DRAP (Drug Regulatory Authority of Pakistan) Act- 2012 (XXI of 2012)

∴ **DATE = 13 NOV, 2012** (By: PrescriptionCracker.com)

"An Act to provide for the Establishment of Drug Regulatory Authority of Pakistan"

PURPOSES/Reasons:-

Whereas it is expedient = Because it is necessary/useful

↳ to establish DRAP for effective coordination and enforcement of Drug Act 1976 (XXXI of 1976)

↳ TO bring harmony in interprovincial trade and commerce (31) of "THERAPEUTIC Goods" (TG).

(trade: part of commerce) (commerce: involves simply buying & selling)

(whole system: covers things like transportation, banking (payments), Insurance, Advertisement)

↳ TO regulate M/I/E/St/D and sale of TG

so, commerce = Trade + other things

- Provices of KPK, punjab & Sindh $\xrightarrow[\text{of constitution of IR- of Pak.}]{\text{Art- 144}}$ Passed Resolution

That Parliament (Majlis-e-Shoora) may by law regulate the issue

↓ TO effect

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1) Short-Title, Extent & COMMENCEMENT

- Called Drug Regulatory Authority of Pakistan Act, 2012.
- Extend to whole of Pakistan
- Shall come into force at once.

DEFINITIONS (Here we have mentioned only complex-Defini, but students Must read all definitions from Act/Book)

★ - Act: means Drug Act 1976 (XXXI of 1976).

★ Alternative Medicine: product used exclusively in Homeopathic, Unani, Ayurvedic, Biochemic, Chinese or other Traditional System of Treatment

★ Civil Servant: means a civil servant as defined in Civil servant Act, 1973

★ Decision: Includes order, Determination or direction of "AUTHORITY OR The BOARD" made in acc. ē Laws, rules & regulations

★ - Fee = Means fee prescribed by BOARD

★ Funds = means DRAP funds.

★ - Health & OTC products: probiotics, & Disinfectants, Nutritional products (Non-Drugs) food supplements, baby milk & food, Medicated cosmetics, medicated soaps & medicated Shampoos.

★ OTC means: Over the counter Non-prescription products

★ Person: Means any individual or legal entity

★ Pension Endowment Fund: means an endowment fund (وقف/مستقل آمدنی) Separate from fund of Authority Dedicated only for the payment of pension benefits of Authority's Employees

* Pharmaceutical Field:- means regulation, manufacturing, Quality control (Detect error), Quality Assurance (Prevent error), Research Academia, Import, Export & pharmacy services in drugs.

⇩

means services rendered by a pharmacist in pharmaceutical care, selection, posology, counselling, dispensing, use, administration, prescription monitoring, pharmacoepidemiology, TG information and poison control, pharmacovigilance, pharmacoeconomics, Storage, sales, procurement (خریداری), forecasting (پیشگوئی), supply chain management, distribution, drug utilization evalution (DUE), Drug utilization review DUR, formulary based drug utilization and managing therapeutic good at all levels including Pharmacy, clinic, medical store, hospital or Medical Institutions.

* Therapeutic Goods: Includes Drugs or Alternative medicines or medical devices or biologicals or other related products as may be notified by Authority

* Pharmaceutical Evaluation: means Assessment of a detailed pharmaceutical dossier submitted for registration of TG

* Secretary: Secretary of Board.

CHAPTER - II
AUTHORITY AND BOARD

3) ESTABLISHMENT OF THE AUTHORITY:-

1) As soon as may be after the commencement of this Act → Fed gov. → Est. DRAP + Notify by Official gazette
↓
To carry out the purpose of this Act.

2) The Authority shall be a body corporate having perpetual succession = (Means it will continue to exist forever, even if people inside changes).

- Common seal = official stamp
- May sue & be sued in its own name = Can file cases in court / Be taken in court
- can make contracts = for the purpose of this Act.
- Buy & own properties { moveable / immoveable } [of every description]
- May convey, assign, surrender, yield up, charge, mortgage (takes loan against it), demise (To transfer property), reassign, transfer or otherwise dispose of or deal in any moveable / immoveable property or any interest vested in it. (Any legal right or ownership it has)

3) DRAP = Autonomous body = work independently But under the supervision of Fed. gov.
↓
HQ = Islamabad.
(Head Quaters)

(4) Set up → sub-offices + Laboratories → Provincial capitals + other places as per need.

- Also existing Fed. drug control Administration & other sub-offices set up in all provinces & laboratories will automatically become part of DRAP after the commencement of this Act.
- Such as:
  - ↳ central Drug Laboratory, Karachi
  - ↳ National control Laboratory for biologicals, Isb
  - ↳ Fed. Drug surveillance Lab., Isb

(5) Common Seal (official Stamp):-

- will be kept by CEO or another authorized person.
- And documents required or permitted to be executed under common seal shall be specified & authenticated in such a manner as may be prescribed (means must follow proper rules).

4) COMPOSITION OF AUTHORITY:-

Policy board recommend → Fed govt → Appoint → CEO of Authority (Full time.)
→ 13 Directors.

1) Director pharmaceutical Evaluation & registration (EAR).
↳ responsible for evaluation, assessment & registration of pharmaceuticals drugs for human being & animals.

2) Director Drug Licensing: → Licensing of Drug + mfging (manufacturing) facilities

3) Director QA and Laboratory Testing:-
Responsible for enforcement of → cGMP
↓ → Testing & research of Drugs.
- Post marketing surveillance.
- Evaluation, coordination & Monitoring of- Safety, efficacy & Quality of registered Drugs & inactive materials
(ECM)
And toxicological study, Drug recalls and withdrawals

4) Director Medical Devices & Medicated Cosmetics:
↳ responsible for Assessment, Enlistment or registration of "Med. Devices, Med. cosmetics, Med. shampoos, Med. soaps" For Human & Animals.

5) Director Biological Drugs:-
EAR and Licensing of biologicals + functions of National control authority for biologicals as required for the prequalification by WHO of locally mfg. human biolog. drugs. (To meet WHO standards and be accepted and sold globally)
↳ (Inspect mfg sites, takes samples + check NCA as well)

6) Director Controlled Drugs:-
In consultation ē Fed. govt. Responsible for regulation and allocation of quota of →
- Narcotic Drugs (e.g Morphine) - Relieve Pain + cause sleep
- psychotropic substances (That affect mind & behavior) e.g Diazepam, Hallucinogen, Amphetamines
- precursor chemicals (used to make drugs)

7) Director pharmacy Services:-
Responsible for develop & promotion of Pharmacy Services.

8) Director Costing & price:-
Resp. for costing & pricing of TG.

9) Director Health & OTC products
Responsible for Assessment, Licensing and Registration of Alternative medicines and food supplements for humans + Animals.

10) Director Budget and Accounts:-
Responsible for budgetary & financial Aspects of Authority and other daily accounting matters

11) Director Administration, HR and logistics:-
Responsible for administration, recruitment, appointments, capacity building and development for Authority

12) Director Legal Affairs:- For Legal Aspects of Authority and other matters connected ē Drug court

13) Director Management Information Services:- Responsible for development of automation of functions using information technology for authority

So All members shall also perform any other matter connected/related to their respective services.

2) The Fed govt may ⟶ ↑se/↓se no. of division/ Directors on recommendation of policy board.
↓
BN recommendation of policy board
↳ Functions/experience/Qualific./Terms/mode/ manner of appointment of Director & related staff.

CHIEF EXECUTIVE OFFICER

ON recommendation of Policy board ⇒ Fed Govt appoint CEO.

* Qualification :→ post grad. degree in pharmacy / Medicine
  * Age : NLT 45yr or NMT 56yrs
  * Experience : Allcast 20yrs in management, Pharmaceutical field or regulatory affairs, in public Sector
    (OR) if not avail from public sector Than from private sector (rest of requirement will remain same)

* Tenure = 3yr (Extendable for 1yrs ONLY) upon recomm. of board.

— FUNCTIONS —

- CEO shall exercise general control + supervision over the affairs of authority.
- ensure provision of the Act, rules, regulation & direction and policies of BOARD are properly executed

— DUTIES OF CEO —

a) Keep in custody ← Records, seal of Authority
b) Submit plan of work + budget estimate of Auth. for approval of board
c) Submit → Reports on Activities of Authority → TO Board as per rules.

(3) POWERS OF CEO —

a) Supervise activities related to → Training / research / institutional consultancies and other services

b) Authorize Expenditure provided in budget — as per rules & regulations
(اخراجات کی منظوری دینا)

c) Re-appropriate funds e/in appr. budget
(دوبارہ مختص کرنا)

d) Delegate his powers to appropriate level of management

e) Issues notices of meeting of → Board (policy board) / Appellate board.
+ Maintain record of minutes & proceedings.

f) Execute deeds / docx. on behalf of board.

g) perform any other function as assigned by board.

4) CEO shall not — allow expenditure on items of civil work (تعمیراتی کام) / capital expenditure on office (دفتر کو بہتر بنانے کے لیے اخراجات) / Lab equip / automobile = UNLESS Approved by BOARD

5) CEO may tender his resign = under his own hand (written + signature, not verbal)

6) In case of vacancy of CEO → Fed govt. appoint any person e prescribed qualification for a period of 3 months or till appointment of CEO whichever is earlier

6) Meetings of Authority:- (call/arrange)
convened by CEO — at any time on his own / directed by Board

POWERS AND FUNCTIONS OF AUTHORITY (10)

a) Administer – Laws specified in Schedule VI (Drug Act 1976) → TO Fed govt (implementation at National Level)
(ڈرگز ایکٹ)
- Advise → Prov. govt. for laws applicable to provinces

b) Monitor Enforcement of Laws – Schedule (VI) D.A 1976
- collect relevant data + info.

c) Issues Guidelines & Monitor enforcemt of:-

(i) Licensing of mfg of TG (ii) Registration of TG

iii) Regulate advertisment (iv) Drug specific & Lab. practices

v) Prosecution & appeal under this Act + Drug Act 1976 relating to Fed. subject.

vi) Regulation + Allocation of = Narcotics/psychotropic/precursor chemical. in consult ē Fed. Gov

vii) Regulation for pricing + Mechanism of price fixation of TG.

viii) Determining standards for = biologicals mfg + testing

ix) Implementation of Internationally Recognised standards such as GLP, cGMP, Good distrib. practice, cold chain management, bioequivalence studies, stability studies anti-spurious codes, clinical trials, biosimilar evaluation and endorsement
AND systemic implementation of WHO, ICH (International council for Harmonization of Technical requirments of Pharmaceuticals for Human use) and FDA (Food & Drug Administration) guidelines.

x) Regulation, enforcement & monitoring of Advertisment + BAN False advertisement.

xi) Mfg. (Manufacturing) of API in all its forms.

xii) Use of central Research fund.

d) Coordinate, Monitor or Engage in conjunction ē other org./ Prov. govt./ Int. agencies ⇒ in training, study or projects related to TGI

- Authority may engage any individual / counsel to advise or work for ⇒ Managing national/ Int. opportunities/ for training/ educ./ seminar/ conferences etc. ē a view to improve capacity building

(کسی تنظیم/ ماحول/ صلاحیتوں کو بہتر بنانا تاکہ بہتر کارکردگی کی جاسکے)

e) facilitate advancement + upgradation of Sector ⟶ To meet ē int standards
- Promote mfg + export of API & TGI.

f) Coordinate at policy level + provide policy guidance to Prov. Gov. in Performance of their function = To bring harmony

g) Facilitate procurement + implementation of = Foreign aided Technical Assistance ↓ [Help/ assistance from other countries] on TGI where such expertise doesn't exist but its existence would Promote public good

h) Develop + Promote pharmacy services (شروع)

i) undertake awareness campaign regarding disease prevention/ Pt. rights / h.c priviliges. = Through media/ seminars/ Publication or other IT means.

j) issue guidelines + monitor proceeding + funding etc = of Health seminars/ workshops / conferences

k) Advise Fed. gov. on issues = Related to obligation/ commitments related to TGI.

l) Appoint employees / consultants / experts (purely on merit) & productivity → on Terms / salaries / remuneration ē consultation & approval of policy board.

m) Prescribe rules for promotion / seniority / code of conduct.

n) Levy such charges / fee for services / facilities (Impose) provided by Authority

o) Enter into contract for Supply of material / execution of work = As may be necessary for discharge of its duties / functions.

p) prepare annual budget for approval BY BOARD.

q) Monitor & regulate Marketing practices = • To ensure rational use of Drug
• ethical promotion of TG criteria for
in line ē int. practices

r) Develop working manuals etc. = ↑ working environment in office

s) prescribe / regulate / implement = Matter related to authority

t) Develop, Issue, Adopt & enforce. = STANDARD Guidelines
To ensure Safety, Quality, efficacy of TG → ē rational use at resonable price.

u) perform "Licensing registration, pricing & Appellate functions"

v) Coordinate ē Prov. Govt + Int. agencies = For smooth implementation of Laws + capacity building + Training of regulatory staff.

w) Develop SOPs/manuals etc + conduct audits ⇒ Transparent working

x) Establish systems of cost recovery = Get expense back i.e through fees likes licensing fee, inspection fee, registeration fee ensure financial autonomy + efficient functioning.

y) Perform & carry out any other act/duty as assign by policy board / Fed. govt.

6) Delegation of Powers:-

Authority & Approval of Board in writing (acc. to laws, rules etc) - Delegate any of its power/function to any OFFICER as it may deem appropriate

(9) POLICY BOARD

9- POLICY BOARD:-

1) ◦ General Direction
◦ Administration } of Authority — shall vest in Policy board.
◦ Monitoring Shall consists of 15 members

1) Secretary of concerned Division (Fed. Secretary BS-22) = Chairperson
2) CEO = Member (secretary of board) ← sub-sec-2.
3) Representative of Ministry of law & Justice (NLT BS-20) = Member
4) Secretary of concerned dept. Govt. of balochistan : Member
5) " " " of Sindh = Member
6) " " " of KPK = Member
7) " " " of Punjab = Member
8) " " " of GB = Member
9) " " " of FATA = Member.
10) 6 experts from public & private sectors ē : Member.
equal repres. from each province = shall be from diff. specialities as in sub-sec-3

↓

Fed. govt → notify offi gazette → appoint 6 experts from each prov. → preferably (1) from each province having speciality in field of.

- Drug manufac.
- Drug regulation
- public health
- pharmacy services
- QC
- Health finance
- Health economics
- Health management
- pharmacology
- Biotechnology.

- Term of office = 2 yrs (shall be eligible for 1 more similar term)
of expert member
↓
(unless remove by Fed. govt).
- Experts may resign by writing — to Fed. gov.
- Experts shall himself attend the meeting: NO representative allowed
4) NO Act shall invalidate due to vaccany in board
5) Fed govt. may ↑/↓ the no. of members — Qualific/~~Term~~/Procedure of Appoin prescribe

10) Meeting of Policy Board:-

- Board meeting convened by secretary ē prior approval of Chairperson
- if chairperson absent = members elect a chairperson for that meeting.
- Held twice/year or more
- Shall make regulations for conduct of its business.
- Quorum = Majority, in case of equality = casting vote ↓ chairperson.
- All decisions = record in writing
- Meeting will be called by an advance Notice = of atleast 7 day

11) FUNCTIONS of POWICY BOARD:-

a) • Frame policy & provide guidelines ⇒ To authority based on global & regional trends
   • Monitor implementation + performance ⇒ of Authority
   Ensuring good governance & Accountability

b) Monitor & supervise all function } of Authority
c) Approve budget
d) Determine fees & levies (impose taxes/hires)

12) Appellate Board & Committees of P. B:-

P. B may as it consider necessary constitute { Appellate board. / committees of exper

Shall act as per regulations of P.B

13) Invitation By Board:-

P. B may invite any person "to { meeting or deliberations (discussion/thoughts/debate) meetings of Appellate board.

advise / attend & it on any matter under discussion.

But have no right to cast vote

14 APPOINTMENT of officer etc of Authority

1) P.B approval — Authority create "posts" ← officers, employees, consultant & experts
   → Decide as per rules → "criteria"
2) Age of Superannuation = 60yrs. (Retirement after which pension will be provided)
3) CEO / Director = Must be citizen of Pakistan

15) INTEGRATION OF FEDRAL DRUG CONTROL ADMINISTRATION, its Sub-offices & Labs:-

upon commencement of this Act → FDCA + its sub-offices + hub } will be referred as "said offices"
↓
Shall become the part of Authority as per Sub-sec 4 of sec-3 of this Act "(Estb. of Authority)

2) All assets (in every form mentioned in Act) and debt (قرض) (in every form mentioned) of said offices
   → Shall stand Transferred to and vest in authority

3) All debts, obligations incurred, contracts entered or rights acquired and all matters & things engaged to be done by, to, or for said offices = Shall deemed to incurred/entered/acquired or to be done by Authority

4) Likewise, for suits & legal proceedings.

5) Notwithstanding (Despite / In spite of) anything contained in any contract or in condition of service:-

(a) every employee of said offices shall take a irrevocable decision (to/in 30days) → either to continue in present pay and service structure as civil servant
→ absorb in Authority →

b) if select Authority Then The Terms & Conditions will be as per This Act and its rules.

c) NO health personal who opt to be governed Under this Act = Shall be entitled to any compensation becoz of such transfer

d) Terms & conditions of all officers etc employed in Drug reg. Agency of Pak. under ordinance-I of (2012) before the Commencement of This Act (i.e powers transferred from ministry of Health to DRAP) ⇒ Shall not be varied to their disadv. under the Authority (i.e Their salary, work condition/benefit can't be made worse after joining the authority)

Handled by ministry of health

16) EXPERTS, CONSULTANTS AND ADVISERS

Shall not be civil servants e/in the meaning of civil servant Act 1973 (LXXI of 1973).

71

17) CEO and OFFICERS = to be public servant e/in the meaning of Sec-21 of Pakistan penal code, 1860 (Act XLV of 1860).

(45)

18) CONFLICT OF INTEREST:-

(1) NO person shall be appointed as CEO, director, consultant, adviser or employee = if he/she has any financial/professional conflict of interest

∴ financial conflict = a person owns shares in company that deal e Authority e.g pharma industry

∴ Professional ✓ = a person work or has close ties to org. that could benefit from authority's decision

2) NO person shall be member of board/Director = if he has immediate family member (parent, child, sibling/spouse) as Senior officials or owner of concern dealing in TGI.

BY: PHARMACO-STUDY

CHAPTER- 3
FUNDS, BUDGET AND ACCOUNTS

19) DRAP- FUNDS:-

1- There shall be a fund = known as DRAP-Fund - shall vest (full owned by) in authority

↓ TO meet its expenses and charges properly incurred in carrying out functions & duties

↓ including but NOT limited to Salaries (Basic pay) & Renumerations (Salary + bonus + Allowances, Travel/Rent) of CEO, director, mem, employ etc.

2- SOURCES OF DRAP- FUND

(a) Grant in aid in terms of salaries or retirement benefits provided by Fed. Govt.

(b) Donations & Endowments (عطیات و وقف)

(c) Grants & Loans by Fed/Prov. Govt.

(d) Loans/grants from National/International agencies ↓ to Fed/prov. ↓ to function the authority

(e) Charges/Fees collected by Authority

(f) Proceeds of any investment which're not required by/for immediate use.

(g) Proceeds from any other services ↓ including inspection foreign/local or Sale of any Publication

(h) Central Research fund (CRF) collected from pharmace. Industry

3) At End of each financial year ↳ Balance sheet prepare → any unspent remaining amount + other collection including CRF → shall be invested only in govt. schemes ↓ TO achieve self-sufficiency of Authority

4) Separate pension Endowment funds shall be establish = for pension of employees

20) FEES AND OTHER CHARGES TO BE LEVIED BY THE AUTHORITY:- (impose charges)

1) Authority ē Approval of Board in accordance ē Rules → shall lewy & collect fees in respect of its functions at such rates as may be determined

2) Central Research Funds (CRF) → Deposit in Non-lapsable sub-account of the (funds that don't expire at end of financial year = allowing unused balance to be carried forward to next year) Authority to be utilized as per existing rules

3) Existing CRF kept ē Fed. gov. → transferred to Authority upon its commencement.
→ upon ending of financial year, other unutilized money in lapsable accounts, if un-spent will go back to govt treasury except if invest before the, in govt scheme to attain financial Autonomy

21) BUDGET:-

1) Every year Authority must make a budget plan (money coming in and money going out) that includes:- } sent to Board for Approval.
   - ↳ Expected income (Receipts)
   - ↳ Expected expenses (expenditure)
   - ↳ updated current budget (Revised budget) and Next year's estimates ↳ [possibly due to inflation etc.]
   - ↳ How much money they need from Fed gov. (grant in aid)
   - ↳ Any foreign currency they might need!

   ↓ if they need foreign currency — it must be sent to govt. so it can arrange it.. [Foreign currency may be required for buying equipment / training program or Foreign experts]

2). If Authority earn its own money = NO Permission from Govt. is require in order to spent it
   - Board can decide → How to use that money

This gives the Authority → financial independence

22) ACCOUNTING AND AUDITS.-

1) Authority open its account ē any scheduled bank or financial institution as per rules
   - For initial fund in this respect ⇒ Authority may approach Fed gov.

2) Accounts → maintained as double entry system in a manner prescibed by Controller General of Accounts.

[Double entry system = where every financial transcation is recorded in two places

e.g you buy furniture
↳ Furniture (Assets ↑) - Debit
↳ Cash (Assets ↓) - Credit

So for every transcation
- one account is debited
- Another account is credited

3) Authority will cause to be carried out Audit by 1 or more auditors registered as CA ē/in the meaning of Chartered accountant (CA) Act 1961 (X of 1961).

4) Auditor General shall have the power to audit or cause to be audited the accounts Notwithstanding the report of auditors mentioned in sub-sec-3

5) copy of Audit + comments of Authority → Sent to Fed. Govt

6) If Auditor General Raise any objection → Authority shall take Necessary steps for Rectification

CHAPTER - IV
"RULES AND REGULATIONS"

23) POWER TO Make Rules:-

ē Apporal of Fed govt → Authority may by Notification in Official gazette, make rules for carrying out the purpose of this Act.

24) POWERS TO MAKE REGULATIONS:-

ē The approval of Board → Authority may by notification in OG, make Regulations for its internal working and Terms and conditions of employees, Not inconsistent ē The provisions of the Act or rules, for carrying out its functions under this Act.

CHAP-5 (MISCELLANEOUS)

25) SUBMISSION OF ANNUAL REPORTS AND RETURNS:-

1) ē/in 3 months of conclusion of financial year → Authority submit report → TO Fed gov.

(in respect of activities of Authority including status of current programs & future plans etc).

(2) Fed. gov. may require to furnish.

(a) — (b) — (c)

- (a) Any return (Actual figures/record data); Statement (General summary); Estimate (Future prediction); Statistics; or other info. regarding any matter under control of Authority
- (b) report on any subject related to Authority
- (c) A copy of any document in custody of Authority

3) Authority shall expeditiously comply ē such directions.

26) Power to call for information:-

Authority may call any person (directly/indirectly) and reasonably belived to have such info. which is required for carrying out the purpose of this Act. → The person shall provide such info in prescribed period.

↓

Failure to do so

↓

" Fine/penalty upto 1 lac rupees "

27) OFFENCES, PENALTIES etc:-

Breaking the rule ← Offences — specified in schedule - III

Prohibitions — schedule - II — punished as per schedule - III

Rules - That don't do it

28) OFFENCES BY COMPANIES:-

If a company, corporate, firm or Institution → commit any offence under this Act or Drug Act 1976

↓

Then every director/partner and employee with whose knowledge or consent → the offence was committed = shall be guilty of offence.

29) COGNIZANCE OF OFFENCE:- (آفنس کا نوٹس)

↳ shall be taken by Inspector in manner specified in schedule - IV

30) COMPLAINTS:-

1) Any aggrieved person may file a written complaint to the Authority against contravention of any provision of this Act or any law specified in Sch-VI → Authority (2) upon receiving the complain

Investigate it

Provide opportunity to

- complinant as well as
- the person against whom the complaint has been made

↓

May take action as per this Act or under Sch- VI

3) Appeals against such decision → Refered to Appeal Board →

→ From it's members → Formulate Appellate board → Final Decision

31) CONFIDENTIAL INFORMATION:-

1) Except as provided under regulations → No person shall communicate or allow access — To information/record etc → To the person not legally entitled to communicated/or have access to such info

2) A person knowingly receives records/info → shall retain it under same restriction as of receiver.

32) ACT NOT TO OVERRIDE OTHER LAW:-

The provisions of this Act shall be in addition to and not in derogation of provisions made in Drug Act 1976 (XXXI of 1976) and any other Law for time being in force.

⇒ In case of inconsistency → The provisions of this Act shall prevails

33) RECOVERY OF ARREARS:- (بقایا جات)

All the amounts due to Authority may be recovered as arrears of land revenue. (tax, fine, fees etc.)

(Any money owed to authority, if not paid, then that can be recovered using the legal procedure meant for collecting unpaid land revenue (land tax))

34) INDEMNITY:- (تحفظ)

Any person for anything done in good faith or intended to be done under this Act → shall not be punishable/no suit/or other legal proceedings.

35) Powers to amend schedule:- Fed. gov. on recommendation of board. → may be notification in off. gazette → Amend the schedule (Add/remove/omit/modify)

Take something out that is already there

Leave something out (not include it)

36) Removal of Difficulties:-

If any difficulty arises in giving effect to any provision of this Act → Fed. gov. may by Notifi. in OG, make such orders to remove difficulty

37) Employment under Authority to be employment under Fed. govt. — for the purpose of Pak. Essential Services (Maintenance) Act, 1952 (LIII of 1952) and the said Act shall have effect accordingly.

- This Law is typically used to
  - ensure continuity of essential services (e.g health sector)
  - Restrict strikes or disruptions in critical services — (to ensure the health services are provided to people on time and don't delay due to strikes etc)

38) Act X of 2012 — NOT to apply to Authority:-

Nothing contained in the Industrial Relations Act (X of 2012) shall apply to or in relation to Authority or any officer/employee.

Meaning: Employees of Authority can't rely on Industrial relations Act for:

- Trade union formation
- Labor dispute mechanisms under that Act.
- Other Labor rights as per that Act.

39)* Co-operation with International Organizations:-

Authority ē prior Approval of Fed gov. → is allowed to collaborate internationally → But also bound to comply ē agreed rules such as funding condition / reporting requirement / Data sharing protocol

- The authority can operate under existing international aggrement or future aggrements

40) Repeal And Savings:-

1) The Drug. Regul. agency of Pak. ordinance 2012 = repealed. (cancel)
(ordinance I of 2012).

2) NOtwithstanding the repeal of Drug.reg.Agency of Pak. 2012. (in spite of)

a) any licence to mfg / registration / Max. retail price fixed for sale / for revalidation of license or registration issued earlier under The Act, for which applic has been made to LB / RB / or Drug pricing comittee as the case may be e/in specified time. } shall continue to be valid.

b) any licence for Import / exp. / sale → continue to be valid for such period as Fed gov may by notifi. in OG (unless expired earlier)

3) All actions of Fed. gov. as mention in per sub-sec-2 since 20th April 2010 shall be deemed to have validly made under this Act.

41) POLICY DIRECTIVE OF FED. GOV.

Fed gov. may issue policy directive | official instructions / guidelines issued by an Authority / Fed gov. to guide decision & Actions |
as per laws → to policy board in respect of its activities, , power & functions → whose compliance shall be binding on Authority e/in stipulated time.

whose decision = final.

↑ refer the case back ← if find difficulty in implementation

to Fed. gov. e/in stipulated time

For e reasons for non implementation

42) WINDING up of Authority :- (dissolution of Authority)

- No provision of any law relating to winding up of bodies corporate shall apply to Authority
- Shall only be wound up by the law to be enacted by parliament for winding up of Authority

(such Laws are for the bodies performing critical public infrastructure → functions like health, regulation & continuity)
This ensures stability

SCHEDULE-I (BIOLOGICALS)

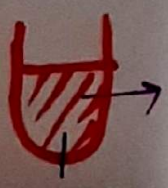
1) Biological Drugs:-

Biological drugs produced by
↓
Biological system → which require Standardization by biological Assay → According to recommendations of WHO ↓ published in
- Technical report series
- Biological Standardization report.

→ And includes:

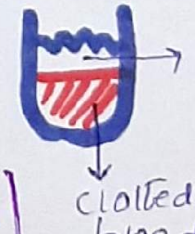
a) Blood products including plasma, Albumin, clotting factors, Factor VIII, IX. Mixed clotting factors fractions*, Fibrinogen, immunoglobulins

b) Immunological products including Antisera (plural of anti-serum)(are blood serum preparations containing antibodies against specific antigens)(usually obtained from immunized animals e.g horses)(e.g anti-snake venom), Antitoxins (type of antiserum specifically directed against toxins produced by microorganisms - usually derived from animals, Neutralize toxin - NOT the bacteria e.g Diphtheria anti-toxin - for Diphtheria and tetanus anti-toxin - for Tetanus), specific immunoglobulins (highly purified antibodies usually Ig G) Obtained from human plasma directed against specific antigen- lower risk of allergic rex. compared to animal sera - due to human origin e.g Tetanus immunoglobulin, Rabies immunoglobulins and Hep-b immunoglobulins - kind of modern, safer alternative to anti-sera)



Uncloted blood

Blood → cells (RBC, WBCs, Platelets)
→ Liquid part "plasma" → including [proteins e.g Albumin, Globulin and clotting Factors + Nutrients]



Clotted blood

Liquid = Serum ↓
- water
- Albumin
- Antibodies but no clotting factor

c) In vivo diagnostics – [Biological substance introduced into body to help diagnose disease by observing a reaction]
- ↳ Tuberculin skin test (Tuberculins) – for detecting TB
- ↳ Lepronin — (for Leprosy)
- ↳ Histoplasmin — (for histoplasmosis – fungal infec. that affect mainly lungs
- ↳ coccidiodin — (for coccidiomycosis – also known as valley fever or san Joaquin fever – a fungal infection – mainly affect lungs
  pronounce as : (wak-Keen)
- ↳ Allergen / Allergen Extract — use in allergy testing e.g Skin Prick test
- ↳ Antibodies conjugated ē Isotopes (radioactive isotopes) — (for tumor detection etc) for imaging studies
  emit radiation → that are detected by imaging machines (when antibody attach ē tumor cells)

d) Antigen, cytokines / antibodies / cells injected to elicit a biological response.

e) vaccines, including:
(i) ↳ Bacterial
- → Live → weakened e.g BCG (TB) – use when strong immunity is needed
- → killed → inactive (whole cell pertusis vaccine
  - whole cell • use when safety is require.
- → protein subunit → acellular pertusis vaccine
- → polysaccharide or glycoconjugate – [sugar + protein]
  - ↳ • Sugar antigen (outer capsule of bacteria) → (PPSV) → pneumococcal polysaccharid vaccine / meningococcal polysacc. vacc.
- → Toxin Derivaties
- → DNA biotechnology Dereloped

∴ glycoconjugate vaccine – [outer sugar + capsule of bacteria + Bacterial protein] → e.g. Hib (Hemophilus influenza Type b)
- pneumococcal conjugate vaccine (PCV)

∴ Toxin Derivative = inactivated bac. toxin
- ↳ e.g. Tetanus / Diptheria toxoid.

∴ rDNA = antigen produce using genetic engineering < safe, pure
- recombinant pertusis vaccine
- " meningococcal "

ii) Viral vaccines:-
- Live (Measles, Mumps Rubella MMR)
- inactivated (polio)(IPV)
- Sub-unit (Hep-b)— contains HBsAg protein produced by rDNA technology
- rDNA
- Conjugated
  - Soberana 02 [covid-19 vaccine [SARS-COV-2 spike protein is conjugated to tetanus toxoid carrier protein]]

∴ But oral polio vaccine (OPV) is live attenuated

iii) Polyvalent (Many. Types) combination of vaccine containing combination of vaccines defined in e(i) and d(ii)
e.g. (1) DTP (Diphtheria, Tetanus, Pertussis) or (2) pentavalent vaccines (DTPHb Hib)
(3) MMR (4) Pneumococcal multivalent (against different strains).

f) Toxins & venoms including snake venom & scorpion venoms etc (used to produce anti-venoms, in research for new drug develop, & in diagnosis or research Assays)

g) Immunostimulants of biological origin including BCG vaccine for immunotherapy. (BCG is normally a vaccine but it is also given to stimulate the immune system strongly — This immune activation is used to fight disease like cancer e.g introduced in bladder — activate immune cells → that attack cancer cells)

h) Biotechnology products which are primarily manufactured using rDNA, vRNA, hybridoma technology (For production of monoclonal antibodies) or other processes involving site specific genetic manipulation techniques

i) Human interferons (protein that fight viral infections & cancers), natural hormones (from biological sources e.g insulin mostly recombi. recombinant antibodies (genetically engineered — Highly specific targeting), monoclonal antibodies and derivatives gene therapy products (deliver genes to correct defective ones

2) Biological Drugs (FINISHED FORM): Biological drugs that are defined in sub-section-1 and are mfg, packed by the manufacturer under his responsibily of QA and is further released by National control Authority (NCA) or National control Laboratory (NCL) of the country of origin under WHO's Lot release System of evaluation.

[manufacturer completes the production of biologicals + DO his own QA tests → Documents submitted to NCA/NCL (regarding test results + mfg details) → NCA/NCL check data may also test sample ↓

if everything meet standard = batch is released
If NOT → batch rejected

" The WHO has created this standard method called Lot release system — which all countries follow — so that biological products are evaluated in consisted, internationally accepted way. "

2) Biological Drugs (Ready-to-gill form):-

↳ Biological drug defined in sub-sec. 1 BUT are mfg at one site in form of "Ready to fill Bulk" but are transfered to another site for final filling, labelling or packaging & QC of finished form.

→ NO further formulation of dilation of "Ready to fill bulk" is allowed in this case on manufacture

→ Final product is released by Pak's National control laboratory for biologicals under WHO's lot release system of evaluation.

4) BIOLOGICAL DRUGS (CONCENTRATED FORM)

Biological drugs mfg at one site but are stored in form of concentrated bulk of active ingre. at controlled temperature → May be transferred to any other site under temp. controlled condition for further ↓

- Dilution
- Stabilization
- filling
- packaging

Finished form of such biologicals Drugs undergoes → require QC test of diluted stabilize bulk

another set of complete QC test

* - Final product is release in same manner as mentioned before.

5) Biological Drugs (Naked vials):-

↓

Biological drugs mfg at one site but final containers are neither Labelled nor packed in cartor Locally → In such cases at least an identity test is required to confirm the positive identification of required antigen

* - Final product release is same manner.

6) Originator Biological Drugs:- means a biological drug which has been licensed by national regulatory authorities on the basis of a full registration dossier i.e the approved indication(s) for use were granted on the basis of full quality, efficacy & safety.

(a) Reference BioTherapeutic product (RBP):
means an originator biological drug product that was licensed on the basis of full registration dossier. It doesn't refer to measurement standards, such as international, pharmacopoeial or national standards or reference standards.

So basically RBP is the same originator drug but used as benchmark. Other products (biosimilar) are compared against it.

b) Biosimilar Biological drugs:- Means similar biotherapeutic Product (SBP) which is similar in terms of Quality, safety and efficacy to an already licensed reference biotherapeutic product

c) Similarity means absence of relevant difference in the parameter of interest

7) NO human biological drug is allowed sale and use until a "Lot Release certificate" from Fed.gov. analyst of NCL for biologicals, Isb has been obtained.

8) PHARMACEUTICAL DOSSIER:-

Set of documents submitted by a person for the registration of a therapeutic good, containing complete info. about:-

a) Master formula;
b) all ingredients both → Active (API), Inactive excipients → safety profile data
c) Complete manufacturing procedure of the drug, biological or medical device;
d) QC steps and procedures at such level of raw material selection, In-process testing, Finished drug testing & stability testing
e) Clinical trial data & published reports about the safety and efficacy of the drugs
f) Complete details of manufacturing plant & equipments, QC Lab and equipments

g) Ware-house capacities and facilities, details of HR available and latest cGMP report shall be part of this docx. set.

h) Any other info. required by the registration board for establishig the safety, efficacy, bioavailability, bioequivalence or biosimilarity of the drug.

2- DRUG: The definitions of drug is same as mentioned in Drug-Act 1976 But here the drug's definition also includes Alternative medicines (Ayurvedic, Unani, Homeopathic, chinese or biochemic system of Treatments). [Read from DRAP-Act as well]

3) MEDICAL DEVICES:-

a) includes Instruments, Medical equipments, implants, disposables and Softwares — used mainly for the purpose of diagnosis, monitoring and treatment of disease. (OR)

b) Any other item which Fed. gov. may be notification in OG, declare as medical device.

4) MEDICATED COSMETICS:- Includes

Cosmetics containing drugs and are defined as articles containing active drug ingredients intended to be rubbed, poured, sprinkled or sprayed on or introduced into or otherwise applied to human body or part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance and articles intended for use as a component of any such article: Except that such term shall not include Soap.

Schedule - II → prohibitions :- Same as that of prohibition of Drug - Act 1976 except that here the word "drug" is replaced by "therapeutic good".
NOTES: Available at Prescriptioncracker.com

Schedule - III → offence
This schedule is different from the offences section of Drug Act 1976 – whose notes are available on
" PRESCRIPTIONCRACKER.COM "
and video lecture is available on
" PHARMACO-STUDY " Youtube channel

Schedule - IV → Cognizance of offence
Same as that of Drug - Act 1976 - except that the word "drug" is replaced by "Therapeutic goods"

Schedule - V :- POWERS OF INSPECTOR :- As of D.A 1976
The word Drug is replaced by "Therapeutic goods"

Schedule - VI DRUG - ACT 1976
↳ lecture NOTES Available at: PRESCRIPTIONCRACKER.com
↳ Video lecture on Youtub: PHARMACO-STUDY