) the equipment used in the laboratory has valid maintenance and calibration certificates;

(c) that the analysis conducted in the laboratory is organised and conducted in such a manner that the findings therefrom are transparent and stand up to retrospective verification;

(d) the roles and responsibilities of the staff of the laboratory are well established and documented before the commencement of the clinical trial;

(e) the laboratory possesses the protocol and any amendments thereto that was approved by the Board for the clinical trial;

(f) the impact of any deviations from the standard operating procedures or documented policies of the laboratory are assessed and documented; and

(g) the laboratory does not perform any analysis on a sample from a clinical trial that is not specified in the protocol that was approved by the Board for the clinical trial.

17. Quality assurance

(1) A sponsor shall develop a quality assurance process that ensures—

(a) that a research centre, researcher, sponsor, clinical research organisation and any other person involved in a clinical trial complies with good clinical practice including ensuring—

(i) that the study benefit outweighs risks;

(ii) that the rights and wellbeing of a participant are protected and preserved;

(iii) that the clinical trial is scientifically sound and performed in accordance with the approved protocol;

(iv) that the core study staff are adequately qualified and trained to perform their duties;

(v) that the confidentiality of the information of a participant is maintained; and

(vi) that informed written consent is obtained from a participant before participation in the clinical trial;

(b) that there is regular and continuous monitoring of the clinical trial and the recommendations of the report thereof are implemented;

(c) that the site where the clinical trial is undertaken has valid registration and approval;

(d) that the safety and confidentiality of the information of a participant are not compromised;

(e) that the analysis or evaluation of a sample from the clinical trial is conducted in accordance with the principles of good clinical practice;

(f) that the analysis or evaluation of samples is performed in accordance with the protocol approved by the Board;

(g) that data from the conduct of the clinical trial is recorded and reported accurately, legibly, completely and in a timely manner;

(h) that the equipment used in the conduct of the clinical trial is regularly maintained; and

(i) that the records, including source documents and final reports, are well kept.

(2) A sponsor shall establish an internal audit program for the conduct of the clinical trial once approval is obtained in accordance with rule 5.

18. Termination of clinical trials

(1) A sponsor shall ensure that the protocol approved by the Board specifies the procedure for the termination of the clinical trial.

(2) If a clinical trial is terminated voluntarily by an investigator or a sponsor, the sponsor shall notify the Board of the termination within fifteen days after the termination.

(3) If a clinical trial is terminated under sub-rule (2), a sponsor shall—

(a) immediately inform, in writing, the investigators of the termination, the reasons for the termination and advise them on the potential risks to the health of a participant or other person;

(b) if the termination is due to an adverse event, ensure that the affected participant receives medical care where the participant develops or experiences an adverse drug reaction to the investigational health product; and

(c) inform the Board, in writing, of—

(i) the reason for the termination;

(ii) the impact of the termination on the proposed or ongoing conduct of the clinical trial on the investigational health product;

(iii) the accountability and disposal of the investigational health product; and

(iv) the maintenance of records of the clinical trial that has been terminated.

(4) The Board may revoke the approval to conduct a clinical trial if the Board determines —

(a) that the safety of a participant has been compromised;

(b) that the scientific reasons for conducting the clinical trial have changed;

(c) that the investigational health product has expired; or

(d) that the investigational health product is not usable.

(5) Where a clinical trial has been terminated, a sponsor shall—

(a) submit an executive summary report of the clinical trial to the Board within thirty days after the termination;

(b) submit a clinical trial report within one hundred and eighty days after the termination; and

(c) dispose of the investigational health products in accordance with the Board's procedures on the safe management of pharmaceutical waste.

PART V – MISCELLANEOUS

19. Amendments to protocol

(1) A sponsor shall promptly apply to the Board for the amendment to the protocol where new information which affects the conduct of the clinical trial, safety of a participant or manufacture of the investigational health product, that necessitates a change to the protocol, becomes available.

(2) A sponsor shall take appropriate urgent safety measures to protect a participant against any hazard where an occurrence referred to in sub-rule (1) is likely to affect the safety of the participant.

(3) An application under sub-rule (1) shall be accompanied by a copy a recommendation from the relevant ethics committee.

(4) A sponsor shall make an application under sub-rule (1) where the proposed amendment includes—

(a) a change that may affect—
  (i) the safety, or physical or mental integrity of a participant;
  (ii) the scientific value of the clinical trial;
  (iii) the conduct or management of the clinical trial;
  (iv) the quality or safety of the investigational health product;
  (v) an objective of the clinical trial;
  (vi) a primary or secondary endpoint of the clinical trial;
  (vii) the addition of a trial arm or placebo group to the clinical trial;
  (viii) the inclusion or exclusion of a criterion of the clinical trial;
  (ix) the monitoring of the clinical trial;
  (x) the data and safety monitoring board;
  (xi) an alternative to an investigational health product;
  (xii) the dosage of an investigational health product;
  (xiii) the mode of administration of an investigational health product;
  (xiv) the design of the clinical trial which has an impact on statistical analysis or the risk-benefit assessment of the clinical trial;
  (xv) an alternative to the sponsor;
  (xvi) the revocation or suspension of the registration of the investigational health product;
  (xvii) the manufacturing process or specifications of an active substance or the investigational health product;
  (xviii) the reference safety information during the conduct of the clinical trial;
  (xix) the site for the conduct of the clinical trial; or
  (xx) an alternative to an investigator;
(b) a change that may affect the selection or discontinuation of a participant;
(c) a change that may affect the effectiveness of the investigational health product and safety of a participant; or
(d) a change that may affect the duration of the clinical trial.

(5) An application under sub-rule (1) shall specify—
(a) the proposed amendment;
(b) the justification for the proposed amendment;
(c) the impact of the proposed amendment on the objectives of the clinical trial;
(d) the impact of the proposed amendment on the endpoints and data generated from the conduct of the clinical trial; and

(e) the impact of the proposed amendment on the safety and wellbeing of a participant.

(6) An application under sub-rule (1) shall be accompanied by a favourable opinion by an Ethics Committee and applicable fees as may be prescribed by the Board.

20. Inspection of clinical trial sites

(1) The Board shall conduct an inspection of the site at which a clinical trial is conducted.

(2) The objectives of an inspection under sub-rule (1) shall be—

(a) to ensure that a participant is not subjected to undue risks;

(b) to ensure that the rights, safety and wellbeing of the participants are protected;

(c) to validate the quality of the data generated;

(d) to investigate a complaint; and

(e) to assess the compliance of a sponsor with the Act and these Rules.

(3) An investigator shall, on the request of the Board, at reasonable times, give the Board access to, and copy and verify any records or reports made by the investigator when conducting the clinical trial.

(4) An inspection may be conducted before the commencement of a clinical trial, or at routine intervals as may be determined by the Board.

(5) The Board may carry out a routine inspection referred to in sub-rule (4) to assess—

(a) the adequacy of the clinical trial;

(b) the protection measures for a participant;

(c) the integrity of the data; or

(d) the historical background of the clinical trial site, a sponsor or an investigator.

(6) Any non-compliance by the sponsor, investigator or any person connected to the clinical trial during an inspection may form the basis of the revocation or suspension of the authorisation to conduct the clinical trial.

21. Clinical trials involving traditional or alternative medicines

(1) A sponsor shall ensure that good clinical practice is applied when conducting a clinical trial involving traditional or alternative medicines.

(2) A sponsor shall ensure that a traditional medicine practitioner who is familiar with the traditional or alternative medicine proposed for investigation develops the protocol for the conduct of the clinical trial.

(3) The protocol developed under sub-rule (3) shall be submitted to the Board for approval before the commencement of the clinical trial.

(4) The protocol developed under sub-rule (3) shall not be amended without the approval of the Board.

22. Online registry for clinical trials

Applications for the conduct of clinical trials shall be registered on the Board's online registry.

23. Clinical trials in special circumstances

(1) The Board may, in special circumstances, through written guidelines, authorise the conduct of a clinical trials under fast-track procedures or non-routine procedures.

(2) The special circumstances referred to in sub-rule (1) may include—

(a) a public health emergency;

(b) the rapid spread of an epidemic disease; or

(c) any other circumstance as may be determined by the Board.

24. Reliance and recognition

The Board may recognise and use of clinical trial decisions, reports or information from other competent authorities in rule of clinical trials.

25. Offences and penalties

Any person who contravenes the provisions of these Rules commits an offence and shall be liable to the penalty prescribed under section 51 of the Act.

FIRST SCHEDULE

[r. 4 (3)(a)]

FORM

Application for Approval to Conduct Clinical Trial

Study Title: Date of Protocol:
Protocol No: Fax Number:
Version No:
Study Drug:
ECCT Ref number (if applicable):
Sponsor:
Contact Person:
Address:
Telephone Number:
Cell Number: E-mail address:
TICK AND PROVIDE NECESSARY DETAILS AS APPROPRIATE
2. NUMBER OF SITES
Single site in Kenya:
If yes, name of site……
Multiple sites in Kenya:
Number of sites anticipated in Kenya ( )
If yes list the sites……
Multiple countries:
Number of states anticipated in the trial ( )
If yes above list the countries…….
Does this trial have a data monitoring committee?
yes # no #
3. PARTICIPANTS (SUBJECTS)
3.1 Number of participants in Kenya:
3.2 Total enrolment in each Kenyan site: (if competitive enrolment, state minimum and maximum number per site.)
3.3 Total participants worldwide:
4.0 AGE SPAN
Less than 18 years yes # no # If yes specify:
In Utero yes # no # Preterm Newborn Infants (up to gestational age < 37 weeks) yes # no # Newborn (0-28 days) yes # no # Infant and toddler (29 days - 23 months) yes # no # Children (2-12 years) yes # no #
Adolescent (13-17 years) yes # no #
18 years and over yes # no # Adult

(18-65 years) yes # no #
Elderly (> 65 years) yes # no #
5.0 GROUP OF TRIAL SUBJECTS
Healthy volunteers yes # no #
Patients yes # no #
Specific vulnerable populations yes # no #
Women of child bearing potential yes # no #
Women of child bearing potential using contraception yes # no #
Pregnant women yes # no # Nursing women yes # no #
Emergency situation yes # no #
Subjects incapable of giving consent personally yes # no #
If yes, specify:
Others: yes # no # If yes, specify:
6.0 GENDER
Female #
Male #
7.0 CO-ORDINATING INVESTIGATOR *(for multicentre trials in Kenya)*
Given name
Middle name, if applicable Family name
Qualification
Professional address:
8.0 PRINCIPAL INVESTIGATOR *(for multicentre trial; where necessary, use additional forms)*
Given name Middle name, if applicable
Family name
Qualification
Professional address
9.0 ORGANISATIONS TO WHOM THE SPONSOR HAS TRANSFERRED TRIAL RELATED DUTIES AND FUNCTIONS (repeat as needed for multiple organisations)
Has the sponsor transferred any major or all the sponsor's trial related duties and functions to another organisation or third party?
yes # no #
Repeat as necessary for multiple organisations: Organisation:
Name of contact person: Address:
Telephone number:
All tasks of the sponsor yes # no #
Monitoring yes # no #
Regulatory (e.g. preparation of applications to CA and ethics committee) yes # no #
Investigator recruitment yes # no #
IVRS – treatment randomization yes # no #
Data management yes # no # E-data capture yes # no # SUSAR reporting yes # no #
Quality assurance auditing yes # no # Statistical analysis yes # no #
Medical writing yes # no #
Other duties subcontracted yes # no #
If yes to other please
specify:
10.0 PRINCIPAL INCLUSION CRITERIA
List them here;

11.0 PRINCIPAL EXCLUSION CRITERIA
List them here;
12.0 PRIMARY END POINT(S):
List them here;
13.0 SCOPE OF THE TRIAL – Tick all boxes where applicable
Diagnosis # Prophylaxis # Therapy # Safety # Efficacy #
Pharmacokinetic #
Pharmacodynamic # Bioequivalence # Dose Response # Pharmacogenetic #
Pharmacogenomic # Pharmacoeconomic # Others # If others, specify:
14.0 TRIAL TYPE AND PHASE
Human pharmacology (Phase I) # Is it:
First administration to humans # Bioequivalence study # Other: #
If other, please specify
Therapeutic exploratory (Phase II) # Therapeutic confirmatory (Phase III) #
Therapeutic use (Phase IV) #
15.0 DESIGN OF THE TRIAL
Controlled yes # no # If yes, specify: Randomised yes # no #
Open: yes # no #
Single blind: yes # no # Double blind: yes # no #
Parallel group: yes # no #
Cross over: yes # no #Other: yes # no #If yes to other specify:If controlled, specify the comparator: Other medicinal product(s) yes # no #
Placebo yes # no # Other yes yes # no #
If yes to other, specify:
16.0 INFORMATION ON PLACEBO (if relevant; repeat as necessary)
Is a there a placebo: yes # no #
Pharmaceutical form:Route of administration:
Composition, apart from the active substance(s): Is it otherwise identical to the INDP? yes # no # If not, specify major ingredients:
17.0 Details of Site(s)
Name of site Physical address Contact details Contact person:
18.0 Capacity of Site(s):
Number of staff (including study co-ordinators, site facilities, emergency facilities, other relevant infrastructure):
Names:
Qualifications: Experience:
19.0 OTHER DETAILS
19.1 If the trial is to be conducted in Kenya and not in the host country of the applicant / sponsor, provide an explanation:
19.2 Estimated duration of trial:
19.3 Name other Regulatory Authorities to which applications to do this trial have been submitted, but approval has not yet been granted. Include date(s) of application:
19.4 Name other Regulatory Authorities which have approved this trial, date(s) of approval and number of sites per country:
19.5 If applicable, name other Regulatory Authorities or Ethics Committees which have rejected this trial and give reasons for rejection:
19.6 If applicable, details of and reasons for this trial having been halted at any stage by other Regulatory Authorities:

SECOND SCHEDULE

[r. 4 (3)(c)]

FEES

	Purpose of Fees	Amount (Kshs.)
1.	Application for Approval to Conduct Clinical Trial	110,000

THIRD SCHEDULE

[r. 4 (3)(c)]

LABELLING REQUIREMENTS

The final copy of the label of an investigational health product shall contain the following minimum information—

(a) a statement indicating that the product is for “clinical trial purpose only”;

(b) the recommended storage conditions;

(c) the protocol code or identification;

(d) the name, address and telephone number of the sponsor, contract research organisation or investigator;

(e) the pharmaceutical dosage form, route of administration, quantity of dosage units, and in the case of open trials, the identifier and the potency;

(f) the batch and code number;

(g) a clinical trial reference code allowing identification of the clinical trial, site, investigator and sponsor, if not given elsewhere;

(h) the identification number or treatment number and, where relevant, the visit number of a participant;

(i) the directions for use;

(j) the period of use in month and year format and in a manner that avoids any ambiguity; and

(k) the complete physical address of the manufacturing site.

THE PHARMACY AND POISONS (PHARMACEUTICAL WASTE MANAGEMENT) RULES

ARRANGEMENT OF RULES

Rule

THE PHARMACY AND POISONS (PHARMACEUTICAL WASTE MANAGEMENT) RULES

[Legal Notice 99 of 2022]

1. Citation

These Rules may be cited as the Pharmacy and Poisons (Pharmaceutical Waste Management) Rules.

2. Interpretation

In these Rules, unless the context otherwise requires —

"cleaner production measures" means preventive measures applied to processes, products and services to minimise waste production and limit environmental pollution;

"cytotoxic pharmaceutical waste" means waste associated with cytotoxic drugs which contain chemicals that are toxic to the cells including materials, equipment and residue that are contaminated by cytotoxic drugs;

"falsified medical products" means products that deliberately or fraudulently misrepresent their identity, source, composition or both;

"incineration" means the use of temperatures in excess of 800 °C dry oxidation process that reduces organic and combustible waste to inorganic, incombustible matter and results in a significant reduction of waste volume and weight;

"segregation" means the separation of waste materials for processing;

"waste generator" means any person whose activities or activities under his or her direction produces pharmaceutical waste or, if that person is not known, the person who is in possession or control of that pharmaceutical waste;

"waste management" means any activities either administrative or operational used in handling, packaging, treatment, condition, storage and disposal of waste; and

"substandard medical products" means products that are authorised but fail to meet their quality standards or specifications.

3. Application of the Rules

(1) These Rules shall apply to the management of pharmaceutical waste including —

(a) waste containing pharmaceuticals that are expired, damaged or no longer needed;

(b) items contaminated by or containing pharmaceutical waste including bottles and boxes;

(c) applicable medical devices;

(d) substandard and falsified medical products;

(e) obsolete investigational medicinal products; and

(f) cytotoxic pharmaceutical waste.

(2) These Rules shall not apply to —

(a) sharps waste;

(b) infectious waste;

(c) pathological waste;

(d) radioactive waste;

(e) chemical waste; or

(f) non-hazardous or general healthcare waste.

4. Pharmaceutical waste minimization

For the purposes of these Rules, a waste generator shall be encouraged to employ pharmaceutical waste minimization through the adoption of the following practices —

(a) checking of the expiry date of all pharmaceuticals at the time of delivery to ensure they have acceptable shelf life;

(b) refusal to accept short-dated pharmaceuticals (less than a third of shelf life remaining) from a supplier except when the consumption rate of the pharmaceuticals is high;

(c) ordering pharmaceuticals from suppliers who accept the return of short-dated pharmaceutical supplies;

(d) implementing a First Expiry First Out stock control system;

(e) dispensing of all the medicines in a given container; and

(f) replacing pre-packaged unit dose liquids with patient-specific oral doses.

5. Management of pharmaceutical waste

(1) A person shall not collect, record, segregate, store, transport or dispose any pharmaceutical waste except in the manner provided in these Rules.

(2) A person who contravenes the provisions of sub-rule (1) commits an offence and shall be liable, on conviction, to the penalty prescribed by section 51 of the Act.

6. Responsibility of waste generator

(1) A waste generator shall collect, record, segregate, store, transport and dispose of pharmaceutical waste in the manner provided for in these Rules.

(2) A waste generator shall adopt cleaner production measures in the management of pharmaceutical waste including —

(a) incorporating environmental considerations in the design and disposal of pharmaceutical waste; and

(b) improvement of the production process through —

(i) the elimination of use of toxic raw materials;

(ii) the minimising of the emission of toxic waste; and

(iii) the conservation of raw materials and energy.

7. Segregation of pharmaceutical waste

(1) A waste generator shall segregate pharmaceutical waste from other forms of medical waste at the point of generation and at all stages thereafter.

(2) The segregation of waste under sub-rule (1) shall be as follows —

(a) cytotoxic pharmaceutical waste shall be segregated from other forms of pharmaceutical waste; and

(b) compressed-container medications (including aerosols and inhalers) shall be segregated from other forms of pharmaceutical waste.

8. Packaging of pharmaceutical waste

(1) A waste generator shall take reasonable steps to ensure that pharmaceutical waste is in a package that is easily identifiable, including being in its original primary packaging, to aid in identification and preventing reaction between incompatible molecules.

(2) The measures envisaged under sub-rule (1) shall include the following —

(a) in as far as may be practicable, ensuring that pharmaceutical wastes are in their original primary packaging; and

(b) securely packaging any pharmaceutical waste in a suitable bag, container or other appropriate packaging; and

(c) appropriately labelling any package containing pharmaceutical waste.

(3) Where a package contains different types of pharmaceutical waste, a waste generator shall include an inventory of all the pharmaceutical waste contained in the package indicating the following —

(a) a description of each pharmaceutical waste and the quantity contained therein;

(b) the total weight of the pharmaceutical waste; and

(c) a label prepared in accordance with these Rules.

9. Labeling of pharmaceutical waste

(1) A waste generator shall ensure that every container or package for storing pharmaceutical waste is labelled in easily legible characters, written in both English and Kiswahili.

(2) The label envisaged under sub-rule (1) shall contain the following information —

(a) a description of the pharmaceutical waste;

(b) the name, physical address and telephone contact of the waste generator;

(c) any of the following warning or caution statements, as may be appropriate —

(i) the words “WARNING” or “CAUTION”;

(ii) the word “POISON”;

(iii) the words “DANGER - KEEP AWAY FROM UNAUTHORIZED PERSONS”; or

(iv) a pictogram of a skull and crossbones.

(3) Where a package contains different types of pharmaceutical waste, it shall be packed in the manner specified under rule 8.

10. Recording of pharmaceutical waste

A waste generator shall maintain records of pharmaceutical waste with updated information on the following —

(a) date;

(b) product trade name;

(c) active pharmaceutical ingredient;

(d) dosage form;

(e) unit of issue;

(f) quantity; and

(g) justification.

11. Handling and collection of pharmaceutical waste

(1) Waste collection and storage bags for pharmaceutical waste needing incineration shall not be made of chlorinated plastics.

(2) Any plastic bag or bin liner used in the storage or transportation of pharmaceutical waste shall be legibly and permanently labelled with the name of the waste generator and the enduser.

(3) A waste generator shall ensure that pharmaceutical waste is transferred to a person who is licensed to dispose such pharmaceutical waste in an approved pharmaceutical waste disposal facility.

12. Storage of pharmaceutical waste

(1) Pharmaceutical waste shall be stored in designated quarantine stores marked with the words “PHARMACEUTICAL WASTE AREA” which shall be away from other usable pharmaceuticals.

(2) A storage facility used for the storage of pharmaceutical waste shall —

(a) be labeled on the outside with the hazard sign of a skull and two crossbones;

(b) have a sign with the words “NO ENTRY FOR UNAUTHORIZED PERSONS”;

(c) be properly secured and locked; and

(d) have a register of persons entering and exiting the facility that shall be kept by the waste generator.

13. Transportation of pharmaceutical waste

(1) A person transporting pharmaceutical waste shall use a means of conveyance so as to prevent scattering, escaping, flowing, spillage or leakage of the pharmaceutical waste.

(2) A person shall not transport pharmaceutical waste destined for another country through any part of the territory of Kenya without a valid Prior Informed Consent for such transportation issued by the National Environment Management Authority.

(3) On-site transportation of pharmaceutical waste should be separated from infectious waste.

(4) A driver engaged in the off-site transportation of pharmaceutical waste shall be medically fit to drive and have appropriate training on the risks and handling of pharmaceutical waste.

(5) A vehicle used in the transportation of pharmaceutical waste shall be licensed by the National Environment Management Authority and meet the following criteria —

(a) be road worthy;

(b) labelled with the words “PHARMACEUTICAL WASTE CARRIER”;

(c) bear the name and address of the pharmaceutical waste carrier;

(d) bear a hazard sign for pharmaceutical waste (skull and two crossbones);

(e) have a suitable system for securing the load during transport;

(f) have empty plastic bags, suitable protective clothing, cleaning equipment, tools and disinfectant, and special kits for dealing with liquid spills;

(g) be designed so as to prevent spillage, leakage or scattering of such pharmaceutical waste.

(6) During off-site transportation of pharmaceutical waste, the driver shall carry a consignment indicating —

(a) the source of the pharmaceutical waste;

(b) the date of pick-up of the pharmaceutical waste;

(c) the details of the driver;

(d) the destination of the pharmaceutical waste;

(e) the number of containers being transported;

(f) the total weight of the pharmaceutical waste; and

(g) any other relevant information.

(7) On the delivery of a consignment of pharmaceutical waste, the consignee shall confirm receipt of the pharmaceutical waste and the driver shall return the consignment note to the waste generator.

14. Importation of pharmaceutical waste

(1) A person shall not import pharmaceutical waste into the territory of Kenya.

(2) A person who contravenes sub-rule (1) commits an offence and shall be liable, on conviction to the penalty prescribed by section 51 of the Act.

15. Export of pharmaceutical waste

(1) A person shall not export pharmaceutical waste without a valid permit issued by the National Environment Management Authority and a valid Prior Informed Consent document issued by the designated national authority of the receiving country.

(2) A person who contravenes sub-rule (1) commits an offence and shall be liable, on conviction to the penalty prescribed by section 51 of the Act.

16. Pharmaceutical waste treatment and disposal methods

(1) Before treatment and disposal, pharmaceutical waste shall be sorted according to dosage, form or active pharmaceutical ingredient, depending on treatment options available.

(2) Pharmaceutical waste shall be disposed of within one year from the date of its generation.

(3) Pharmaceutical waste shall be disposed of based on dosage in the manner set out in the First Schedule.

17. Supervision of disposal of pharmaceutical waste

(1) The disposal of pharmaceutical waste shall be done under the supervision of the Board at a pharmaceutical waste disposal site approved by the National Environmental Management Authority.

(2) The application for the disposal of pharmaceutical waste shall be made to the Board in the form set out in the Second Schedule and accompanied by the fee set out in the Second Schedule.

(3) The Certificate of Safe Disposal of Pharmaceutical Waste shall be in the form set out in the Second Schedule and shall be issued by the Board within thirty days after the receipt of the application for the disposal of pharmaceutical waste.

18. Disposal under section 46

Where goods are to disposed under section 46 of the Act, the goods shall be destroyed or disposed of in the manner set out in these Rules and in an environmentally-sound manner.

FIRST SCHEDULE

[r. 16 (3)]

MANNER OF DISPOSAL

A. Disposal of small quantities of pharmaceutical waste

The following are the options for disposal of small quantities of pharmaceutical waste:

1. Return of expired pharmaceuticals to the donor or manufacturer where possible

2. Encapsulation and burial in a sanitary landfill

3. Inertization with subsequent—

(a) production of cubes or pellets which are then transported to a suitable storage site

(b) pouring of the liquid homogenous mass onto the surface of previously landfilled municipal waste and then covering with fresh municipal waste

4. Chemical decomposition in accordance with the manufacturer' recommendations if expertise and materials are available

5. Discharge into a sewer with or without dilution for intravenous electrolyte solutions and water for injection

6. Dilution in large amounts of water and discharge into a sewer for solutions containing vitamins and aminoacids

B. Disposal of large quantities of waste

The following are the options for disposal of large quantities of pharmaceutical waste:

1. Encapsulation and burial in a sanitary landfill

2. Inertization with subsequent:

(a) Production of cubes or pellets which are then transported to a suitable storage site

(b) Pouring of the liquid homogenous mass onto the surface of previously landfilled municipal waste and then covering with fresh municipal waste

3. Incineration in kilns that operate at high temperatures (in excess of 800 °C).

4. Discharge into a sewer with or without dilution for intravenous electrolyte solutions and water for injection

5. Dilution in large amounts of water and discharge into a sewer for solutions containing vitamins and aminoacids

C. Disposal of Cytotoxic drugs

The following are the recommended disposal methods for pharmaceutical waste comprised of cytotoxic drugs such as antineoplastic agents—

1. Cytotoxic drugs should never be landfilled.

2. Return to original supplier

3. Chemical degradation in accordance with manufacturer's instructions

4. Incineration at high temperature. Full destruction of cytotoxic drugs may require incineration temperatures up to 1200 °C

SECOND SCHEDULE

[r. 17(2), (3)]

PART A - FORMS

APPLICATION FOR DISPOSAL OF PHARMACEUTICAL WASTE

PHARMACY AND POISONS BOARD. P.O. BOX 27663 – 00506,

NAIROBI.

1. Name of applicant: _____

2. Applicant address:

Physical: _____

Postal: _____ Telephone: _____

Email: _____

3. Description of pharmaceutical products to be disposed

S/N	Product trade name	Active Pharmaceutical Ingredient (s)	Dosage form	Unit of issue	Quantity	Proposed method of disposal

For public health facilities attach the Report of the Board of Survey on Stores (Unserviceable and Surplus to Requirements) – FO 58

4. Justification for disposal of pharmaceutical waste

_____

5. Proposed disposal site

Name: _____

Location: _____

6. Applicant details

Name: _____

Designation: _____

Signature: _____

Date: _____

Certificate of safe disposal of pharmaceutical waste PHARMACY AND POISONS BOARD

P.O. BOX 27663-00506 NAIROBI

Certificate of Safe Disposal of Pharmaceutical Waste This is to certify that the pharmaceutical waste:

From (company) _____

Application reference number _____

Weighing _____

was safely disposed off on _____

Through the following disposal method _____ and at the following pharmaceutical waste disposal site _____

In compliance with the Pharmacy and Poisons (Pharmaceutical Waste Management) Rules, 2022 and the Pharmacy and Poisons Board Guidelines on Safe Management of Pharmaceutical Waste.

Signed:

_____

Chief Executive Officer,

Pharmacy and Poison Board, Kenya.

PART B - FEES

Particulars	**Amount (Kshs)**
Application for the disposal of pharmaceutical waste	**2500**

THE PHARMACY AND POISONS (PHARMACOVIGILANCE AND POST MARKET SURVEILLANCE) RULES

ARRANGEMENT OF RULES

PART I – PRELIMINARY

Rule

CERTIFICATE OF GOOD PHARMACOVIGILANCE PRACTICES

THE PHARMACY AND POISONS (PHARMACOVIGILANCE AND POST MARKET SURVEILLANCE) RULES

[Legal Notice 96 of 2022]

PART I – PRELIMINARY

1. Citation

These Rules may be cited as the Pharmacy and Poisons (Pharmacovigilance and Post Market Surveillance) Rules.

2. Application

These Rules shall apply to health products and technologies manufactured, imported, distributed, marketed, licensed or used in healthcare practice in Kenya.

3. Interpretation

In these Rules, unless the context otherwise requires ─

"Act" means the Pharmacy and Poisons Act;

"active surveillance" means prospective measures taken to detect adverse drug reactions and adverse events and involves active follow-up during and after treatment of patients where the events may be detected by asking the patient directly or screening patient records;

"adverse event" means any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with the treatment;

"adverse drug reaction" means a response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function and is characterized by the suspicion of a causal relationship between a medical product and an occurrence;

"Centre" means the National Pharmacovigilance Centre established under rule 5;

"falsified product" means health products and technologies that are deliberately or fraudulently misrepresented in identity, composition or source;

"healthcare provider" means a health care professional and any other person who provides health care services;

"health product" has the meaning assigned under the Act;

"marketing authorization holder" means an individual or a corporate entity responsible for placing a health product or technology in the market either through importation, donation, distribution or sale in Kenya;

"manufacturer" means a person who sells a product under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person or the body, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the product, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf;

“medical device” means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose;

“passive surveillance” means that no active measures are taken to look for adverse effects other than the encouragement of health professionals and others to report safety concerns;

"parallel importer" means a person licensed to import medicinal substance other than the marketing authorization holder or his or her technical representative of the following medicinal substances which should have been granted marketing authorization in Kenya—

(a) patented medicinal substances under section 58(2) of the Industrial Property Act (Cap. 509);

(b) non-patented medicinal substances;

(c) generic medicinal substances;

"pharmacovigilance" means the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible health product related problem;

"post-marketing surveillance" has the meaning assigned under the Act;

"pharmacovigilance electronic reporting system" means a suite of software applications implemented by the Pharmacy and Poisons Board for collection and processing of information on suspected Adverse drug reactions or adverse events and suspected poor-quality health products or technologies;

"product" means a health product and technology;

"qualified person for pharmacovigilance" means an individual appointed by a marketing authorization holder or a parallel importer as the main person responsible for ensuring that the company meets legal obligations for monitoring of the quality, safety and efficacy of the product marketed in Kenya;

"quality control testing laboratory" means the National Quality Control Laboratory, the Pharmacy and Poisons Board Quality Control Laboratory and other sub-contracted quality control laboratories as defined by the Board;

"quality defect" means attributes of a health product or health technology or component which may affect the quality, safety or efficacy of the product, or which are not in line with the approved market authorization requirements;

"quarantine" means the isolating, holding and restricting movement, physically or by other effective means a medical product and health technology. During quarantine period the product is not available for distribution or use;

"rapid alert system" refers to a system designed to ensure a timely, proportionate, accurate and consistent response to health events arising from sub-standard and falsified health products and technologies which represent a significant threat to health and safety of the public;

"recall" means the removal of a specific batch of a health product and technology from the market for products that do not meet marketing authorization requirements including reasons relating to deficiencies in the quality, safety, efficacy or effectiveness;

"withdrawal" refers to the total removal of health products and technologies from the market for reasons relating to deficiencies in the quality, safety, efficacy leading to cessation of its market authorization;

"wholesale dealer" means entity or individual licenced as such by the Board and as provided by section 27 of the Act.

4. Objects and purpose

The purpose of these Rules shall be to—

(a) improve patient care and safety in relation to the use of health products and technologies;

(b) improve public health and safety in relation to the use of medicines;

(c) facilitate the detection of problems related to the use of health products and technologies and the communication of the findings in a timely manner;

(d) facilitate the assessment of benefit, harm, effectiveness and risk of a health product or technology, leading to the prevention of harm and maximization of benefits of the health product or technology;

(e) encourage the safe, rational and more effective, including cost effective, use of medicines;

(f) increase the trust of patients on medication and health care system;

(g) enhance distribution of information needed to improve drug prescribing and regulation;

(h) promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public;

(i) strengthen the processes of monitoring quality, safety and efficacy of medical products and health technologies;

(j) enhance prevention, detection and response to substandard medical products and health technologies in Kenyan market;

(k) enhance monitoring of status of market authorization of medical products and health technologies in Kenya; and

(l) promote understanding, education training in post-marketing surveillance programs and activities and their effective communication to the public.

PART II – THE NATIONAL PHARMACOVIGILANCE SYSTEM

5. Establishment of the Centre

(1) The Board shall establish a National Pharmacovigilance Centre which shall set up and manage the national pharmacovigilance and post marketing surveillance system to receive and maintain all relevant information about suspected adverse drug reactions and adverse events to health products or health technologies which have been authorised by the Board.

(2) The Centre shall be the single, government recognized integrated system with the clinical and scientific expertise to collect, collate, analyse and give advice on all information related to drug safety.

(3) The Centre shall, through the national system, collect, manage, assess, analyse, identify signals and communicate safety information related to health products and technologies authorised by the Board.

(4) The Centre shall consist of—

(a) the national pharmacovigilance and post marketing quality surveillance system with designated and qualified staff;

(b) the national spontaneous reporting system with reporting forms comparable to the international standards;

(c) the national database for collating and managing safety reports; and

(d) expert committees to provide technical assistance on causality assessment, risk management and case investigation of pharmacovigilance related issues.

(5) The system shall contain data and reports from—

(a) public, private and faith-based health facilities;

(b) other ministry departments, county health departments and public health programs;

(c) health practitioners, health organizations and institutions;

(d) marketing authorisation holders;

(e) regional economic communities;

(f) international agencies; and

(g) patients or members of the public.

6. Stakeholders under the system

The system shall work with the support of the ministry responsible for matters related to health, County governments, healthcare providers, health regulatory bodies, the pharmaceutical industry, marketing authorisation holders, public health programs members of the public, development partners and other relevant stakeholders.

7. Roles and responsibilities of healthcare providers

A health care provider shall—

(a) promote rational drug use;

(b) conduct patient education on adverse drug reactions and adverse events including counselling on medication use;

(c) detect and initiate appropriate clinical management and treatment of patients presenting with adverse reactions or events;

(d) report all suspected adverse drug reactions and adverse events and send the reports immediately to the County Vigilance focal persons or directly through the Pharmacovigilance Electronic Reporting System;

(e) utilize the collated data on adverse drug reactions and adverse events for decision making at the facility level; and

(f) participate in capacity building of other health care providers and public on pharmacovigilance.

8. Responsibility of patients and members of the public

A patient or the general public shall report, to the Board, any suspected adverse effect or suspected poor-quality health product or technology dispensed to them.

9. Roles and responsibilities of public health programs

The Ministry through its designated public health programs and in collaboration with the Board shall—

(a) provide public information during the launch of new drug regimens;

(b) ensure training of health facility staff in use of medicines or regimens and monitoring for any adverse events that may arise;

(c) conduct passive and active surveillance of medical products and health technologies in collaboration with the Board;

(d) when necessary, be called upon by the Board and to determine the risk-benefit assessment of health products and technologies, in order to update treatment guidelines and initiate new training and communications to health providers and the general public;

(e) provide technical support to the investigation teams on quality and safety issues at the County and Sub-County levels;

(f) conduct post-marketing quality surveys of health products and technologies;

(g) participate in activities of the National Pharmacovigilance and Post-marketing surveillance Technical Working Group;

(h) make programmatic decisions as concerns matters related to quality, safety and efficacy of health products and technologies;

(i) conduct education, training and advocacy to the relevant stakeholders;

(j) plan and budget for pharmacovigilance activities; and

(k) mobilize resources for pharmacovigilance and post marketing surveillance activities.

10. Role of county governments

(1) The County governments shall, in collaboration with the Ministry responsible for matters related to health and the Board—

(a) plan and budget for pharmacovigilance activities at county level;

(b) implement pharmacovigilance and post market surveillance activities within the county;

(c) coordinate and participate in the investigations of serious adverse reactions, events, signals and quality defects of health products and technologies;

(d) conduct post market quality surveys of health products and technologies;

(e) submit safety reports and reports on suspected poor quality health products and technologies to the Board within the prescribed timelines;

(f) notify the Board in cases of quality defects that have high public health impact including quality defects that affect vaccines and other biological products within twenty-four hours;

(g) notify the Board on serious adverse events and serious adverse reactions within twenty-four hours;

(h) participate in training of healthcare professionals and the public on pharmacovigilance and post market surveillance in the county in collaboration with the other stakeholders;

(i) facilitate dissemination of feedback on pharmacovigilance and post marketing surveillance including information on product quarantine or recalls within 24 hours of receipt of communication, from the Board to the health care professionals where necessary; and

(j) collaborate with the National Pharmacovigilance and Post Marketing Surveillance Technical Working Group established under these Rules.

(2) The County Government shall designate a County Vigilance focal person to coordinate the implementation of the pharmacovigilance and post market surveillance activities within the County in collaboration with the Board.

(3) A person shall qualify for designation as the County vigilance focal person if that person has—

(a) at least Bachelor's degree in pharmacy; and

(b) valid practicing license issued by the Board.

11. Responsibilities of a marketing authorisation holders

(1) A marketing authorization holder, parallel importer or local technical representative shall be responsible for the quality and compliance with the conditions of the marketing authorization and all other aspects of the health product or technology they have placed in the market.

(2) Every marketing authorization holder, local technical representative and parallel importer shall establish and maintain a pharmacovigilance system for managing safety information of health products and technologies they have placed in the market.

(3) A marketing authorization holder or a parallel importer shall—

(a) appoint a qualified person to be responsible for pharmacovigilance;

(b) prepare reports to the Board in accordance with the requirements of the Act and these Rules;

(c) upon request by the Board, provide additional information necessary for the evaluation of the risks and benefits of a medicinal product;

(d) inform the Board of any prohibition or restriction imposed by the regulatory authorities of any country in which the medicinal substance or health technology is marketed and of any other new information which might influence the evaluation of the benefits and risks of the product in a timely manner;

(e) be responsible for the accuracy of the documents and of the data submitted;

(f) establish and maintain an updated pharmacovigilance system master file which shall be made available to the qualified person for pharmacovigilance;

(g) ensure that the pharmacovigilance system master file is readily available for inspection, at the site where it is kept;

(h) notify the Board on serious medical device (including in vitro diagnostics) incidents and any field safety corrective actions taken in a timely manner;

(i) submit to the Board, in electronic and hard copy, the pharmacovigilance system master file not later than seven days after receipt of the request from the Board; and

(j) submit to the Board a surveillance or data collection plan for review.

12. Qualified person for pharmacovigilance

(1) A person shall be qualified for appointment under rule 11(3)(a) if the person—

(a) is a resident of Kenya;

(b) has a Bachelor's Degree in Pharmacy;

(c) has a certificate, diploma, fellowship or post graduate training in good pharmacovigilance practices from an institution recognized by the Board; and

(d) has a valid practice license issued by the Board.

(2) A person appointed to be responsible for pharmacovigilance under rule 11(3)(a) shall—

(a) maintain the marketing authorization holder's pharmacovigilance system master file;

(b) have sufficient authority to influence the performance of the quality system and the good pharmacovigilance practices;

(c) have oversight over the functioning of the pharmacovigilance system in all relevant aspects including quality management system;

(d) act as a single point of contact for the Board on all matters relating to the product safety and quality of their marketed products including pharmacovigilance inspections;

(e) be aware of the validation status of the adverse reaction database if applicable, including any failures that occurred during validation and the corrective actions that have been taken to address the failures;

(f) prepare and submit safety reports that include the following to the Board through established channels and as stipulated by the Board—

(i) adverse events to health products and technologies;

(ii) periodic safety update reports and periodic benefit-risk evaluation reports;

(iii) company-sponsored pre- and post-registration study reports;

(iv) field safety corrective action reports and field safety notices;

(v) ongoing pharmacovigilance evaluation during the postauthorization period; and

(vi) field safety corrective action reports and field safety notices.

(g) ensure that any request from the Board for additional information deemed necessary for the evaluation of the riskbenefit ratio of a marketed product, is provided to the Board fully and promptly;

(h) oversee the safety profiles of the company's marketed products and any emerging safety concerns;

(i) ensure that all personnel involved in pharmacovigilance activities, which may include customer service and sales representatives etc. have their specific duties recorded in a written description and have adequate authority to carry out their responsibilities;

(j) ensure that all personnel involved in pharmacovigilance activities are aware of the principles of pharmacovigilance that affect them, and they receive relevant training;

(k) ensure that training is provided prior to implementation of new or revised procedures and that the training records are maintained; and

(l) participate in post-authorization safety studies and provide results as requested by the Board.

13. Investigations for adverse drug event

The Board shall conduct investigations, relating to a health product or technology where —

(a) a serious adverse reaction or event is reported;

(b) it is suspected or found that a product does not comply with the requirement of the Act;

(c) there is an international alert with regard to such a product;

(d) it is recalled in Kenya or in any other country;

(e) there is need for additional investigations into the product;

(f) there is need for educational initiatives to improve the safe use of the products;

(g) there is a change in the scheduling or manufacture of the product to make it safer;

(h) for regulatory and health promotion interventions, as the situation may warrant, including change in supply status or withdrawal; or

(i) the Board for any other reason considers it fit to conduct an investigation on the product.

14. Good pharmacovigilance practices

Every marketing authorisation holder, health practitioner and other stakeholders in pharmacovigilance shall comply with good pharmacovigilance practice requirements issued by the Board.

PART III – POST-MARKETING SURVEILLANCE SYSTEM

15. Enforcement

(1) The Board shall establish mechanisms to prevent, detect and respond to the risk of substandard and falsified medical products and health technologies.

(2) The Board shall implement and enforce regulatory actions to prevent and respond to risk of substandard and falsified medical products and health technologies. Such regulatory actions include but not limited to quarantine, recalls, withdrawals of medical products and health technologies, restriction of import or sale of products, suspension of registration, licences and marketing authorization or revocation of registration, licences and market authorizations.

16. Sampling of medical products and health technologies

(1) An authorised officer who obtains a sample of any medical product for testing, examination or analysis shall notify the person or owner from whom the sample was obtained of his intention to submit a sample thereof to the Board for examination or analysis by an approved analyst.

(2) An authorized officer shall collect adequate quantities of the dosage unit of sample to allow for initial testing and repeat testing in cases of non-compliance and for any arising disputes.

(3) Every authorized officer or appointed officer shall follow the guidelines issued by the Pharmacy and Poisons Board regarding procedure of collecting samples for test, examination or analysis.

17. Recalls and withdrawals

(1) The Board shall recall any medical product or health technology for which a notice has been issued by the Board to remove, ban or withdraw from use in accordance with section 3A(d), 3B(2)(l) and 3B(2)(m) of the Act, if the medical product does not meet the required standard or specification or its continued use would pose a risk to safety and health of the public.

(2) The Board shall undertake the following classes of recall—

(a) class I recall where there is a reasonable probability that the use of, or exposure to, a defective product will cause serious adverse health consequences or death;

(b) class II recall where the use of, or exposure to a defective product may cause temporary adverse health consequences, or where the probability of serious adverse health consequences is remote;

(c) class III recall where the use of, or exposure to a defective product is not likely to cause adverse health consequences.

(3) A person shall not sell, offer or expose for sale or supply medical product subjected to recall.

(4) The Board may recall any medical product or health technology based—

(a) on a certificate of analysis issued by the Pharmacy and Poisons Board Quality Control Laboratory;

(b) on the recommendation of Quality, Safety and Efficacy Committee;

(c) on safety alerts issued by the World Health Organization or any other competent National Regulatory Agency;

(d) on quality alerts issued by the World Health Organization or any other competent National Regulatory Agency; or

(e) on quality notification submitted to the Board by manufacturers or market authorization holders.

(5) The Board may recall such medical products or health technologies by—

(a) issuing a product recall notice on the Pharmacy and Poisons Board website;

(b) broadcasting or publishing to the general public through mass media; or

(c) issuing a product alert notice on receipt of reliable information of a falsified, smuggled, diverted, adulterated or prohibited medical product in circulation.

(6) A recall may be a permanent or temporary removal of medical product in order to correct a particular product quality defect or safety issue such as a labelling error.

(7) A recall shall be enforced on part of a consignment, one or more batches, or on the entire product, depending on the extent of the quality defect or safety (1) In the event of a recall, the Board shall—

(a) carry out investigations into the quality or safety issue;

(b) carry out an evaluation of the health risk posed by a product being recalled or considered for recall taking into account, among others, the following factors —

(i) whether any disease or injuries have already occurred from the use of the product;

(ii) whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health risk supported by scientific documentation or statements that the conclusion is the opinion of the individual making the health risk determination;

(iii) assessment of the degree of seriousness of the health risk to which the populations at risk would be exposed;

(iv) assessment of the likelihood of occurrence of the risk; and

(v) assessment of the consequences (immediate or longrange) of occurrence of the risk.

(c) assign the recall a classification in the form of Class I, Class II, or Class III, to indicate the relative degree of health risk of the product being recalled or considered for recall;

(d) ensure effective implementation of the recall;

(e) carry out special good manufacturing practices inspection of manufacturing site if deemed necessary by the Board;

(f) suspend or revoke certificate of registration and any related licenses for a period as shall be determined by the Board, if in the opinion of the Board—

(i) the quality defect or safety issue is persistently reported;

(ii) the quality defect or safety issue is resulting from negligence or deliberate omissions by the manufacturer; or

(iii) the findings of the Good Manufacturing Practice inspection are not satisfactory.

18. Responsibilities of Market authorization holders

A market authorization holder shall—

(a) recall every defective batch, consignment or entire product of the particular product under recall;

(b) ensure recalls are implemented in an effective manner and within given time frames and in levels specified in the recall guidelines issued by the Board;

(c) inform the Kenya Medical Supplies Authority and other central procurement agencies of the recall to ensure recalls of products circulating in the public sector;

(d) inform the ministry responsible for matters related to health and the county governments of the recall action to ensure recalls of products circulating in the public sector;

(e) collaborate with the Board on action taken to prevent or reduce risks posed to the health and safety of the public by the specific batch or entire product;

(f) liaise with manufacturer if the market authorization holder is not the manufacturer of the medical product, to investigate the reasons for the reported quality defect or safety issue and to implement corrective and preventive actions;

(g) correct the quality defect or safety issue and seek approval from the Board before re-supplying the product to the market;

(h) provide certificates of analysis for new batches as requested by the Board;

(i) release new batches to the market only after obtaining approval from the Board;

(j) voluntarily recall a medical product in part or whole if the Board approves such a recall after evaluation of the reasons and justification of the recall;

(k) inform the Board within twenty-four hours (24) of receiving information on the quality defect or safety issue that forms the basis of the recall;

(l) furnish the Board with all such information that is relevant to recalls as and when required by the Board;

(m) submit to the Board a weekly progress report of recall and the final report after completion of a recall which includes reconciliation between supplied and recovered quantities of the product; and

(n) carry out the recall within the time frame specified in the recall guidelines prescribed by the Board and as applicable to each class of defect.

19. Establishment of the Technical Working Group

(1) The Board shall establish a working group to be known as the National Pharmacovigilance and Post-Marketing Surveillance Technical Working Group.

(2) The Technical Working Group shall comprise of the following members—

(a) one representative from the Directorate of Pharmaceutical Services, Ministry of Health who shall be the chair of the technical working group;

(b) two representatives from the Board's department responsible for Pharmacovigilance and Post Market Surveillance who shall be the secretariat;

(c) one representative from each of the Ministry of Health's Public Health Programs;

(d) one representative from Kenya Medical Supplies Authority;

(e) one representative from Mission for Essential drugs and supplies;

(f) two representatives from the National Quality Control Laboratory;

(g) one representative from teaching institutions offering programs in pharmacovigilance and post market surveillance;

(h) one representative from research institution relevant for pharmacovigilance and post market surveillance;

(i) one representative from Council of Governors;

(j) one representative from county governments with experience in pharmacovigilance and post market surveillance; and

(k) other members who shall be co-opted on ad hoc basis.

(3) The National Pharmacovigilance and Post-marketing surveillance Technical Working Group shall—

(a) provide technical guidance on the design, development and implementation of pharmacovigilance and post-marketing quality surveillance guidelines in Kenya including post-marketing quality surveillance forms and procedures;

(b) oversee the development and implementation of pharmacovigilance and post marketing surveillance strategies;

(c) provide technical guidance for the implementation of pharmacovigilance and post-marketing quality surveillance activities to ensure quality, safe and efficacious medical

products and health technologies;

(d) provide technical assistance and guidance on the development of databases and information sharing system on quality profiles of medical products and health technologies;

(e) identify the logistical and resources needs for the implementation of pharmacovigilance and post-marketing quality surveillance activities;

(f) provide a forum for private and public sector groups to consider and recommend policy direction on pharmacovigilance and post marketing surveillance program in Kenya;

(g) participate in the review of training and sensitization materials for health care workers;

(h) provide a platform for the development, review and approval of pharmacovigilance and post-marketing quality surveillance messages for the health care workers and the general public;

(i) mobilize partners and advocate for funds for pharmacovigilance and post marketing surveillance research and surveys;

(j) provide a platform for the review and dissemination of reports on status of pharmacovigilance and post-marketing quality surveillance in Kenya; and

(k) provide a platform for mutual information sharing on risk communication among the Hospital Medicines and Therapeutic Committees.

20. Manufacture of health product technologies

(1) A person shall not manufacture, import, export, supply, possess or offer for sale falsified medical product or health technology.

(2) A falsified medical product shall include—

(a) a product which is deliberately or fraudulently mislabelled with respect to its identity;

(b) a product manufactured under a name which belongs to another product;

(c) 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 medical product;

(d) it has been substituted wholly or in part by any other medicinal substance;

(e) it purports to be a product of a manufacturer of whom it is not truly theirs;

(f) it is a medical product which or the container or labelling of which, without authorization, bears;

(g) the trademark, trade name or any other identifying mark, imprint, or device; or

(h) the likeness of manufacturer of medical product, processor, packer or distributor, other than the person who in fact manufactured, processed, packed, or distributed the medical product and which thereby falsely purports or is represented to be the product of or to have been packed or distributed by the other product manufacturer, processor, packer or distributor.

21. Surveillance system

The National Post-marketing quality surveillance system established under 5 (1) shall comprise of the—

(a) the national reporting system for substandard and falsified products;

(b) the National Pharmacovigilance and Post-marketing Surveillance Technical Working Group; and

(c) the quality control testing laboratories.

22. Post-marketing surveillance approaches

(1) The Board shall in order to ensure effective post-marketing surveillance of health products and technologies undertake—

(a) active Post-marketing quality surveillance; and

(b) proactive Post-marketing quality surveillance.

(2) In order to undertake effective active post-marketing quality surveillance, the Board shall—

(a) establish a national reporting system for suspected substandard and falsified medical products and health technologies;

(b) ensure the reporting system shall be both electronic and manual; and

(c) establish a system of investigating and review of reports on substandard and falsified medical products and health technologies and subsequent implementation of regulatory actions.

(3) The Board shall ensure that the system established under paragraph (2)(c) can support simplified reporting, search analysis, tracking and improved data quality.

(4) In order to undertake effective proactive post-marketing quality surveillance, the Board shall—

(a) carry out routine scientific, systematic, structured, risk based quality surveys to cover expanded scope of medical products and health technologies; and

(b) apply findings from post-marketing quality surveys to implement regulatory actions.

23. Roles of patients and the public

Any patient or member of the public shall be required to—

(a) report any suspected substandard and falsified medical product dispensed to them to a healthcare provider or the nearest health facility or directly to the Board through email, telephone, walk in, or electronic reporting system;

(b) submit samples of suspected substandard and falsified products to a healthcare provider, or to the nearest healthcare facility or to the Board offices where applicable;

(c) report any deviations in handling and storage requirements to the Board;

(d) comply with regulatory actions in collaboration with the Board, including quarantine or recall of medical products; and

(e) support, detect and report suspected substandard and falsified medical products health technologies and submit the reports to the Board through the electronic reporting system or manual reports and copy to County Vigilance Focal Person.

24. Role of healthcare providers

In order to facilitate post-marketing surveillance, every healthcare provider shall—

(a) report any suspected substandard and falsified health product and technologies they may be aware of to the County Vigilance focal person or directly to the Board through email, telephone, walk in, or electronic reporting system;

(b) submit samples of suspected substandard and falsified products to a healthcare provider or to the nearest healthcare facility or to the Board offices where applicable;

(c) report any deviations in handling and storage requirements to the Board;

(d) implement regulatory actions in collaboration with the Board, such regulatory actions include quarantine, recall and withdrawal of health products and technologies;

(e) detect and report suspected substandard and falsified health products and technologies and submit the reports to the Board through the electronic reporting system and copy to County Vigilance Focal Person; and

(f) submit reports on antimicrobial use and consumption to the Board.

25. Role of market authorization holders

(1) A market authorization holder shall ensure that his or her products meet the quality, safety and efficacy at all times while the product is on the Kenyan market.

(2) A market authorization holder shall share data on quality surveillance detected and any local reports on quality of medical products which are brought to their attention, whether reported spontaneously by healthcare professionals, consumers or occurring in the context of market surveillance study, with the Board within seventy-two hours of receipt of the data or report.

(3) Where, in the event of reporting referred in subrule (1), and where cases of quality defect have high public health impact, a market authorization holder shall—

(a) implement directives of the Board on investigations of quality of the health products and technologies as well as implementation of regulatory actions;

(b) collaborate with the Board by providing any information or data on quality of their products when required to do so by the Board;

(c) inform the Board about product deterioration or detection of substandard and falsified products within twenty-four hours, from the time the information becomes available;

(d) establish an emergency plan to ensure effective implementation of recalls or withdrawals of products with voluntary or statutory recalls;

(e) ensure effective and efficient recall action or withdrawal of medical products where applicable;

(f) notify the Board, within seven days, of any quality defects or regulatory actions affecting their products in other markets, other than Kenya, by submitting a report on products similar to those circulating in Kenya including the impact of such quality defects and regulatory actions on the quality of products circulating in Kenya;

(g) submit data on antimicrobials supplied to the market on quarterly basis, or when required by the Board; and

(h) in cases of quality defects or problems with use of medical devices (including in-vitro diagnostics—

(i) follow corrective actions or preventive actions procedures under the manufacturer ‘s or distributor’s quality management system;

(ii) inform the users about the problem of the medical device (including in-vitro diagnostic);

(iii) make corrections to the device or in-vitro diagnostics; and

(iv) removal i.e., recall the medical device (including in-vitro diagnostics) from the market where applicable;

(i) notify the Board where the following actions need to be taken as regards medical devices (including in-vitro diagnostics)—

(i) correcting product on the market;

(ii) removing product from the market; or

(iii) issuance of field safety corrective action;

(iv) issuance of field safety notice;

(v) advising users of an issue with a medical device.

(4) All the requirements applying to market authorization holders shall apply to parallel importers.

26. Role of manufacturers

A manufacturer shall for the purposes of post-marketing surveillance—

(a) cooperate with the Board on matters of investigations on quality defects of medical products including among others—

(i) carrying out internal investigations and preparing root cause analysis reports, submitting the reports to the Board;

(ii) submitting data or information as required by Board and implementation of the proposed corrective and preventive actions; and

(iii) updating the board on implementation of and participating in special Good Manufacturing Practice inspections by the Board to investigate quality defects;

(b) submit a root cause investigation report to the Board within two weeks from the date of receipt of the request from the Board;

(c) inform the Board, following detection of non-compliance during manufacturing for a product that is already in the Kenya market, within seventy-two hours after the information becomes available;

(d) implement directives of the Board on investigations of quality of the products and implementation of regulatory actions;

(e) submit data on antimicrobials supplied to the market on quarterly basis, or when required by the Board;

(f) notify the Board where the following actions need to be taken as regards medical devices (including in-vitro diagnostics)—

(i) correcting product on the market;

(ii) removing product from the market;

(iii) issuance of field safety corrective action; or

(iv) issuance of field safety notice;

(g) in cases of quality defects or problems with use of medical devices (including in-vitro diagnostics);

(h) follow corrective actions or preventive actions procedures under the manufacturer's or distributor's quality management system;

(i) inform the users about the problem of the medical device (including in-vitro diagnostic); and

(j) make corrections to the device (including in-vitro diagnostic) and recall the medical device (including in-vitro diagnostic) from the market where applicable.

27. The Quality Control Testing Laboratory

The Quality Control Testing Laboratory shall for the purposes of post-marketing surveillance—

(a) test health products and technologies on request of the Board or any other entity;

(b) prescribe testing methods, standards or specifications based on internationally acceptable standards including pharmacopeia standards;

(c) issue Certificates of Analysis on each sample tested to the clients in the format developed by the Board;

(d) participate in development and review of post-marketing surveillance protocols;

(e) train staff from the Board and other staff on MiniLab activities; and

(f) participate in the activities of the National Pharmacovigilance and Post-marketing Surveillance Technical Working Group.

28. Role of wholesale dealers

The Wholesale dealers shall—

(a) participate in matters of investigations on quality defects of health products and technologies;

(b) submit data on antimicrobials supplied to the market on quarterly basis, or when required by the Board;

(c) notify the Board where the following actions need to be taken as regards medical devices, including in-vitro diagnostics—

(i) correcting product on the market;

(ii) removing product from the market; or

(iii) issuance of field safety corrective action;

(iv) issuance of field safety notice;

(v) advising users of an issue with a medical device;

(d) in cases of quality defects or problems with use of medical devices (including in-vitro diagnostics)—

(i) follow corrective actions or preventive actions procedures under the manufacturer's or distributor's quality management system;

(ii) inform the users about the problem of the medical device (including in-vitro diagnostic;

(iii) make corrections to the device or including in-vitro diagnostics; and

(iv) removal i.e., recall the medical device (including in-vitro diagnostics) from the market where applicable.

29. Role of the central procurement agencies

The central procurement agencies shall in order to support post-marketing surveillance —

(a) participate in the activities of the National Pharmacovigilance and Post-marketing Surveillance Technical Working Group;

(b) participate in investigations on quality defects of medical products;

(c) share post-marketing quality surveillance data, and any local reports on quality of medical products which are brought to their attention, whether reported spontaneously by healthcare professionals or consumers or occurring in the context of market surveillance study, with the Board within seventy-two hours of receipt of the data or report and immediately in cases where the quality defect has high public health impact.

30. Role of the Board

The Board shall for the purposes of post-marketing—

(a) receive and review reports on suspected poor quality medical products from healthcare providers, County vigilance focal persons, public, Central procurement agencies, market authorization holders and manufacturers;

(b) investigate suspected sub-standard and falsified medical products and health technologies;

(c) implement risk based expanded post-marketing quality surveys to cover broad category of products;

(d) implement, oversee and enforce regulatory actions including quarantine, recalls, suspension of marketing authorization and suspension of manufacturing licenses;

(e) provide feedback to reporters of poor-quality medical products on completion of the investigation report;

(f) disseminate findings from post-market surveillance activities to all relevant stakeholders;

(g) establish the Quality, Safety and Efficacy Committee which shall be responsible for the review of investigation reports and findings of post-market surveillance activities and make recommendations for appropriate regulatory actions;

(h) establish mechanisms for the coordination, communication and involvement of all relevant stakeholders and various departments or units within the Board in post-marketing surveillance programs;

(i) establish and provide secretariat to the National Pharmacovigilance and Post-Marketing Surveillance Technical Working Group;

(j) conduct advocacy, training, education and sensitization on post-marketing surveillance related activities;

(k) develop and disseminate information, education and communication materials;

(l) carry out communication to healthcare providers and the public on market surveillance related activities;

(m) maintain database on antimicrobial consumption in Kenya;

(n) maintain a rapid alert list;

(o) notify other National Regulatory Authorities and the World Health Organization on falsified products, where appropriate;

(p) participate in the World Health Organisation member state mechanism on substandard and falsified products;

(q) carry out routine analysis of quality data to inform regulatory actions and policy decisions;

(r) rely on and recognize regulatory decisions related to quality, safety and efficacy of medical products and health technologies that are made in other jurisdictions, where the Board considers it applicable to Kenya; and

(s) partner with stakeholders on post marketing surveillance activities as and when needed.

(t) receive and evaluate field safety corrective actions for medical devices (including in-vitro diagnostics);

(u) monitor implementation of field safety corrective actions for medical devices (including in-vitro diagnostics);

(v) collaborate with regional and international organizations on matters of quality, safety and efficacy of health products and technologies;

(w) collaborate with Ministry of Health to establish and implement a system for reporting on antimicrobial use and consumption by healthcare providers, importers, marketing authorization holders and local manufacturers of antimicrobial agents.

31. Rapid alert system

(1) The Board shall establish a rapid alert system designed to ensure a timely, proportionate, accurate and consistent response to health events arising from sub-standard and falsified medical products which represent a significant threat to health and safety of the public.

(2) The Rapid alert system shall be applied to transmit alerts on quality, safety and efficacy of medical products and health technologies, alerts which cannot permit any delay.

(3) The Rapid alert system shall be triggered after new information on public health is received from any source, reviewed and validated and determined that the quality defect presents critical risk to public health.

(4) Pursuant to these Rules, the sources of information may include—

(a) market authorisation holder;

(b) patients or members of the public;

(c) media;

(d) healthcare providers;

(e) manufacturers;

(f) central procurement agencies; and

(g) other National Regulatory Authorities, Literature review or international organizations like the World Health Organization.

(5) A rapid alert notification shall include—

(a) quality defects and medical device deficiencies identified by the Board that requires urgent regulatory actions including Class I recalls, product withdrawal and product quarantine;

(b) quality defects for medical products of high public health impact including, among others, vaccines, parenteral formulations, male latex condoms, female condoms, surgical

gloves, sutures;

(c) World Health Organisation alerts of finished products and Active Pharmaceutical Ingredients regarding safety issues;

(d) follow up actions on rapid alert notification;

(6) The Board may issue further guidance on the rapid alert system.

PART IV – GENERAL PROVISIONS

32. Offences

A marketing authorisation holder, local technical representative or parallel importer or health care provider who—

(a) omits important safety warning;

(b) fails to report serious adverse reaction or event;

(c) delays or fails to submit safety reports to the Board; or

(d) fails to comply with the requirements of these Rules;

commits an offence and shall be liable, upon conviction to the penalty set out in section 51 of the Act.

33. Pharmacovigilance Assessment and Inspections

(1) The Board shall carry out pharmacovigilance audits and good pharmacovigilance practices inspections on manufacturers, marketing authorization holders, local technical representatives, parallel importers, distributors and any outsourced persons or companies in order to ensure compliance with good pharmacovigilance practice and these Rules.

(2) The Board shall conduct routine inspections every three years and may conduct frequent inspections on a case-to-case basis depending on other considerations such as risk-based inspections.

(3) Upon completion of the inspection under this regulation, the Board shall issue a certificate of good pharmacovigilance practices, in the Form set out in the Schedule, to manufacturers, marketing authorization holders, local technical representatives, parallel importers and outsourced persons or companies who have complied with the inspection.

(4) The Board shall periodically conduct pharmacovigilance assessments for the public health programs, health facilities, marketing authorization holders and central procurement agencies using such tools as the Board may determine from time to time.

34. Safety studies

For a period of three years or such other period as may be determined by the Board, after the initial placing of a product in the Kenyan market, the Board may request that the marketing authorization holder to arrange for specific pharmacovigilance data to be collected from targeted groups of population or under specific conditions.

35. International collaboration for pharmacovigilance activities

The Board shall work closely with other regulatory authorities at regional and international level, development partners and the World Health Organisation for purposes of sharing information on safety issues and anticipated regulatory action.

36. Reliance

The Board shall consider and rely on pharmacovigilance decisions from other competent national, regional and international regulatory authorities, where necessary.

SCHEDULE

[r. 33(3)]

CERTIFICATE OF GOOD PHARMACOVIGILANCE PRACTICES

Pharmacy and Poisons Board	CERTIFICATE OF COMPLIANCE WITH GVP	FOM023/VMS/SOP/021

Rev No: 0

Certificate of Compliance Form: FOM023/VMS/SOP/021

On the basis of the inspection carried out on [date] _____ we certify that the company/entity indicated on this certificate:

Name of company/entity: .....

Postal address: .....

Physical address (building, road/street, City/town): .....

.....

complies with Good Pharmacovigilance Practices in Kenya.

This certificate remains valid until [date] _____. It becomes invalid if areas certified herewith are changed or if the company/entity is no longer considered to be in compliance with GVP.

Date:

Note

1. This certificate certifies the status of the company/entity listed in the certificate

2. This certificate shall remain valid for a period of 3 years from the date of issue, but can be revoked at any time if there is evidence that the company/entity no longer complies with the current PPB Pharmacovigilance regulations.

Pharmacy and Poisons Board	NOTICE OF CONCERN LETTER	FOM024/VMS/SOP/021

Rev No

Notice of concern Letter Form: FOM024/VMS/SOP/021

Ref No.....

RE: NON- COMPLIANCE WITH GOOD PHARMACOVIGILANCE PRACTICES

On basis of the inspection carried out on (Dates of inspection) ..... we certify that at the time of inspection (Name of the company/entity inspected)....., located at (Physical address of the company/entity)....., DID NOT Comply with current Good

Pharmacovigilance Practices for all the activities undertaken at the site.

You may however apply for re-inspection of the facility once corrective actions contained in the report attached to this letter have been addressed. The inspection however will not be undertaken earlier than six months from the date of this letter.

Thank you for your cooperation in this matter.

THE PHARMACY AND POISONS (REGISTRATION OF HEALTH PRODUCTS AND TECHNOLOGIES) RULES

ARRANGEMENT OF RULES

THE PHARMACY AND POISONS (REGISTRATION OF HEALTH PRODUCTS AND TECHNOLOGIES) RULES

[Legal Notice 100 of 2022]

PART I – PRELIMINARY

1. Citation

These Rules may be cited as the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules.

2. Interpretation

In these Rules, unless the context otherwise requires—

"Act" means the Pharmacy and Poisons Act (Cap. 244);

"blood product" means a medicinal product based on a blood constituent which is prepared industrially and includes albumin, immunoglobulin and a coagulating factor;

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

"good manufacturing practice certificate" means a document issued by a competent regulatory authority that certifies compliance to good manufacturing practice;

"immunogenic substance" means an unformulated active substance which may be—

(a) subsequently formulated with excipients to produce a medicinal product;

(b) whole bacterial cells, viruses, or parasites whether live or killed, split bacterial cells, viruses, or parasites, crude or purified antigens isolated from killed or living cells;

(c) crude or purified antigens secreted from living cells, recombinant or synthetic carbohydrate, protein or peptide antigens, polynucleotides; or

(d) conjugates;

"import" includes importation in accordance with the Pharmacy and Poisons (Parallel Imported Medicinal Substances) Rules, 2019 (L.N. 126/2019);

"in-vitro diagnostics medical device" means a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes;

"medicinal product" means a natural or synthetic active substance or combination of substances administered to a human being with a view to treating or preventing a disease, making a diagnosis, correcting or modifying a physiological function;

"medicinal substance" means a substance, the origin of which may be human, animal, vegetable or chemical including human blood and human blood products, micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products, micro-organisms, plants, parts of plants, vegetable secretions, extracts, elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis;

"parallel importation" means the importation of patented drugs under section 58(2) of the Industrial Property Act (Cap. 509);

"permanent residence" means a status granted to a person under section 37 of the Kenya Citizenship and Immigration Act (Cap. 170);

"registered health product or technology" means a health product or technology for human use, approved by the Board, and presented into the market in a ready form, in a special package and with a specific name;

"vaccine" means heterogeneous class of medicinal substance containing immunogenic substances capable of inducing specific, active and protective host immunity against infectious diseases.

PART II – REGISTRATION OF HEALTH PRODUCTS AND TECHNOLOGIES

3. Control of the manufacture, etc., of drugs

A person shall not import, manufacture or sell a health product or technology in Kenya unless that health product or technology has been registered under these Rules.

4. Application for registration of health product or technology

(1) A person who intends to import, manufacture or sell a health product or technology shall apply to the Board for the registration of the health product or health technology in Form 1 set out in the First Schedule.

(2) An applicant subrule (1) shall—

(a) specify the particulars of the person with appropriate knowledge of all aspects of the health product or health technology who shall be responsible for all communication between the applicant and the Board in the declaration page of the application form; and

(b) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, appoint a local representative who shall be a citizen of Kenya, a person who is has permanent residence or a company incorporated in Kenya.

(3) The application made under subrule (1) shall be accompanied by—

(a) a proposed label for use on the health product;

(b) a copy of the manufacturing licence of the health product, where applicable;

(c) a copy of the good manufacturing practice certificate from the Board and the regulatory authority of the country where the health product is manufactured;

(d) a copy of a certificate of analysis from a quality control laboratory recognised by the Board, where applicable;

(e) a copy of the marketing authorisation or certificate of registration of the health product or technology from the regulatory authority of the country where the health product or technology is sold;

(f) the available data on the quality, safety, efficacy and performance of the health product or technology submitted in a common technical dossier format;

(g) a sample of the health product;

(h) proof of ownership of the site for the manufacture of the health product, if applicable;

(i) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative;

(j) where the application relates to a health product or technology which is registered with a foreign regulatory body—

(i) a copy of the certificate of registration;

(ii) the professional information relating to the health product or technology; and

(iii) the conditions of the registration of the health product or technology;

(k) proof that the applicant holds #

(i) a valid practicing licence issued in accordance with section 9A of the Act;

(ii) a valid wholesale dealer's licence issued in accordance with section 27 of the Act;

(iii) a valid licence to deal in poisons for mining or agricultural purposes issued in accordance with section 28 of the Act;

(iv) a valid licence to sell Part II poisons issued in accordance with section 32 of the Act; or

(v) a valid manufacturing licence issued in accordance with section 35A of the Act; and

(l) proof of payment of the application fees set out in the Second Schedule.

(4) An applicant shall notify the Board of any variation to the agreement appointing the local representative within seven days of the variation.

5. Processing of application for registration of health product or technology

(1) The Board shall consider the application made under rule 4, and, shall, if it is satisfied of the safety, efficacy, quality, performance and economic value of the health product or technology, register the health product or technology and issue a certificate of registration in Form 2 set out in the First Schedule.

(2) The Board may, while considering the application made under rule 4, approve the details as supplied by the applicant or approve it with such amendments as it may consider appropriate in respect of the following particulars—

(a) the name under which the health product or technology may be sold;

(b) the labelling of the health product;

(c) the statement of the representations to be made for the promotion of the health product regarding—

(i) the claim to be made for the health product;

(ii) the route of administering the health product;

(iii) the dosage of the health product;

(iv) the storage conditions of the health product;

(vi) the contra-indications, the side effects and precautions, if any of the health product; and

(vii) the package size of the health product.

(3) When evaluating an application made under rule 4, the Board may—

(a) subject a sample of the health product to an evaluation by an analyst; and

(b) consider the evaluation report of an institution that has evaluated the health product.

(4) The Board shall issue a certificate of registration under subrule (1) if the applicant has—

(a) a valid practicing licence issued in accordance with section 9A of the Act;

(b) a valid wholesale dealer's licence issued in accordance with section 27 of the Act;

(c) a valid licence to deal in poisons for mining or agricultural purposes issued in accordance with section 28 of the Act;

(d) a valid licence to sell Part II poisons issued in accordance with section 32 of the Act; or

(e) a valid manufacturing licence issued I accordance with section 35A of the Act.

(5) If the Board is not satisfied as to the quality, safety efficacy and performance, or economic value of the health product, it may, after providing an opportunity to the applicant to be heard, reject the application made under rule 4 and inform the applicant the reasons for rejection in writing.

6. Register of health products and technologies

The Registrar shall maintain a register of health products and technologies registered in under there Rules in Form 3 set out in the First Schedule.

7. Collaborative measures when processing application for registration

When processing an application made under rule 4, the Board may liaise with any other regulatory authority or institution in respect of matters of common interest or a specification investigation.

8. Annual retention

(1) A person who holds a certificate of registration under rule 5(1) who wishes to have the product retained in the register shall annually apply for the retention of the product in the register in the in Form 4 set out in the Schedule.

(3) An application made under subrule (1) shall specify information on—

(a) the product summary;

(b) the finished product manufacturing sites;

(c) the active ingredient manufacturing sites;

(d) the approved presentations of actual product and product appearance;

(e) the approved batch formula and batch sizes;

(f) the approved specifications and analytical procedures; and

(g) the steps taken post-registration including variations, if any.

(3) An application made under subrule (1) shall be accompanied by ─

(a) a copy of a valid good manufacturing certificate; and

(b) the annual retention fees specified in the Second Schedule.

9. Renewal of certificate of registration

(1) A person who intends to renew their registration shall apply for renewal of registration in Form 4 set out in the First Schedule.

(2) A person who makes an application under sub-rule (1) shall—

(a) have paid the retention fees referred to in rule 8; and

(b) comply with the prescribed guideline for Re-registration and Renewal of health products and technologies.

(3) An application made under sub-rule (1) shall specify information on—

(a) the health product or technology;

(b) non clinical study reports;

(c) clinical study report;

(d) variations;

(e) quality review of the health product or technology; and

(f) vigilance and product safety reports, including product complaints and market surveillance.

(4) The Board shall consider the application made under subrule (1), and, shall, if it is satisfied of the safety, efficacy, quality, performance and economic value of the health product or technology, register the health product or technology and renew the registration and issue a Renewal of Registration Certificate in Form 3 set out in the First Schedule.

10. Validity of certificates

(1) A certificate of registration issued under rule 5(1) or a renewal certificate under rule 9(3), shall be valid for five years from the date of issue.

(2) If an application made under rule 9 is submitted before the expiration of the period referred to in subrule (1), the certificate shall remain in force until the Board makes a decision on the application.

11. Withholding, Suspension, or revocation of certificate of registration

(1) The Board may withhold, suspend, or cancel the registration of a health product or health technology if—

(a) the person issued with a certificate of registration requests the Board to cancel the registration of the health product or technology;

(b) the person who was issued with the certificate misrepresented the information contained in the application made under rule 4;

(c) the certificate was acquired fraudulently;

(d) the person who was issued with the certificate has failed to comply with—

(i) the Act;

(ii) these Rules; or

(iii) a condition of the certificate;

(e) the formulation, composition, design specification, quality, safety or presentation of the health product has changed to the extent that it renders the health product unsuitable to continue to be registered; or

(f) it is in the public interest to do so.

(3) The Board shall, before suspending or cancelling the registration of health product or technology under subrule (1), issue a notice of intention to suspend or cancel the registration of a health product or technology in Form 5 set out in the First Schedule to the person who was issued with the certificate of registration and give the person an opportunity to be heard.

12. Withdrawal of certificate of registration

The person to whom a certificate of registration is issued is required to notify the Board, in Form 6 set out in the First Schedule, of his intention to withdraw the registration for a health product and technology.

PART III – MISCELLANEOUS

13. Variation of information on health product or technology

(1) Where there is a change in a health product or technology or the Board is satisfied that a variation to a registered health product or technology is required, the Board may, by notice in writing given to the person to whom a certificate of registration was issued, make such variation as it considers appropriate and enter the variation in the Register.

(2) Where there is a change in the product details of a health product or technology, the person to whom a certificate of registration is issued shall report the Board—

(a) any quality and safety changes or any defect which could impact patient safety of a marketed product; or

(b) any marketing or regulatory decisions made in the country of origin or in another country where the product is marketed.

14. Registration during emergency

(1) The Board may, where it considers it necessary to protect public or animal health or in the event of a threat to human or animal life or health, the Board, issue a provisional certificate of registration for a health product or technology.

(2) A person who intends to obtain the provisional certificate of registration for a health product or technology under subrule (1) shall apply to the Board, in Form 2 set out in the First Schedule.

(3) Where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, the applicant shall appoint a local representative who shall be a citizen of Kenya, a person who is has permanent residence or a company incorporated in Kenya.

(4) An application under subrule (2) shall be accompanied by—

(a) such documents as may be necessary to support the application;

(b) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative;

(c) proof that the applicant holds#

(i) a valid practicing licence issued in accordance with section 9A of the Act;

(ii) a valid wholesale dealer's licence issued in accordance with section 27 of the Act;

(iii) a valid licence to deal in poisons for mining or agricultural purposes issued in accordance with section 28 of the Act;

(iv) a valid licence to sell Part II poisons issued in accordance with section 32 of the Act; or

(iv) a valid manufacturing licence issued in accordance with section 35A of the Act; and

(e) the fees specified in the Second Schedule.

(5) When determining an application under subrule (1), the Board shall consider the facts established from the valid marketing authorisation for the health product or technology and the report on the assessment of the health product or technology obtained from the authority competent for medicinal products, if available.

(6) The person to whom the certificate of registration is issued under subrule (1) shall be responsible for the labelling, packaging, advertising and pharmacovigilance system of the health product or technology.

(7) The Board shall issue a provisional certificate of registration under subrule (1) if the person has—

(a) a valid practicing licence issued in accordance with section 9A of the Act;

(b) a valid licence to deal in poisons for mining or agricultural purposes issued in accordance with section 28 of the Act;

(c) a valid licence to sell Part II poisons issued in accordance with section 32 of the Act; or

(d) a valid manufacturing licence issued I accordance with section 35A of the Act.

(8) A provisional certificate of registration issued under subrule (1) shall be valid for two years from the date of issue or until the declaration made under section 35 of the Public Health Act (Cap. 242) is revoked.

(9) Any variation to the agreement appointing the local representative to the application made under subrule (2) shall be notified to the Board within seven days of the variation.

15. Registration for compassionate use

(1) The Board may, where it considers it necessary register a health product or technology, for compassionate use by a person whose application under rule 4 is pending or a sponsor of a clinical trial in relation to an investigational health product.

(2) An application for the registration of a health product or technology for compassionate use of the health product or technology in Form 7 set out in the First Schedule.

(3) Where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, the applicant shall appoint a local representative who shall be a citizen of Kenya, a person who is has permanent residence or a company incorporated in Kenya.

(4) An application under subrule (1) shall be accompanied—

(a) by relevant documents indicating#

(i) that the health product or technology is authorised in a country with equivalent requirements as regards the quality, safety efficacy and performance of the health product or technology;

(ii) where the health product or technology does not have a marketing authorisation, the quality analysis of the health product or technology;

(iii) that the health product or technology constitutes a significant therapeutic, scientific and technical innovation;

(iv) that the health product or technology is intended for a group of patients with chronic or severely debilitating disease that cannot be satisfactorily treated with any health product or technology that has been registered by the Board;

(v) the related adverse effects, which shall be prepared or confirmed by the competent clinical department;

(vi) the protocol for treatment with the health product or technology; and

(vii) the warranties of the manufacturer of the health product or technology as specified in subrule (3);

(b) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative; and

(c) the fees specified in the Second Schedule.

(5) The manufacturer of a health product or technology which is the subject of the application made under subrule (1) shall—

(a) supply the health product or technology for at least one year after the expiry of the period specified in the certificate of registration issued under this rule;

(b) avail the health product or technology free of charge during the period specified in the certificate of registration issued under this rule; and

(c) label the health product or technology in accordance with section 41 of the Act.

(6) If the health product or technology relates to a clinical trial in relation to an investigational health product, the applicant shall attach the recommendation of the National Clinical Trial Expert Committee.

(7) The Board shall consider the application made under subrule (2), and, if it is satisfied of the safety, efficacy, quality, performance and economic value of the health product or technology, register the health product or technology and issue a certificate of registration in Form 2 set out in the First Schedule.

(8) Any variation to the agreement appointing the local representative to the application made under subrule (3) shall be notified to the Board within seven days of the variation.

16. Authorisation of unregistered health product or technology

(1) The Board may, in writing, authorise a person to import or distribute for a specified period to a specified person or institution a specified quantity of a particular health product that is not registered.

(2) A health product distributed pursuant to authorisation granted under subrule (1) may be used for such purposes and in such manner and during such period as the Board may in writing determine.

(3) A person who intends to obtain the authorisation under subrule (1), for purposes other than a clinical trial, shall apply to the Board, in Form 8 set out in the First Schedule.

(4) Where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, the applicant shall appoint a local representative who shall be a citizen of Kenya, a person who is has permanent residence or a company incorporated in Kenya.

(5) The application made under subrule (3) shall be accompanied by—

(a) a product brochure containing relevant chemical, pharmaceutical, pre-clinical pharmacological and toxicological data and where applicable, human or animal pharmacological and clinical data with the health product concerned;

(b) witnessed informed written consent document, where applicable;

(c) details of registration or pending registration of the health product with any other regulatory authority, if available;

(d) evidence of compliance of the manufacturer of the health product with Good Manufacturing Practice standards as determined by the Board;

(e) reasons why a registered health product cannot be used;

(f) where the applicant is not a citizen of Kenya or is a company incorporated outside Kenya, a copy of the agreement appointing the local representative;

(g) proof that the applicant holds #

(i) a valid practicing licence issued in accordance with section 9A of the Act;

(ii) a valid wholesale dealer's licence issued in accordance with section 27 of the Act;

(iii) a valid licence to deal in poisons for mining or agricultural purposes issued in accordance with section 28 of the Act;

(iv) a valid licence to sell Part II poisons issued in accordance with section 32 of the Act; or

(v) a valid manufacturing licence issued in accordance with section 35A of the Act; and

(h) the fees specified in the Second Schedule.

(6) The Board shall grant authorisation under subrule (1) if the applicant has—

(a) a valid practicing licence issued in accordance with section 9A of the Act;

(b) a valid wholesale dealer's licence issued in accordance with section 27 of the Act;

(c) a valid licence to deal in poisons for mining or agricultural purposes issued in accordance with section 28 of the Act;

(d) a valid licence to sell Part II poisons issued in accordance with section 32 of the Act; or

(e) a valid manufacturing licence issued I accordance with section 35A of the Act.

(7) Where the Board issues an authorisation under subrule (1), the person to whom the authorisation is issued shall submit to the Board—

(a) progress reports after every six months from the date when the authorisation was issued;

(b) any adverse event report, whenever an adverse event occurs; and

(c) a progress report within thirty days after the completion or termination of the use of the health product.

(8) The Board may, if the Board is of the opinion that the safety of any patient or animal is compromised or the scientific reasons for administering the unregistered health product have changed—

(a) impose any additional conditions;

(b) request additional information;

(c) inspect the site where the unregistered health product is manufactured, stored or administered; or

(d) withdraw the authorisation to treat the patient or animal.

(9) The Board may, by notice in writing withdraw the authorisation issued under subrule (1) if the any of purposes or the manner specified in subrule (2) is contravened.

(10) A health product authorised under this rule shall be labelled in accordance with section 41 of the Act.

(11) An applicant shall notify the Board of any variation to the agreement appointing the local representative within seven days of the variation.

(12) The requirements in this regulation shall apply to applications for donations of health products and technologies.

17. Revocation of LN 147 of 1981

The Pharmacy and Poisons (Registration of Drugs) Rules are revoked.

FIRST SCHEDULE

[r. 4(1), 14(2)]

APPLICATION FOR REGISTRATION OF
HEALTH PRODUCT OR HEALTH TECHNOLOGY

FORM 1

To:

The Registrar

Pharmacy and Poisons Board

Nairobi.

1. Name of Applicant .....

2. Address of Applicant .....

3. Contact of Applicant .....

4. Name of health product or health technology .....

5. Type of health product or technology .....

6. Presentation of health product or technology .....

7. Physical appearance of health product .....

8. Therapeutic classification of health product or technology .....

.....

9. Name of manufacturer of health product .....

10. Address of manufacturer of health product .....

11. Country of origin of health product or technology .....

12. Registration numbers and countries of registration of the health product or technology .....

13. Pharmaceutical Formula of the health product .....

14. Name and structural formula of the active ingredient of the health product

.....

.....

15. Specifications for all the active and inactive raw materials used in themanufacturing process .

.....

.....

16. Analytical control procedures which are performed on all active and inactive materials before the materials are used in the manufacturing process

.....

.....

17. Analytical control procedures and the frequency with which they are performed in the manufacturing process .....

.....

18. Full specifications of the final manufactured health product .....

.....

19. The analytical procedures performed on the final manufactured health product

.....

20. The inferred shelf life of the final manufactured health product .....

.....

21. Method of packaging of the final manufactured health product .....

.....

22. Summary of the experimental details of the tests performed on the health product or technology to confirm its pharmaceutical effects....

23. Proposed dosage of the health product .....

.....

.....

24. Summary of the experimental details of the tests performed on the health product ortechnology to confirm its physiological ability.....

.....

.....

.....

25. Declaration by the applicant: .....

.....

.....

Name of the responsible person .....

Signature of applicant.....Date of application .....

FORM 2 [r. 5(1), 9(3), 15(7))(r. 4(1), 14(2)]

CERTIFICATE OF REGISTRATION/RENEWAL OF REGISTRATION OF HEALTH PRODUCT OR HEALTH TECHNOLOGY

Serial Number.....

It is notified that the health product or health technology described in this certificate has been registered by the Pharmacy and Poisons Board subject to the conditions specified in this certificate.

1. International Non-proprietary name of health product or technology

.....

2. Name under which the health product or technology is to be marketed (Trade Name)

.....

3. Registration number of the health product or technology

.....

4. Quantities per unit (strength) of the health product

.....

5. Dosage Form of preparations .....

6. Conditions under which the health product or technology is registered

.....

7. Name, address and contact information of the manufacturer of the health product

.....

8. Date of registration .....

9. Date of expiry of registration .....

10. Authorised signature of the Board ..... Date.....

FORM 3 (r. 6)

REGISTER OF HEALTH PRODUCTS

No.	**Brand Name**	**Generic**	**Strength**	**Dosage form**	**Pack Size**	**Certificate of Registration Holder**	**Local Technical Representative**	**Country of Origin**	**Registration Date**

FORM 4 (r. 8(1), 9(1))

APPLICATION FOR RE-REGISTRATION/RENEWAL OF CERTIFICATE OF REGISTRATION

TYPE OF APPLICATION – HUMAN PRODUCT (Registration/Re-Registration)

MODULE 1: ADMINISTRATIVE INFORMATION

SECTION 1: PARTICULARS OF THE PRODUCT

1.0 Name and address of Applicant

1.1	Type of the Medicinal product licence application Type of the medicinal product application New/innovator Generic Conditional Authorization Emergency Use Authorization Extension application Duplicate license Renewal/Re-registration* * If variation has been made, information supporting the changes should be submitted. See variation guidelines for registered medicinal products.
1.2	Trade/Proprietary name (proprietary Product name):
1.3	Approved / generic name/Active Pharmaceutical Ingredient:
1.4	Strength of the Active Pharmaceutical Ingredient (API) per unit dosage of the product and

	specifications of the API:
1.5	Dosage form
1.5.1	Pharmaceutical Dosage form of the product:
1.5.2	Therapeutic Indication (s):
1.5.2	Route(s) of administration (use current list of standard terms - European Pharmacopoeia):
1.6	Packing/Pack size of the product:
1.6.1	Pack size:
1.6.2	Primary packing materials:
1.6.3	Secondary packing materials:
1.7	Visual Description of the product
1.8	Proposed/Approved Shelf life of the product (In months):
1.9	Pharmacotherapeutic group and ATC Code
1.10	Legal category
1.11	Country of origin or country of release:
1.12	Product Marketing Authorisation in the country of origin. (Attach certificate of pharmaceutical product from competent regulatory authority)
1.12.1	Registration status from countries with Stringent Regulatory Authorities where applicable
1.12.2	List of countries in which a similar application has been submitted
1.12.3	Statement on whether an application for the Marketing Authorisation has been previously rejected, withdrawn or repeatedly deferred in the East Africa Community Partner States
1.12.4	Certificates of approval of Drug Master File by Stringent Regulatory Authority
1.12.5	Manufacturing Licence and Product registration certificate/Licence
1.13	Name(s) and complete address (es) of the manufacturer(s)
1.13.1	Name and complete address(es)of the manufacturer(s) of the FPP, including the finished pharmaceutical product release if different from the manufacturer.
1.13.2	Name(s) and complete address (es) of the manufacturer(s) of the active pharmaceutical ingredient
1.14	Compliance to Good Manufacturing Practice and Good Clinical Practice
1.14.1	Good Manufacturing Practice from the Board

1.14.2	Good Clinical Practice or Good Laboratory Practice
1.15	Name and complete address of the Local Technical Representative of Manufacture (for finished pharmaceutical Product)
1.16	Product Information: Summary of Product Characteristics, Prescribers/ Patient information leaflet, Mock-ups and Photo scan of the product:
1.17	State the reference/monograph standard used for Finished Medicinal Product.
1.18.1	Specification of active ingredient(s) from active pharmaceutical ingredient manufacturer (Specification number and Version):
1.18.2	Specification of active ingredient(s) from FPP manufacturer (Specification number and Version):
1.18.3	Specification of Finished Pharmaceutical Product (Specification number and Version):
1.19	Name and address (physical and postal) of the Contract Research Organisation(s) where the clinical studies of the product were conducted. *(If applicable)*
1.20	DECLARATION BY AN APPLICANT That information is true and correct Name, position and signature ……. Official stamp:…….. ** Note: If fees have been paid, attach proof of payment*

FORM 5 (r. 11(3))

NOTICE OF INTENTION TO WITHHOLD, SUSPEND OR CANCEL THE REGISTRATION OF A HEALTH PRODUCT OR TECHNOLOGY

Date Month Year

TYPE OF MEDICAL PRODUCT OR HEALTH TECHNOLOGY

□ Human health product	□ Veterinary health product	□ Herbal product	□ Parallel product	□ Medical device

PRODUCT DETAILS

Certificate of registration No.

Name of product

Strength

Dosage/pharmaceutical form

Certificate of registration holder

DETAILS OF CONTACT PERSON

Name
Address
Telephone No.
E-Mail Address
REASON FOR WITHHOLDING, SUSPENSION OR CANCELATION/REVOCATION
SIGNATURE
Date Name Signature

FORM 6 (r. 12)

NOTICE OF INTENTION TO WITHDRAW THE REGISTRATION OF A HEALTH PRODUCT OR TECHNOLOGY

Date Month Year

TYPE OF MEDICAL PRODUCT OR HEALTH TECHNOLOGY

□	□	□	□	□
Human health product	Veterinary health product	Herbal product	Parallel product	Medical device

PRODUCT DETAILS
Certificate of registration No.
Name of product
Strength
Dosage/pharmaceutical form
Certificate of registration holder
DETAILS OF CONTACT PERSON
Name
Address
Telephone No.
E-Mail Address
REASON FOR WITHDRAWAL
SIGNATURE
Date Name Signature

FORM 7 (r. 15(2))

APPLICATION FOR COMPASSIONATE USE OF HEALTH PRODUCT AND TECHNOLOGIES

Date
Application No.
Active substance[s]:
Orphan indication
1. Description of the condition under which the HPT is to be used
1.1. Details of the condition
1.1.1 Definition
1.1.2 Aetiology
1.1.3 Specific characteristics; pathophysiological, histopathological, clinical characteristics
1.1.4. Classification
1.1.5 Diagnosis and symptoms
1.2. Proposed indication
1.3. Medical plausibility
1.3.1. Active substance: description of the medicinal product, pharmacological class and mode of action

1.3.2. Plausibility of the condition; data with the specific product as applied for designation in specific models or in patients affected the condition
1.4. Justification of the life-threatening or debilitating nature of the condition
2. Prevalence of the condition
2.1. Prevalence of the disease or condition in the Kenya
2.2. Prevalence and incidence of the condition in the Kenya
3. Other methods for diagnosis, prevention or treatment of the condition
3.1. Details of any existing diagnosis, prevention or treatment methods
3.2. Justification as to why methods are not satisfactory (Applicable/Not applicable. (Delete as appropriate) (Note that sections 3.2 and 3.3 are mutually exclusive.)
3.3. Justification of significant benefit Applicable/Not applicable. (Delete as appropriate)
4. Description of the stage of development
4.1. Summary of the development of the product
4.1.1 Quality aspects
4.1.2 Non-clinical aspects
4.1.3 Proof-of concept in relevant model
4.1.4 Pharmacology
4.1.5 Pharmacokinetics
4.1.6 Toxicology
4.1.7 Clinical aspects
4.1.8 Pharmacokinetics
4.1.9 Pharmacodynamics
4.1.10 Clinical efficacy
4.1.11 Dose-response studies and main clinical studies
4.1.12 Clinical studies in applied condition
4.1.13 Planned clinical studies
4.1.14 Clinical safety
4.1.15 Adverse events
4.1.16 Serious adverse events and deaths
4.2. Details of current regulatory status and marketing history in the Kenya and other countries
5. Applicant's position:
(Please delete any paragraph above that does not apply.)

FORM 8 (r. 16(3))

Application Form for Unregistered Health Product and Technologies
<Date>
Application No.
Active substance[s]:
Orphan indication
1. Description of the condition under which the HPT is to be used
1.1. Details of the condition
Definition
Aetiology
Specific characteristics; pathophysiological, histopathological, clinical characteristics
Classification
Diagnosis and symptoms
1.2. Proposed indication
1.3. Medical plausibility

1.3.1. Active substance: description of the medicinal product, pharmacological class and mode of action
1.3.2.Plausibility of the condition; data with the specific product as applied for designation in specific models or in patients affected the condition
1.4. Justification of the life-threatening or debilitating nature of the condition
2. Prevalence of the condition
2.1. Prevalence of the disease or condition in the Kenya
2.2. Prevalence and incidence of the condition in the Kenya
3. Other methods for diagnosis, prevention or treatment of the condition
3.1. Details of any existing diagnosis, prevention or treatment methods
3.2. Justification as to why methods are not satisfactory *or* Not applicable. *(delete as appropriate)*
Note that sections 3.2 and 3.3 are mutually exclusive.
3.3. Justification of significant benefit *or* Not applicable. *(delete as appropriate)*
4. Description of the stage of development
4.1. Summary of the development of the product
Quality aspects
Non-clinical aspects
Proof-of concept in relevant model Pharmacology
Pharmacokinetics Toxicology Clinical aspects Pharmacokinetics
Pharmacodynamics Clinical efficacy
Dose-response studies and main clinical studies Clinical studies in applied condition
Planned clinical studies Clinical safety
Adverse events
Serious adverse events and deaths
4.2. Details of current regulatory status and marketing history in the Kenya and other countries
Applicant's position:
Please delete any paragraph above that does not apply.

SECOND SCHEDULE

[r. 4(3)(l)), 8(3)(b), 14(4)(d), 15(4)(c), 16(5)(h)]

FEES

	Purpose of Fees	**Amount (USD.)**
1.	Application for registration of health product not manufactured in Kenya.	1,000.00
2.	Application for registration of health product manufactured in Kenya.	500.00
3.	Application for renewal of registration of health product not manufactured in Kenya.	1,000.00
4.	Application for renewal of registration of health product manufactured in Kenya.	500.00

5.	Application for Fast tracking Evaluation of applications for Health product not manufactured in Kenya	2,000.00
6.	Application for donated health products	0
7.	Application for Issuance of Emergency Use Authorization for a Medical Devices and In-Vitro Diagnostic	2,500.00
8.	Application for registration of Class A Medical Device	100.00
9.	Application for registration of Class B Medical Device	200.00
10.	Application for registration of Class C Medical Device	1,000.00
11.	Application for registration Class D Medical Device	1,000.00
12.	Application for renewal of a Class A Medical Device	100.00
13.	Application for renewal of a Class B Medical Device	200.00
	Purpose of Fees	Amount (USD.)
14.	Application for renewal of a Class C Medical Device	1,000.00
15.	Application for renewal of a Class D Medical Device	1,000.00
16.	Application for registration of health product not manufactured in Kenya. (Food Supplement, Cosmetics and Borderline Products)	500.00
17.	Application for registration of health product manufactured in Kenya. (Food Supplement, Cosmetics and Borderline Products)	100.00
18.	Application for renewal of registration of health product not manufactured in Kenya. (Food Supplement, Cosmetics and Borderline Products)	500.00
19.	Application for renewal of registration of health product manufactured	100.00

	in Kenya. (Food Supplement, Cosmetics and Borderline Products)	
20.	Application for registration of health product (Traditional Health Products – Locally Manufactured)	50.00
21.	Application for renewal of registration/listing of health products (Traditional Health Products – Locally Manufactured)	20.00

THE PHARMACY AND POISONS (TRANSPORTATION OF PHARMACEUTICALS) RULES

ARRANGEMENT OF RULES

PART I – PRELIMINARY

Rule

THE PHARMACY AND POISONS (TRANSPORTATION OF PHARMACEUTICALS) RULES

[Legal Notice 97 of 2022]

PART I – PRELIMINARY

1. Citation

These Rules may be cited as the Pharmacy and Poisons (Transportation of Pharmaceuticals) Rules.

2. Interpretation

In these Rules, unless the context otherwise requires—

"cold chain" means any material, equipment, process or procedure used to maintain a product within the required temperature range of 2# to 8# or according to the manufacturer's recommended storage conditions from the time of manufacture until the product is administered to an individual;

"consignment" means the quantity of pharmaceuticals supplied at one time in response to a particular request or order and may comprise one or more packages or containers which may include pharmaceuticals belonging to more than one batch;

"consignor" means a person engaged in the activity of distributing pharmaceuticals;

"consignee" means a person to whom goods or documents are officially sent or delivered;

"container" means the material employed in the packaging of a pharmaceutical and may include a primary or secondary transportation container;

"importation" means the act of bringing or causing any pharmaceuticals to be brought into Kenya;

"primary container" means a container that is intended to be in direct contact with a product;

"product recall" means the removal of specific batches of a pharmaceutical from the market due to deficiency in quality, safety or efficacy of a pharmaceutical;

"secondary container" means a container that is not intended to be in direct contact with a product;

"storage" means the storing of pharmaceuticals up to the point of use;

"transit" means the period during which pharmaceuticals are in the process of being carried, conveyed or transported across, over or through a passage or route to reach the destination; and

"vehicle" means a carrier which can be used to convey pharmaceuticals from one point to another and includes a motorcycle, bicycle, truck, van, bus, minibus, car, trailer, aircraft, railway carriage, boat or other means which are used to convey pharmaceuticals.

3. Objectives of the Rules

The objectives of these Rules are to—

(a) provide for the licensing transporters of pharmaceuticals;

(b) provide for the enforcement transportation requirements;

(c) ensure the security of pharmaceuticals while on transit;

(d) ensure that any pharmaceuticals within the possession of transporters are accounted for; and

(e) ensure that any transported pharmaceuticals conform to the prescribed standards of quality, safety and efficacy.

4. Application

These Rules shall apply to any person who is authorized to store, distribute or transport pharmaceuticals.

PART II – REQUIREMENTS FOR TRANSPORTATION OF PHARMACEUTICALS

5. Transportation licence

(1) A person who intends to engage in the business of transporting pharmaceuticals shall make an application for a licence to the Board in Form 1 set out in the Schedule.

(2) An application under subrule (1) shall be accompanied by the following documents—

(a) a certificate of incorporation for a company, a registration certificate for a business name or partnership deed for a partnership;

(b) a certificate of registration of a registered pharmacist or an enrolment certificate of an enrolled pharmaceutical technologist appointed by the applicant;

(c) registration and inspection documents for any vehicles or vessel to be used in transporting pharmaceuticals issued by the relevant regulatory agencies;

(d) a licence for every operator of a vehicle;

(e) inspection reports on the suitability of any vehicle for transportation of pharmaceuticals from a competent authority;

(f) a declaration on the type of pharmaceuticals that the applicant intends to transport;

(g) for any vehicle that is to be used in the transportation of cold-chain products, a copy of a job card showing the installation and validation of the cold-chain control, monitoring and recording system with in-built alarm and alert capabilities from a duly registered and authorized firm; and

(h) any other information as shall be required by the Board.

(3) The Board shall review the application made under paragraph (1) and may approve or reject the application.

(4) Where the Board approves the application, the Board shall issue a licence in the Form 2 set out in the Schedule.

(5) Where the Board rejects the application, the Board shall, within fifteen days from the date of receipt of the application, communicate to the applicant the decision specifying reasons for the rejection, in writing.

(6) A person who is aggrieved by the decision of the Board may appeal to the High Court.

6. Enforcement

(1) A licence issued under rule 5 may be revoked, suspended or modified for any of the reasons specified in subrule (3).

(2) The Board may prohibit the possession of a pharmaceutical product for any of the reasons specified in subrule (3).

(3) A person is liable to a decision of the Board under paragraph (1) or (2) if the person—

(a) contravenes these Rules; or

(b) an agent of the person provides misleading information.

(4) A person who is aggrieved by the decision of the Board under subrule (1) or (2) may appeal to the High Court.

7. Verification

(1) A consignor shall, before commencing transportation, verify—

(a) the type of the pharmaceuticals that are to be transported and identify the appropriate protection arrangements for the consignment; and

(b) that the consignee is authorized to possess the pharmaceuticals.

(2) A person shall not transport any radioactive material without authorization from the Board.

(3) The Board may, before authorizing a person to transport radioactive material, consult the Nuclear Regulatory Authority and any relevant body established by any written law to regulate the transportation of radioactive materials.

(4) A person shall not use a motorcycle to transport narcotic, psychotropic substances or precursor chemical substances in accordance with the Single Convention on Narcotic Drugs of 1961, the Convention on Psychotropic Substances 1971, and the UN Convention against Illicit Traffic Drug and Psychotropic Substances, 1988.

(5) A person who contravenes subrules (1), (2) or (4) commits an offence and shall, on conviction, be liable to the penalty prescribed in section 51 of the Act.

8. Security during transportation

A person who is engaged in the transportation of pharmaceuticals shall—

(a) ensure that each vehicle is equipped with lockable doors or where possible an intruder alarm;

(b) document and track all deliveries; and

(c) keep signed dispatch and arrival records.

PART III – CATEGORIES OF TRANSPORT

9. Obligations of air transporters

A person who is engaged in the transportation of pharmaceuticals by air shall ensure that—

(a) the pharmaceuticals meet the handling requirements stipulated by the manufacturer;

(b) that a time and temperature sensitive label is affixed on any shipment booked as time and temperature sensitive cargo;

(c) that an acceptance checklist for any time and temperature sensitive shipment is executed; and

(d) that an authorized officer of the Board is notified on the arrival of the shipment at the port of entry for pre-clearance inspection.

10. Obligations of sea transporters

(1) A person who is engaged in the transportation of pharmaceuticals by sea shall ensure that—

(a) the pharmaceuticals are packaged in a refrigerated container for transporting temperature sensitive cargo in accordance with the storage specifications of the manufacturer;

(b) the importation of pharmaceuticals shall be through a Gazetted ports of entry that are equipped to handle the products;

(c) upon arrival at the port of entry, the pharmaceuticals are removed from the transporting vessel as soon as possible and moved to a safe and suitable temperature-controlled storage location to minimize the risk of temperature related damage and theft;

(d) he receives and forwards records of storage conditions during transportation to the authorized officer of the Board at the port of entry to confirm that storage is compliant while on transit;

(e) any excursion is reported to the owner of the consignment and the authorized officer of the Board at the port of entry so that it can be adequately addressed; and

(f) an authorized officer of the Board is notified on the arrival of the shipment at the port of entry for pre-clearance inspection.

(2) The conditions under subrule (1) shall also apply to the exportation of pharmaceuticals.

(3) A consignor shall ensure that a shipping container—

(a) protects the personnel and the general public from any hazard arising from spillage or leakage;

(b) protects the product being transported against mechanical damage and the temperature changes encountered during transit;

(c) is closed in a manner that allows the recipient of the consignment to establish that the product has not been tampered with during transportation; and

(d) is insulated.

(4) A consignor shall ensure that chemical or electric freeze indicators, electronic loggers or any other suitable indicators are used to monitor temperature or humidity exposure during transportation.

11. Obligations of road transporters

A person who is engaged in transportation of pharmaceuticals by road shall ensure—

(a) that any vehicle or equipment used to distribute pharmaceuticals is suitable for its purpose and is appropriately equipped;

(b) that the design and use of any vehicle aims to minimize the risk of errors on the product being distributed;

(c) that tracking devices and engine kill buttons are installed on every vehicle; and

(d) the use of dedicated vehicles and equipment.

PART IV – SPECIFICATIONS

12. Loading and receiving bays

A person who is licensed to transport pharmaceuticals under these Rules shall ensure that—

(a) every loading, receiving or dispatch bay has sufficient facilities and space allowance to ensure pharmaceuticals are protected from adverse environmental conditions;

(b) any area where pharmaceuticals are temporarily held during arrival or dispatch is—

(i) maintained within the temperature and humidity range specified for the goods being handled;

(ii) protected from direct sunlight, dust or rain; and

(iii) adequately ventilated and lit;

(c) temperature and humidity are monitored at all times and documented in temperature logs or humidity logs which shall be maintained and readily available;

(d) any equipment, appliance or gadget used in temperature control is connected to uninterruptible power supply system and power back up; and

(e) temperature control equipment is calibrated as recommended by the manufacturer and the records are maintained.

13. Transport and delivery

An authorized person shall ensure that any vessel used for transportation of pharmaceutical products is—

(a) equipped with calibrated temperature and humidity monitoring devices with sensors located at points representing temperature extremes;

(b) equipped with alarms to alert the operator in the event of temperature or humidity excursions or refrigeration unit failure; and

(c) fitted with doors with security seals or security locks that protect against unauthorized access during transit.

14. Monitoring of storage conditions during transit

A person who is engaged in the transportation of pharmaceuticals shall ensure any vessel used in transportation is fitted with—

(a) temperature control systems that are able to continuously maintain air temperature within the set points and the accuracy shall be within 0.5 #; and

(b) humidity control systems with an accuracy of + or -5% relative humidity.

15. Temperature controlled vehicles

A consignor shall ensure that a temperature-controlled vessel demonstrates—

(a) that the air temperature and humidity is uniformly distributed in the temperature controlled compartment of the vessel by installing temperature probes; and

(b) the time taken for temperatures to exceed the designated maximum in the event that the temperature controlling unit fails.

16. Calibration of vessels

(1) Any vessel used for transportation of pharmaceuticals shall undergo routine inspection.

(2) Any vessel used for transportation of temperature sensitive pharmaceuticals shall undergo calibration of devices for temperature and humidity control in accordance with recommendations of the manufacturer or at least once every year by the Kenya Bureau of Standards or any other certified standards accreditation body to ensure compliance.

17. Insulated containers

(1) A consignor shall ensure that—

(a) for short terms periods of transportation of pharmaceuticals, insulated containers with icepacks are used; and

(b) for long periods of transportation of pharmaceuticals, insulated containers of up to ninety six hours are used.

(2) The sender shall ensure that the packaging system is capable of maintaining the pharmaceuticals within the temperature range.

(3) A consignee shall ensure that non-conforming pharmaceuticals are quarantined and shall, as soon as possible, report to the Board.

18. Contingency planning

A consignor shall put in place contingency plans for the safe storage of pharmaceuticals in cases of extended power outages, equipment failure or vehicle breakdown in transit.

19. Record keeping

(1) A transporter shall maintain records in paper and electronic formats.

(2) The paper records shall be—

(a) stored and maintained so that they are easily accessible;

(b) labeled, dated and filed for easy identification;

(c) protected against deterioration and loss due to fire, flood or other hazards;

(d) kept secure and protected against unauthorized access; and

(e) signed and dated by the authorized persons and not changed without due authorization;

(3) Electronic or computer records shall be—

(a) logically filed for easy identification and retrieval;

(b) kept secure and protected against unauthorized access;

(c) where feasible, manually signed, dated and scanned; and

(d) regularly backed-up and archived.

(4) The records referred to in paragraph (1) shall be kept for a period of at least two years and made available for inspection by authorized officers of the Board.

20. Standard operating procedures

Every transporter, authorized persons, consignors and consignees shall comply with good distribution, transportation and storage practices requirements issued by the Board.

21. Compliance

A person who intends to store, distribute or transport pharmaceuticals shall, within six months from the date of publication of these Rules, comply with the requirements under these Rules.

22. Offences and penalties

A person who contravenes any of the provisions of these Rules commits an offence and shall be liable to the penalty prescribed under section 51 of the Act.

SCHEDULE

FORMS

Form 1 (r. 5(1))

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD
APPLICATION FOR LICENSE TO TRANSPORT PHARMACEUTICALS FOR DISTRIBUTION

I /We, ... of ..... here by apply for a license to transport pharmaceuticals

Part 1 - Details of the applicant:

(a) Name of applicant: .....

(b) Designation: ..... Registration/Enrolment No. .....

(c) National Identity Card/Passport No. .....

(d) Mailing address: .....

(e) E-mail address .....

(f) Telephone No. .....

Part 2 - Details of business

(a) Transportation of pharmaceuticals Where Part 2(a) is requested, attach copy of Premises Registration Certificate and Wholesale Dealer's license

Part 3 - Type(s) of pharmaceuticals intended to be transported.

(a) Biological Products
(b) Vaccines
(c) Medical devices
(d) Finished Pharmaceutical products
(e) Active Pharmaceutical Ingredients

Part 4 - Details of vehicle(s) /vessel(s)to be used in transport

Type of Vehicle	***Car***	***Van***	***Freezer truck***	***Others***
Vehicle Registration number				

(Add more lines if necessary)

Declaration

I, the undersigned, certify that all information in this application for license to transport pharmaceuticals for distribution is true and correct.

I understand that I have the responsibility to inform the Authority with immediate effect of any change to the information provided in this application.

Signature: .....

Applicant: .....

Name: .....

Designation: .....

Date: .....

Form 2 (r. 5(4))

REPUBLIC OF KENYA

MINISTRY OF HEALTH PHARMACY AND POISONS BOARD
LICENSE TO TRANSPORT PHARMACEUTICALS

Messrs.....Address.....is registered to carry on the business of transportation of pharmaceuticals in the listed vessels and approved warehouse(s) as per the type(s) indicated.

i. Type(s) of pharmaceuticals transported.....

ii. Source and destination.....

iii. Registration number of the vessel.....

iv. Name and ID. No of the operator.....

Note:

a) This registration expires on 31st December.....

b) No change of the transport vessel without the authority of the Board.

c) Any new vessel must be inspected by the Board before certification.

d) This registration shall become void upon expiration of 30 days from any change of the nature of the business.

Chief Executive Officer.....

Signature.....

Date.....