TO BE PUBLISHED IN THE NEXT ISSUE OF BALOCHISTAN GAZETTE.

BALOCHISTAN PROVINCIAL ASSEMBLY SECRETARIAT

NOTIFICATION.

Dated Quetta, the 25th November,2022.

No.PAB/Legis:V(30)/2022/9394. The Balochistan Drugs (Amendment) Bill 2022, (Bill No.30 of 2022), having been passed by the Provincial Assembly of Balochistan on 19th November, 2022 and assented to by the Governor Balochistan, on 23rd November, 2022 is hereby published as an Act of the Balochistan Provincial Assembly.

THE BALOCHISTAN DRUGS (AMENDMENT) ACT 2022, ACT NO. XXXVI OF 2022

AN

ACT

further to amend the Drugs Act, 1976 (Act No. XXXI of 1976), in its application to the Balochistan Province, for control and eradication of spurious, adulterated and substandard drugs.

Preamble. WHEREAS It is essential further to amend the Drugs Act, 1976 (XXXI of 1976), in its application to the Balochistan Province, *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.

It is hereby enacted as follows: -

Short title and commencement. **1.** (1) This Act may be called as the Balochistan Drugs (Amendment) Act, 2022.

(2) It shall come into force at once.

Amendment of Section-3, Act XXXI of 1976. **2.** In the Drugs Act, 1976 (XXXI of 1976), for brevity cited as the said Act, in Section-3, –

(a) 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 sub-Section (2) of Section-15 of the Act;"

(b) 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 11-B of the Act;"

(c) for clause (zz), the following shall be substituted and inserted:-

"(zd) "sub-standard drug" means a drug which is not of specifications; *and*

"(ze) "Drug Control Administration" means, officers appointed under Section-16 & 17 of the Act.

Amendment of Section-11 of Act XXXI of 1976.

3. In the said Act, in Section-11, in sub-section (5)—

(a) in clause (h), the word "and" appearing after the semicolon shall be omitted;

(b) 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;

(c) after clause (i), as amended, the following new clauses (j) and (k) shall be inserted: -

"j) to submit a monthly report of the decisions and activities to the Federal Government and the Provincial Government; *and*

"k) committee mean committee of the Board."

(d) after sub-section (6), the following new sub-section (7) shall be inserted:-

"(7) The Provincial Quality Control Board may constitute a committee or committees, consisting of the members of the Board and delegate to the committee any of its powers and functions under sub-section (5) for exercise within the specified area."

Insertion of Section 11-B in Act XXXI of 1976.

4. In the said Act, after Section 11-A, the following new Section 11-B 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 members including Chairperson from the Drug Control Administration 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, make regulations to regulate the conduct of its business.

(4) The Provincial Drugs Monitoring Team may—

a) subject to sub-section (6), exercise the powers of an Inspector under the 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 license 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;

c) 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 this 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 this 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 two officers of Drug Control Administration."

Insertion of Section 11-C in Act XXXI of 1976.

5. In the said Act, after Section 11-B, the following new Section 11-C shall be inserted: -

"11-C. Independent inspection. –
(1) Subject to sub-section (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 and Government Analyst and is an expert in the relevant field and no firm shall be so engaged unless it has in-house capacity for the task and has in its service persons who are qualified to be appointed as Inspectors and 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.".

Amendment of Section-15, Act XXXI of 1976.

6. In the said 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 (s) 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."

Amendment of Section-19, Act XXXI of 1976.

7. In the said Act, in Section-19, in sub-section (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."

Amendments of Section-22, Act XXXI of 1976.

8. In the said Act, in Section-22, –

(a) in sub-section (2), after the words "any other laboratory", the words "or the Notified Drugs Laboratory" shall be inserted;

(b) in sub-section (4)—

i. after the words "Government Analyst", the words "or the Notified

Drugs Laboratory" shall be inserted; *and*

ii. for the words "thirty days", the words "ten days" shall be substituted; *and*

(c) in sub-section (5), after the words "Federal Government", the words "or the Provincial Government" shall be inserted

Insertion of Section 22-A, in Act XXXI of 1976.

9. In the said Act, after Section-22, the following new Section 22-A 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."

Amendments of Section-27, Act XXXI of 1976.

10. In the said Act, in Section-27, –

(a) for sub-section (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 which causes death or physical disability or any drug which is not registered;

b) manufactures for sale any drug without a license;

c) imports without license any drug for the import of which a license 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.";

(b) in sub-section (2), for the expression "or with fine which may extend to one lakh rupees, or with both", the expression "or with fine which may extend to ten million rupees or with both but which shall not be less than three million rupees" shall be substituted;

(c) in sub-section (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 thirty days and with fine which may extend to one million rupees but which shall not be less than “five hundred thousand” shall be substituted;

(d) after sub-section (3), as amended, the following new sub-sections (3-A), (3-B), (3-C) and (3-D) shall be inserted:-

“(3-A) Whoever is responsible for variation in the specification which is physically or chemically ten percent different from the specification labelled on a drug, shall be punishable with imprisonment for a term which may extend to five years or with fine which may extend to one hundred thousand rupees or with both.

(3-B) Whoever is responsible for variation in the specification which is physically or chemically more than ten per cent but is not more than twenty per cent different from the specification labelled on a drug, shall be punishable with imprisonment for a term which may extend to five years or with fine which may extend to four hundred thousand rupees or with both.

(3-C) Whoever is responsible for variation in the specification which is physically or chemically more than twenty per cent but is not more than fifty per cent different from the specification labelled on a drug, shall be punishable with imprisonment for a term which may extend to five years or with fine which may extend to seven hundred thousand rupees or with both.

(3-D) Whoever is responsible for variation in the specification which is physically or chemically more than fifty per cent different from the specification labelled on a drug, shall be punishable with imprisonment for a term which may extend to five years or with fine which may extend to one million rupees or which is three times the value of the drug taken into custody, whichever is higher, or with both and the manufacturing of

the product shall remain suspended till such time that the responsibility for the lapse is fixed and remedial measures, taken.";

(e) for sub-section (4), the following shall be substituted:-

"(4) Subject to the provisions of sub-sections (1), (2), (3), (3-A), (3-B), (3-C) and (3-D), whoever himself or by any other person on his behalf contravenes any of the provisions of the Act or the rules, shall be punishable with imprisonment for a term which may extend to five years and with fine which may extend to five hundred thousand rupees or with both.".

Insertion of Section 27-A, in Act XXXI of 1976.

11. In the said Act, after Section-27, the following new Section 27-A shall be inserted: -

"17-A. 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 extent 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."

Amendments of Section-28, Act XXXI of 1976.

12. In the said Act, in Section-28, –

(a) in sub-section (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" shall be substituted;

(b) in sub-section (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;

(c) after sub-section (2), the following new sub-section (2-A) shall be inserted:-

"(2-A) Whoever having been convicted of an offence under sub-section (3-A), (3-B), (3-C) and (3-D) of Section-27, is convicted for a subsequent offence under any of those sub-sections shall, if the drug is not recalled as prescribed by the Provincial Government, be punishable with imprisonment for a term which shall 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*

(d) in sub-section (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" shall be substituted.

Insertion of Section 28-A in Act XXXI of 1976.

13. In the said Act, after Section-28, the following new Section 28-A shall be inserted: -

"28-A. Recall of drugs. –A person charged with the commission of an offence under sub-section (3) of Section 28, shall be deemed to have committed no offence when the drug which is subject of that offence, has not caused any death or physical disability and is recalled as prescribed by the Provincial Government."

Amendments of Section-30, Act XXXI of 1976.

In the said Act, in Section-30, for sub-section (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 sub-section (1) of section 27 shall be cognizable and non-bailable; *and*

(b) all offences under this Act shall be non-bailable.

(2-A) No court other than a Drug Court established under this Act shall try an offence punishable under this Act.".

Amendments of Section-31, Act XXXI of 1976.

14.. In the said Act, in Section-31, –

(a) for the words "Federal Government" wherever occur, the words "Provincial Government" shall be substituted.

(b) for sub-section (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 two full-time members who are experts in medical field:

Provided that all the powers exercisable by the Federal Government under the said Act in respect of existing Drug Court in the Balochistan shall be the powers of the Provincial Government on and from the commencement of this Act.

(c) sub-sections (7) and (8) shall be omitted.

Insertion of Section 31-A, in Act XXXI of 1976.

15. In the said Act, after Section-31, the following new Section 31-A shall be inserted:-

"**31-A. 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 Balochistan 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:

Provided that the Chairman and one of the members shall constitute quorum of a Drug Court for the purposes of deciding all the matters under the Act other than the final hearing and decision of a case.

(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."

Insertion of Section 41-A, in Act XXXI of 1976.

16. In the said Act, after Section-41, the following new Section 41-A shall be inserted:-

"**41-A. Suspension of license by the Provincial Quality Control Board**.

(1) Notwithstanding anything contained 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 Balochistan for such period not exceeding fifteen 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 sub-section (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 license have been remedied, it shall restore the license 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 contained in sub-section (3) or sub-section (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 license, the Board shall refer the matter to the Central Licensing Board for immediate cancellation of the manufacturing license.

(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.".

Insertion of Section 43-A, in Act XXXI of 1976.	**17.**	"**43-A. 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.

(TAHIR SHAH KAKAR)
Secretary.

No.PAB/Legis:V(30)/2022/9393. **Dated Quetta, the 25th November, 2022.**

A copy is forwarded to the Chief Controller, Government Printing Press, Balochistan, Quetta for favour of publication in the next issue of Balochistan Gazette. Before final printing, a copy thereof be sent to this Secretariat for proof reading. Fifty copies of the Act may please be supplied to this Secretariat for record.

(ABDUL REHMAN)
Special Secretary (Legis:)

No.PAB/Legis:V(30)/2022/9393 **Dated Quetta, the 25th November, 2022.**

A Copy is forwarded for information and necessary action: -

1. The Principal Secretary to Governor Balochistan, Quetta.
2. The Principal Secretary to Chief Minister Balochistan, Quetta.
3. The Secretary Government of Balochistan Health Department, Quetta.
4. The Secretary, Government of Balochistan, Law and Parliamentary Affairs Department, Quetta.
5. The Director General, Public Relations, Balochistan, Quetta.
6. The System Analyst, Balochistan Provincial Assembly.
7. P.S. to Secretary, Balochistan Provincial Assembly.

Special Secretary (Legis:)