# CHAPTER 244

# PHARMACY AND POISONS ACT

SUBSIDIARY LEGISLATION

*List of Subsidiary Legislation*

**THE POISONS LIST CONFIRMATION ORDER**

ARRANGEMENT OF ORDERS

*Order*

[Subsidiary]

# THE POISONS LIST CONFIRMATION ORDER

[L.N. 168/1961, Corr. No. 66/1961, L.N. 250/1961, L.N. 423/1961, L.N.146/1963, L.N. 242/1963, L.N. 93/1964, L.N. 150/1968, L.N. 15/2002.]

[Section 25.]

## 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.

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SCHEDULE

[Paragraph 2.]

POISONS LIST

[Corr. No. 66/1961, 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.
   - Cotarnine.
   - Curare, alkaloids of; curare bases.
   - Ecgonine; its esters.
   - Emetine.
   - Ephedra, alkaloids of.

   Ergot, alkaloids of, homologues and hydrogenated.

   Gelsemium, alkaloids of.

SCHEDULE—*continued*

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. Allylisopropylacetylurea.
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-Aminopropylbenzene 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, N-methylephedrine, 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.

SCHEDULE—*continued*

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 sativa Linn); the resin of cannabis; extracts of cannabis; tinctures of cannabis; cannabin tannate.
43. Cantharidin; cantharidates.

SCHEDULE—*continued*

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. Dehydroemetine; its salts.
66. Demecarium bromide.
67. Desipramine; 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-Diamidino-diazoaminobenzene; its salts.
75. Diampromide, its salts and other compounds containing the chemical structure of 1:4 benzodiazepine substituted to any degree; their salts.
76. Diazepam.
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. Dimepheptanol; its salts.
84. Dinitrocresols (DNC); their compounds with a metal or a base.
85. Dinitronaphthols; 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.

SCHEDULE—*continued*

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 following—
polymethylene 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.

SCHEDULE—*continued*

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. Mannityl 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 ($CH_3$) 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. Monofluroacetic 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.

SCHEDULE—*continued*

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-O, methyl, demeton-S-methyl, diethyl 4-methyl-7-coumarinyl phosphorothionate, diethyl p-nitrophenyl phosphate, dimefox, disulfoton, ethion, ethyl p-nitrophenyl phenyl-phosphonothionate, 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.

SCHEDULE—*continued*

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.
240. 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 1/6th 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

[L.N. 36/1963, L.N. 526/1997, L.N. 128/1998.]

[Section 43.]

**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 and the poison set out in the Schedule is prohibited.

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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.

**3.** Pearl Omega.

**4.** Polyatomic Oxygen (Ozone).

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## THE PHARMACY AND POISONS RULES

ARRANGEMENT OF RULES

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

# THE PHARMACY AND POISONS RULES

[L.N. 186/1957, L.N. 443/1957, L.N. 332/1958, L.N. 426/1958, L.N. 498/1958, L.N. 550/1959, L.N. 114/1960, L.N. 587/1961, L.N. 242/1963, L.N. 631/1963, L.N. 92/1964, L.N. 365/1964, L.N. 115/1968, L.N. 125/1969, L.N. 248/1969, L.N. 41/1971, L.N. 120/1984, Corr. No. 52/1984, L.N. 51/1985, L.N. 61/2002, L.N. 91/2004, L.N. 191/2010.]

## 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;
(y) medroxyprogeshrone and its salt; and
(z) 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 | USD 4,000 |
| (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

[Rule 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 colchicine. |
| 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. Thebaine | 1.00 percent. |
| 31. Veratrum, alkaloids of | 1.00 percent. |
| 32. Adrenalin, its salts, in preparations for external use only | 0.10 percent. |

SCHEDULE I—*continued*

| *Poison* | *Percentage of poison content below which substance is exempted* |
|---|---|
| 33. Amino-alcohols, esterified with benzoic acids, phenylacetic acid, phenylpropionic acid, cinnamic acid or the derivatives of these acids | 10.00 per cent of esterified amino-alcohols. |
| 34. Antimonial poisons | Equivalent 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 0.50 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. Chloral hydrate | 10.00 percent. |
| 41. Digitalis, glycosides and other active principles of | One unit of activity (as defined in the *British Pharmacopala*) 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. |

SCHEDULE I—*continued*

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

[Rule 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. Stavesacre, alkaloids of | Soaps; ointments; lotions for external use. |
| 12. Ammonia | Substances not being solutions of ammonia or preparations containing solutions of ammonia substances containing less than 5 per cent weight in weight of ammonia ($NH_3$); 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 conltaining arsenical poisons as naturaimpurities. |
| 17. Barium, salts of | Witherite other than finely ground witherite. |

SCHEDULE II—*continued*

| | *Poison* | *Substance or article in which exempted* |
|---|---|---|
| 18. | Beta-aminopropylbenzene; its salts; its N-alkyl derivatives; their salts; beta-aminoisopropyl-benzene; 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 applicaton 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 of lead acetate. |
| 25. | Lead, compounds of | Machine-spread plasters. |
| 26. | Mercuric chloride | Batteries. |
| 27. | Mercuric chloride; mercuric iodide; organic 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 ($HNO_3$). |
| 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. | Phenylcinchoninic 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, |

SCHEDULE II—*continued*

| *Poison* | *Substance or article in which exempted* |
|---|---|
| | pessaries, ointments or suppositories containing less than 2.5 per cent of phenols; paratertiaryamyl phenol; smelling bottles; soaps for washing; solid substances other than pastilles, lozenges, capsules, pessaries, ointments and suppositories, containing less than 60 per cent of phenols; tar (coal or wood), crude or refined; tertiary butylcresol; thymol; animal dips containing less than 6 per cent of phenols. |
| 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 preparations containing not more than 0.01 per cent of phenylmercuric salts as a preservative, and textiles containing not more than 0.01 %, as a bacteriostat and fungicide. |
| 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 ethyl 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 ..... | Substance 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 ($H_2SO_4$); accumulators, batteries; fire extinguishers. |

SCHEDULE III

[Rule 5.]

[L.N. 248/1969.]

SUBSTANCES EXEMPT FROM CERTAIN LABELLING REQUIREMENTS

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.

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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 N-methylephedrine, N-diethylamioethylephedrine, phenylpropanolamine and prenylamine; any salt of any substance falling within this item.
18. Captodiame; its salts.
19. Carbromal.

SCHEDULE IV—*continued*

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.

SCHEDULE IV—*continued*

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.

SCHEDULE IV—*continued*

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 para-aminobenzene-sulphonamide having any of the hydrogen atoms of the para-substituted group or any of the sulphonamide group substituted by another radical; their salts.
6. Quinapyramine; its salts.

SCHEDULE V

[Rules 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

[Rule 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 ..... | |

SCHEDULE VI—*continued*

| *Name of poison* | *Particulars* |
|---|---|
| 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. |

SCHEDULE VI—*continued*

| *Name of poison* | *Particulars* |
|---|---|
| 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—<br>(a) the number of units of activity as defined in the *British Pharmacopoeia* contained in a specified quantity of the preparation; or<br>(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<br>(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 (K2O) 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 (Na20) 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—<br>(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<br>(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—<br>(a) the proportion of thyroid gland contained in the preparation; or |

SCHEDULE VI—*continued*

| *Name of poison* | *Particulars* |
|---|---|
| | (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

[Rule 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.

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## SCHEDULE VIII

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

### FORMS

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).

SCHEDULE VIII—*continued*

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)).

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**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*

---

SCHEDULE VIII—*continued*

**FORM 2**

REGISTER OF PHARMACISTS

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

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**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*

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**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.

SCHEDULE VIII—*continued*

**FORM 5**

REGISTER OF PREMISES

| REGISTRATION | | 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 |
|---|---|---|---|---|
| No. | Date | | | |
| | | | | |

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**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.

---

SCHEDULE VIII—*continued*

**FORM 8**

REGISTER OF WHOLESALE DEALERS

| REGISTRATION | | 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 |
|---|---|---|---|---|
| No. | Date | | | |
| | | | | |

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**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 .....
.....
.....
.....

SCHEDULE VIII, Form 10—*continued*

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

---

**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.

---

SCHEDULE VIII—*continued*

**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.

---

SCHEDULE VIII—*continued*

**FORM 15**

REGISTER OF LICENCES ISSUED TO SELLERS OF PART II POISONS

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

---

**FORM 16**

POISONS BOOK

| Date of sale | Name and quantity of poison supplied | PURCHASER'S | | | 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 |
|---|---|---|---|---|---|---|---|---|
| | | Name | Address | Business trade or occupation | | | | |
| | | | | | | | | |

---

**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.<br>Proforma Invoice No.<br>Date: ..... Reference: ..... |
| IMPORTER'S BANK AND BRANCH: | TOTAL AMOUNT IN FOREIGN CURRENCY:<br>In Figures:<br>In Words:<br>Exchange rates:<br>Kenya Currency equivalent Sh. |
| SELLER'S FULL NAME AND ADDRESS: | APPLICABLE SCHEDULE: |
| | COUNTRY OF ORIGIN: |

SCHEDULE VIII—*continued*

| 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 |
|---|---|---|---|---|
| | | | | |

SCHEDULE VIII—*continued*

**FORM 18**

APPLICATION FOR PHARMACEUTICAL REPRESENTATIVE'S PERMIT

I/We .....,
of (postal address) .....,
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.

SCHEDULE VIII, Form 20—*continued*

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)

SCHEDULE VIII, Form 21—*continued*

*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 immediately.

---

**FORM 22**

LICENCE TO MANUFACTURE DRUGS FOR SALE

.....

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 .....

at .....

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<br>Port of discharge: | | | F.O.B. Value: | | | |
| Generic Name | Trade Name | Pack Size | Unit Price | Quantity | Batch No. | Country of Manufacture |
| | | | | | | |

SCHEDULE VIII, Form 23—*continued*

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 .....

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**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

---

SCHEDULE VIII—*continued*

**FORM 25**

ROLL OF PHARMACEUTICAL TECHNOLOGISTS

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

SCHEDULE VIII—*continued*

**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

---

SCHEDULE VIII—*continued*

**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

---

SCHEDULE VIII—*continued*

**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

SCHEDULE VIII , Form 31—*continued*

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 of ..... 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.

SCHEDULE VIII—*continued*

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 (CONTROL OF DRUGS) RULES, 1969

[L.N. 180/1969, L.N. 247/1969, L.N. 228/1974.]

**1.** These Rules may be cited as the Pharmacy and Poisons (Control of Drugs) Rules, 1969.

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

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

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

**5.** A 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

[L.N. 147/1981, L.N. 142/1991, L.N. 192/2010.]

## 1. Citation

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

## 2. Interpretation

In these Rules, **"drug"** means a 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, 2001.

[L.N. 192/2010, r. 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 provision of these Rules.

[L.N. 192/2010, r. 4.]

## 4. Application for registration of drug

(1) An application for registration of a drug shall be in Form 1 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.

[L.N. 142/1991, r. 2, L.N. 192/2010, r. 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 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 be in 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, r. 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 provision 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 subrule (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) the matters stated in the application on which the certificate of registration was granted were false or incomplete in a material particular;

(b) that a provision of the certificate 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; or

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

### 9. Conditions of registration of a new drug

(1) The Board shall, before registering a new drug for which the research work has been conducted in another 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 subrule (1), the Board may register a new drug and require the investigations and clinical trials specified in subrule (1) to be conducted after its registration.

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

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

**9A.** (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 in the manufacturing of the drug and make a report to the Board.

### 11. Offences and penalties

A 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 a fine and such imprisonment.

FIRST SCHEDULE

[L.N. 147/1981, L.N. 192/2010, r. 9.]

**FORM 1** **(r. 4)**

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 .....
5. (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:
   .....
   .....
   .....
   .....

FIRST SCHEDULE , FORM 1—*continued*

PART II

8. Pharmaceutical Formula of the Product

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

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 final 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.

FIRST SCHEDULE , FORM 1—*continued*

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.

---

SCHEDULE

**FORM 1A**

APPLICATION FOR RE-REGISTRATION OF A DRUG

(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 .....
   .....
4. (a) Therapeutic classification(s) .....
   .....
   .....
   (b) Specific indication(s).....
   .....
   .....

FIRST SCHEDULE, FORM 1A—*continued*

(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? .....

f yes, state the new changes .....

.....

.....

10. Have you made any other changes in quality control of finished products, analytical procedures and packaging specifications? .....

If yes, state new specifications .....

.....

.....

11. Provide recent (5-10 years) pharmacological, physiological, clinical, toxilocological and bioavailability 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;

FIRST SCHEDULE, FORM 1A—*continued*

(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) reapplication 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

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**FORM 2** **(r. 6.)**

PHARMACY AND POISONS (REGULATION OF DRUGS) RULES

REGISTRATION OF DRUGS CERTIFICATE

Number .....

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

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

[L.N. 192/2010, rr. 52(b), 9(1B).]

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, 1985

[L.N. 52/1985.]

**1.** These Rules may be cited as the Pharmacy and Poisons (Conduct of Inquiries) Rules, 1985.

**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 re-examined 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.

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SCHEDULE

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

[Rule 6(2).]

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

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**THE PHARMACY AND POISONS (PARALLEL IMPORTED MEDICINAL SUBSTANCES) RULES**

ARRANGEMENT OF RULES

*Rule*

# THE PHARMACY AND POISONS (PARALLEL IMPORTED MEDICINAL SUBSTANCES) RULES, 2019

[L.N. 126/2019.]

PART I — PRELIMINARY

## 1. Citation

These Rules may be cited as the Pharmacy and Poisons (Parallel Imported Medicinal Substances) Rules, 2019.

## 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, 2001 (No. 3 of 2001);

(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, (No. 17 of 2015);

(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, 2015 (No. 17 of 2015);

(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

(1) 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

**FORM 1**

[Rules 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 of parallel importation | | Renewal of certificate of parallel importation | | 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. 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**

[Rules 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 .....

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 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 .....

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**Form 3**

[Rule 11(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

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SECOND SCHEDULE

[Rules 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.

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THIRD SCHEDULE

[Rule 48.]

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.