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PROVINCIAL ASSEMBLY OF THE PUNJAB REPORT OF THE STANDING COMMITTEE ON HEALTH REGARDING THE PUNJAB DRUGS (AMENDMENT) BILL 2017 (BILL NO. 2 OF 2017)

The Punjab Drugs (Amendment) Bill 2017 (Bill No. 2 of 2017) was referred to the Standing Committee on Health on 23 January 2017. The Committee considered the Bill in its meeting held on 31 January 2017.

- 2. The following were present:-
 - 1. Mr Nishat Ahmed Khan Daha, MPA (PP-214) Chairman
 - 2. Mr Amjad Ali Javaid, MPA (PP-86) Member
 - 3. Dr Najma Afzal Khan, MPA (W-320) Member
 - 4. Dr Nausheen Hamid, MPA (W-356) Member
- 3. Mr Shahbaz Ahmad, Deputy Secretary, Primary and Secondary Healthcare Department and Mr Mohsin Bukhari, Deputy Director, Law and Parliamentary Affairs Department represented their Departments. Hafiz Muhammad Shafiq Adil, Special Secretary, Provincial Assembly of the Punjab functioned as Secretary to the Committee.
- 4. Mr Mohsin Bukhari, Deputy Director, Law and Parliamentary Affairs Department apprised the Committee about the aims and objects of the Bill. He stated that it was necessary further to amend the Drugs Act, 1976 (XXXI of 1976) in its application to the Province of the Punjab, inter alia, for coping with the increasing menace of spurious, adulterated and substandard drugs, for provision of quality drugs to the people by updating the enforcement mechanism and providing an operative and regular monitoring system and stricter penalties, and for ancillary matters in the manner hereinafter appearing. He stated that in consequence of the Constitution (Eighteenth Amendment) Act 2010, the subject of drugs/medicines was devolved to the Provinces on abolition of the concurrent legislative list of the Constitution. Accordingly, the Drugs Act, 1976 came within the legislative competence of the Provinces in terms of Article 142 (c) of the Constitution. It was imperative to strengthen the Provincial Institutions such as Provincial Quality Control Board, Chief Drugs Controller office and the Drugs Testing Laboratories in the Punjab. People of Punjab may not be exposed to the perils of spurious and substandard drugs. It was, therefore, essential to amend the Drugs Act, 1976 in order to cope with the emerging menace of spurious, adulterated, substandard, counterfeit and illegal drugs. The prime object of the proposed amendments in the Act ibid was to plug the loopholes in the existing provisions of the law and to enhance the punishments for the persons involved in the offences relating to spurious and substandard drugs. He requested the Committee that the Bill, as introduced, may be recommended to be passed by the Assembly.

5. The Committee after hearing the Members, having view point of the Administrative Department as well as Law and Parliamentary Affairs Department and discussing various points, unanimously decided to recommend that the Bill may be passed by the Assembly subject to the following amendments:-

AMENDMENTS IN THE BILL

(1) CLAUSE 1

in the marginal heading, after the word "title" comma and word ", extent" be added

(2) CLAUSE 4

- (i) in sub-clause (3), the word "make" occurring in line 3, be substituted by the word "frame":
- (ii) in sub-clause (4), in para (a) the word "the" occurring before the word "Act" in line 2, be substituted by the word "this";
- (iii) in para (b), (d) and (f), the word "this" occurring before the word "Act", be substituted by the word "the"; and
- (iv) sub-clause (6) be renumbered as sub-clause (5).

(3) CLAUSE 7

para (3) be substituted as under:-

"(3) in subsection (5), for the words "Government Analyst's report" occurring in line 2, the words "report of Government Analyst or of Notified Drgus Laboratory" be substituted; and after the words "Federal Government", the words "or the Provincial Government" shall be inserted."

(4) CLAUSE 9

in section 23B, the word "the" occurring before the word "Act" in line 6, be substituted by the word "this".

(5) CLAUSE 10

in section 27, in para (6), in subsection (5), in para (a), (c) and (d), the word "this" occurring before the word "Act" be substituted by the word "the".

(6) **CLAUSE 11**

in section 27A, the word "the" occurring before the word "Act" in line 2, be substituted by the word "this".

(7) CLAUSE 12

in section 28, in subsection (1), the word "lakhs" occurring in line 2. be substituted by the word "lakh".

Contd...P/3

(8) CLAUSE 13

in section 30:-

- (i) in the subsection (2), in para (c), the word "this" occurring before the word "Act", be substituted by the word "the"; and
- (ii) in subsection (2a), the word "this" occurring twice before the word "Act" in line 2, be substituted by the word "the".
- **6.** A copy of the Bill as introduced in the Assembly is at Annexure-A and a copy of the Bill as recommended by the Committee is at Annexure-B.

(MR NISHAT AHMED KHAN DAHA)

Chairman Standing Committee on Health

Lahore 31 January 2017

Lahore 31 January 2017

(RAI MUMTAZ HUSSAIN BABAR)

Secretary

(BILL AS INTRODUCED IN THE ASSEMBLY) PROVINCIAL ASSEMBLY OF THE PUNJAB

Bill No. 02 of 2017

THE PUNJAB DRUGS (AMENDMENT) BILL 2017

A BILL

further to amend the Drugs Act, 1976, in its application to Province of the Punjab, for control and eradication of spurious, adulterated and substandard drugs.

It is essential further to amend the Drugs Act, 1976 (XXXI of 1976), in its application to the Province of the Punjab, *inter alia*, for coping with the increasing menace of spurious, adulterated and substandard drugs, for provision of quality drugs to the people by updating the enforcement mechanism and providing an operative and regular monitoring system and stricter penalties, and for ancillary matters in the manner hereinafter appearing.

Be it enacted by Provincial Assembly of the Punjab as follows:

- 1. Short title and commencement.— (1) This Act may be cited as the Punjab Drugs (Amendment) Act 2017.
 - (2) It extends to whole of the Punjab.
 - (3) It shall come into force at once.
- 2. Amendment in section 3 of Act XXXI of 1976.— In the Drugs Act, 1976 (XXXI of 1976), for brevity cited as the Act, in section 3:
 - (i) after clause (s), the following new clause (sa) shall be inserted:
 - "(sa) "Notified Drugs Laboratory" means the drug testing laboratory notified by the Provincial Government under subsection (2) of section 15 of the Act;";
 - (ii) after clause (t), the following new clause (ta) shall be inserted:
 - "(ta) "Provincial Drugs Monitoring Team" means one or more Provincial Drugs Monitoring Team constituted under section 11B of the Act;";
 - (iii) for clause (zz), the following shall be substituted and inserted:
 - "(zd) "sub-standard drug" means a drug which is not of specifications;"; and
 - (ze) "professional member" means a person who is qualified for appointment as Inspector or Government Analyst and appointed by the Provincial Government in such manner and on such terms and conditions as may be prescribed."
- 3. Amendment in section 11 of Act XXXI of 1976.— In the Act, in section 11, in subsection (5):
 - (1) in clause (h), the word "and" shall be deleted;
 - (2) for clause (i), the following shall be substituted:
 - "(i) to specify, by general or special order, the drugs which may be sent for test and analysis to the Notified Drugs Laboratory for drug testing and analysis; and";

after clause (i), as amended, the following new clause (j) shall (3)be inserted:

to submit a monthly report of the decisions and "(i) activities to the Federal Government and the Provincial Government."; and

after subsection (6), the following new subsection (7) shall be (4)

inserted:

The Provincial Quality Control Board may constitute a committee or committees, consisting of the members of the Board and other persons including at least two professional members and delegate to the committee any of its powers and functions under subsection (5) for exercise within the specified area.".

Insertion of section 11B in Act XXXI of 1976.-In the Act, after section 11A, 4.

the following new sections 11B and section 11C shall be inserted:

"11B. Provincial Drugs Monitoring Teams.- (1) The Provincial Government may, by notification, constitute one or more Provincial Drugs Monitoring Team consisting of the Chairperson and members including at least two professional members on such terms and conditions as the Provincial Government may determine.

The Chairperson and members of the Provincial Drugs Monitoring Team shall hold office during the pleasure of the Provincial

Government.

The Provincial Drugs Monitoring Team shall, with the (3)approval of the Provincial Government and by notification in the official Gazette, make regulations to regulate the conduct of its business.

The Provincial Drugs Monitoring Team may -(4)

subject to subsection (6), exercise the powers of an

Inspector under the Act;

inspect any premises where any drug is being, or (b) is to be, manufactured or sold and, in addition to any other action under the Act, recommend to the appropriate authority for the cancellation or suspension of the licence to manufacture or sell drugs held by any person who is found to be contravening, or to have contravened, any of the provisions of this Act or the rules;

advise the Provincial Government on ways and (c) means to ensure the provision of quality drugs

to the people;

ascertain the names of such directors, partners (d) and employees of the company, corporation, firm or institution who are prima facie responsible for the commission of any offence under this Act or the rules and recommend to the appropriate authority action against such persons;

submit a monthly report of the recommendations (e) and activities to the Provincial Government; and

(f) perform such other functions under this Act or the rules as the Provincial Government may, by notification, assign.

The Provincial Drugs Monitoring Team shall exercise the powers of an Inspector in the presence of at least

one professional member."

11C. Independent inspection - (1) Subject to subsection (2), the Provincial Government may, on the recommendations of the Provincial Quality Control Board, engage the services of a consultant or a firm of consultants for independent inspection and evaluation of units for manufacture of drugs, distribution networks or sale-points as the Government may specify.

No person shall be engaged as consultant unless he is qualified to be appointed as an Inspector or Government Analyst and is an expert in the relevant field and no firm shall be so engaged unless it has inhouse capacity for the task and has in its service persons who are qualified to be appointed as Inspectors or Government Analysts and

are experts in the relevant field

The consultant or the firm of consultants shall submit the report to the Provincial Quality Control Board within the specified time and the Board shall take necessary action on the report in accordance with law

- For purposes of inspection and evaluation, the consultant or the experts engaged by the firm of consultants shall have the powers of an Inspector.
- Amendment in section 15 of Act XXXI of 1976.- In the Act, for section 15, 5. the following shall be substituted:

"15. Provincial Drugs Testing Laboratory.- (1) The Provincial Government shall, as soon as may be, set up one or more Provincial Drugs Testing Laboratory for such purposes as may be prescribed.

The Provincial Government may, by notification, engage or authorize a reputed drugs testing laboratory, within the country or abroad, for test and analysis of the drug samples."

Amendment in section 19 of Act XXXI of 1976.- In the Act, in section 19, in subsection (3), for clause (i), the following shall be substituted:

- one portion or sample he shall send to the Government Analyst or, if so specified by the Provincial Quality Control Board, to the Board for sending it to the Notified Drugs Laboratory.".
- Amendments in section 22 of Act XXXI of 1976.- In the Act, in section 22: 7.
 - in subsection (2), after the words "any other laboratory", the words "or the Notified Drugs Laboratory" shall be inserted:
 - (2) in subsection (4):
 - after the words "Government Analyst", the words "or the Notified Drugs Laboratory" shall be inserted;

for the words "thirty days", the words "ten days" (ii) shall be substituted; and

in subsection (5), after the words "Federal Government", (3)the words "or the Provincial Government" shall be inserted.

Insertion of section 22A in Act XXXI of 1976.- In the Act, after section 22,

the following new section 22A shall be inserted:

"22A. Reports of the Notified Drugs Laboratories.- (1) The Notified Drugs Laboratory shall submit its report to the Chairperson of the Provincial Quality Control Board.

(2) The provisions of section 22 of the Act shall as far as may be,

apply to the report of a Notified Drugs Laboratory.

The Board shall take necessary action on the report in accordance with the Act and the rules."

Insertion of sections 23A, 23B and 23C in Act XXXI of 1976.- In the Act, after section 23, the following new sections 23A, 23B & 23C shall be inserted:

"23A. Prohibition on aiding, abetment or association in contravention of the Act.- No one shall participate in, associate or conspire to commit, or attempt to commit, aid, abet, facilitate, incite, induce or counsel the commission of an offence punishable under this

23B. Prohibition of acquisition and possession of assets derived

from contravention of the Act - No person shall knowingly:

- possess, acquire, use, convert, assign or transfer any assets which have been derived, generated or obtained, (a) directly or indirectly, either in his own name or in the name of his associates, relative or any other person through an act or omission which contravenes any of the prohibitions contained in section 23 of the Act;
- hold or possess on behalf of any other person any assets (b) referred to in clause (a); and
- conceal or disguise the true nature, source, location, disposition, movement, title or ownership of such assets (c) by making false declaration in relation thereto.
- 23C. Prohibition on owning, operating premises or machinery for manufacture of drugs, etc. - No one shall own, manage, operate or control any premises, place, equipment or machinery for purposes of manufacture of any drugs save in accordance with the conditions of a valid and extant licence issued by the Licensing Authority."
- Amendments in section 27 of Act XXXI of 1976.— In the Act, in section 27: 10.
 - for subsection (1), the following shall be substituted: "(1) Whoever himself or by any other person on his behalf:

- (a) exports, imports, manufactures or sells any spurious drug or adulterated drug or any drug which is not registered;
- (b) manufactures for sale any drug without a licence;
- (c) manufactures, transports or sells a temperature sensitive drug in conditions which are likely to cause the drug to lose its potency; or
- (d) imports without licence any drug for the import of which a licence is required -

shall be punished with imprisonment which may extend to ten years but which shall not be less than three years and with fine which may extend to fifty million rupees but which shall not be less than twenty five million rupees.";

- in subsection (2), for the expression "or with fine which may extend to one lakh rupees, or both", the expression "but which shall not be less than two years and with fine which may extend to ten million rupees but which shall not be less than three million rupees" shall be substituted;
- in subsection (3), for the expression "one year, or with fine which may extend to ten thousand rupees, or with both", the expression "one year but which shall not be less than fourteen days and with fine which may extend to one million rupees but which shall not be less than five hundred thousand rupees" shall be substituted;
- (4) after subsection (3), as amended, the following new subsections (3a), (3b) and (3c) shall be inserted:
 - "(3a) Whoever himself or by any other person on his behalf, exports, imports, manufactures for sale or sells any substandard drug shall be punishable with imprisonment for a term which may extend to five years but which shall not be less than six months and with fine which may extend to fifty million rupees but which shall not be less than ten million rupees.";
 - (3b) Whoever himself or by any other person contravenes the provisions of section 23B shall be punishable with imprisonment which may extend to ten years but which shall not be less than three years and with fine which shall not be less than the prevailing value of the assets and such assets shall also be liable to forfeiture to the Provincial Government.
 - (3c) Whoever himself or by any other person contravenes the provisions of section 23C shall be punishable with imprisonment which may extend to fourteen years but which shall not be less than five years and with fine which shall not be less than the prevailing value of the assets and such assets shall also be liable to forfeiture to the Provincial Government.
- (5) for subsection (4), the following shall be substituted:

- "(4) Subject to the provisions of subsections (1), (2), (3), (3a), (3b) and (3c), whoever himself or by any other person on his behalf contravenes any of the provisions of this Act or the rules shall be punishable with imprisonment for a term which may extend to five years but which shall not be less than thirty days and with fine which may extend to five million rupees but which shall not be less than five hundred thousand rupees."; and
- (6) after subsection (4), the following new subsection (5) shall be inserted:

"(5) If a Provincial Inspector or an official of the Provincial Drugs Testing Laboratory:

- (a) is guilty of any willful breach or neglect of any provisions of this Act or the rules or any order which he is bound to observe and obey;
- (b) is guilty of dereliction of duty;
- (c) extends any assistance to any person in contravention of this Act or the rules; or
- (d) abets the contravention of any provisions of this Act or the rules shall, without prejudice to any other action in accordance with law, be liable to imprisonment for a term which may extend to three years but which shall not be less than six months and with fine which may extend to one million rupees but which shall not be less than one hundred thousand rupees."
- **11. Insertion of section 27A in Act XXXI of 1976.** In the Act, after section 27, as amended, a new section 27A shall be inserted:

"27A. False statement.— When any person is required under the Act to prepare a report, make a statement or furnish an information, prepares the report or makes the statement or furnishes the information which is false in any material particular and which he knows or has reasonable cause to believe to be false, or does not believe to be true, shall be punishable with imprisonment for a term which may extend to three years but which shall not be less than six months and with fine which may extend to one million rupees but which shall not be less than one hundred thousand rupees."

- 12. Amendments in section 28 of Act XXXI of 1976.— In the Act, in section 28:
 - in subsection (1), for the expression "five years and with fine which may extend to two lakhs rupees", the expression "ten years and with fine which may extend to one hundred million rupees but which shall not be less than fifty million rupees" shall be substituted;

(2) in subsection (2), for the expression "which shall not to be less than two years or more than ten years, or with fine which may extend to two lakh rupees, or with both", the expression "which may extend to ten years but which shall not be less than five years and with fine which may extend to seventy million rupees but which shall not be less than thirty million rupees" shall be substituted;

(3) after subsection (2), the following new subsection (2a)

shall be inserted:

"(2a) Whoever having been convicted of an offence under subsection (3a) of section 27 is convicted for a subsequent offence under that subsection shall be punishable with imprisonment for a term which may extend to seven years but which shall not be less than two years and with fine which may extend to seventy five million rupees but which shall not be less than twenty five million rupees."; and

(4) in subsection (3), for the expression "seven years, or with fine which may extend to one lakh rupees or with both", the expression "ten years but which shall not be less than ninety days and with fine which may extend to ten million rupees but which shall not be less than one million

rupees.".

13. Amendment in section 30 of Act XXXI of 1976.— In the Act, in section 30, for subsection (2), the following shall be substituted:

Notwithstanding anything contained in the Code of

Criminal Procedure, 1898 (V of 1898):

(a) an offence punishable under subsection (1) of section 27 shall be cognizable and non-bailable;

- (b) an offence other than the offence mentioned in subsection (1) of section 27, shall be cognizable on the complaint of the Provincial Quality Control Board or the Provincial Drugs Monitoring Team; and
- (c) all offences under this Act shall be non-bailable.
- (2a) No court other than a Drug Court established under this Act shall try an offence punishable under this Act.".
- 14. Amendment in section 31 of Act XXXI of 1976.— In the Act, in section 31:

(1) for subsection (2), the following shall be substituted:

- "(2) A Drug Court shall consist of the Chairperson who is or has been, or is qualified for appointment as a Judge of High Court, and one full-time member who is an expert in the medical field and another full-time member who is an expert in pharmaceutical field."; and
- (2) subsection (7) and subsection (8) shall be omitted.
- 15. Insertion of section 31A in Act XXXI of 1976.— In the Act, after section 31, the following new section 31A shall be inserted:

- "31A. Appeal.— (1) The Provincial Government or the person sentenced by a Drug Court may, within sixty days, file an appeal against the final order of the Drug Court to Lahore High Court and the appeal shall be heard by a Bench of that Court consisting of not less than two Judges.
- (2) The Drug Court shall, as soon as possible, supply copies of the final order to the parties free of cost.
- (3) The provisions of sections 5 and 12 of the Limitation Act, 1908 (IX of 1908) shall be applicable to an appeal under this section."
- 16. Insertion of section 41A of Act XXXI of 1976.— In the Act, after section 41, the following new section 41A shall be inserted:
 - "41A. Suspension of license by Provincial Quality Control Board.—
 (1) Notwithstanding anything in section 41, the Provincial Quality Control Board may, subject to the conditions mentioned in that section, and after affording an opportunity of hearing to the manufacturer and recording detailed reasons including the grounds of suspension, suspend the manufacturing license of a manufacturer within the Punjab for such period not exceeding thirty days as the Board may determine and shall, as soon as may be, report the matter to the Central Licensing Board for such action as the Board may deem appropriate.
 - (2) A copy of the order under subsection (1) shall immediately be supplied to the manufacturer, requiring him to take appropriate remedial measures.
 - (3) The manufacturer shall take remedial measures and shall request the Provincial Quality Control Board for an immediate inspection of the unit, and the Board shall promptly arrange an inspection.
 - (4) If the Board is satisfied that the grounds leading to the suspension of the licence have been remedied, it shall restore the licence of the manufacturer and report the matter to the Central Licensing Board but if the Board is not so satisfied, it may require the manufacturer to take the remaining remedial measures.
 - (5) Notwithstanding anything in subsection (3) or subsection (4), the Board shall arrange inspection of the Unit for manufacture of drugs at five days prior to the expiry of the period of suspension and if it is of the view that sufficient remedial steps have not been taken, the Board may, from time to time and after recording reasons, extend the period of suspension up to the maximum period of ninety days in all.
 - (6) If the manufacturer does not take effective remedial steps during the period or extended period of suspension of the licence, the Board shall refer the matter to the Central Licensing Board for immediate cancellation of the manufacturing licence.
 - (7) Any manufacturer aggrieved by the order of suspension may, within seven days from the receipt of the order, prefer an appeal to the appellate authority as notified by the Government and the appellate authority shall dispose of the appeal maximum within seven days."

17. Insertion of section 43A of Act XXXI of 1976.— In the Act, after section 43, the following new section 43A shall be inserted.

"43A. Power to delegate.— (1) The Provincial Government may, subject to such conditions as it may determine, delegate any of its functions to the Provincial Quality Control Board or to any other person or authority.

(2) The Provincial Quality Control Board may, subject to such conditions as it may determine, delegate any of its functions and powers under this Act or the rules to the Monitoring Committee or any other person or authority."

STATEMENT OF OBJECTS AND REASONS

In consequence of the Constitution (Eighteenth Amendment) Act 2010, the subject of drugs/medicines was devolved to the provinces on abolition of the concurrent legislative list of the Constitution. Accordingly, the Drugs Act, 1976 came within the legislative competence of the provinces in terms of Article 142 (c) of the Constitution. It is imperative to strengthen the provincial institutions such as Provincial Quality Control Board, Chief Drugs Controller office and the Drugs Testing Laboratories in the Punjab. People of the Punjab may not be exposed to the perils of spurious and substandard drugs. It is, therefore, essential to amend the Drugs Act, 1976 in order to cope with the emerging menace of spurious, adulterated, substandard, counterfeit and illegal drugs. The prime object of the proposed amendments in the Act ibid is to plug the loop holes in the existing provisions of the law and to enhance the punishments for the persons involved in the offences relating to spurious and substandard drugs. Hence this Bill.

MINISTER INCHARGE

Lahore: 23 January 2017 RAI MUMTAZ HUSSAIN BABAR Secretary

ANNEXURE-B

(BILL AS RECOMMENDED BY THE STANDING COMMITTEE ON HEALTH)

A BILL

further to amend the Drugs Act, 1976, in its application to Province of the Punjab, for control and eradication of spurious, adulterated and substandard drugs.

It is essential further to amend the Drugs Act, 1976 (XXXI of 1976), in its application to the Province of the Punjab, *inter alia*, for coping with the increasing menace of spurious, adulterated and substandard drugs, for provision of quality drugs to the people by updating the enforcement mechanism and providing an operative and regular monitoring system and stricter penalties, and for ancillary matters in the manner hereinafter appearing.

Be it enacted by Provincial Assembly of the Punjab as follows:

- 1. Short title, extent and commencement.— (1) This Act may be cited as the Punjab Drugs (Amendment) Act 2017.
 - (2) It extends to whole of the Punjab.
 - (3) It shall come into force at once.
- 2. Amendment in section 3 of Act XXXI of 1976.— In the Drugs Act, 1976 (XXXI of 1976), for brevity cited as the Act, in section 3:
 - (i) after clause (s), the following new clause (sa) shall be inserted:
 - "(sa) "Notified Drugs Laboratory" means the drug testing laboratory notified by the Provincial Government under subsection (2) of section 15 of the Act;";
 - (ii) after clause (t), the following new clause (ta) shall be inserted:
 - "(ta) "Provincial Drugs Monitoring Team" means one or more Provincial Drugs Monitoring Team constituted under section 11B of the Act;";
 - (iii) for clause (zz), the following shall be substituted and inserted:
 - '(zd) "sub-standard drug" means a drug which is not of specifications;"; and
 - (ze) "professional member" means a person who is qualified for appointment as Inspector or Government Analyst and appointed by the Provincial Government in such manner and on such terms and conditions as may be prescribed.".
- 3. Amendment in section 11 of Act XXXI of 1976.— In the Act, in section 11, in subsection (5):
 - (1) in clause (h), the word "and" shall be deleted;
 - (2) for clause (i), the following shall be substituted:
 - (i) to specify, by general or special order, the drugs which may be sent for test and analysis to the Notified Drugs Laboratory for drug testing and analysis; and";
 - (3) after clause (i), as amended, the following new clause (j) shall be inserted:

- "(j) to submit a monthly report of the decisions and activities to the Federal Government and the Provincial Government."; and
- (4) after subsection (6), the following new subsection (7) shall be inserted:
 - "(7) The Provincial Quality Control Board may constitute a committee or committees, consisting of the members of the Board and other persons including at least two professional members and delegate to the committee any of its powers and functions under subsection (5) for exercise within the specified area."
- 4. Insertion of section 11B in Act XXXI of 1976.—In the Act, after section 11A, the following new sections 11B and section 11C shall be inserted:
 - **"11B. Provincial Drugs Monitoring Teams.—** (1) The Provincial Government may, by notification, constitute one or more Provincial Drugs Monitoring Team consisting of the Chairperson and members including at least two professional members on such terms and conditions as the Provincial Government may determine.
 - (2) The Chairperson and members of the Provincial Drugs Monitoring Team shall hold office during the pleasure of the Provincial Government.
 - (3) The Provincial Drugs Monitoring Team shall, with the approval of the Provincial Government and by notification in the official Gazette, <u>frame</u> regulations to regulate the conduct of its business.
 - (4) The Provincial Drugs Monitoring Team may -
 - (a) subject to subsection (6), exercise the powers of an Inspector under this Act;
 - (b) inspect any premises where any drug is being, or is to be, manufactured or sold and, in addition to any other action under the Act, recommend to the appropriate authority for the cancellation or suspension of the licence to manufacture or sell drugs held by any person who is found to be contravening, or to have contravened, any of the provisions of the Act or the rules;
 - advise the Provincial Government on ways and means to ensure the provision of quality drugs to the people;
 - (d) ascertain the names of such directors, partners and employees of the company, corporation, firm or institution who are *prima facie* responsible for the commission of any offence under the Act or the rules and recommend to the appropriate authority action against such persons;
 - (e) submit a monthly report of the recommendations and activities to the Provincial Government; and

(f) perform such other functions under the Act or the rules as the Provincial Government may, by notification, assign.

(5) The Provincial Drugs Monitoring Team shall exercise the powers of an Inspector in the presence of at least

one professional member."

11C. Independent inspection.— (1) Subject to subsection (2), the Provincial Government may, on the recommendations of the Provincial Quality Control Board, engage the services of a consultant or a firm of consultants for independent inspection and evaluation of units for manufacture of drugs, distribution networks or sale-points as the Government may specify.

- (2) No person shall be engaged as consultant unless he is qualified to be appointed as an Inspector or Government Analyst and is an expert in the relevant field and no firm shall be so engaged unless it has inhouse capacity for the task and has in its service persons who are qualified to be appointed as Inspectors or Government Analysts and are experts in the relevant field.
- (3) The consultant or the firm of consultants shall submit the report to the Provincial Quality Control Board within the specified time and the Board shall take necessary action on the report in accordance with law.
- (4) For purposes of inspection and evaluation, the consultant or the experts engaged by the firm of consultants shall have the powers of an Inspector.
- **5.** Amendment in section 15 of Act XXXI of 1976.— In the Act, for section 15, the following shall be substituted:

"15. Provincial Drugs Testing Laboratory.— (1) The Provincial Government shall, as soon as may be, set up one or more Provincial Drugs Testing Laboratory for such purposes as may be prescribed.

(2) The Provincial Government may, by notification, engage or authorize a reputed drugs testing laboratory, within the country or abroad, for test and analysis of the drug samples."

6. Amendment in section 19 of Act XXXI of 1976.—In the Act, in section 19, in subsection (3), for clause (i), the following shall be substituted:

- "(i) one portion or sample he shall send to the Government Analyst or, if so specified by the Provincial Quality Control Board, to the Board for sending it to the Notified Drugs Laboratory."
- 7. Amendments in section 22 of Act XXXI of 1976.— In the Act, in section 22:
 - (1) in subsection (2), after the words "any other laboratory", the words "or the Notified Drugs Laboratory" shall be inserted:
 - (2) in subsection (4):
 - (i) after the words "Government Analyst", the words "or the Notified Drugs Laboratory" shall be inserted;

- (ii) for the words "thirty days", the words "ten days" shall be substituted; and
- in subsection (5), for the words "Government Analyst's report" occurring in line 2, the words "report of Government Analyst or of Notified Drgus Laboratory" be substituted; and after the words "Federal Government", the words "or the Provincial Government" shall be inserted.
- **8. Insertion of section 22A in Act XXXI of 1976.** In the Act, after section 22, the following new section 22A shall be inserted:
 - **"22A. Reports of the Notified Drugs Laboratories.** (1) The Notified Drugs Laboratory shall submit its report to the Chairperson of the Provincial Quality Control Board.
 - (2) The provisions of section 22 of the Act shall as far as may be, apply to the report of a Notified Drugs Laboratory.
 - (3) The Board shall take necessary action on the report in accordance with the Act and the rules."
- 9. Insertion of sections 23A, 23B and 23C in Act XXXI of 1976.— In the Act, after section 23, the following new sections 23A, 23B & 23C shall be inserted:
 - "23A. Prohibition on aiding, abetment or association in contravention of the Act.— No one shall participate in, associate or conspire to commit, or attempt to commit, aid, abet, facilitate, incite, induce or counsel the commission of an offence punishable under this Act.
 - 23B. Prohibition of acquisition and possession of assets derived from contravention of the Act. No person shall knowingly:
 - (a) possess, acquire, use, convert, assign or transfer any assets which have been derived, generated or obtained, directly or indirectly, either in his own name or in the name of his associates, relative or any other person through an act or omission which contravenes any of the prohibitions contained in section 23 of this Act;
 - (b) hold or possess on behalf of any other person any assets referred to in clause (a); and
 - (c) conceal or disguise the true nature, source, location, disposition, movement, title or ownership of such assets by making false declaration in relation thereto.
 - 23C. Prohibition on owning, operating premises or machinery for manufacture of drugs, etc...—No one shall own, manage, operate or control any premises, place, equipment or machinery for purposes of manufacture of any drugs save in accordance with the conditions of a valid and extant licence issued by the Licensing Authority."
- 10. Amendments in section 27 of Act XXXI of 1976.— In the Act, in section 27:
 - (1) for subsection (1), the following shall be substituted:"(1) Whoever himself or by any other person on his behalf:

- (a) exports, imports, manufactures or sells any spurious drug or adulterated drug or any drug which is not registered;
- (b) manufactures for sale any drug without a licence;
- (c) manufactures, transports or sells a temperature sensitive drug in conditions which are likely to cause the drug to lose its potency; or
- (d) imports without licence any drug for the import of which a licence is required -

shall be punished with imprisonment which may extend to ten years but which shall not be less than three years and with fine which may extend to fifty million rupees but which shall not be less than twenty five million rupees.";

- in subsection (2), for the expression "or with fine which may extend to one lakh rupees, or both", the expression "but which shall not be less than two years and with fine which may extend to ten million rupees but which shall not be less than three million rupees" shall be substituted;
- in subsection (3), for the expression "one year, or with fine which may extend to ten thousand rupees, or with both", the expression "one year but which shall not be less than fourteen days and with fine which may extend to one million rupees but which shall not be less than five hundred thousand rupees" shall be substituted;
- (4) after subsection (3), as amended, the following new subsections (3a), (3b) and (3c) shall be inserted:
 - "(3a) Whoever himself or by any other person on his behalf, exports, imports, manufactures for sale or sells any substandard drug shall be punishable with imprisonment for a term which may extend to five years but which shall not be less than six months and with fine which may extend to fifty million rupees but which shall not be less than ten million rupees.";
 - (3b) Whoever himself or by any other person contravenes the provisions of section 23B shall be punishable with imprisonment which may extend to ten years but which shall not be less than three years and with fine which shall not be less than the prevailing value of the assets and such assets shall also be liable to forfeiture to the Provincial Government.
 - (3c) Whoever himself or by any other person contravenes the provisions of section 23C shall be punishable with imprisonment which may extend to fourteen years but which shall not be less than five years and with fine which shall not be less than the prevailing value of the assets and such assets shall also be liable to forfeiture to the Provincial Government.
- (5) for subsection (4), the following shall be substituted:

- "(4) Subject to the provisions of subsections (1), (2), (3), (3a), (3b) and (3c), whoever himself or by any other person on his behalf contravenes any of the provisions of this Act or the rules shall be punishable with imprisonment for a term which may extend to five years but which shall not be less than thirty days and with fine which may extend to five million rupees but which shall not be less than five hundred thousand rupees."; and
- (6) after subsection (4), the following new subsection (5) shall be inserted:
 - "(5) If a Provincial Inspector or an official of the Provincial Drugs Testing Laboratory:
 - (a) is guilty of any willful breach or neglect of any provisions of the Act or the rules or any order which he is bound to observe and obey;
 - (b) is guilty of dereliction of duty;
 - extends any assistance to any person in contravention of the Act or the rules; or
 - (d) abets the contravention of any provisions of the Act or the rules -

shall, without prejudice to any other action in accordance with law, be liable to imprisonment for a term which may extend to three years but which shall not be less than six months and with fine which may extend to one million rupees but which shall not be less than one hundred thousand rupees."

11. Insertion of section 27A in Act XXXI of 1976.— In the Act, after section 27, as amended, a new section 27A shall be inserted:

"27A. False statement.— When any person is required under this Act to prepare a report, make a statement or furnish an information, prepares the report or makes the statement or furnishes the information which is false in any material particular and which he knows or has reasonable cause to believe to be false, or does not believe to be true, shall be punishable with imprisonment for a term which may extend to three years but which shall not be less than six months and with fine which may extend to one million rupees but which shall not be less than one hundred thousand rupees."

- 12. Amendments in section 28 of Act XXXI of 1976.—In the Act, in section 28:
 - (1) in subsection (1), for the expression "five years and with fine which may extend to two <u>lakh</u> rupees", the expression "ten years and with fine which may extend to one hundred million rupees but which shall not be less than fifty million rupees" shall be substituted;

- (2) in subsection (2), for the expression "which shall not to be less than two years or more than ten years, or with fine which may extend to two lakh rupees, or with both", the expression "which may extend to ten years but which shall not be less than five years and with fine which may extend to seventy million rupees but which shall not be less than thirty million rupees" shall be substituted;
- (3) after subsection (2), the following new subsection (2a) shall be inserted:
 - "(2a) Whoever having been convicted of an offence under subsection (3a) of section 27 is convicted for a subsequent offence under that subsection shall be punishable with imprisonment for a term which may extend to seven years but which shall not be less than two years and with fine which may extend to seventy five million rupees but which shall not be less than twenty five million rupees."; and
- (4) in subsection (3), for the expression "seven years, or with fine which may extend to one lakh rupees or with both", the expression "ten years but which shall not be less than ninety days and with fine which may extend to ten million rupees but which shall not be less than one million rupees."
- **13.** Amendment in section 30 of Act XXXI of 1976.— In the Act, in section 30, for subsection (2), the following shall be substituted:
 - "(2) Notwithstanding anything contained in the Code of Criminal Procedure, 1898 (V of 1898):
 - (a) an offence punishable under subsection (1) of section 27 shall be cognizable and non-bailable;
 - (b) an offence other than the offence mentioned in subsection (1) of section 27, shall be cognizable on the complaint of the Provincial Quality Control Board or the Provincial Drugs Monitoring Team; and
 - (c) all offences under the Act shall be non-bailable.
 - (2a) No court other than a Drug Court established under the Act shall try an offence punishable under the Act.".
- 14. Amendment in section 31 of Act XXXI of 1976.- In the Act, in section 31:

(1) for subsection (2), the following shall be substituted:

- "(2) A Drug Court shall consist of the Chairperson who is or has been, or is qualified for appointment as a Judge of High Court, and one full-time member who is an expert in the medical field and another full-time member who is an expert in pharmaceutical field."; and
- (2) subsection (7) and subsection (8) shall be omitted.
- **15. Insertion of section 31A in Act XXXI of 1976.** In the Act, after section 31, the following new section 31A shall be inserted:

- "31A. Appeal.- (1) The Provincial Government or the person sentenced by a Drug Court may, within sixty days, file an appeal against the final order of the Drug Court to Lahore High Court and the appeal shall be heard by a Bench of that Court consisting of not less than two Judges.
- (2)The Drug Court shall, as soon as possible, supply copies of the final order to the parties free of cost.
- The provisions of sections 5 and 12 of the Limitation Act. 1908 (IX of 1908) shall be applicable to an appeal under this section.".
- Insertion of section 41A of Act XXXI of 1976.- In the Act, after section 41, the following new section 41A shall be inserted:
 - "41A. Suspension of license by Provincial Quality Control Board.-(1) Notwithstanding anything in section 41, the Provincial Quality Control Board may, subject to the conditions mentioned in that section, and after affording an opportunity of hearing to the manufacturer and recording detailed reasons including the grounds of suspension. suspend the manufacturing license of a manufacturer within the Punjab

for such period not exceeding thirty days as the Board may determine and shall, as soon as may be, report the matter to the Central Licensing Board for such action as the Board may deem appropriate.

(2) A copy of the order under subsection (1) shall immediately be supplied to the manufacturer, requiring him to take appropriate remedial measures.

- The manufacturer shall take remedial measures and shall (3)request the Provincial Quality Control Board for an immediate inspection of the unit, and the Board shall promptly arrange an inspection.
- If the Board is satisfied that the grounds leading to the suspension of the licence have been remedied, it shall restore the licence of the manufacturer and report the matter to the Central Licensing Board but if the Board is not so satisfied, it may require the manufacturer to take the remaining remedial measures.
- Notwithstanding anything in subsection (3) or subsection (4), the Board shall arrange inspection of the Unit for manufacture of drugs at five days prior to the expiry of the period of suspension and if it is of the view that sufficient remedial steps have not been taken, the Board may, from time to time and after recording reasons, extend the period of suspension up to the maximum period of ninety days in all.
- If the manufacturer does not take effective remedial steps during the period or extended period of suspension of the licence, the Board shall refer the matter to the Central Licensing Board for immediate cancellation of the manufacturing licence.
- Any manufacturer aggrieved by the order of suspension may, within seven days from the receipt of the order, prefer an appeal to the appellate authority as notified by the Government and the appellate authority shall dispose of the appeal maximum within seven days.".

Insertion of section 43A of Act XXXI of 1976.- In the Act, after section 43, the following new section 43A shall be inserted.

"43A. Power to delegate.- (1) The Provincial Government may, subject to such conditions as it may determine, delegate any of its functions to the Provincial Quality Control Board or to any other person

or authority.

The Provincial Quality Control Board may, subject to such conditions as it may determine, delegate any of its functions and powers under this Act or the rules to the Monitoring Committee or any other person or authority.".