An Act to regulate the import, export, manufacture, storage, distribution and sale of drugs

Preamble: Whereas it is expedient to regulate the import, export, manufacture, storage, distribution and sale of drugs:

It is hereby enacted as follows:--

CHAPTER V
Miscellaneous

43. Power of Federal Government to make rules: (1) Subject to section 44, the Federal Government may, by notification in the official Gazette, make rules for carrying out the purposes of this Act.

(2) In particular and without prejudice to the generality of the foregoing provision, such rules may--

(a) prescribe the functions of the Federal Drug Laboratory and any other laboratory set up under section 14 or specified under section 22 or section 33 and the procedure for the submission to any such laboratory 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 and such other matters as may be necessary for any such laboratory to perform its functions;

(b) prescribe specifications, including the strength, potency, purity, quality or other property, of any drug, and the methods of test or analysis to be employed in determining whether a drug is of required specifications:

(c) prescribe the maximum proportion of any poisonous or other substance which may be added to or contained in any drug, or extracted or omitted therefrom; prohibit the import, 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;
such licence may be issued, the person under whose signature the same be issued and the fees payable therefor; (h) require the date of manufacture and the date of expiry of potency to be clearly and truly stated on the label and container of any specified drug or class of drugs and prohibit the sale, stocking or exhibition for sale or distribution of the said drug or class of drugs after the expiry of a specified period from the date of manufacture or after the expiry date and prescribe the manner of disposal of such drug or class of drugs; (i) prescribe the conditions to be observed in the packing in bottles, packages and other containers of drugs and prohibit the sale, stocking or exhibition for sale or distribution of drugs packed in contravention of such conditions; (j) regulate the mode of packing and packaging, including its size, dimensions, fill and other specifications, the material used therefor and mode of labelling packed drugs and prescribe the matters which shall or shall not be included in such labels or on the leaflets accompanying the drugs; (k) require that the non-proprietary or chemical or accepted scientific name or the proprietary name of any specified drug or any ingredient thereof shall be displayed in the prescribed manner; (l) prescribe the requirements and conditions in respect of good practices in the manufacture and quality control of drugs; (m) prescribe conditions for distribution of samples for sales promotion of drugs; prescribe the procedure for introduction in Pakistan of a new drug; (o) prescribe terms and conditions of members of the Central Licensing Board and the Registration Board; (p) prescribe types of registration of drugs, the form of application for such registration, the conditions subject to which such registration may be granted, the manner of registration and post-registration and surveillance and deregistration of registered drugs and the fees payable therefor; (q) prescribe conditions for registration of importers, importers, wholesalers and distributors within Pakistan and any establishment within any foreign country engaged in the manufacture for export of a drug and prescribe conditions providing effective and adequate means, by arrangement with the Government of such foreign country or otherwise, to enable the licensing authority or the Registration Board to determine from time to time whether drugs manufactured in such establishment, if imported or offered for import into Pakistan, shall be refused admission where the public interest so requires; (r) prescribe the form of warranty for manufactured drugs; (s) specify offences in relation to which the stock of drugs, articles or things shall be liable to forfeiture under this Act; (t) prescribe the qualifications, and regulate the procedure for exercise of powers and performance of functions, of Federal Inspectors; (u) prescribe the laboratories to which the Federal Inspectors shall submit samples of drugs taken for the purpose of test and analysis and the form and procedure for submitting the report of such test and analysis and the fee payable therefor, where so required; (v) prescribe measures for securing and maintaining supplies of drugs at reasonable prices, conditions to be met in respect of manufacture, production, pricing, keeping, movement and disposal of drugs and to fix prices, commissions, discount of the manufacturer, wholesaler, distributor, retailer or any other dealer of drugs, to control giving of bonus in cash or kind or in any other manner to any of the said parties and for collecting or calling for any information, statistics, records or books with a view to regulating the matters aforesaid; (w) specify drugs which may be advertised and the conditions subject to which such drugs may be advertised; (x) prescribe conditions subject to which small quantities of drugs may be imported or manufactured or exported for the purpose of examination, test or analysis, clinical trial or personal use; and (y) prescribe any other matter which is to be, or may be, prescribed by the Federal Government. (3) The power to make rules conferred by this section shall, except on the first occasion of the exercise thereof, be subject to the condition of previous publication. 44. Power of the Provincial Government to make rules: (1) The Provincial Government may by notification in the official Gazette, make rules in respect of the following matters, namely :- (a) the establishment of laboratories for testing and analysing drugs; (b) the qualifications and the procedure, for exercise of powers and performance of functions of Provincial Inspectors; (c) the forms of reports to be given by Government Analysts and the manner of application for test or analysis and the fees payable therefor; (d) the conditions to regulate sale or storage or distribution of drugs or any specific drug or class of drugs; (e) the offences against this Act or any rule in relation to which the stock of drugs shall be liable to confiscation and destruction under this Act; (f) the forms of licences for the sale or distribution of drugs or any specified drug or class of drugs, the authority empowered to issue the same, the form of applications for such licences, the fees payable therefor and the condition subject to which such licences may be issued; (g) the procedure to be followed by the Provincial Quality Control Board; and any other matter which is to be or may be, prescribed by the Provincial Government. (2) The power to make rules conferred by this section shall, except on the first occasion of the exercise thereof, be subject to the condition of previous publication. 45. Repeal and savings: [(1) The Drugs Act, 1940 (XXIII of 1940), the Drugs (Generic Names) Act, 1972 (XXIV of 1972), and the Drugs Ordinance, 1976 (IV of 1976), are hereby repealed. (2)
Notwithstanding the repeal of the Drugs Act, 1940 (XIII of 1940), by sub-section (1),-- (a) any licence to manufacture for sale issued thereunder to any person, for the revalidation of which an application has already been made to the Central Licensing Board within the date specified by the Federal Government shall continue to be valid until orders are passed by the said Board in this behalf; (b) any licence for import or export of drugs issued thereunder to any person, shall, unless it expires earlier under the terms thereof, continue to be valid for such periods as the Federal Government, or as the case may be, the Provincial Government may by notification in the official Gazette, specify in this behalf: Provided that in case of drugs to be imported or exported licences may continue to be issued under the rules framed under the Drugs Act, 1940, till the rules under this Act are framed or, as the case may be, a date is fixed under sub-section (6) of section 7 in respect of drugs in the finished form ready for use. ">

(d) specify the drugs or classes of drugs for the import or export of which a licence is required, the testing of such drugs, and prescribe the form and conditions of such licences, the authority empowered to issue the same, and the fees payable therefor;  
(e) prescribe the places at which any specific drug or drugs may be imported, prohibit their import at any other place, and control their import through any specified agency;  
(f) prescribe the evidence to be supplied, whether by accompanying documents or 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;  
(g) prescribe the forms of licences for the manufacture for sale of drugs or any specified drugs or class of drugs, the form of application for such licences, the conditions subject to which such licence may be issued, the person under whose signature the same be issued and the fees payable therefor;  
(h) require the date of manufacture and the date of expiry of potency to be clearly and truly stated on the label and container of any specified drug or class of drugs and prohibit the sale, stocking or exhibition for sale or distribution of the said drug or class of drugs after the expiry of a specified period from the date of manufacture or after the expiry date and prescribe the manner of disposal of such drug or class of drugs;  
(i) prescribe the conditions to be observed in the packing in bottles, packages and other containers of drugs and prohibit the sale, stocking or exhibition for sale or distribution of drugs packed in contravention of such conditions;  
(j) regulate the mode of packing and packaging, including its size, dimensions, fill and other specifications, the material used therefor and mode of labelling packed drugs and prescribe the matters which shall or shall not be included in such labels or on the leaflets accompanying the drugs;  
(k) require that the non-proprietary or chemical or accepted scientific name or the proprietary name of any specified drug or any ingredient thereof shall be displayed in the prescribed manner;  
(l) prescribe the requirements and conditions in respect of good practices in the manufacture and quality control of drugs;  
(m) prescribe conditions for distribution of samples for sales promotion of drugs; prescribe the procedure for introduction in Pakistan of a new drug;  
(o) prescribe terms and conditions of members of the Central Licensing Board and the Registration Board;  
(p) prescribe types of registration of drugs, the form of application for such registration, the conditions subject to which such registration may be granted, the manner of registration and post-registration and surveillance and deregistration of registered drugs and the fees payable therefor;  
(q) prescribe conditions for registration of indentors, importers, wholesalers and distributors within Pakistan and any establishment within any foreign country engaged in the manufacture for export of a
drug and prescribe conditions providing effective and adequate means, by arrangement with the Government of such foreign country or otherwise, to enable the licensing authority or the Registration Board to determine from time to time whether drugs manufactured in such establishment, if imported or offered for import into Pakistan, shall be refused admission where the public interest so requires;

(r) prescribe the form of warranty for manufactured drugs;

(s) specify offences in relation to which the stock of drugs, articles or things shall be liable to forfeiture under this Act;

(t) prescribe the qualifications, and regulate the procedure for exercise of powers and performance of functions, of Federal Inspectors;

(u) prescribe the laboratories to which the Federal Inspectors shall submit samples of drugs taken for the purpose of test and analysis and the form and procedure for submitting the report of such test and analysis and the fee payable therefor, where so required;

(v) prescribe measures for securing and maintaining supplies of drugs at reasonable prices, conditions to be met in respect of manufacture, production, pricing, keeping, movement and disposal of drugs and to fix prices, commissions, discount of the manufacturer, wholesaler, distributor, retailer or any other dealer of drugs, to control giving of bonus in cash or kind or in any other manner to any of the said parties and for collecting or calling for any information, statistics, records or books with a view to regulating the matters aforesaid;

(w) specify drugs which may be advertised and the conditions subject to which such drugs may be advertised;

(x) prescribe conditions subject to which small quantities of drugs may be imported or manufactured or exported for the purpose of examination, test or analysis, clinical trial or personal use; and

(y) prescribe any other matter which is to be, or may be, prescribed by the Federal Government.

(3) The power to make rules conferred by this section shall, except on the first occasion of the exercise thereof, be subject to the condition of previous publication.

44. Power of the Provincial Government to make rules: (1) The Provincial Government may by notification in the official Gazette, make rules in respect of the following matters, namely :-

(a) the establishment of laboratories for testing and analysing drugs;
(b) the qualifications and the procedure, for exercise of powers and performance of functions of Provincial Inspectors;
(c) the forms of reports to be given by Government Analysts and the manner of application for test or analysis and the fees payable therefor;
(d) the conditions to regulate sale or storage or distribution of drugs or any specific drug or class of drugs;
(e) the offences against this Act or any rule in relation to which the stock of drugs shall be liable to confiscation and destruction under this Act;
(f) the forms of licences for the sale or distribution of drugs or any specified drug or class of drugs, the authority empowered to issue the same, the form of applications for such licences, the fees payable therefor and the condition subject to which such licences may be issued;
(g) the procedure to be followed by the Provincial Quality Control Board; and any other matter which is to be or may be, prescribed by the Provincial Government.

(2) The power to make rules conferred by this section shall, except on the first occasion of the exercise thereof, be subject to the condition of previous publication.

45, Repeal and savings : [(1) The Drugs Act, 1940 (XXIII of 1940), the Drugs (Generic Names) Act,
1972 (XXIV of 1972), and the Drugs Ordinance, 1976 (IV of 1976), are hereby repealed.

(2) Notwithstanding the repeal of the Drugs Act, 1940 (XII of 1940), by sub-section (1),--

(a) any licence to manufacture for sale issued thereunder to any person, for the revalidation of which an application has already been made to the Central Licensing Board within the date specified by the Federal Government shall continue to be valid until orders are passed by the said Board in this behalf;

(b) any licence for import or export or sale of drugs issued thereunder to any person, shall, unless it expires earlier under the terms thereof, continue to be valid for such periods as the Federal Government, or as the case may be, the Provincial Government may by notification in the official Gazette, specify in this behalf:

Provided that in case of drugs to be imported or exported licences may continue to be issued under the rules framed under the Drugs Act, 1940, till the rules under this Act are framed or, as the case may be, a date is fixed under sub-section (6) of section 7 in respect of drugs in the finished form ready for use.