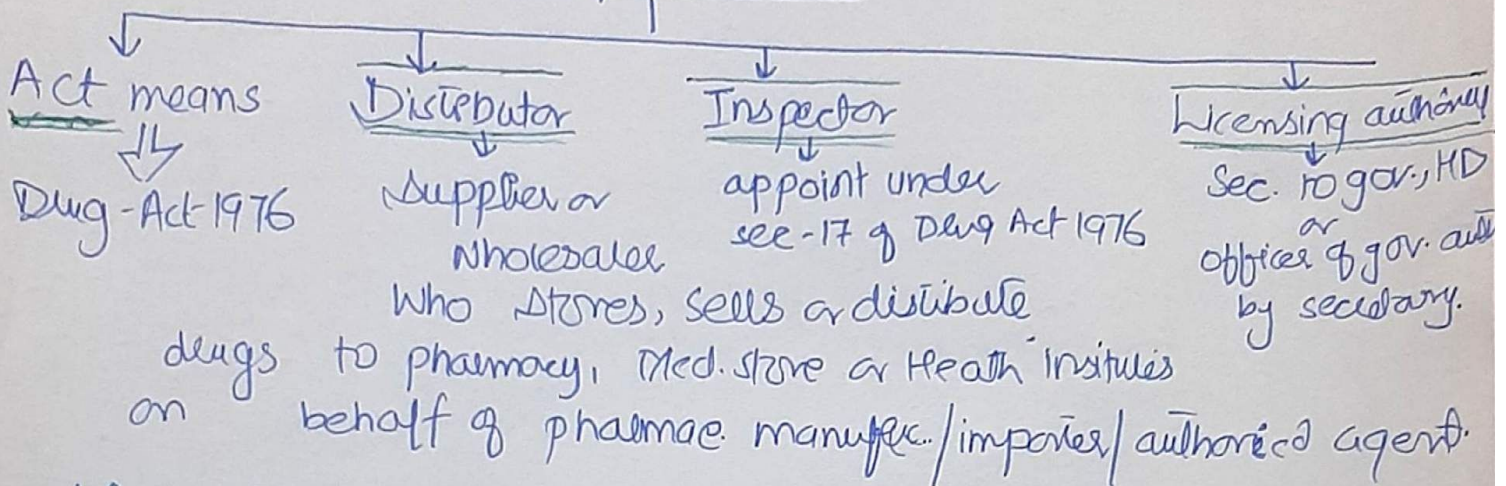


PUNJAB DRUG RULES, 2007

[18th - September, 2007]

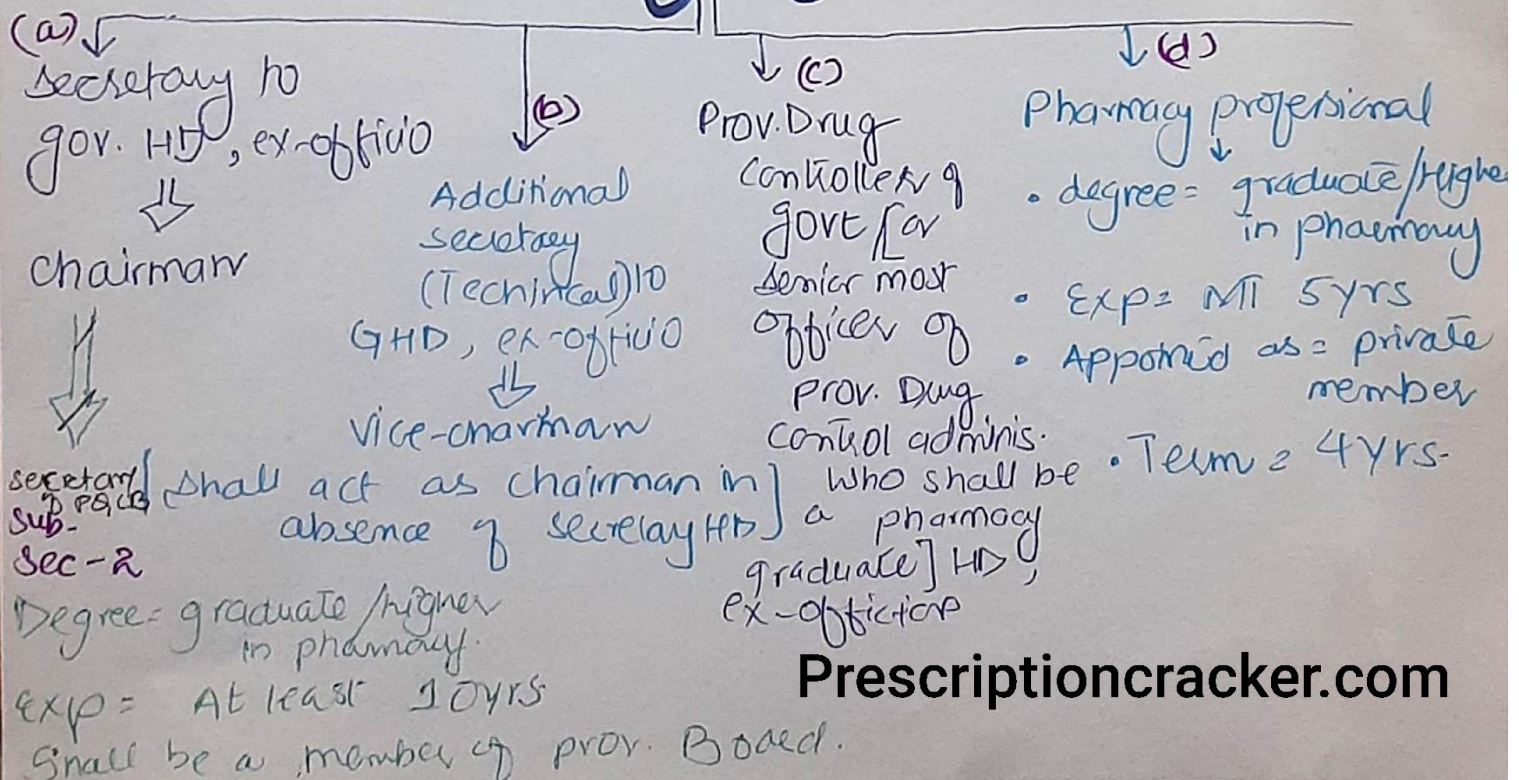
Rules framed acc. to the powers given to governor of Punjab under "Secti - 44 of Drug-Act-1976"
 "Sec-44" Powers of Prov. gov. to make rules

Chapter - 1



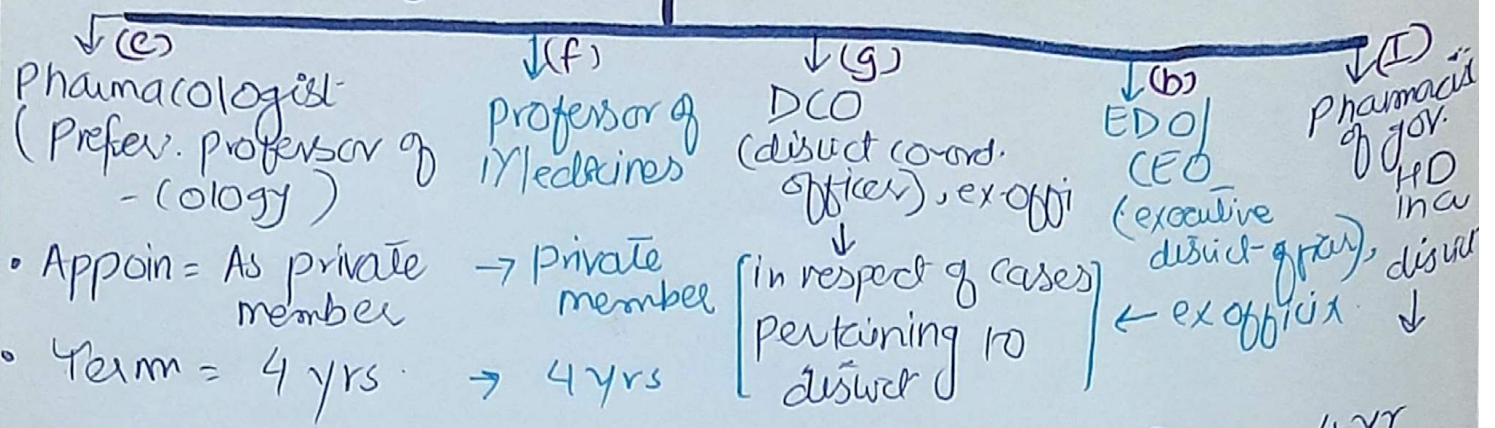
* Medical Store:- premises where the drug, EXCLUDING the DRUGS SPECIFIED IN Sch-G, are stored, sold or offered for sale

PQCB [Sec-3][1]



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Sec-3(4) PQCB - CONT.



(3) Gov. may appoint { Pharm expert
expert of Medicine } in respect
of district → Term = 4 yrs.

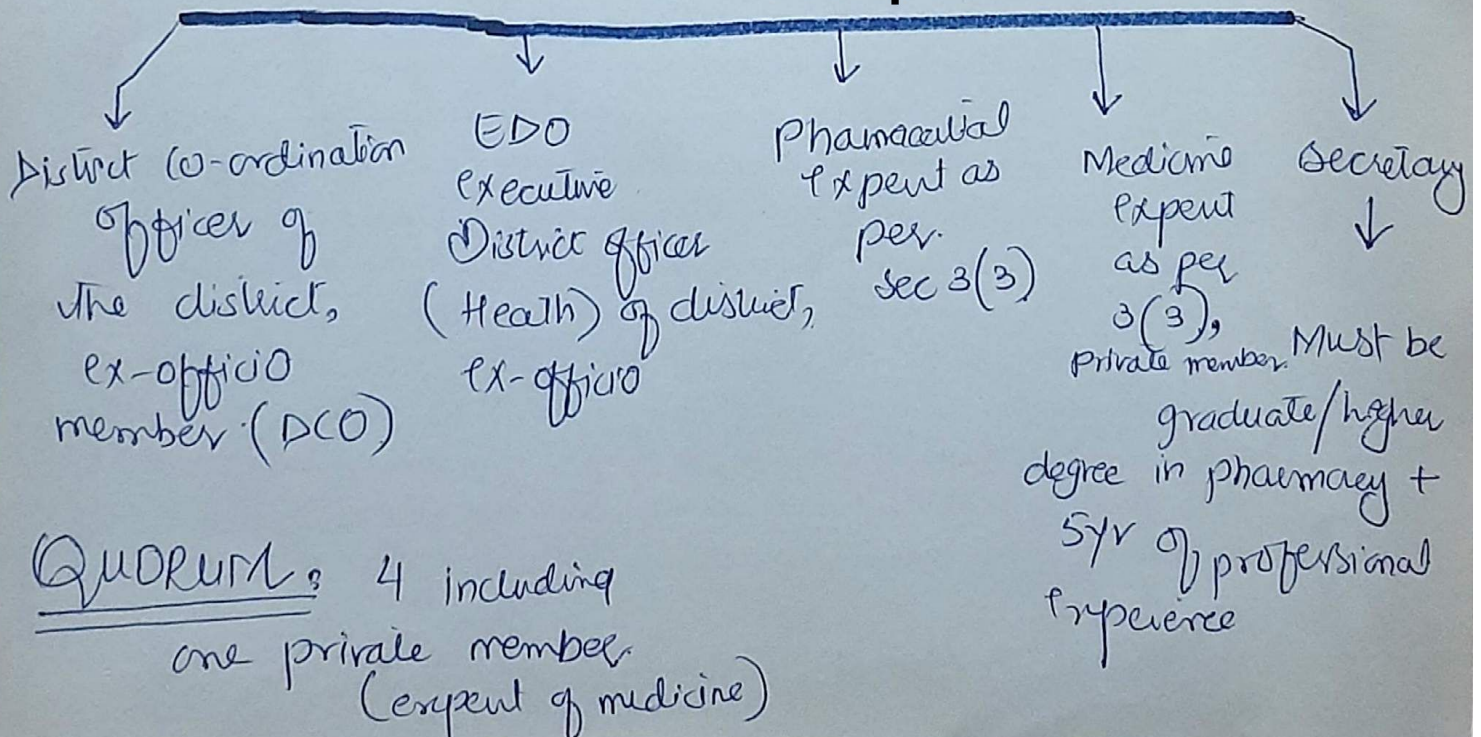
QUORUM:- 5 members (including chair/vice-chairperson + 1 member from concerned district)

(6) The govt/Board may co-opt any other qualified expert having formal training & experience in ph. field

Sec-4 DQCB

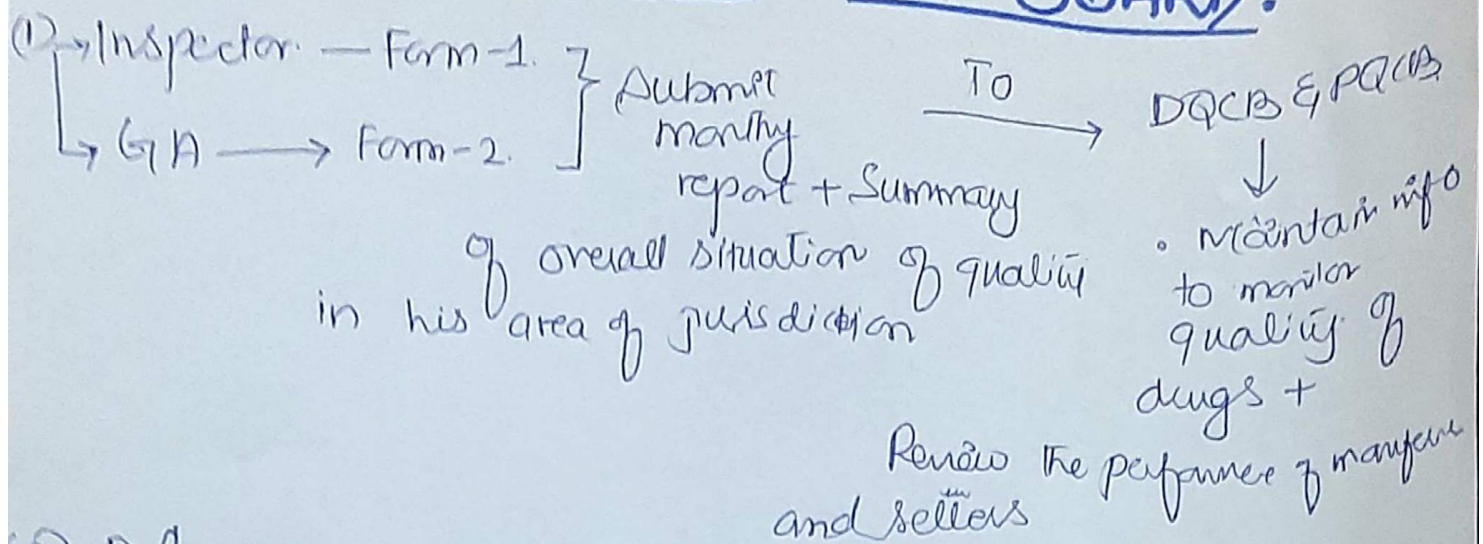
estab. subject to Sec-11(6) of Drug-Act-1976 by PQCB

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QUORUM: 4 including one private member (expert of medicine)

Section - 5 - PROCEDURE OF BOARD:-



② Meeting = PQCB/DQCB → shall meet at least ONCE a month for the concerned matters

③ Show-Cause-NOTICE:- PQCB/DQCB → examine case. referred to it by Inspector. — issue show-cause notice if found contravention to the accused person before prosecution/suspension/cancellation of license.

④ Ascertain the Names:- Before referring case to Drug-cont PQCB/DQCB shall ascertain the name of Director, partner & employee of company etc who is Prima facie responsible for contravention AND Allow inspectors to institute prosecution.

⑤ MINOR CONTRAVENTION:- direct improvement/issue warning / order de-sealing / recall of batches

⑥ FORBID NOT TO DISPOSE:- any drug/article for a period of NMT 3 months, that may be act as evidence

PHARMACO-STUDY YOUTUBE CHANNEL

6 - Qualification of Inspector/GA

graduate of pharmacy
from a uni recognised by pharmacy
council of Pakistan

graduate in
pharmacy + 3yr
of experience preferably
in mfg, testing or analysis
of drugs.

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7 - DUTIES OF INSPECTOR

- (a) Inspect + Maintain record of inspection of Med. store
- pharmacy
 - Drug Mfg. Premises
- Inspect = ONCE / 3 months
- (b) Satisfy ^{himself} that condi. of license are being observed.
- (c) If find contravention regarding drug being mfg; sold, stocked or exhibited for sale - shall take samples of drug/article and send to DTH for testing.
- (d) Investigate any complaint
- (e) Prosecution on direction of PQCB/DQCB.
- (f) Maintain record of his working & submit report to PQCB/DQCB
- (g) Stop manufacture/sale of drug in contravention
- * Record in writing on Form-4 = intimation for taking samples to person from whom samples is taken.

and Form-5 = Receipt for stock of drug/other materials seized under sec-18(1) of drug-Act 1976

7(b) Inspect a place licensed under the Act or the rules before renewal of license.

Sample sent to GA for testing = Form-6 [Part of Rule-10] a specimen impression of his seal

(8) Prohibition of disclosure of information

(9) Form of order NOT TO DISPOSE OF STOCK = Form-3
proceeding under power of sec 18(1) of DM-1976

(11) DUTIES of Government Analyst:-

(1) Test and analyse the sample sent to him under Act or the rules = furnish report on

↓
FORM-7

(3) Submit Monthly report to govt. regarding the samples tested

(2) Also test the samples sent by govt-dep, person, public institutions

PHARMACO-STUDY YOUTUBE CHANNE

(12) PROCEDURE ON RECEIPT OF SAMPLES FROM INSPECTOR:-

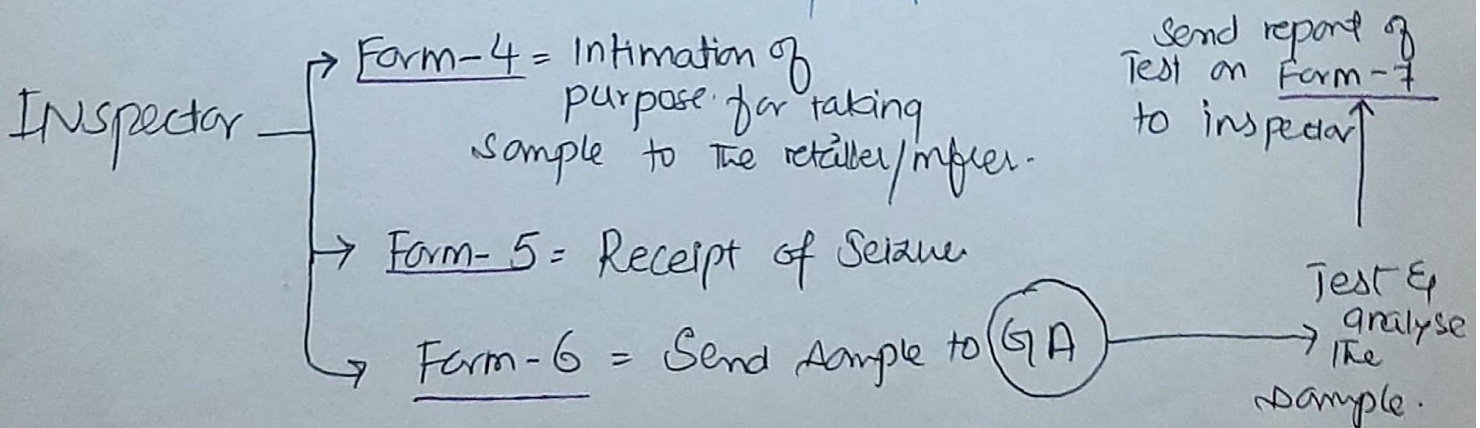
ON RECEIVING the sample from Inspector, The GIA shall

- compare seal on packet & specimen impression received and shall note the condition of seal on package.

- After Test and analysis - Forward report. → Inspector
→ Board.
or in case of person/govt-dep to the concerned person

(13) Fee For The Test & Analysis = As per sch - C

SUMMARY OF FORMS



CHAPTER NO: III

SALE OF DRUGS

14) Licences under the Rule

Licensing authority (L.A)

issue
licence

Pharmacy

Med. store

distributor

Sec-15
Forms

B(A)

B(B)

B(C)

on forms

15) Application AND Fee for licence:

(1) A person will apply to L.A for grant/renewal of licences

(2) Submit fee for a licence in Head of Account NO.

1252-Health-Other receipt, at following rates:-

→ Pharmacy	3K	For renewal 2K
→ Medical store	2K	1K
→ Distributor	5K	3K

(4) The applicant shall pay 50% of the fee for

Change of
AP

For duplicate
copy of licence

16) FORM of Licences TO SELL DRUGS:

- Pharmacy — Form-9
- M. store — Form-10
- Distributor — Form-11

17) SALE AT NOT ONE PLACE:-

Separate licence required for a place where drug is
at more than one place EXCEPT, if drug are

Stored in godown who only for storage. and

Storage conditions
are met

complete address
entered in licence

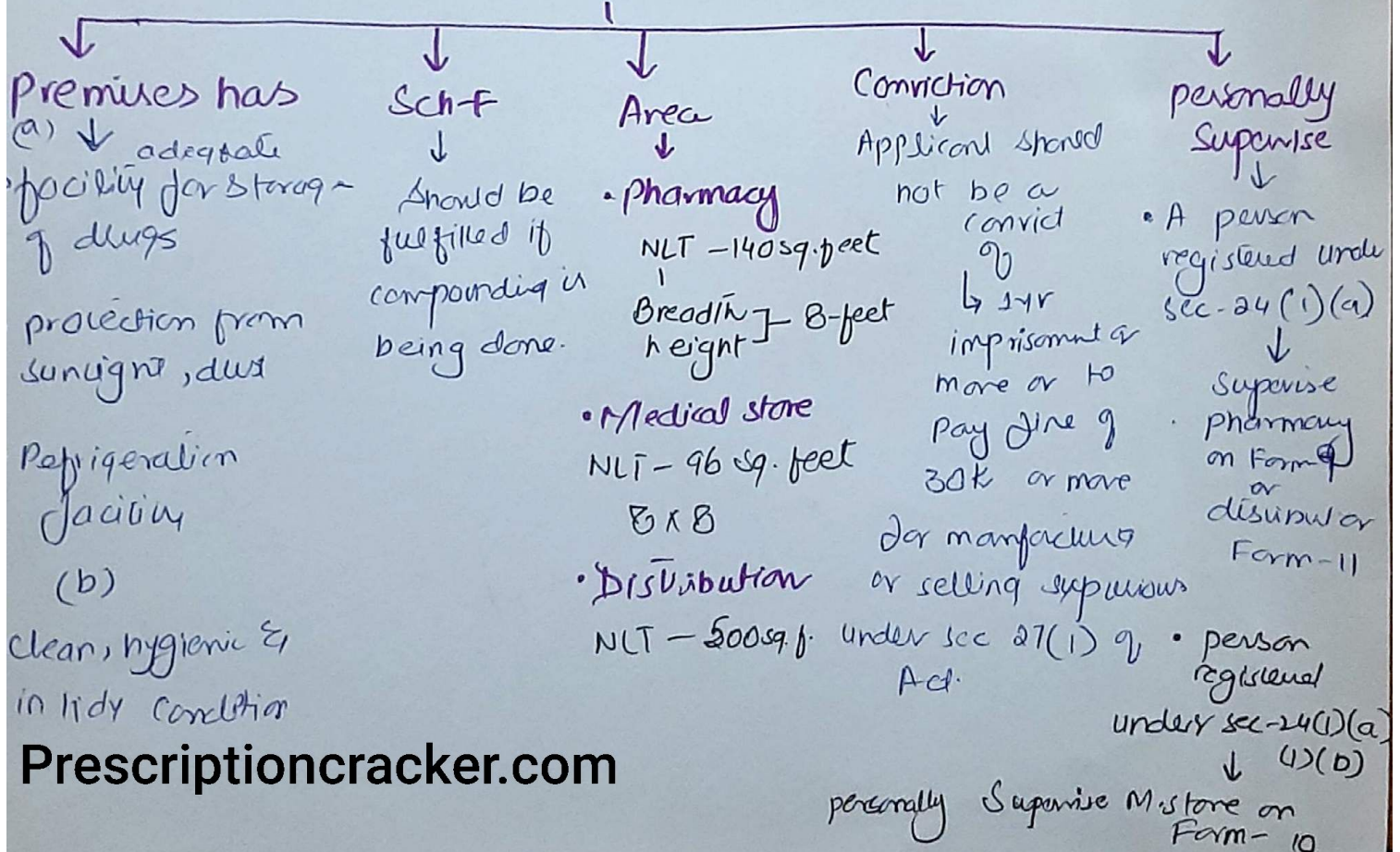
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18) DURATION OF LICENCE:-

- (1) Validation of licence = 8 yrs
- (2) Grace period after expiry of licence = 30 days
- (3) L.A shall dispose of an application for renewal/ licence within 45 days of receipt of application.
↓
- (6) if fail to dispose of application e/in spec time, it shall record reason for its failure
- (7) L.A may refuse the application as per public interest
- (8) L.A shall not renew a licence without the inspection of the inspector.

CONDITION FOR ISSUANCE OF LICENCE

(1) L.A shall not issue licence on Form-9, 10, 11 unless



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L.A shall not issue licence.

- (2) without the inspection report of.
- Secretary PQCB/DQCB (or)
 - Inspector of the area.
- (3) to a distributor &/or the verification of computerised facilities for sale/purchase of drug.

(20) CONDITION OF LICENCE:-

(1) L.A shall issue licence subj to condition as follow.

- (a) Pharmacy board
- white writing - "pharmacy"
 - green board
 - Minimum length = 5F
width 2.5F
- Medical store
- white writing "Med-store"
 - Dimensions same as pharmacy.
- (b) personally supervise as describe previously
- (c) Record keeping
- Invoices of sale, bills (supply) or counter foil shall be preserved for a period of atleast 3yrs from the date of sale
- (d) Sch-B & D drugs.
- Sale on prescription of a R.M.P.E original prescrip to be retained by pharmacy/M.S.
 - Sale recorded in register
 - No prescription needed for the sale of MIBBS, hospital dispensary or any other institution.
- (e) Sch-G drugs not to be sold/store by M.S.
- (f) Register particulars for Sch-B & D.
- SR.NO - also entered on prescrip.
 - Date of sale
 - Name of prescriber
 - Quantity sold.
 - Batch
 - Qty purchase/balance.
 - Sign of AP
- (2) Prescription
- in writing
 - signed
 - pt name/email
 - Drug Qty + dose
 - Dated
- (3) OF Exemption (For) MIBBS for DSH
- if the drug is for his pts
 - Record of sch-B/D maintained as Prescribed.
- (4) M.I.S - shall shall the drug only to a holder of valid DSH, MIBBS
- (5) if this is the case, the M.I.S shall send a copy of Invoice + counter foil to the inspectors
- shall issue warranty + invoice at the time of sale.

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- 7) How The invoice & warranty should look like.
↳ full name and address of purchaser
↳ Signed by warrantor — indicating name + date

8) **MIS** — Shall maintain the record of purchase or sale of drug = for a period of 3 years containing following particulars:-

↓ date of purchase or sale	↓ name & address of concern ↳ purchaser ↳ seller	↓ • Drug name • Batch No • Qty • Expiry	↓ Name of manufacturer
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9) General record also to be preserved for a period of NOT 3 yrs

10) Licensee { record/register maintained under these rules
 other info } To Inspector — as the inspector may require

11) Storage guidelines For Sch-E and Sch-B:-

11(a) in the part of premises to which customers don't have access

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(b) in locked almirah, cupboard, or drawers, reserved solely for storage of substance/drug

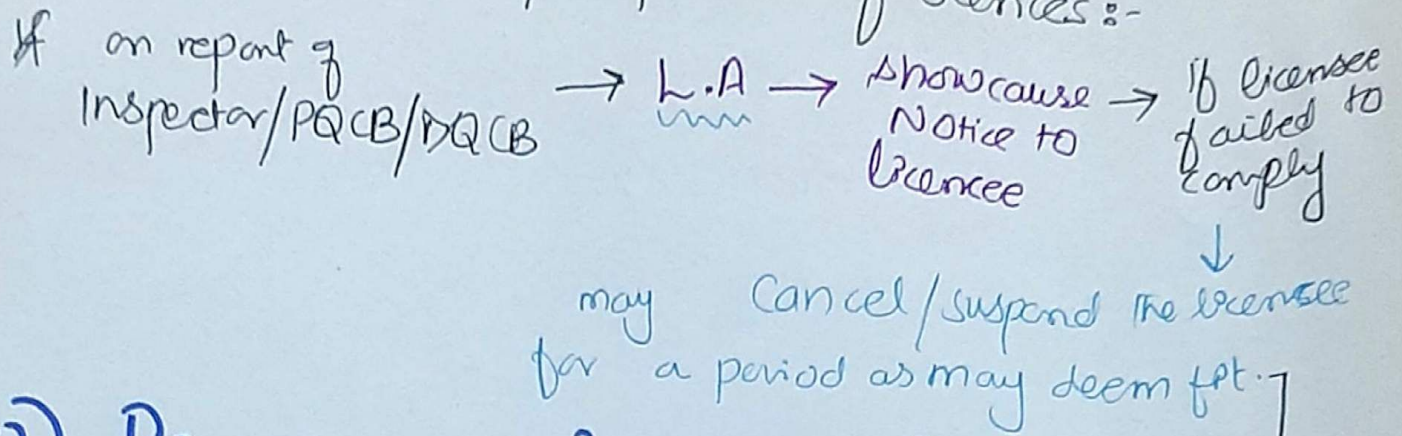
12) Spec. guidelines For Sch-E medicines:-

A sub-jail under list of poisons in Sch-E shall be stored in container, impervious to the poisons & sufficiently stout to prevent leakage.

↓
(13) Should be labelled with word "POISON"

14) Distributor's licensee shall maintain computerized record of inventory control for sale & purchase of drug.

Sec-21:- Cancellation / suspension of licences:-



22) PROVINCIAL - APPELLATE AUTHORITY:-

- (1) If a person is aggrieved by the order of L.A
↓
in 30 days of orders.
Appeal to PAA
- (2) Additional chief secretary of government = PAA for the purpose of hearing against the order of L.A.
- (3) PAA may direct an officer / official of govt to assist the authority
- 4) PAA, after giving appellant an opportunity of hearing
↓
pays the final orders → That will be the final and non-questionable

23) Good Storage & distribution practice

