

DRUG - ACT - 1976.

Prescriptioncracker.com

Key POINTS :-

- 1) Regulation & prohibition of import of Drugs = Federal government
- 2) Regulation of manufacture of drugs = Central Lic. Bor. setup by Federal gov.
- 3) Regulation of sales of drugs = provincial government
[repres = from both Prov + Fed. Gov.]
- 4) Registration of Drugs = Registration board setup by fed. gov.
as well as cancellation of any reg. drug. Vice versa
prov. gov. also takes steps to ensure compliance of conditions of registration.
- 5) Pakistan National FORMULARY: - compile & By = Federal Govt.
Publish
- 6) Appellate Board = Federal Government [mem. from both P & F Govt.]
 - Meet 9 month & decide appeals in 60 days.
 - disputed cases from CLB, R.B & Licensing authority

disputed cases from L.A → Appeal to provincial Appellate authority set-up by provincial government
- 10) EXPERT COMMITTEES: set up by Fed. gov.
- 11) P&CB: set up by provincial gov.
 - Submit monthly report of decision & activities to Federal gov.
- 12) POWERS TO fix MAX. Prices: Fed. gov.
- 13) Fed gov → Fed. Drug/Gov. analyst + Inspector
Prov. Gov → Prov. drug/gov. Analyst + Inspectors

★ Authorities having power of Inspectors:- 2

- (1) central Licensing board (CLB) (3) Appellate board
(2) Registration board (4) PQCB

→ provincial. inspector = reports to prov. government. unless.
refer case other board specified

→ Federal inspector refer case to = CLB or Reg's. board

→ Inspector will take - 5 samples/ portions from retailer & give
 within 7 days.

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Retailer DTL PQCB Warantor Manufacturer

From manufacturer → Divide into 3 portions

↗ DTL
 ↘ PQCB

⇒ Government Analyst within 60 days of receiving sample submit report in quadruplicate

↓ ↓ ↓ ↓ ↓

Deliver 1 to person from whom the sample is taken one to wallantar CLB/ RB/POCB Retain 4th to himself

awardantor/relater = can appeal within 30 days¹ to.
CLB/PQCB/ RB/ Drug court.

→ Federal inspector - clause-h of sub-sec-1 of sec-23
or 24 or any section
relating to Im/Exp/mfg/sale-of

- PENALTIES - SEC-27 - - DRUG - ACT - 1976 -

(1)
★ SIME — $\left\{ \begin{array}{l} \text{any Apurious drug / Non-reg. drug} \\ \text{iii) mfg for sale w/o licence} \\ \text{iv) import w/out licence} \end{array} \right\} \begin{array}{l} 3 < 10 \text{ yr} \\ \text{fine (upto 1 lakh)} \end{array}$
 $\therefore$ Except if D count $\downarrow$ Term to < 3

(2)
★ IMS — counterfeit drug
 ★ False warranty / insuff / incorrect to purchaser
 ★ Applies / permit to applies false warranty
 ★ MIS — any drug under name other than registered name
 ★ SIME — any adulterated drug

Punishment upto 7 yr
 $\bar{e}/\bar{e}.o$
 ≤ 1 lakh fine.

(3)
★ OBstruct an inspector $\rightarrow 1 \text{ yr } \bar{e}/\bar{e}.o 10,000$

(4)
★ Any provision / any rule of ^{may extend to} this Act. $\rightarrow 5 \text{ yr } \bar{e}/\bar{e}.o 50,000$

Subsequent offence - Sec-28

- Subseq. for sub-sec-1 — imprisonment for life or imprisonment $MT < 5 \text{ yr}$ + fine upto 2 lakhs.
- Subseq. Off. for sub-sec-2 — NLT 2 yr or MT 10 yr or $\bar{e}/\bar{e}.o$ fine upto 2 lakhs.
- Subseq. off for sub-sec-4 — upto 7 yr $\bar{e}/\bar{e}.o 1$ lac.

- Sec-31- DRUG COURT: - Establish by Fed. Govt
- ↓
- Members → Chairman - ^{who has been or is qualified as Judge of High court}
 2 members expert of Medical & Pharm field
- Quorum → chairman + anyone Member for decision
- code of criminal procedure - 1898 - conferred powers to D. Court and follows it in case of matters not described by this Act
- Sub-se 70 - Appeal → High court in 30 day (panel NLT 2 judges)
 ↳ provisions of Sec-5 & Sec-12 of limitation act 1908 shall be applicable to appeal referred in sub-sec-7
- * custom Act - 1969 (IV of 1969) - import of drug regulated by it
- custom officer or Fed. inspector → suspecte imported package to contains drug prohibited under this Act may detain → report such detain to licensing authority
- * - publication of offender's → name, place of residence, offence & penalty
 in newspaper or such other manner as the Drug court may direct
- * - Inspector to be public servant = within meaning of Sec-21 of Pak. Penal cod (Act XLV of 1860)
- * - Repealed Acts - Drug Act - 1940
 D. A - 1972 • Drug ordinance 1976

PHARMACO-STUDY YOUTUBE CHANNEL

ALWAYS CHECK RECENT AMENDMENTS OF LAWS

SCHEDULE - III - OFFENCE (Sec-27-DRAP-2012)

clause.

- (1)
- SIMLE - any suspicious therapeutic good/ T.G. which is not register
 - Mfg for sale T.G. e/o license
 - import e/o license.
- Punishment
NLT 3yr or MT-10yr
+
fine which may extend to 10 lakh
- Drug cont may ↓ term

- 2) • IMS - counterfeit T.G.
- False warranty to purchaser
 - applies or permit to be applied, warranty or any other T.G.
 - MIS - T.G. under the name other than reg. name.
 - SIMLE - adulterated T.G.
- Punish - may extend to
7yr
+/-
5 lakh fine

- 3) Obstruction of inspector → 1yr e/e.o 1 lakh fine
- 4) Any provision of JMS Act → 5yr +/- 1 lakh fine

PENALTY FOR SUBSEQUENT OFFENCE

- Sch-III - clause (1) - subsequent offence → ^{NLT} 5yr + 5 Lakh
- PENALTY FOR VIOLATING the prohibitions - Sch-II
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punish upto 5yr + fine 5 lakh

These sections are of DRAP ACT 2012 (Added for comparison purpose)

DRUG ACT 1976 11-may

- 1) Short title, Extent and commencement
- 2) Application of other laws NOT Barred
- 3) Definitions
- 4) Regulation of Prohi of import etc of drugs
- 5) Regu. of manu. of drugs (BY CLB)
- 6) Regu. of sales of drugs
- 7) Registration of drugs (RB^{or})
- 8) Pakistan National formulary
- 9) Appellate Board
- 10) Expert committees
- 11) PQCB 11(A) conflict of interest
- 12) Powers to fix max. price of drugs etc
- 13) Directions to Provin. Govt.
- 14) FDL and institutes etc
- 15) PDIL
- 16) Govt Analyst
- 17) Inspector
- 18) Powers of Inspector
- 19) Procedure for Inspe.
- 20) person bound to disclose place where drugs are mfg or kept.
- 21) Disclosure of name of manuf.
- 22) Reports of Govt Analyst
- 23) Import, manuf & sales of drugs
- 24) control of adver.
- 25) control of sampling
- 26) control of printing labelling
- 27) Penalties
- 28) Penalty for subseq. offence.

DRAP, 2012 ^(XXI OF) 13, November

- 1) Short title, Extent & commencement
- 2) Definitions
- 3) Establishment of Authority
- 4) Composition of Authority
- 5) CEO
- 6) Meetings of Authority
- 7) Powers & functi of Authority
- 8) Delegation of powers
- 9) policy Board
- 10) Meeting of policy Board
- 11) Functions of Board.
- 12) Appellate Board & committees of policy Board
- 13) Invitation by board
- 14) Appointment of officers and employees etc of Authority
- 15) Integration of Fed Drug Control Adm. its sub-officers & laboratory.
- 16) Experts, consultants & advisers NOT to be civil servants
- 17) CEO & Officer To BE Public servant
- 18) Conflict of Interest
- 19) DRAP Funds
- 20) Fees & other charges to be levied by The Authority
- 21) Budget
- 22) Accounting & Audits
- 23) Powers to make rules
- 24) Powers to make regulations

- 21) Forfeiture
- 30) Cognizance of offences
- 31) Drug courts
- 32) Pleas
- 33) Application of laws relating to customs & powers of officers of customs
- 34) offences by companies
- 35) publication of offender name
- 36) powers to exempt
- 37) Inspect. to be public servant
- 38) Indemnity
- 39) finality of orders.
- 40) public of results of tests or analysis
- 41) cancellation or suspension of licence etc
- 42) cancellation or suspension of registration of reg. drugs.
- 43) powers of Fed Govt. to make rules
- 44) powers of prov. Govt to make rules.
- 45) Repeal & savings.

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- a) Imp. manuf & sales of therapeutic goods
 - b) control of advertisement
 - c) control of sampling
 - d) control of printing of labelling

- 25) Submission of annual reports & returns
- 26) powers to call for information
- 27) offences & penalties etc
- 28) offences By companies
- 29) cognizance of offence
- 30) complaints
- 31) confidential. Infor.
- 32) Act NOT to override other rules.
- 33) Recovery of arrears
- 34) Indemnity
- 35) power to amend schedule
- 36) Removal of difficulties
- 37) Employ^{ment} under the authority to be employment under Fed Govt.
- 38) Act X of 2012 NOT to be apply to Authority
- 39) co-operation with Internal organi-
- 40) Repeal & savings
- 41) policy Directive of Fed Govt
- 42) winding up of Authority

- Sched-I** (Biological, Drugs, Med. devices, Medicated cosmetics) ^{dossier}
- Sched-II** (Prohibitions) ^(control of advert.)
- Sched-III** (Offence)/Penalty
- Sched-IV** (Cognizance of offence)
- Sched-V** (powers of Inspectors) ^(Procedure)
- Sched-VI** Drug Act 1976