By Permission
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GOVERNMENT OF PAKISTAN

THE

DRUGS ACT, 1940

(XXIII OF 1940)

(As modified up to the 20th September, 1964)

ALL PAKISTAN LEGAL DECISIONS
NABHA ROAD, LAHORE

LIST OF ABBREVIATIONS USED

A. 0., 1949	.....	*for* Adaptation of Central Acts and Ordinances Order, 1949 (G.G.O.No.4of 1949).
A. O., 1961	.....	*for* Central Laws (Adaptation) Order, 1961.
Art.		*for* Article.
Cls.	.....	*for* Clauses.
G. G. O.	.....	*for* Governor General's Order.
Govt.	.....	*for* Government.
N.-W.F. P.	.....	*for* North-West Frontier Province.
P.	.....	*for* Page.
Pt.	.....	*for* Part.
Rep.	.....	*for* Repealed.
S.	.....	*for* Section.
Sen.	.....	*for* Schedule.
Subs.	.....	*for* Substituted.

THE DRUGS ACT, 1940

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MISCELLANEOUS

'ACT NO. XXIII OF 1940

An Act to regulate the import, [2]|export,] manufacture, distribution and sale of drugs.

WHEREAS it is expedient to regulate the import into, ^export from,] and the manufacture, distribution and sale in, ^Pakistan] of dings ;

AND WHEREAS the Legislatures of all the Provinces have passed resolutions in terms of section 103 of the Government of India Act, 1935. in relation to such of the above-mentioned matters and matters ancillary thereto as are enumerated in List II of the Seventh Schedule to the said Act:

It is hereby enacted as follows:—

CHAPTER 1

INTRODUCTORY

Short title-, extern and commence-ment

1.—(1) This Act may be called the Drugs Act, 1940.

[5][(2) It extends to the whole of Pakistan].

(3) It shall come into force at once: but Chapter III shall take effect only from such [6]date as the Central Government may, by notification in the official Gazette, appoint in this behalf, and Chapter IV shall take effect in a particular

1 For Statement of Objects and Reasons, *see* Gazelle of India, 1940. Pt. V, p. 34 ; for Report of Select Committee, *see.ibidl.*. p 143.

This Act has been applied to: — (i) Baluchistan, *see* Notification No. I0X-N. dated the 17th October. 1940, Gazetle of India.

1940. Pt. I. p. 1478.

(ii) Phulera in the Excluded Area of Upper Tanawal to the extent the Act is applicable in the N.-W.F.P. and extended to the Excluded Area of Upper Tanawal (N.-W.F.P.) other than Phulera with effect from such date and subiecl lo such modifications as may be notified, *see* N.-W. F. P. (Upper Tanawal) (Excluded Area) Laws Regulation. 1950. This Acl has been extended to: -¦ (i) the Leased Areas of Baluchistan by Hie Leased Areas (Laws) Order. 1950 (G.G.O. 3 of

1950); (ii) the'Baluchistan States Union by the Baluchistan Stales Union (Federal Laws) (Extension)

Order. 1953 (G.G.O. 4 of 1953) ; din the Stale of Bahawalpur by the Bahawalpur (Extension of Federal Laws) Order. 1953

(G.G.t). I 1 of 1953). as amended ; (iv) the whole of **the** Province of Wesl Pakistan by the Wesl Pakistan Act 14 ot 1958. s. 2.

The Act has been and shall be deemed lo have Ken brought into force in Gwadur with effect from the 8th September. 1958 by the Gwadur (Application of Central Laws) Ordinance. 1960 (37 of I960), s. 2.

2 The word and comma "export." ins. by Act 22 ot 1963. s. 2.

3 The words and comma "export from," ins. *ihitl.*, s. 3.

4 Subs, by Ordinance No. 21 of 1960. s. 3 and Second Schedule, for the words "the Provinces and the Capital of the Federation" which were subs, by the A.O.. 1949. for "British India".

5 Subs, by Ordinance No. 21 of 1960, s. 3 and Second Sch.. for subsection (2) which was amended by the A.O., 1949.

6 The 1st April, 1947, as the dale from which Chapter III shall take effect, *see* Gazette of India. 1946. Pt. I. p. 1349.

Province only from such date as ihc Provincial Government may, by like notification, 'appoint in this behalf.

Application oi other laws not barred.

2. The provisions of this Act shall be in addition to, and not in derogation of, the Dangerous Drugs Act, 1930 and any other law for the time being in 1930 force.

Definitions.

3, In this Act, unless there is anything repugnant in the subject or context,—

(a) "the Board" means the Drugs Technical Advisory Board constituted under section 5;

[2][(b) 'drug' includes—

(i) all medicines for internal or external use of human beings or animals, and all substances intended to be used for or in the treatment, mitigation or prevention of diseases in human beings or animals, not being medicines and substances exclusively used or prepared for use in accordance with the ayurvedic, unani, homoeopathic or biochemic system of medicine,

- (ii) diagnostic, abortive and contraceptive substances, surgical ligatures, sutures, bandages, absorbent cotton, bacteriophages, adhesive plasters, gelatine capsules and antiseptic solutions,

(iii) such substances (other than food) intended to affect the structure or any function of (he human body or intended to be used for the destruction of vermins or insects which cause disease in human beings or animals,

(iv) any substance, mentioned as monograph in any of the editions of the British Pharmacopoeia or the British Pharmaceutical Codex or the United States Pharmacopoeia or the National Formulary of the United Stales or the International Pharmacopoeia, whether alone or in combination with any substance exclusively used in the unani, ayurvedic. homoeopathic or biochemic system of medicine and intended to be used for any of the purposes mentioned in sub-clauses (i). (ii) and (iii). and

tv) any other substance which the Central Government may, by notification in the official Gazette, declare to be a drug for the purposes of this Act];

'[(ba) 'to export' means to take out of Pakistan by sea, land or air;

I The 1st day of September 1964 was appointed as the dale on which Chapter IV shall take effect in Baluchistan, *.we* Gazette of Pakistan, 1954. Pi. I. p. 215.

: Subs, by Act No. 22 of 1 96}. s. 4. for clause (h. .1

Clauses (ha), (bb) and (be), ins. *ibid.*

(Chapter I.—Introductory. Chapter II.—The Drugs Technical Advisory Board, the Central Drugs Laboratory and the Drugs Consultative Committee)

(bb) 'licensing authority' means such authority as may be prescribed;

(be) 'manufacture' in relation to any drug includes any process or part or stage of process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug with a view to its sale and distribution, but does not include the compounding and dispensing or the packing of any drug in the ordinary course of retail business or on a prescription of a registered medical practitioner or dentist or of a veterinarian, and 'to manufacture' shall be construed accordingly;]

(c) "to import", with its grammatical variations and cognate expressions, means to bring into '[Pakistan];

(d) "patent or proprietary medicine" means a drug which is a remedy or prescription prepared for internal or external use of human beings or animals, and which is not for the time being recognised by the Permanent Commission on Biological Standardisation of the [2][World Health Organisation] or in the latest edition of the British Pharmacopoeia or (lie British Pharmaceutical Codex or any other pharmacopoeia authorised in this behalf by the Central Government after consultation with the Board:

(e) "prescribed" means prescribed by rules made under Chapter II or Chapter III [3][or Chapter IIIA) by the Central Government, or under Chapter IV by the Provincial Government.

Presumption as to poisonous substances.

4. Any substance specified as poisonous by rule made under Chapter III or Chapter IV shall be deemed to be a poisonous substance for the purposes of Chapter III or Chapter IV, as the case may be.

CHAPTER II

Tun DRUGS TECHNICAL ADVISORY BOARD, Tin-: CENTRAL DRUGS LABORATORY AND *nm* DRUGS CONSULTATIVE COMMITTEE

The Drugs Technical Advisory Bo aid

5.—(1) The Central Government shall, as soon as may be, constitute a Board (to be called the Drugs Technical Advisory Board) to advise the Central Government and the Provincial Governments on technical matters arising out of

1 Subs, by Ordinance No. 21 of 1960. s. 3 and Second Schedule (with effect from 14-10-1«>55) for the words "the Provinces and the Capital of the Federation" which were subs, by the A.O., 1949. for "British India".

2 Subs, by Act No. 22 of 1963. s. 4. for the words "League of Nations".

3 The words "or Chapter IIIA" ins. *ibid.*

the administration of this Act and to carry out the other functions assigned to it by this Act.

H(2) The Board shall consist of the following members, namely :— (i)

The Director General. Health, *ex officio.* who shall be Chairman:

(ii) The Director of the Central Government Bureau of Laboratories. Pakistan, *ex officio;*

(iii) The Director, Central Drugs Laboratory, *ex officio;*

(iv) The Head of the Pakistan Animal Husbandry Research Institute. *ex officio;* ¦

(v) One person directly connected with the administration of this Act to be nominated by the Central Government;

(vi) Two persons directly connected with the administration of this Act, one to be nominated by each Provincial Government:

(vii) Two persons holding the appointment of Government Analyst under this Act, one to be nominated by each Provincial Government;

(viii) One person to be nominated by the Central Government from amongst the professors of medicine serving in the medical colleges affiliated to universities in Pakistan;

(ix) One person to be nominated by the Central Government from amongst the pharmaceutical chemists recommended by the universities in Pakistan;

(x) One person to be elected by the Medical Council of Pakistan from amongst the professors of medicine serving in the medical colleges affiliated to universities in Pakistan:

(xi) One person belonging to pharmaceutical profession to be nominated by the Central Government: and

(xii) One person to be elected by the Central Council of the Pakistan Medical Association:

Provided that the members shall be so elected or nominated as to secure, as far as practicable, equality in the number of members belonging to each Province.

(2a) The meetings of the Board shall be held alternatively in Hast Pakistan and West Pakistan].

(3) The nominated and elected members of the Board shall hold office for three years but shall be eligible for re-nomination and re-election.

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1 Subs, by Act No. 22 of 1963. s. 5. lor subsection (2) which was successively amended by the A.O., 1949 and Act 26 of 1951.

(4) The Board may. subject to the previous approval of the Central Government, make 'bye-laws fixing a quorum and regulating its own procedure and the conduct of all business to be transacted by it.

(5) The Board may constitute sub-committees and may appoint to such sub committees for such periods, not exceeding three years, as it may decide, or temporarily for the consideration of particular matters, persons who are not members of the Board.

(6) The functions of the Board may be exercised notwithstanding any vacancy therein.

(7) The Central Government shall appoint a person to be Secretary of the Board and shall provide the Board with such clerical and other staff as the Central Government considers necessity.

The Central Drugs Laboratory.

6.—(1) The Central Government shall, as soon as may be, establish a Central Drugs Laboratory under the control of a Director to be appointed by the Central Government, to carry out the functions entrusted to it by this Act or any rules made under this Chapter:

Provided that, if the Central Government so prescribes, the functions of the Central Drugs Laboratory in respect of any drug or class of drugs shall be carried out at [2]lany -[1]*] prescribed Laboratory and the functions of **the** Director of the Central Dings Laboratory in respect of such drug or class of drugs shall be exercised by die Director of that [4]* * * Laboratory,[5]* * *.

(2) The Central Government may, alter consultation with the Board, make rules prescribing—

(a) the functions of the Central Drugs Laboratory;

[6]* * * * . * *

(d) the procedure for the submission to the said Laboratory under Chapter IV of samples of drugs for analysis or test, the forms of the Laboratory's reports thereon and the fees payable in respect of such reports;

(c) such other matters as may be necessary or expedient to enable the said Laboratory to carry out its functions :

(f) the matters necessary to be prescribed for the purposes of the proviso to subsection (1).

The Drugs Consultative Committee.

7.—(1) The Central Government may constitute an advisory committee to be called "the Drugs Consultative Committee" to advise the Central

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1 For the Drugs Technical Advisory Board Bye-laws. 1963, *see* Gazelle of Pakistan, 1963. Pt. I. p. 46')

2 Subs, by the AC. 1949, for "the Central Research Institute, Kasauli. or al any other".

3 The word "prescribed" omitted by the Federal Laws (Revision and Declaration) Act. 1951 (26 of 19M), s. 3 and Second Sell.

4 The words "institute or of that other" omitted by the A.O.. 1949.

5 The words "as the case may be" rep. by the Federal Laws (Revision and Declaration) Act. 19? 1 (26 ol 1951), s. 3 and Second Sell.

6 Clauses (b) and (c), omitted by Act No. 22 of 1963. s. 6.

Government, the Provincial Governments and the Drugs Technical Advisory Board on any matter tending to secure uniformity throughout ^Pakistan] in the administration of this Act.

(2) The Drugs Consultative Committee shall consist of two representatives of the Central Government to be nominated by that Government and one representative of each Provincial Government to be nominated by the Provincial Government concerned.

(3) The Drugs Consultative Committee shall meet when required to do so by the Central Government and shall have power to regulate its own procedure.

CHAPTER III

IMPORT OF DRUGS

Standards of quality.

8.—(1) For the purposes of this Chapter the expression "standard quality" when applied to a drug means that the drug complies with the standard set out in the Schedule.

(2) The Central Government, alter consultation with the Board and after giving by notification in the official Gazette not less than three months' notice of its intention so to do, may by a like notification add to or otherwise amend the Schedule for the purposes of this Chapter, and thereupon the Schedule shall be deemed to be amended accordingly.

Misbranded drugs.

9. For the purposes of this Chapter a drug shall be deemed to be misbranded—

(a)' if it is an imitation of, or substitute for, or resembles in a manner likely to deceive, another drug, or bears upon it or upon its label or container the name of another drug, unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

(b) if it purports to be the product of a place or country of which it is not truly a product; or

(c) if it is imported under a name which belongs to another drug; or

(d) if it is so coloured, coated, powdered or polished that damage is concealed, or if it is made to appear of better or greater therapeutic value than it really is; or

(e) if it is not labelled in the prescribed manner; or

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1 Subs, by Ordinance No, 21 of I960, s. 3 and Second Schedule (with effect from 14-10-55), for "the Provinces".

(f) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular; or

(g) if the label or container bears die name of an individual or company purporting to be the manufacturer or producer of the drug, which individual or company is fictitious or docs not exist.

Prohibition of import of certain drugs.

10. From such 'date as may be fixed by the Central Government by notification in the official Gazette in this behalf, no person shall import—

(a) any drug which is not of standard quality,

(b) any misbranded drug;

(c) any drug for the import of which a licence is prescribed, otherwise than under, and in accordance with, such licence;

(d) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof cither the uuc formula or list of ingredients contained in it in a manner readily intelligible to members of the medical profession [2]1* * *];

(e) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect, as may be prescribed;

(0 any drug the import of which is prohibited by rule made under this Chapter:

Provided that nothing in this section shall apply to the import, subject to prescribed conditions, of small quantities of any drug lor the purpose ol examination, test or analysis or for personal use:

Provided further that the Central Government may, alter consultation with the Board, by notification in the official Gazette, permit, subject to any conditions specified in the notification, the import of any drug or class of drugs not being of standard quality.

Explanation.—The formula or list of ingredients mentioned in clause (d) shall be deemed to be true and a sufficient compliance with that sub-clause if, without disclosing a full and detailed recipe of the ingredients, it indicates correctly all potent or poisonous substances contained therein together with an approximate statement of the composition of the medicine.

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1 The 1st April, 1947, for cls. (a), (h), (c), (e). and (f), *see* Gazette of India. 1947. Pt. I. p. 189; the 1st July 1950, for clause (d), *see* Gazette of Pakistan, 1950, Pt. I, p. 25.

2 The comma and words ", or the number of the certificate or registration granted in the prescribed manner in respect of such medicine by the Central Drugs Laboratory after being correctly informed of the formula of such medicine", omitted by Act No. 22 of 1963. s. 7.

Application oi" law relating to sea customs and powers of Customs officers.

11.—(1) The law for the lime being in force relating to sea customs and to goods, the import of which is prohibited by section 18 of the Sea Customs Act, 1878, shall, subject to the provision of section 13 of this Act, apply in respect of drugs the import of which is prohibited under this Chapter, and officers of Customs and officers empowered under that Act to perform the duties imposed thereby on a Customs Collector and other officers of Customs, shall have the same powers in respect of such drugs as they have for the time being in respect of such goods as aforesaid.

(2) Without prejudice to the provisions of subsection (1), the Customs Collector, or any servant of the [State] authorized by the Provincial government in this behalf, may detain any imported package which he suspects to contain any drug the import of which is prohibited under this Chapter, and shall forthwith report such detention to the Director of the Central Drugs Laboratory and, if required by him. forward the package or samples of any suspected drug found therein to the said Laboratory.

Power of Central Government to make rules.

12.—(1) The Central Government may, after consultation with the Board and after previous publication by notification in the official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter.

(2) Without prejudice to the generality of the foregoing power, such rules may-

(a) specify the drugs or classes of drugs for the import of which a licence is required, and prescribe the form and conditions of such licences, the authority empowered to issue the same, and the fees payable therefor;

(b) prescribe the methods of test or analysis to be employed in determining whether a drug is of standard quality.

(c) prescribe, in respect of biological and organo-metallic compounds, the units or methods of standardisation;

(d) specify the diseases or ailments which an imported drug may not purport or claim to cure or mitigate and such other effects which such drug may not purport or claim to have;

(e) prescribe the conditions subject to which small quantities of drugs, the import of which is otherwise prohibited under this Chapter, may be imported for the purpose of examination, test or analysis or for personal use;

(f) prescribe the places at which drugs may be imported, and prohibit their import at any other place;

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1 Subs. by the A.O.. 1%1. Art. 2 and Sell., (with effect from 2 ' -.' 1956) for "Crown".

(g) require the dale of manufacture and the dale of expiry of potency to be clearly and truly stated on the label or container of any specified imported drug or class of such drug, and prohibit the import of the said drug or class of drug after the expiry of a specified period from the date of manufacture;

(h) regulate the submission by importers, and the securing, of samples of drugs for examination, test or analysis by the Central Drugs Laboratory, and prescribe the lees, if any, payable for such examination, test or analysis;

(i) prescribe the evidence to be supplied, whether by accompanying documents for otherwise, of the quality of drugs sought to be imported, the procedure of officers of Customs in dealing with such evidence, and the manner of storage at places of import of drugs detained pending admission;

(j) provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter and the rules made thereunder of drugs imported for the purpose only of transport through, and export from, '[Pakistani;

(k) prescribe the conditions lo be observed in the packing in bottles, packages or other containers, of imported drugs;

(1) regulate the mode of labelling drugs imported for sale in packages, and prescribe the matters which shall or shall not be included in such labels;

(m) prescribe the maximum proportion of any poisonous substance which may be added to or contained in any imported drug, prohibit the import of any drug in which that proportion is exceeded, and specify substances which shall be deemed to be poisonous for the purposes of this Chapter and the rules made thereunder;

(n) require that the accepted scientific name of any specified drug shall be displayed in the prescribed manner on the label or wrapper of any imported, patent or proprietary medicine containing such drug;

(o) provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter or the rules made thereunder, of any specified drug or class of drugs.

Offences

13.—(1) Whoever contravenes any of the provisions of this Chapter or of any rule made thereunder shall, in addition to any penalty to which he may be liable under the provision of section 11, be punishable with imprisonment which

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1 Subs, by Ordinance No. 21 of 1060. s. 3 and Second Sell., for the words "the Provinces and the Capital of the Federation" which were subs, by the A.O.. 1049. for "British India."

may extend lo one year, or with line which may extend to live hundred rupees, or with both.

(2) Whoever, having been convicted under subsection (1), is again convicted under that subsection shall, in addition to any penalty as aforesaid, be punishable with imprisonment which may extend to two years, or with line which may extend to one thousand rupees, or with both.

Confiscation.

14. Where any offence punishable under section 13 has been committed, the consignment of the drug in respect of which the offence has been committed shall be liable to confiscation.

Jurisdiction.

15. No Court inferior to that of a ' * * * Magistrate of the first class shall try an offence punishable under section 13.

CHAPTER IIIA

EXPORT OF DRUGS

Prohibition of export of drugs without licence.

15A. From such date as may be fixed by the Central Government by notification in the official Gazette in this behalf, no person shall export any drug for the export of which a licence is prescribed, otherwise than under, and in accordance with, such licence :

Provided that nothing in this section shall apply to the export, subject to the prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis or for personal use.

Power of Central Government to make rules.

151$.—(1) The Central Government may, alter consultation with the Board and after previous publication by notification in the official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter.

(2) Without prejudice to the generality of the foregoing power, such rules may—

(a) specify the drugs or classes of drugs for the export of which a licence is required, and prescribe the form and conditions of such licences, the authority empowered to issue the same, and the fees payable therefor;

(b) prescribe the conditions subject to which small quantities of drugs, the export of which is otherwise prohibited under this Chapter, may be exported for the purpose of examination, test or analysis or for personal use;

(c) prescribe the places at which drugs may be exported, and prohibit their export at any other place;

(d) regulate the submission by exporters of samples of drugs for examination, test or analysis by the Central Drugs Laboratory, and

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1 The words "Presidency Magistrate or of a" omitted by the Pakistan Drugs Act Adaptation Order. 1948 (G.G.O. 5 of 1948), An. 3.

2 Chapter IIIA ins. by Act No. 22 of 1963. s. 8.

prescribe the fees, if any, payable for such examination, tesi or analysis;

(e) prescribe the evidence to be supplied, whether by documents or otherwise, of the quality of drugs sought to be exported.

15C. Whoever contravenes any of the provisions of section 15A or of any rule made under section 15B shall be punishable with fine which may extend to five thousand rupees.]

CHAPTER IV

MANUFACTURE, SALE AND DISTRIBUTION OF DRUGS

Standards of quality. the

16.—(1) For the purposes of this Chapter the expression "standard quality" when applied to a drug means that the drug complies with the standard set out in Schedule.

(2) The Provincial Government, after consultation with the Board and after giving by notification in the official daze-tie not less than three months notice of its intention so to do, may by a like notification add to or otherwise amend the Schedule for the purposes of this Chapter, and thereupon the Schedule shall be deemed to be amended accordingly.

Misbranded drugs

17. For the purposes of this Chapter a drug shall be deemed to be misbranded—

(a) if it is an imitation of, or substitute for, or resembles in a manner likely to deceive, another ding, or bears upon it or upon its label or container the name of another drug, unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug: or

(b) if it purports to be the product of a place or country of which il is not truly a product; or

(c) if it is sold, or offered or exposed for sale, under a name which belongs another drug; or

(d) if it is so coloured, coated or powdered or published that damage is concealed, or if it is made to appear of better or greater therapeutic value than it really is; or

(e) if it is not labelled in the prescribed manner: or

(f) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular, or

(g) if the label or container bears the name of an individual or company purporting to be the manufacturer or producer of the drug which individual or company is fictitious or does not exist.

Prohibition of manufacture and sale of certain drugs.

18. From such date as may be fixed by the Provincial Government by notification in the official Gazette in this behalf, no person shall himself or by any other person on his behalf—

(a) manufacture for sale, or sell, or stock or exhibit for sale, or distribute—

(i) any drug which is not of standard quality; (ii)

any misbranded drug;

'(iii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof either the true formula or list of ingredients contained in it in a manner readily intelligible to members of the medical profession [2][* * *1;

(iv) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect as may be prescribed;

(v) any drug, is contravention of any of the provisions of this Chapter or any rule made thereunder;

(b) sell, or stock, or exhibit for sale, or distribute any drug which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder;

^c) manufacture for sale, or sell, or stock or exhibit for sale, or distribute any drug, except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter:

Provided that nothing in this section shall apply to the manufacture, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis:

Provided further that the Provincial Government may. after consultation with the Board, by notification in the official Gazette, permit, subject to any conditions specified in the notification, the manufacture for sale, sale or distribution of any drug or class of drugs not being of standard quality.

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1 Tins sub-clause was brought into force in--
(i) the Capital of die Federation, with effect on and from die 1st July. 1953. *sec* Gazette of Pakistan. 1952. Pi. VI. p. 154.
(II) Sind. with effect from the 1st July. 1 <J53. *see* Sind Govt. Gazelle. 1952, Pt. I. p. 63X.
(iii) East Bengal, with effect on and from the 1st Jan.. 1955, *see* Dacca Gazette. 1951. Pi. I, p. 1218.
(iv) Punjab, with effect on and from (he 1st July. 1951. *see* Punjab Gazette, 1950, Pt. I. p. 372.

2 The commas and words, "or die number of the certificate of registration granted, in the manner prescribed by the Central Government, in respect of such medicine by the Central Drugs Laboratory after being correctly informed of the formula of such medicine" omitted by Act No. 22 of 1963. s. 9.

Explanation.— The formula or list of ingredients mentioned in sub-clause (iii) of clause (a) shall be deemed to be true and a sufficient compliance with that sub-clause if, without disclosing a lull and detailed recipe of the ingredients, it indicates correctly all the potent or poisonous substances contained therein together with an approximate statement of the composition of the medicine.

19.—(1) Save as hereinafter provided in this section, it shall be no defence picas, in a prosecution under this Chapter to prove merely that the accused was ignorant of the nature, substance or quality of the drug in respect of which the offence has been committed or of the circumstances of its manufacture or import, or that a purchaser, having bought only for the purpose of test or analysis, has not been prejudiced by the sale.

(2) For the purposes of section 18 a drug shall not be deemed to be misbranded or to be below standard quality only by reason of the fact that—

(a) there has been added thereto some innocuous substance or ingredient because the same is required for the manufacture or preparation of the drug as an article of commerce in a stale fit for carriage or. consumption, and not to increase the bulk, weight or measure of the drug or to conceal its inferior quality or other defects; or

(b) in the process of manufacture, preparation or conveyance some extraneous substance has unavoidably become intermixed with it: provided that this clause shall not apply in relation to any sale or distribution of the drug occurring alter the vendor or distributor became aware of such intermixture.

(3) A person, not being the manufacturer of a drug or his agent for the distribution thereof, shall not be liable for a contravention of section 18 if he proves—

(a) that he did not know, ;ind could not with reasonable diligence have ascertained, that the drug in any way contravened the provisions of that section, and that the drug while in his possession remained in the same state as when he acquired it; or

(b) that he acquired the drug from a person resident in '[Pakistan] under a written warranty in the prescribed form and signed by such person that the drug does not in any way contravene the provisions of section 18, and that the drug while in his possession remained in the same state as when he acquired it:

Provided that a defence under clause (b) shall be open to a person only— (i) if he has, within seven days of the service on him of the summons, sent to the Inspector a copy of the warranty with a written notice

1 Subs, by Ordinance No. 21 of I960, s. 3 and Second Soli., (with effect from 14-10-1955). for **tlii.**- words "the Provinces and (lie Capital of the Federation" which were .subs, by the A.O.. 1949, for "British India"

stating that he intends to rely upon it and giving the name and address of the warrantor, and

(ii) if he proves that he has, within the same period, sent written notice of such intention to the said warrantor.

Government Analysts.

20. The Provincial Government may, by notification in the official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysis for such areas and in respect of such drugs or classes of drugs as may be specified in the notification:

Provided that a servant of the '[State] serving under the Central Government or another Provincial Government shall not be so appointed without the previous consent of the Government under which he is serving.

Inspectors.

21.—(1) The Provincial Government may, by notification in the official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Inspectors for the purposes of this Chapter within such local limits as it may assign to them respectively:

Provided that no person who has any financial interest in the manufacture, import or sale of drugs shall be appointed to be an Inspector under this subsection.

(2) Every Inspector shall be deemed to be a public servant within the meaning of the Pakistan Penal Code, and shall be officially subordinate to such authority as the Provincial Government may specify in this behalf.

Powers of Inspectors

[2]22.—(1) Subject to the provisions of section 23 and of any rules made by the Provincial Government in this behalf, an Inspector may, within the local limits lor which he is appointed, and in any other area with tlie permission of the licensing authority,—

(a) inspect any premises wherein any drug is being manufactured, the plant and process of manufacture, tlie means employed for standardising and testing the drugs and all records and registers, relating thereto:

(b) inspect any premises wherein any drug is being sold or is stocked or exhibited for sale or is being distributed, the storage arrangement and all relevant records and registers:

(c) take samples of any drug which is being manufactured, or being sold or is slocked or exhibited for sale or is being distributed;

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1 Subs, by the A.O., 1961, Art. 2 and Sell., (with effect from 23-3-1956). for "Crown"
2 Subs, by Act No. 22 of 1963, s. 10. for the original section 22.

(d) enter and search at all reasonable times with, such assistance, it any. as he considers necessary, any building, vessel or place, in which he has reason to believe, from personal knowledge or from information given by any person and taken down in writing, that an offence under this Act or any rules made thereunder, has been or is being committed;

(e) seize such drug and all materials used in the manufacture thereof and all other articles including registers, cashmemos, invoices, bills which he has reason to believe may furnish evidence of the commission of an offence punishable under this Act and any rules made thereunder;

(0 call any person from the neighbourhood to be present as witness in course of search, seizure or in connection with, any other matter where the presence of witnesses is necessary;

(g) require any person to appear before him at any reasonable time at any proper place to give statement, assistance or information relating to, or in connection with the investigation of an offence under this Act or rules made thereunder:

Provided that the exemptions under sections 132 and 133 of the Code of Civil Procedure, 1908 (Act V of 1908), shall be applicable to requisitions for attendance under this clause;

(h) lock and seal any factory, laboratory, shop, building, storehouse or godown or a part thereof where any drug is, or is being. manufactured, stored, sold or exhibited for sale without the necessary licence under this Act, or where he has reason to believe that an offence under this Act has been committed or may continue to be committed;

(i) forbid for a reasonable period not exceeding three months any person in charge of any premises from removing or disposing of any drug, article or other thing likely to be used in evidence ol the commission of an offence under this Act or any rules made thereunder;

(j) exercise such other, powers as may be necessary for carrying out the purposes of this Act or any rules made thereunder.

(2) The provisions of the Code of Criminal Procedure, 1H98 (Act V of 1898), in so far as they are not inconsistent with the provisions of this Act, shall apply to searches and seizures made under this Chapter.

(3) If any person wilfully obstructs an Inspector in the exercise of the powers conferred upon him by or under this Chapter or disobeys the lawful

authority of an Inspector, he shall be punishable with imprisonment which may extend to three years, or with fine, or with both.]

[1] * * * * * *]

[2][(2) Where the Inspector seizes any drug or any other article under section 22, he shall tender a receipt therefore in the prescribed form).

(3) Where an Inspector takes a sample of a drug for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he wilfully absents himself, shall divide the sample into four portions ;md effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of (lie portions so sealed and marked:

Provided that where the sample is taken from premises whereon the drug is being manufactured, it shall be necessary to divide the sample into three portions only:

Provided further that where the drug is made up in containers of snuill volume, instead of dividing a sample as aforesaid, the Inspector may. and if the drug be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or tour, as the case may be. of the said containers after suitably marking the same and, where necessary, sealing them.

(4) The Inspector shall restore one portion of a sample so divided or one container, as the case may be. to the person from whom he takes it, and shall retain the remainder and dispose of the same as follows:—

(i) one portion or container he shall forthwith send to the Government Analyst for test or analysis: (ii) the second he shall produce to the Court before which proceedings, if any, are instituted in respect of the drug: and

(iii) the third, where taken, he shall send to the warrantor, it any. named under the proviso to subsection (3) of section 19.

(5) Where an Inspector takes any action under -'|* * *\ section 22,--

(a) he shall use all despatch in ascertaining whether or not the drug contravenes any of the provisions of section IS and. if it is ascertained that the drug docs not so contravene, forthwith revoke the order passed under the said [4][section] or, as the case may be, take such action as may be necessary for the return of the stock seized ;

(b) if he seizes the stock of the drug, he shall as soon as may be inform a Magistrate and take his orders as to the custody thereof:

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1 Subsection (I). omitted by Act No. 22 of l<)63. s. 11.

2 Subs, *ibid.,* for the original subsection (2).

3 The words "clause (c) of" omitted by Act No. 22 of 1%3, s. 11.

4 Subs. *ibul.* for "clause".

(c) without prejudice to the institution of any prosecution, it the alleged contravention be such that the defect may be remedied by the possessor of the drug, he shall, on being satisfied that the defect has been so remedied, forthwith revoke his order under the said [1]1 section].

Persons boun to disclose place where drugs are manufactured or kept.

24. Every person for the time being in charge of any premises whereon any drug is being manufactured or is kept for sale or distribution shall, on being required by an Inspector so to do, be legally bound to disclose to the Inspector the place where the drug is being manufactured or is kept, as the case may be.

Reports of Government Analysts.

25.—(1) The Government Analyst to whom a sample of any drug has been submitted for test or analysis under subsection (4) of section 23, shall deliver lo the Inspector submitting it a signed report in triplicate in the prescribed form

(2) The Inspector on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken and another copy lo the warrantor, if any, named under the proviso to subsection (3) of section I'), and shall retain the third copy for use in any prosecution in respect of the sample.

(3) Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence of the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken or the said warrantor has. within twenty-eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion ofihc report.

(4) Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under subsection (3) notified his intention of adducing evidence in controversion of a Government Analyst's report, the Court may. of its own motion or in its discretion at the request either of the complainant or the accused, cause the sample ol the drug produced before Ihe Magistrate under subsection (4) of section 23 lo be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by, or under the authority of. the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence ol Ihe facts staled therein.

(5) The cost of a lesl or analysis made by the Central Drugs Laboratory under subsection (4) shall be paid by the complainant or accused as the Court shall direct.

Purchaser of drug enabled to obtain test or analysis.

26. Any person shall, on application in the prescribed manner and on payment of the prescribed fee. be entitled to submit for test or analysis lo a Government Analyst any drug purchased by him and lo receive a report ol such test or analysis signed by the Government Analvst.

Subs, by Act No. 22 of l') 63 s. 11 for \ clause '.

Penalty for manufacture, sale, etc., of' drugs in contravention of this Chapter.

27. Whoever himself or by any other person on Iris behalf manufactures for sale, sells, stocks or exhibits for sale, or distributes any drug in contravention of any of the provisions ol this Chapter or any rule made thereunder shall be punishable with imprisonment which may extend to [three years or with fine], or with both.

Penalties for giving false warranty or misuse o! warranty.

28.—(1) Whoever in respect of any drug sold by him whether as principal or agent, gives to the purchaser a false warranty that the drug does not in any way contravene the provisions of section IX shall, unless he proves that when he gave the warranty he had good reason to believe the same to be true, be punishable with imprisonment which may extend to one year, or with line which may extend to five hundred rupees, or with both

(2) Whoever applies or permits to be applied to any thug sold, or stocked or exhibited for sale, by him. Whether on the container or label or in any other manner, a warranty given in respect of any oilier drug, shall be punishable with imprisonment which may extend to one year, or with line which may extend to five hundred rupees, or with both.

Penalty for use of Government Analyst's report for advertising.

29. Whoever uses any report of a test or analysis made by the Central Drugs Laboratory or by a Government Analyst, or any extract from such report for the purpose of advertising any drug, shall be punishable with fine which may extend to live hundred rupees.

Penalty for subsequent offences

-|30.—(I) Whoever, having been convicted of an offence under section 27, is again convicted of an offence under that section shall be punishable with imprisonment which may extend to live years, or with line, or with both.

(2) Whoever, having been convicted of an offence under section 28 or section 29. is again convicted ol an offence under either of those sections shall be punishable with imprisonment which may extend to two years, or with line, or with both.]

Confiscation.

31. Where any person has been convicted under this Chapter for contravening any such provision of this Chapter or any rule made thereunder as may be specified by rule made in this behalf the stock of the drug in respect of which the contravention has been made shall be liable to confiscation.

Cognisance of offences.

32.—(1) No prosecution under this Chapter shall be instituted except by an Inspector.

(2) No Court inferior to that of a [v]* * * Magistrate of the first class shall try an offence punishable under this Chapter.

Subs. h) Act No. 22 of I963. s. 12. for the words and commas "one year, or with line which may extend lo live hundred rupees.". Subs. *thttJ*. .for the original section 30.

The words "Presidency Magistrate or of a" omitted by the Pakistan Drugs Act Adaptation Order. 194X (G.G..O. 5 of 1948). Art. 3

(3) Nothing contained in this Chapter shall be deemed to prevent any person from being prosecuted under any other law lor any act or omission which constitutes an offence against this Chapter.

33. —(1) The Provincial Government may. alter consultation with the Board and alter previous publication by notification in the official Gazette, make 'rules for the purpose of giving effect to the provisions of this Chapter.

(2) Without prejudice lo the generality of the foregoing power, such rules may—

(a) provide for the establishment of laboratories for testing and analysing drugs;

(b) prescribe die qualifications and duties of Government Analysts and the qualifications of Inspectors;

(c) prescribe the methods of test or analysis lo be employed in determining whether a drug is of standard quality.

(d) prescribe, in respect of biological and organo-melallic compounds, the units or methods ol standardisation:

(e) prescribe the forms of licences for the manufacture for sale, for the sale and lor the distribution of drugs or any specified drug or class of drugs, the lorm of application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same and the lees payable therefor:

(f) specify the diseases or ailments which a drug may not purport or claim to cure or mitigate and such other effects which a drug may not purport or claim to have:

(g) prescribe the conditions subject lo which small quantities of drugs may be manufactured for the purpose of examination, test or analysis:

(h) require the date ol manufacture and the dale ol expiry ol potency to be clearly and truly slated on the label or container of any specified drug or class of drugs, and prohibit the sale, slocking or exhibition for sale, or distribution of the said drug or class of drugs after the expiry of a specified period from the dale of manufacture or alter the expiry (>l the dale of potency;

(i) prescribe the conditions lo be observed in the packing in hollies, packages and other containers of drugs, and prohibit the sale. slocking or exhibition for sale, or distribution of drugs packed in contravention of such conditions:

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1 For the West Pakistan Drugs Rules l958. framed under this section *sec* West Pakistan Gazette 1958 Ext. pp. 1255-56.

(j) Regulate the mode of labelling packed drugs, and prescribe the (halters which shall or shall not be included in such labels:

(k) prescribe the maximum proportion of any poisonous substance which may be added to or contained in any drug, prohibit the manufacture, sale -or stocking or exhibition for sale, or distribution of any drug in which that proportion is exceeded, and specify substances which shall be deemed to be poisonous for the purposes of this Chapter and the rules made thereunder;

(1) require that the accepted scientific name of any specified drug shall be displayed in the prescribed manner on the label or wrapper ol any patent or proprietary medicine containing such drug;

(in) prescribe the form of warranty referred (o in subsection (1) of section 19;

(n) regulate (he powers and dulies of Inspectors:

(o) prescribe the forms of report to be given by Government Analysts, and the manner of application for lest or analysis under section 26 and the fees payable therefor:

(p) specify the offences against this Chapter or any rule made thereunder in relation lo which the slock of the drug shall be liable to confiscation under section 31:

(q) provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter or the rules made thereunder, of any specified drug or class of drugs.

11+ * i. ‡ * v

CHAPTER V

MISCELLANEOUS

35. No patent or proprietary medicine or pharmaceutical specialty or any other medicine, whether allopathic, unani. ayurvedic, homoeopathic or biochemic, for the time being not recognised by the accepted pharmacopoeias. shall be offered for sale to the public or advertise for such sale, unless two sample thereof shall have been sent to the Director. Central Urug Laboratory, and the later shall have determined that the medicine or specialty is suitable or proper for use by the public.

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1. Section 34 omitted by Act No. 22 of 1963. s
2. Chapter V, added //.;,/.. s. 15.

Prohibition to sell drugs in public streets etc.

36. No person shall, in any public street, highway, footpath or park or on any public transport or conveyance, peddle, hawk or offer for sale or distribute free of charge any medicine of pharmaceutical speciality whether allopathic, unani, ayurvedic, homoeopathic or of any oilier description.

1'cnally.

37. Any person who contravenes any of the provisions of section 35 or section 36 shall be punishable with imprisonment which may extend to two years, or with fine, or with both.

Offences by companies, etc.

38. Where the person guilty of an offence under this Act is a company, corporation or firm every director, partner and officer of the company, corporation or firm with whose knowledge and consent the offence was committed shall be guilty of the like offence.

Powers to try offence summarily

39. Any Magistrate of the first class or any bench of Magistrates invested with the powers of a Magistrate of the first class empowered for the time being to try in a summary way the offences specified in subsection (1) of section 260 of the Code of Criminal Procedure, 1898 (Act V of 1898), may, on application in this behalf being made by the prosecution, try in accordance with die provisions contained in sections 262 to 265 of that Code, any such offence punishable under this Act and any rules made thereunder as may lie prescribed.

Special provision regarding imprisonment and line.

40. Notwithstanding anything contained in section 32 of the C<xle of Criminal Procedure, 1898 (Act V of 1898), it shall be lawful lor any Magistrate of the first class to pass any sentence authorised by this Act even if such sentence exceeds his powers under section 32 of that Code.

Protection to persons acting under this Act.

41. No suit, prosecution or other legal proceeding shall lie against any person for anything which is in good faith done or intended to be done under this Act or any rules made thereunder. |

THE SCHEDULE

(See sections 8 and 16)

Standards to be complied with by imported drugs and b\ drugs manufactured for sale, sold, stocked or exhibited for sale, or distributed.

Class of drug.	Standard to be complied with.
Patent or proprietary medicines...	The formula or list of ingredients displayed in the prescribed manner on the label or container. |* * *|.

I The commas and words, "or the formula disclosed to the Central Drugs laboratory, as the case may be" omitted by Act No. 22 of 1963. s. 16.

Class of drug.	Standard to be complied with.
2. Substances commonly known as vaccines. sera. toxins, loxoids. antitoxins, and antigens and biological products of such nature.	The standards maintained at the National Institute for Medical Research. London, and such further standards of strength, quality and purity as may be prescribed.
3. Vitamins,. hormones analogous products A. Such standards as my be prescribed.	The standards maintained at the National Institute for Medical Research. London, and such further standards of strength, quality and purity as may be prescribed. Substances (other than food) intended to affect the structure or any function *of* the human body or intended to be used for the destruction of vermins or insects which cause disease in human beings or animals.]
4. Other drugs.....	The standards of identity, purity and strength specified in the latest edition of the British Pharmacopoeia or the British Pharmaceutical Codex or any other prescribed pharmacopoeia, or adopted by the Permanent Commission on Biological Standardisation of the -[World Health Organisation.

Serial No, 3-A, ins. by Act No. 22 of 1963. s. 16.
Subs. Ibid., for the words "League of Nations".

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