The sale, purchase, and compounding of medicines are activities subject to regulations by the State to the extent necessary to protect the public health. There is nothing in the Drugs and Cosmetics Act 1940 and the rules framed under it to curtail the exercise of the power by the State to regulate the sale or compounding of medicines. Rather, law gives wide powers to the State administration to regulate these activities in the interest of the public. The power of the State to regulate the distribution of medicines is not only restricted to substances that are inherently dangerous but also extends to all drugs including those patently harmless. But the extent of regulation may vary depending upon the degree of its dangerous nature. The patent, proprietary medicines are thus subject to regulation and it is considered to be a valid exercise of power.

The Act is based on the premise that the drugs are not like ordinary commodities whose sale can take place anywhere or can be effected by any person and be left to the ordinary commercial pressures of the market. Though criminal sanctions are also envisaged, the general framework for controlling sale and distribution is a system of statutory licensing administered by a body constituted under the rules. The justification for insisting on the license with regard to sales and distribution of drugs is that special care is needed because of the revolutionary
changes that are taking place in modern drugs and because of the possibility that they could have dangerous properties or dangerous side effects. In fact such possibility was made real in the Thalidomide tragedy. An additional factor of course is that the consumers are in a very vulnerable position of having no choice to exercise when it comes to prescribed drugs for they simply rely on their medical practitioners.

The licensing procedure and the conditions to be imposed before granting any licence on any application for sale and distribution of drugs is analysed in this context. Under the rules, drugs are now divided into various categories (1) those which may be sold only from registered pharmacies under the supervision of a qualified person and upon the prescription of medical practitioners and (2) those without supervision of a qualified person with reasonable safety. This categorization was considered necessary because special care and precaution is required where there is more toxicity hazard in respect of some drugs and where the hazards to health and risk of misuse are minimal and the need to take special precaution in handling is small in respect of some other drugs.

The civil liability of druggist in case of his negligence or breach of duty is also discussed here with the support of case law available from common law countries.

The law intends multiple controls on the drugs. They include prohibition on sale of any drug which is not of standard quality. Even exhibiting or offering for sale of a misbranded, adulterated or spurious drug comes under prohibited activity. As

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1 For a detailed discussion of this aspect see Chapter V supra.
2 See ibid.
part of regulatory measures, dealing with the drugs is permitted under certain conditions. This may include certain general conditions like proper labelling before the sale of any medicine or drug. The other means of control is by way of administrative control like licencing. Under the regulatory system of drugs control, one can sell or stock or exhibit for sale or distribute any drug only under licence. It is necessary to understand the meaning of the words 'sale', stock and 'distribute' before dealing with the licensing system.

The meaning of 'sale' and 'offer for sale':

To constitute sale for the purpose of the Drugs and Cosmetics Act 1940, it must be for human consumption or use. It may be a whole sale or retail. It may include sale for cash or on credit or an agreement for sale. Though an agreement for sale is conceptually distinct from actual sale, an agreement for sale is was also made penal. In the sale, property in the goods passes to the buyer immediately whereas in the 'agreement to sell', transfer of property is conditional. In an offer for sale only

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3 See Chapter VII supra.
4 Drugs and Cosmetics Act 1940 Section 18(c). It reads: "18. Prohibition of manufacture and sale of certain drugs and cosmetics - From such date as may be fixed by the State government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf -

(c) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic, except under, and in accordance with the conditions of, a licence issued for such purpose under this chapter."

5 Sale of Goods Act 1930 Sec 4 (1),(3)& (4) clearly brings out its meaning. The section runs as follows -

"(1) A contract of sale of goods is a contract by seller to transfer or agrees to transfer the property in the goods to the buyer for price."

(3) where under the contract of sale the property in the goods is transferred from seller to buyer, the contract is called a sale, but where the transfer of the property in the goods is to take place at a future time or subject to some condition there after to be fulfilled, the contract is called an agreement to sell.

(4) An agreement to sell becomes a sale when the time lapses or the conditions are fulfilled subject to which the property in goods is to be transferred."
one of the two ingredients which go to constitute a contract or agreement is present. The other ingredient being acceptance is absent. An agreement is bilateral whereas an offer is unilateral affair. But under the Drugs and Cosmetics Act, mere exposure for sale is covered. Hence distinction between these phrases has lost its relevance.

**Meaning of 'Stock for Sale':**

This phrase 'stock for sale' has been extensively used in the Act and the rules framed under it. These provisions do not use the word in any technical sense. The plain meaning, of the word 'stock' in these provisions is 'to keep'. The injunction of the law is that no person should keep for sale a drug in contravention of the Act. It is not necessary that the drug should be stored in a place in order that it can be said to have been stocked for sale. If any one keeps or carries a drug on his person in contravention of the terms of the Act and if it is proved that the drug is kept or carried for sale, the act must fall within the ambit of law under consideration. The Supreme Court in *S.K. Amir v. The State of Maharashtra*, discussed the meaning of the word 'stock for sale'. The brief facts of this case were that the appellant obtained a delivery of a parcel. The parcel was found to contain 95,000 capsules of Seco Barbital Sodium which is a sedative agent and is commonly used for intoxication. He was apprehended by police and tried under the Drugs and Cosmetics Act 1940, on the charge that he had 'stocked for sale' a misbranded drug and that he had no licence for stocking the drug for sale.

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1. See Drugs and Cosmetics Act, 1940 Ss. 18(a), 18(c) and 27(a) and the rules framed under these provisions.
2. A.I.R. 1974 S.C. 467
It was urged before the court on behalf of the accused that the fact that the drug was found on the person of the appellant was not enough to establish that he had stocked the drug. The court said,

"In busy commercial cities, streets are crowded with mobile hawkers who display their wares on their person. It is neither sound common sense nor sound law to say that such wares are not 'stocked for sale'. What is intended for sale can as much be stocked on one's person or in a shop or in a godown. ‘Keeping’ for sale is of the essence of the matter, not the mode of and manner of keeping. To keep for sale is to stock for sale."\(^8\)

Again in *Mohd. Shabbir v. State of Maharashtra*,\(^9\) the Supreme Court got the opportunity to interpret these words. In this case the Drugs Inspector found the appellant in a railway station with 17 plastic containers containing 17,000 white coloured tablets. Samples of the tablets were sent to public analyst and after receiving his report the complaint was filed. The issue before the court was when a person is in the possession of tablets of a very huge quantity, a presumption can be drawn that they were meant for sale or for distribution. The court interpreted the words by saying that the absence of any comma after the word ‘stocks’ clearly indicated that the clause “stocks or exhibits for sale” is one indivisible whole and it contemplated not merely stocking the drugs but stocking the drugs for the purpose of sale and unless all the ingredients are satisfied the Act would not be attracted. The court found that there was no evidence to show that the appellant had either got these tablets for sale or

\(^8\) *Id.* at p. 470.

\(^9\) A.I.R. 1979 S.C. 564
was selling them or had stocked them for sale. In the opinion of the Court before a person was to be made liable for prosecution under these provisions "it must be proved by the prosecution affirmatively that he was manufacturing the drugs for sale or was selling the same or has stocked them or exhibited the articles for sale. The possession simplicit of the articles does not appear to be punishable under any of the provisions".

It may be stated that the interpretation of the Court was very narrow. What is required in such cases is the broader interpretation by keeping in view the objectives of the legislation. Hence, the interpretation, by presuming that the drugs in possession especially of such large quantity, as in this case, were meant for sale or distribution would have been a reasonable interpretation.

In Khasim Bhai v. State, eight tubes of date expired pencillin ointment were recovered from the shop. The court held that there was nothing in the statement or evidence produced to show that those tubes kept in the shop were not for the purpose of sale but for any other purpose. Hence the court presumed that they are stocked for sale. In yet another case Supreme Court appeared to have given a wider meaning to these words by keeping the legislative intention in mind. In Swantraj v. State of Maharashtra, the petitioners were whole sale dealers having licence to stock drugs at Bombay and were having further licence to distribute the drugs through the motor van throughout the territory of the State of Maharashtra. But one of the partners of the petitioner released the goods from the transport operator at a place called Yeotmal.
and temporarily kept them in the godown of a local dealer. The petitioner claimed that they intend to load the van subsequently with those drugs and distribute the drugs as permitted by the licence.

The question before the Supreme Court was whether the act of the appellant in temporarily storing drugs, not for immediate sale there but intended for ultimate sale in various parts of the State, was contrary to section 18(c). Interpreting the provision Krishna Iyer, J., laid down the law as:

"If any godown, depot or premises become the nidus of spurious, time expired or unscientifically stored drugs, can they be allowed to escape the coils of the penal law on the plea that they are not to be sold there, without great peril to patients? Then legal shelter for spurious drug rackets would be judicially ensured. And this colours construction. Stocked for sale there and then? or to be sold certainly but elsewhere later? are the two alternatives flowing from the language of section 18(c). The former permits abuse through loopholes, the latter tightens up but loads the dealer with expenses and need for more licences. Since risk to life and health is avoided by the latter interpretation, we hold that the storage, even through for short spell and on ad hoc basis and without intent to sell at that place but as part of the sales business, comes within the scope of the 'storage for sale' in section 18(c) and rule 62. To loosen the law in its joints is to play with life and therefore anti-humanistic"¹³.

¹³ *Id.* at p.520
Meaning of distribution:-

Distribution means the act of dealing out to others or dispensation. The word distribution has not been defined under the Act. According to dictionary it means delivery of something to several persons. Several meanings have been given to the word distribution in various dictionaries. Accordingly it means to divide among several or many, to deal out a portion or allot, spread out as a cover, a surface or space, or to divide or separate especially into classes, orders, kinds. According to Lexicon of Law, distribute means the act of spreading of goods anywhere by whatever means that may be employed.

In State v. Nathumal Damumal,44 the word ‘distribution’ has been interpreted while deciding a case under this Act. A person who was trading at Nasik, purchased certain drugs from Calcutta and transported them to Nasik. Those drugs were not found to be of standard quality by the Drugs Inspector, and prosecution was launched at Nasik. A point was taken in course of trial at Nasik that the purchase was made at Calcutta and therefore, the court at Nasik had no jurisdiction. It was held that “the word distribute was wide enough to include the repose of goods at Nasik even though the sale was completed at Calcutta”15. It was further held that the process of distribution started at Calcutta and ended at Nasik16.

The ordinary and general meaning of the word ‘distribute’ conveys spreading of the goods any where by whatever means that may be employed.

44 A.I.R. 1962 Bom. 21
15 Id. at p23
16 Ibid.
Conditions to be satisfied before a licence is granted:-

1. Application for licences in prescribed forms:-

An application in the prescribed form accompanied by a prescribed fee should be made to the licensing authority appointed by the state government, for the grant or renewal of a licence to sell, stock or exhibit for sale or distribute drugs. The form prescribed varies depending upon the various categories of drugs for which licence is sought. The licensing authority may delegate the power to sign licence to any person under his control with prior approval of the state government. If the drugs are sold or stocked for sale at more than one place, separate application forms should be made and a separate licence must be obtained in respect of each place. But for the itinerant vendors who have no specified place of business and who will be licensed to conduct business in a particular area within the jurisdiction of the licensing authority the above provision is not applicable.

Restricted Licences:-

In respect of drugs whose sale does not require supervision of a qualified person, the licensing authority can issue the restricted license to dealers or firms in a separately prescribed form.

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17 See Forms 19 to 21CC in Schedule A for prescribed form through which an application can be made. Form and fees vary depending upon the category of drugs for sale of which the applicant is seeking licence.
18 See Drugs and Cosmetics Rules, 1945 Rule 59.
19 See id., Rule 61 to 65B
20 See id., Rule 60
21 See id., Rule 62
22 Drugs and Cosmetics Rules 1945, Form 20A and Form 21A under Rule 62A, (a) in Schedule - A. Also see section 51 and orders under the Medicines Act 1968 (England) for similar provisions. In England these drugs are specified in the general sale list which can be sold through the automatic machine without the supervision of a qualified person.
In exceptional circumstances licences may be issued for bonafide travelling agents or firms dealing in drugs or for vendor who purchases drugs from a licensed dealer for distribution in sparsely populated rural areas where other channels of distribution of drugs are not available. The restricted licence may also be issued to a travelling agent of a firm for the specific purpose of distribution of samples of biological and other special products specified in schedule C to medical practitioners or dealers. But the travelling agents of licensed manufactures, agents of such manufactures and importers of drugs are exempted from taking licence if they are distributing samples of medicines among members of the medical profession, hospitals, dispensaries and the medical institutions or research institutions.

Such of these restricted licences will be granted by the authority only if it is satisfied that the premises in respect of which the licence is to be granted are adequate and equipped with proper storage accommodation for preserving the properties of drugs to which the licence apply. The authority granting such licence is also empowered to take into account the number of licences already granted in that locality within one year immediately preceding and the occupation, trade or business carried on by such applicant before granting licence. The licencing authority may refuse to grant or renew the licence in respect of persons who are convicted for any offence under the Act or rules or the authority is of the opinion that the applicant is not a fit person to whom such licence should be granted.

23 See id., Rule 62A (c)
24 See id., proviso to Rule 62A (c)
25 See id., Rule 62B(1)
26 See id., proviso to Rule 62B(2)
3. Licence other than restricted licence.

A licence other than a restricted licence to sell, stock are exhibit for sale or distribute drugs cannot be granted to a person unless the licensing authority is satisfied that the premises are in-charge of a person competent, in the opinion of the licensing authority, to supervise and control the sale, distribution and preservation of drugs. The premises in respect of which the licence is to be granted must be adequate and equipped with proper storage accommodation for preserving the properties of the drugs to which licence applies. But in the case of pharmacy license, the same cannot be granted unless the authority is satisfied that the requirements prescribed for a pharmacy have been complied with. Same requirements are made applicable to a chemist and druggist.

4. Pharmacy licence:-

Pharmacy here means and includes every store or shop or other place where drugs are dispensed, where prescriptions are compounded or where drugs are prepared. It also includes the place which has displayed upon it a sign bearing the word or words “pharmacy”, “pharmacist”, “Dispensing chemist” or “pharmaceutical chemist”.

In granting licence under rule 64 of the rules the licensing authority must have regard to the average number of licences granted during the period of three years.

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27 See id., rule 64
28 See id., Schedule N
29 See id., Explanation to Rule 64 (1)
immediately preceding. He must also take note of the occupation, trade or business ordinarily carried on by such applicant during the period of three years immediately preceding.

5. General condition

These conditions\(^{30}\) are generally imposed by the licensing authority for all licences except licences to dealers in respect of drugs whose sale does not require supervision of a qualified person.

Every drug must be compounded only under the direct or personal supervision of a qualified person. The supply of any drug on the prescription of a registered medical practitioner can be made only by or under the supervision of a qualified person. The supply of any drug on a prescription of a registered medical practitioner must be recorded in a register specially maintained for this purpose. Such register has to contain the particulars like serial number of the entry, the date of supply, the name and address of the prescriber, the name and address of the patient, or the name and address of the owner of the animal if the drug is supplied for veterinary use and the name of the drug or preparation and the quantity and in the case of medicine made up by the licensee, the ingredients and the quantities of it.\(^{31}\)

In the case of drugs specified in Schedules C or H, the name of the manufacturer of the drug, its batch number and the date of expiry of potency must be recorded before any sale of such drug is made and the signature of the qualified

\(^{30}\) See id., Rule 65 generally
\(^{31}\) Rule 65 (3)(1)
person under whose supervision the medicine was supplied is a must. But
maintenance of the above register is not required in the case of drugs which are not
compounded in the premises and which are supplied from the original containers
and when these particulars are already entered in cash or credit memo book. If the
medicine is supplied on a prescription on which the medicine has been supplied on
previous occasion and entries are made in the prescription register, it is sufficient if
the new entry in the register includes a serial number and date of supply, the quantity
supplied with a sufficient reference to an earlier entry. Maintenance of such register
is also not required for any drugs supplied against prescription under Employees
State Insurance Scheme if all the above particulars are given in that prescription and
any drug other than that specified in Schedule C or H if it is supplied in the original
unopened container of the manufacturer and if the prescription is duly stamped at the
time of supply with the name of the supplier and the date on which the supply was
made.\textsuperscript{32}

The supply by retail of a drug other than one on prescription specified in
Schedule C must be recorded in a register maintained for this purpose and it should
contain the entries like serial number of the entry, date of supply, the name and address
of the purchaser, the name of the drug and quantity of it, the name of the manufacturer,
the batch number and the date of expiry of potency and the signature of the person
under whose supervision the sale was effected.\textsuperscript{33}

\textsuperscript{32} \textit{Ibid.}
\textsuperscript{33} \textit{Id.}, Rule 65 (4)(1)
6. Records to be maintained by retailer of drugs:-

The retailer is required to maintain the records of purchase of drugs which are intended for sale. Such record must contain the details regarding date of purchase, name and address of the person from whom the drugs are purchased and the number of the relevant licence held by him, the name of the drug, the quantity and the batch number and the name of the manufacturer of drug.\(^{34}\)

7. Conditions on the supply of drugs by whole sale:-

The supply of a drug by whole sale should be made only against a cash or credit memo bearing the name and address of the licences and his licencee number. The cash memo should cover the particulars relating to date of sale, the name, address of the licencee to whom drugs are sold and his sale licence number. In case of sale to an authority purchasing on behalf of government or to a hospital, medical, educational or research institution or a registered medical practitioner for the purpose of supply to his patients, it has to contain the name and address of the authority, institution or the medical practitioner as the case may be. In addition to these particulars, the name of the drug, the quantity and the batch number, and the name of the manufacturer must be mentioned in the cash or credit memo as the case may be.\(^{35}\)

The copies of cash or credit memo should be preserved as records for a period of three years from the date of the sale of the drug. The licensee should produce for inspection by an inspector all registers and records maintained by him and he

\(^{34}\) Id., Rule 65(4)

\(^{35}\) Id., Rule 65(5)(1)\(\text{a}\)-(3)
has to supply all information to the inspector to satisfy him that the provisions of the Act and rules have not been violated. These rules appear to have been intended to ensure that no sale of any drug can be made to a person who is not holding the requisite licence to sell, stock or exhibit or to distribute the drug.

8. Sale on prescription and conditions there to:-

Substances specified in Schedule 'H' or Schedule 'X' should not be sold by retail except in accordance with the prescription of a registered medical practitioner and in the case of substances specified in the Schedule X, the prescription shall be in duplicate. One copy of such prescription must be retained by the licensee for a period of two years. But if such substances are supplied to registered medical practitioners, hospitals, dispensaries and nursing homes, the same can be made against the signed order in writing which has also to be preserved by licensee for a period of two years. For this purpose the prescription must be in writing and be signed by the person giving it with his usual signature and be dated by him. It should also specify the name and address of the person for whose treatment it is given or the name and address of the owner of the animal if the drug is meant for veterinary use. The prescription must also indicate the total amount of medicine to be supplied and dosages to be taken.

The person dispensing a prescription containing a drug specified in Schedule H and Schedule X has to comply with further requirement in addition to the above requirements. The prescription must not be dispensed more than once unless the

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34 See id., Rule 65(9)a
35 See id., Rule 65(9)b
36 Id., Rule 65(10)
37 See id., Rule 65(11)
prescriber has stated on it that it may be dispensed for more than once. If the prescription contains direction that it may be dispensed in a stated number of times or at stated intervals, it must not be dispensed otherwise than in accordance with such directions. Another requirement is that at the time of dispensing prescription it must be noted on the prescription above the signature of the prescriber, the name and address of the seller, and date on which the prescription is dispensed.

It is mandatory that a person should not supply any other preparation whether it contained the same substance or not while dispensing a prescription containing substances specified in Schedule H and X. Substances specified in Schedule X kept in a retail shop or premises must be stored under lock and key in cupboard or drawer reserved solely for the storage of these substances or in a part of the premises separated from the remainder of the premises and to which only responsible persons have access.

9. Description of the premises:-

The licensee who do not require the services of a qualified person should display a description as “drugstore” on the premises. The description “Chemist and Druggist” should be displayed by such licensee who employ the services of a qualified person but who do not maintain a pharmacy for compounding against prescription. The description ‘pharmacy’, ‘pharmacist’ ‘dispensing chemist’ or ‘pharmaceutical chemist’ should be displayed by such licensee who employ the services of qualified persons.

*Id., Rule 65(11A)
person and also maintain a pharmacy for compounding against prescription.\footnote{Id., Rule 65 (15)}.

For the purpose of this rule qualified person means a person who holds a diploma or degree in pharmacy or pharmaceutical chemistry of an institute approved by the licensing authority\footnote{See Pharmacy Act, 1948, Ss 31,32, 32 A & 32 B}. Under these provisions the qualified person also includes a person possessing qualifications to have his name entered in the register but whose name has not been entered because the first register of pharmacist was not prepared at that time and it includes a person who has not less than four years practical experience of dispensing which is in the opinion of the licensing authority adequate and has been approved by that authority as a 'qualified person'\footnote{See Drugs and Cosmetics Rules., Rule 65(15)(c). It may be noted that these provisions are applicable to those who acquired such qualifications before 31-12-1969}.

10. Dealing with expired drugs:-

No drug should be sold or stocked by the licensee after the date of expiration of potency recorded on its container, label or wrapper, or in violation of any statement or directions recorded in such container, label or wrappers. Date of expiry means the date that is recorded on the container, label or wrapper as the date up to which the substance may be expected to retain potency or not to acquire toxicity greater than that required or permitted by the prescribed test\footnote{See Id., Schedule P for life period of various drugs}.

Where the licensee has taken steps in respect of such drugs with the manufacturer or his representative for the withdrawal, reimbursement or disposal of the same, such drugs may be stocked after the date of expiration of potency pending
such withdrawal, reimbursement or disposal. But the same should be stored separately from the trade stocks. All such drugs are to be kept in packages or cartons, the top of which must display prominently, the words ‘not for sale’.

Hence there is nothing in the rules to make it obligatory upon a licensee to destroy or throw away the stock as soon as it crosses the date of expiry. It was held in *Aftab Ahmad v. State*, that if for claiming rebate from income tax and sales tax departments, the licensee keeps expired date medicines in his stock, due precaution is to be taken so that everybody should know that the same were not intended for sale. Then he can not be said to have committed any offence.

11. Sale of free samples:-

Drugs intended for distribution to the medical profession as free samples which bears a label on the containers or carton or wrappers and drugs meant for consumption under Employees State Insurance Scheme, the Central Government, Health Scheme, the Govt Medical Stores depots, the Armed Forces Medical Stores or other government institutions which bear a distinguishing mark or any inscription on the drug or on the label affixed to the container indicating such purpose should not be sold or stocked by the licensee on his premises. Of course, this rule provided exemption to licensees who have been appointed as approved chemists by the State govt in writing under the ESI scheme for drugs meant for consumption under the scheme.

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65 *Id.*, Rule 65(17) proviso
66 1978 Cr. L.J. 1333
67 See Drugs and Cosmetics Rules 1945., Rule 15(18) and proviso
12. Supply of drug in containers:-

The retailer is required to supply the drug only in container through which the manufacturer has marketed the drug. The supply by retail of any drug in a container other than the one in which the manufacturer has marketed the drug is allowed only by dealers who employ the services of a qualified person. Such supply is to be made only under the direct supervision of the qualified person and in an envelope or other suitable wrappers or container showing the name and quantity of the drug supplied and the name and address of the dealer.48

13. Sale of Veterinary drug:-

The medicines for treatment of animals kept in a retail shop or premises must be labelled with words clearly stating that these are not for human use but are only meant for treatment of animals. These drugs are to be stored in a cupboard or drawer reserved solely for the storage of veterinary drugs. Otherwise, these medicines are to be kept in a part of the premises separated from the remainder of the premises. Customers should not be permitted to have any access to such premises49.

14. Separate Register for supply of Schedule X drugs:-

The supply of drugs specified in Schedule ‘X’ should be recorded in a register bound and serially numbered and specially maintained for this purpose and separate pages are be allotted for each drug. It may be noted that all the entries must be made

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48 _Id._, Rule 65(19).
49 See _id._, Rule 65(20).
only at the time of supply of the drug. The particulars to be entered in the register are
date of transaction, quantity received, the name and address of the supplier and the
number of the relevant licence held by the supplier. Name of the drug, quantity supplied,
manufacturer’s name, batch number or lot number, name and address of the patient
or purchaser, reference number of the prescription against which supplier were made,
bill number and date in respect of purchases and supplies made by him, are to be
entered in the register in addition to signature of the person under whose supervision
the drugs have been supplied. Obviously these stringent conditions are intended to
ensure the safety of the consumers because of their toxic content and fatal
consequences that may flow out of the misuse of these drugs.

It may be stated that these rules relating to prescription drugs appeared to
have been observed more by violation though the authorities claim that their inspectors
regularly conduct surprise checks on the retail outlets to monitor these regulations.
Consumer associations pointed out that most of the retail outlets do not have the
qualified pharmacist to supervise the sales though it is mandatory under law that
every chemists shop should have such qualified person. The result, according to
them is that drugs which do not fall under ‘over the counter’ category are being sold
freely in the market without prescription. According to them any drug can be purchased
over the counter in India without any prescription.

See id., Rule 65 (21) (a) & (b)

Power to demand information:-

The licensing authority at any time may call for any information from the applicant for licence. It may demand for documentary evidence in respect of the ownership or occupation on rental or other basis of the premises specified in the application for licence. Other details required may include the constitution of the firm or any other relevant matter necessary for the purpose of verifying the correctness of the statements made by the applicant while applying for the license. Similar information may be called even from those who have already been licenced.\textsuperscript{52}

Cancellation and suspension of licences:-

The licensing authority may cancel a licence by an order stating the reasons in writing for such cancellation. But before passing such an order the licensee should be given an opportunity to show cause why such an order should not be passed. It may suspend the licence instead of cancellation for such period as it thinks fit. This suspension may be in respect of some of the substances to which the licence relates if in its opinion, the licensee has failed to comply with any of the condition of licence or with any of the provisions of the Act or rules. But where such failure or contravention is in consequence of an act or omission on the part of an agent or employee, the licence can not be cancelled or suspended if the licensee proves to the satisfaction of the licensing authority that the act or omission was not instigated or connived at by him\textsuperscript{53}. And it cannot also be cancelled if he or his agent or employee had not been

\textsuperscript{51} See Drugs and Cosmetics Rules 1945. Rule 65(A).
\textsuperscript{52} See id., Rule 66
guilty of any similar act or omission within twelve months before the date on which
the act or omission in question took place. Where his agent or employee had been
guilty of any such act of omission, the licensee had no knowledge or could not
reasonably have had knowledge of that previous act or omission, action can not be
taken against him. Also licence can not be cancelled if the licensee proves to the
satisfaction of the authority that he had used due diligence to ensure that the conditions
of licence or the provision of the Act or the rules were observed.54

Procedure for disposal of drugs in the event of cancellation of licence.

In case a licensee, whose licence has been cancelled, desires to dispose of
the drugs in his possession at the premises in respect of which the licence has been
cancelled, he can apply in writing to the licensing authority for this purpose. In that
case he has to give the particulars as to the name and address of the person to
whom the drugs are proposed to be sold or supplied. It must also contain the particulars
relating the number of the license which the buyer possess for sale or manufacture
and the names of the drugs together with their quantities and batch numbers. It must
also contain the particulars relating to the dates of expiry of the drugs proposed to be
sold55. The licensing authority after examination of the particulars and if necessary,
after inspection by an inspector of the premises where the drugs are stocked may
grant the necessary permission for their disposal.

54 Ibid.
55 Id., Rule 66A
Minimum space and facilities required for premises or pharmacy in respect of which license is to be granted:

Space that is required at the premises where the business is to be carried out depends upon the nature of the business to be carried out by the applicant for licence. If the applicant desires to have both whole sale and retail business in drugs at the same place, obviously the required space for dispensing the drugs must be more. This appears to be evident from the rules.

In respect of application for grant of licence for sale of drugs by whole sale, the licensing authority is to be satisfied that the premises in respect of which a whole sale licence is to be granted are of an area of not less than ten square meters. The same space is required for the grant of licence in sales by retail. But in respect of an application for grant of a licence for both wholesale and retail sales in drugs the licensing authority shall satisfy itself that the premises are of an area for which the licence is sought is not less than fifteen square meters. Perhaps the amended provisions are intended to ensure sufficient space for dispensing the drugs when the applicant is seeking licences for both whole sale and retail sales and also for more variety of drugs at the same premises.

Minimum equipment for the pharmacy:

The front of a pharmacy should bear an inscription pharmacy. The premises

54 Id., Second proviso to Rule 64 (2)
55 Id., Rule 64 (2), see 1997 CCL 95 part III for amendments made to the Rules.
of pharmacy should be separated from rooms for private use. The premises should be well built, dry, well lit and ventilated and of sufficient dimensions to allow the goods in stock, especially the medicaments and poisons to be kept in a clearly visible and appropriate manner. The area of the section to be used as dispensing department should not be less than 6 square meters for one pharmacist with additional two square meters for each additional pharmacist. The height of the premises is to be at least 2.5 meters.

The floor of the pharmacy should be smooth and washable. The walls should be plastered and tiled or oil painted so as to maintain smooth, durable and washable surface devoid of holes, cracks and crevices. The pharmacy must be provided with ample supply of good quality water. The dispensing department should be separated by a barrier to prevent the admission of the public. The furniture and apparatus of a pharmacy is to be adequate for the uses for which they are intended and correspond to the size and requirements of the establishment.

Drugs, chemicals and medicaments should be kept in a room appropriate to their properties and in such special containers to prevent any deterioration of the contents. Drawers and glasses and other containers used for keeping medicaments must be suitable in size and are to be capable of being closed tightly to prevent the entry of dust. Every container should bear a label of appropriate size, easily readable with names of medicaments as given in the pharmacopoeia.

See id., Schedule N and rule 64(1)
Hbid.
Hbid.
Hbid.
A pharmacy is required to be provided with a dispensing bench the top of which is to be covered with washable and impervious material like stainless steel, laminated or plastic. The pharmacy is also required to be provided with a cupboard with lock and key for the storage of poisons and should be clearly marked with the word “Poisons” in red letters on a white background. Containers of all concentrated solutions should bear special label or marketed with words “to be diluted”.

The pharmacy has to be provided with the minimum apparatus and books necessary for making of official preparation and prescriptions. The books on current edition of Indian Pharmacopeia and National Formulary of India along with Drugs and Cosmetics Act and rules and Indian Pharmacy Act should also be provided at the pharmacy. The requirement of this literature at the pharmacy is required obviously to enable the pharmacist to consult these books in case of any doubt relating to compounding of any drugs and to follow the rules scrupulously.

A pharmacy is to be conducted under the continuous personal supervision of a registered pharmacist whose name has to be displayed conspicuously in the premises. The pharmacist should always put on clean white overalls. The premises and fittings of the pharmacy should be properly kept and everything must be in good order and clean. All records and registers are to be maintained in accordance with the laws in force.

Any container taken from the poison cupboard must be replaced there immediately after use and the cupboard is to be locked. The keys of the poison
cupboard are to be kept in personal custody of the responsible person. The medicaments when supplied should have labels conforming to the provisions of laws in force.

It must be noted that the above requirements are subject to modification at the discretion of the licencing authority. If he is of the opinion that it is necessary to relax the above requirements or to impose additional requirements in the circumstances of a particular case and depending upon the drugs dispensed, compounded or prepared by the licensee he can take an appropriate decision. For instance the items like Pill Machine, Pill boxes, and suppository mould are to be provided in the pharmacy only by those who intend to dispense pills or suppositories as the case may be. Anyhow, the decision of the licensing authority in that regard is final.

A critique of the format of licence:

From the reading of Rule 61 and 62 it is clear that six prescribed forms of licences are available to make applications to sell drugs by retail or whole sale. Of these, three forms are for licences to sell drugs in schedule C and C(1) and other three for licences to sell other drugs by retail or whole sale. Obviously there is no seperate form prescribed to obtain licence to stock or store the drugs for a brief period under circumstances that may necessitate during the course of transit where the drugs are to be taken delivery from railway or other public transport and loading into some other mobile van. If the time gap between taking of delivery from one
vehicle to the other vehicle is more and the goods are to be stored in a godown, the
licence obtained for distributing the drugs through vehicle may not be sufficient to the
requirements of law. No separate forms are provided for licences for itinerant vendors
for an area who are required to take licences under law. The Supreme Court in Swantra
v State of Maharashtra⁶¹ has pointed out that it was a glaring deficiency that when
the rules visualized wholesale distribution licences, the forms do not spell out licences
for mobile vans or distribution depots which are essential for wholesale distribution
system. The Court said,

"there is no doubt that if a scientific system of overseeing
whole sale distribution and viable scheme of protected distribution
is to be devised, licences for large and well equipped conveyances
and storage depots is desirable, nay necessary⁶².

The court also pointed out that storage in transit must also be licenced so
that medicines do not suffer in the process. At present no rules take care of transit by
road or rail. Actually, cold storage or air conditioned facilities for sensitive medicines
are scarce in nationalized and private transport services and the drugs rules do not
appear to have taken cognizance of this fact. Therefore, the forms do not provide for
storage depots or medical vans for wholesale supplies. The court urged for the
legislative intervention by saying,

"social guilt attaches to legal lacuna, the community being
the victim. Arguments in this case have exposed these short falls in
the law and we state them for legislative attention."63

In fact the statutory scheme does provide for retail and wholesale sales and storages for sale. It does prescribe forms for itinerant retailers for specified areas. But storage for sale in mobile vans resorted to by wholesalers is not expressly covered by statutory forms. There is also no express power to modify the forms prescribed by the rules or innovate according to need though it is desirable. If the licences are not insisted on for every place or makeshift storage in a far flung area served by wholesaler, it would be unsafe for the people who are susceptible to ailments and who are largely ignorant of health hazards. Then purpose of regulation through licensing will not be a vigilant medical watch over drugs and medicines. The Supreme Court pointed out that "if godowns, temporary stores and depots can remain unlicensed, they escape official attention and can deteriorate into foci of dubious or deceptive drugs harmful to society".64

Hence there is a need that every place where storage for sale is made must be licensed. That is to be the plain meaning of section 18(c) in fulfillment of the clear purpose in reasonable defence of the sick and ailing.

Regulations for collection, storage and supply of blood:-

Blood is treated as a 'drug' under the Act65. Blood is an essential component

63 Ibid.
64 Id. at 8520
65 See Drugs and Cosmetic Rules 1945, Part XII B. It may be noted that blood was not defined under rules as drug. As it was brought under the controlling provisions, it may be treated on par with drugs for all purposes of its collection, manufacture, storage and supply
of the body which provides sustenance to life. There can be no greater service to humanity than to offer one’s blood to save the life of other fellow human being. At the same time instead of saving life can also lead to the death of the person to whom the blood is given if it is contaminated. As a result of the developments in medical science, it is possible to preserve and store blood after it has been collected so that it can be made available in case of need. There are blood banks which undertake the task of collecting, testing and storing the whole blood and its compounds and make the same available when needed.

In view of the dangers inherent in supply of contaminated blood it is necessary to ensure that the blood that is made available for use is healthy and free from infection. Hence, in the Drugs and Cosmetics Rules, provision regarding equipment and supplies required for a blood bank were made. In these rules, requirement regarding equipment, blood collection, supplies, canter equipment and emergency equipment for the blood donor room were prescribed. Similarly provisions were made for the laboratory, general supplies, technical staff, accommodation for blood bank, label for whole blood and colour scheme for label. These rules have been revised to govern the licensing operation of the blood banks also. These rules prescribe the requirements for collection, storage, processing and distribution of human blood and human blood components by blood banks. The manufacture of blood products are also regulated. The procedure for granting and of renewal of licence for the operation of the blood bank is also prescribed. Under the provisions,
licence can be granted or renewed only with the approval of the Central Licence Approving Authority that is the Drug Controller of India.

**A Critique of the functioning of the blood banks**

A report submitted to the government highlighted the deficiencies with regard to the facilities of testing blood, licencing of blood banks, storage of blood and the problem of professional donors. It was stated in the report that out of the total number of 1018 blood banks as many as 611 are reported to be unlicensed. There are only 201 licensed commercial blood banks. The supply of blood by licenced commercial blood banks is only about 1/4th of the blood used in the hospitals of the country. The report also said that no medical check up is done on the blood donors, and their health status is not examined.

It is a mandatory requirement to conduct tests on blood which is to be administered to a patient or to be issued to hospitals for transfusion. The blood so issued has to be free from AIDS, Viral Hepatitis, Malaria, Venereal diseases etc. It was reported that mandatory tests which are required to be done are rarely conducted and the blood banks have been thriving on bleeding the professional blood donors. These professional donors, according to the report, are the victims of ill health, low haemoglobin level and many infections.

The blood banks have to necessarily possess facilities like refrigerators exclusively for storage of blood with a specified range of temperature for ensuing

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68 Ibid
70 Ibid.
71 Ibid.
The storage facilities in the blood banks are reported to be far from satisfactory. In the existing blood banks many items of equipment remain unattended for years, electricity failure are frequent, generators are rarity. This applies not only to private commercial blood banks but also to government hospitals. It was also reported that these blood banks are located in unhygienic environment and they collect and store blood in a very dirty conditions. In some places, it was reported that strong middle men operate for the blood banks by arranging donors. The middle men dictate the charges to be paid and take a heavy commission. The report says that a large part of the professional donors are alcoholics or drug abusers. Thet do have indiscriminate sexual habits and are high risk group for Hepatitis and AIDS.\(^2\)

Trained personnel are generally not available in blood banks. It was reported that drug control department, which is expected to ensure the appropriate functioning of blood banks do not themselves have specified trained personnel.\(^3\)

The Supreme Court in \textit{Common Cause v. Union of India},\(^4\) made several recommendations for the improvement in the functioning of the blood banks in the country on the basis of the recommendation made by the committee constituted for this purpose by the Court. The Supreme Court among other things, has recommended for launching of effective motivation campaign through utilization of all media for stimulating voluntary blood donations in educational institutions.\(^5\) It directed the government to undertake the comprehensive programme for training the personnel

\(^{2}\) \textit{Ibid.}
\(^{3}\) \textit{Ibid.}
\(^{4}\) \textit{A.I.R. 1996 S.C. 929}
\(^{5}\) \textit{Ibid.}, p 934
operating in various aspects of functioning of blood banks. The court also directed that the system of licensing of blood banks should be strengthened to ensure that all quality banks operating in the country are equipped with licences within a period of one year and said that the system of professional donors of blood should be discouraged through all appropriate media. 76

The Court agreeing with the recommendation of the committee held the view that the entire range of schemes relating to operation and requirements of blood banks including the launching of effective motivation campaign for stimulating voluntary blood donations, and training of personnel should be entrusted to an autonomous representative body at national level which may be called at the National Council on Blood Transfusion. 77

Administrative machinery:-

Effective administrative measures are required to supervise, monitor and to ensure that the conditions of licences are fulfilled by the licensee. This require the establishment of enforcement machinery with all adequate facilities to efficiently discharge their duties under the laws and rules. For this purpose, law provides for the establishment of inspectorate at the grass root level and sufficient number of drugs laboratories. The system of inspections is to ensure effective enforcement of all laws relating to quality in manufacture, sale and distribution. Drugs control laboratories are intended to analyse the drug samples sent to them by the inspectors

77 *Id.* at p 935
or by the affected person or consumer groups. The person in charge of these laboratories who are responsible for analyzing drugs are known as government analysts. The law prescribes qualifications and duties for the inspectors and govt analysts.

A person to be appointed as a government analyst should be a graduate in either medicine, science pharmacy or pharmaceutical chemistry of a recognized university. He must also possess post graduate experience of not less than five years in the testing of drugs in laboratories approved by the government for this purpose. But an experience of not less than three years would be sufficient for a post graduate in any of the above fields of science. The person to be chosen for this post should not have connections either directly or indirectly with the manufacturers of drugs. Similar qualifications in veterinary science are required for persons to be appointed to examine veterinary medicines.78

A person to be appointed as an inspector should be a graduate in pharmacy or pharmaceutical chemistry or post graduate in chemistry with pharmaceutics of a recognized university. An experience of not less than one year in post graduate training in an approved laboratory is required for the other graduates in science and medicine. To inspect the veterinary products, the inspector must be a graduate in veterinary science or other sciences with an experience of 18 months in the manufacture of biological products.79

78 Drugs and Cosmetics Rules 1945, Rule 44
79 Id., Rule 49
There is no bar on the government in prescribing different qualifications for inspectors for different purposes. It has full freedom to prescribe any qualification and can prescribe one set of qualifications for an inspector for one purpose and another set of qualifications for an inspector for another purpose. It can therefore prescribe lower qualifications for an inspector for inspection of shops and higher qualification for inspection of manufacturing units.\textsuperscript{90} Post graduate experience or training was held\textsuperscript{91} to mean the experience or training that has to be gained after obtaining graduation. The object of the provision is to ensure that to be eligible for the post, the person concerned must have received training under any of the authorities after graduation in medicine or science.

**Duties of government analyst and inspectors:-**

It is the duty of the government analyst to analyse or test the samples of drugs that are sent to him by inspectors or other persons and furnish reports of the results of tests or analysis in accordance with the rules and procedure framed under the law.\textsuperscript{92} According to the procedure laid down under rules, he has to compare the seals on the packet with the specimen impressions and also make note of the condition of the seals on receipt of the package of sample drugs for test. The report of the analyst should contain the particulars of full protocols of the test or analysis carried out by him.\textsuperscript{93} It may be stated that the protocols of test and analysis may vary depending upon the pharmacopoeia to which the drug relates. Where there are no prescribed

\textsuperscript{89} See Rajkrishnav. State, A.I.R 1960 All. 460
\textsuperscript{90} See Maheswar Prasad Sreevastava v. Suresh Singh, (1977) 1 S.C.C 627
\textsuperscript{91} Drugs and Cosmetics Rules 1945, Rule 45
\textsuperscript{92} Id., Rule 46
methods of tests available in any pharmicopoeia for a drug, the analyst may furnish the description of the test evolved by him basing on the relevant books and journals.

All inspectors are under the control of an officer appointed by the state government for this purpose. It is the duty of the inspector to inspect all the premises licensed for the sale of drug in an area assigned to him for not less than twice a year. He has to satisfy himself that the conditions of licences are being compiled with by the sales units. Either on a complaint received by him or on his own if he has a reason to suspect that certain drugs are sold in contravention of the law, he can procure and send such drugs for test or analysis. In respect of any breach of the law he can initiate legal action including prosecution of the person responsible for breach. He has to maintain a record of all inspections made and action taken by him in performance of his duties, including the taking of samples and seizure of the stocks and has to submit the copies to the controlling authority in the State. He can detain the imported packages of drugs if has reason to suspect that they are imported in contravention of law. He can make all such enquiries and inspections which are considered by him as necessary to detect sale of drugs in contravention of the law.84

Critical analysis:-

A study of the staff and facilities available to them would reveal that the government has to bestow much thought of expansion of the department for more stringent enforcement of drugs laws. The control of sale and distribution of qualitative drugs is a gigantic problem which requires much bigger and closer net work of

84 See id., Rule 50 and 51
organization. Given the task assigned to them, it is necessary to provide adequate staff and facilities to the department. As per the yard stick prescribed by the Task Force, there must be one drug inspector for every 25 manufacturing concerns and one drug inspector for every hundred sales concerns. A drug control laboratory at every State headquarters is required to achieve the target of analyzing a minimum of 3000 drugs per annum.

According to the Drug Controller of India the drug control organization remains as it was several years ago though there has been a constant growth in the number of manufacturing and sales units. It seems the staff available is only one fourth of the number required by them. According to him there are no Special Cells to unearth spurious drug rackets and an intelligence wing is required for each State. It appears that there is not even a single vehicle available at the disposal of drugs inspectors in each district. This facility is required to check the movement of spurious drugs from one place to the other and take timely action against offenders and also to conduct surprise check and raids as and when necessary.

Most of the states do not have the laboratories to test the genuineness of drugs and those that do have laboratories, do not have the staff to conduct these tests. Only very few states have laboratories with adequate staff and facilities. Therefore, there is no guarantee for the protection of the consumer of pharmaceutical

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81 See the brochure brought out by the Directorate of Drugs Administration, November 1st, 1987, Hyderabad.
82 Ibid.
83 See Indian Express, Oct 18, 1989
84 Ibid
85 Supra n. 85
86 Ibid. See also Indian Express, May 26, 1998 at p. 12
products if this situation continues. What has been said by the expert committee on
the functioning and facilities of blood banks may be equally applicable to the drugs
sale units in the country.

**Liability of the seller for injuries arising from sale and distribution of drugs.**

A seller of a drug is not liable for any injury resulting from the use of a drug
which he dispenses unless failure to exercise proper care is imputed to him. But he
is subjected to a positive duty, independent of the contract of sale, to use such care
as is ordinarily possessed and exercised by the members of his profession in selling
and dispensing drugs. He may be held liable in damages for any injuries which
proximately result from his failure to exercise such care.

The mere refusal of a druggist to fill a prescription does not render him liable.
As a chemist, he may have cause to suspect that the physician has erred. Sometimes
he may not have at hand the ingredients prescribed or he may distrust his own ability
to prepare the prescription or he may perceive other causes that disincline him to
undertake filling the prescription presented to him. A druggist is entitled to retain a
prescription as a record of his business after filling it and delivering the medicine
and in some cases he is required by law to retain the prescription. But a druggist
has no right to retain a prescription presented to him when he refuses to deliver the
medicines called for.

*See Drugs and Cosmetics Rules 1945, Rule 65(9b)*
Liability for breach of warranty:-

A druggist is held to impliedly warrant that he will deliver the drug required by the customer and he would be liable on breach of warranty for injuries resulting from a mistake in giving the wrong article. The implied warranty of fitness would be conditioned upon buyer's reliance upon the skill and judgement of the druggist. In selling a harmless drug a pharmacist is to be held to warrant the safety of the preparation by implication.

When a retail druggist fills a prescription or buys in bulk and bottles the drug and places his own label on it, he impliedly warrants the preparation to be what he represents it to be. But a druggist can not be held liable on the theory of breach of implied warranty for injuries resulting from the taking of a drug furnished on a doctor's prescription directing that the drug be supplied and which was available only to those who could present such a prescription which was filled precisely in accordance with the direction of the prescription from the manufacturer's original packet. And a druggist who merely recommends in good faith a prescription of another person is not liable for injuries to a customer who orders and uses the prescription, when there is no want of skill and no departure from the recipe in compounding the prescription.

Liability for Negligence:-

A registered pharmacist or other person who undertakes to act in the capacity of a qualified person in preparing medicines and filling physicians prescriptions must

92 See Sale of Goods Act 1930, Section 16(1)
be competent to perform the duties of his profession and is expected to possess and exercise the degree of knowledge and skill ordinarily exercised by other members of his profession. It is therefore incumbent upon a druggist to understand his business, to know the properties of the drugs and to be able to distinguish them from each other. It is his duty to attend to the business of compounding and vending medicines to see that one drug may not be sold for another and that proper medicines are used in mixing and compounding prescription. Moreover a druggist who employs others to compound prescriptions in his place of business has a duty to hire only qualified persons who are capable of differentiating between drugs offered for sale.

In keeping, handling and disposing of dangerous drugs and medicines, the public safety and security against the serious or even fatal consequences of negligence is a consideration which no druggist can safely ignore. An imperative duty requires him to take such precautions as are likely to prevent death or injury to those who may be exposed to the dangers incidental to the business in which he is engaged. A druggist must give his customers the benefit of his best judgement. He must be certain that he does not deliver to a purchaser or send a patient with a poison in place of a harmless drug. He must take care not to furnish a drug which, though not pemicious, is calculated to produce a different effect from the one requested.

Standard of care:-

The standard of care which is imposed on a pharmacist or other qualified

dispenser of drugs and medicines is generally described as ordinary care in the conduct of his business.\textsuperscript{94} The ordinary care required of him in compounding and selling drugs and medicines is that degree of diligences and prudence which is commensurate with the dangers involved and the consequences which may attend because of inattention on his part. The poisonous character of many of the drugs with which he deals and the grave and fatal consequences which may flow for want of due care must be considered. Accordingly the standard required of them must be that degree of caution and care called for by the peculiar and dangerous character of the business i.e., the highest degree of care and prudence for the safety of consumers known to practical men.\textsuperscript{95} The reason for holding druggist to such a high standard of care in self evident. People trust not merely their health but their lives to the knowledge, care is and prudence of druggist and a slight want of care may prove fatal.

It may be stated that the rights of the consumers can be preserved and responsibilities of the retail druggist are established by the concept that druggist who sells a prescription warrants that he compounded the drugs prescribed and used proper care in filling the prescription and that the drug has not been infected with some adulterous foreign substance. But the concept of strict liability without fault may not be applied to a druggist who furnishes a drug to a customer presenting a doctor's prescription precisely in accordance with the directions of the prescription from the manufacture's original packet. A druggist selling patent or proprietary remedies generally is not liable for injurious consequences to the purchaser from

\textsuperscript{94} Id at p. 444

\textsuperscript{95} See Northern Western Utilities Ltd. v London Guarantee and Accident Co. Ltd. [1936] A.C. 108, Part v, Stepney Borough Council, [1951] 1 All E.R. 42 (H.L.) and The Wagon Mound (No.2) [1960] 1 All E.R. 709, also see Margaret Brazier, Street on Torts, (eighth edition) Butterworths, at p. 196.
use of such remedies and the latter must look to the manufacturer for redressal.96

In compounding drugs and medicines druggists are required not only to be skillful, but to be exceedingly cautious and prudent. The care employed should correspond with superior knowledge which the law requires of the profession. Moreover the care required of a pharmacist is generally commensurate with the dangers involved. The greater the danger, the greater the care that must be exercised. Thus, a druggist is bound to exercise the highest degree of care in dispensing drugs.

All persons engaged in the business of handling drugs, whether as distributor, seller or otherwise, are bound to exercise the same degree of care and may be held liable for their failure to do so.

Proximate Cause

Failure of a druggist to exercise the standard of care required of him constitutes negligence which renders him liable in damages for any injury sustained as a result of proximate cause. The rule of liability is the same as that which governs the liability of all other professional persons whose work requires special knowledge or skill.97 Thus, a druggist is not responsible for an unintentional injury resulting from a lawful act if the failure to exercise due care cannot fairly be imputed to him. Although a druggist is not necessarily responsible for the results of an error of judgement which is reconcilable and consistent with the exercise of ordinary skill and care, a presumption or an inference sufficient to require the druggist to disprove negligence

96 See Sale of Goods Act 1930, proviso to subsection (1) of s. 16
97 See Margaret Brazier, Street on Torts, (8th Edn) Butterworths p. 210 - 211
arises upon proof of mistake or inadvertence on his part.

Where a druggist negligently sells a dangerous product to a person who uses it to commit suicide or acquires through its use a state of mind which leads to suicide the druggist is not generally liable for the customer’s death, since the sale is not deemed the proximate cause of the suicide. In a case reported from the US, the druggist sold barbiturate capsules to cure nervous condition without prescription. He committed suicide by hanging after taking the medicine. The American Supreme Court held that the druggist was not liable since the person whom the drug was sold was capable of consenting and was not under the influence of any drug when it was sold to him.

If some ingredient not called for by the prescription is included without notice to the purchaser, the liability for injury may be fixed on a druggist who sells a drug to one who is allergic to it. In an action against a druggist to recover damages for injuries allegedly sustained as a result of his failure to exercise due care, the negligence of the defendant and its operation as a proximate cause of the plaintiff’s injuries are to be proved and are questions of fact for the determination of court in each case.

**Mistake in filling prescription**

In filling prescription a druggist must exercise the highest possible degree of prudence, thoughtfullness and diligence. He must employ the most exact and reliable safeguards consistent with the reasonable conduct of the business. Druggists

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are liable for injurious effects as a consequence of negligence in compounding a prescription when the ingredients are improperly mixed. The legibility of the prescription is a circumstance to be considered in determining the negligence of the druggist who fills it. But the illegibility of a writing may not lessen or otherwise affect the obligation of the druggist. He has to take extra precaution especially when his first perusal indicates that the prescription calls for the inclusion of a drug which in the quantity specified is likely to be harmful. Accordingly if the dosage of a poisoning drug prescribed by the physician appears to be unusual it is prudent for druggist filling the prescription to make enquiry of the physician to ensure that there has been no error.

It a druggist is negligent in filling a prescription, he can not escape liability merely because the doctor who wrote the prescription is also liable. But it does not follow that because the physician is liable the druggist who filled the prescription is also liable. The druggist may be liable for filling a prescription as written if it calls for dosages that are obviously fatal.\(^{100}\)

**Sale of substance other than that requested:**

A druggist may be held liable for negligence in selling a harmful drug or medicine in place of the harmless one asked for by the purchaser or prescribed by his physician. Moreover, since the druggist is held to warrant that he will deliver the drug asked for by the customers, he may be liable on grounds of breach of warranty for injuries resulting from a mistake in giving the wrong product. A dealer in drugs is

liable for injury sustained by a consumer who was deliberately given a drug other than the one he was requested when the preparation asked for being out of stock.\textsuperscript{101}

**Failure to warn about dangerous properties of substances sold:**

The duty of care imposed upon a druggist comprehends a duty to warn of known dangers connected with drugs and medicines which he compounds and sells. In the absence of a contributory negligence on the part of the plaintiff, a druggist is generally liable for injury resulting from his negligence in selling a poisonous drug or a dangerous substance unaccompanied by a proper warning. A different question may arise if a druggist sells an inadequately labelled substance whose dangerous properties are generally known and recognized. In this situation, though no instructions as to the use of the product were given, the dealers should know or should have known, from the circumstance of the transaction, that the purchaser could not safely be entrusted with the preparation requested. And this is true regardless of how little knowledge the buyer had of the dangerous properties of the substance.\textsuperscript{102} The reason advanced to this rule of non-liability is that a person who has reached the age of discretion and is in apparent possession of his mental faculties, in asking a druggist for a particular preparation, represents by implication that he knows the properties of the substance requested and that he is fit person to whom it may be sold.

The fact that a letter ordering 'phosphorous' is incorrectly worded and spelled and that the writing is poor, is not of itself sufficient to charge the sellers with notice.

\textsuperscript{101} Wilcox\textit{v. Butt's Drug Stores}, 38 NM 502, 94 ALR 726 quoted from 25 Am Jur 355 (2nd)

\textsuperscript{102} Id. at p. 334
that the purchaser can not be entrusted with the article without instructions as to how to handle it safely.\textsuperscript{103} A druggist is obliged to warn a customer of the effects of a drug which is harmless but injurious when combined with another and the druggist has reason to know that the substance will be so used. And a druggist is liable for resulting injuries where unable to supply the kind of medicine called for by a customer, he fills the order with other medicine and represents that it is as good as that requested, without explaining that it contains poison in quantities harmless only when administered in proper doses.

**Liability of druggist for negligence of employee or agent:**

A druggist who employs others to compound prescription in his place of business is obliged to hire only qualified persons who are capable of discriminating between drugs offered for sale.\textsuperscript{104} Where a druggist undertakes as part of his regular business to fill prescriptions, it is immaterial to a customer, so far as the druggist's liability is concerned, whether the prescription is filled by the druggist personally or by one of his employees. Accordingly, where one is injured as a result of negligence of a druggist's employee, acting in the course of his employment, the druggist is liable in damages.\textsuperscript{105} Similarly, a corporation, as owner of a drugstore is liable for the negligence of its manager.\textsuperscript{106}

Where a clerk negligently sells an injurious drug to a customer instead of the harmless one asked for, the latter has a cause of action against the employer of the

\textsuperscript{103} Gibson v. Torbert, 115 Iowa 163, 88 NW 443 quoted in Id. at P. 334
\textsuperscript{104} See Drugs and Cosmetics Rules 1945, Rule 65(1)
\textsuperscript{106} Drugs and Cosmetics Act 1940. Section 34(1)
clerk for the pain and suffering caused by the mistake. And if a druggist’s employee departs from a prescription or ignorantly, carelessly or negligently introduces other drugs, his employer is responsible for the consequences to the person injured. Moreover, the fact that the employee who compounds the prescription is a competent registered druggist of wide experience does not relieve the employer from liability for the employee’s negligence. A druggist is also answerable for the act of his employee who in response to a request for a solution of a particular chemical, sells a solution of such abnormal strengths as to cause serious injury to the user.

A dealer in drugs and medicines whose agent or employee carelessly labels a deadly poison as a harmless medicine and sends it into the market, is liable to all persons who are injured by using the substance in consequence of the false label.107

**Liability of druggist for injuries resulting from sale of patent or proprietary medicine:**

Where a druggist sells a patent or proprietary remedy in the original package, accompanied by the directions of its use prepared by manufacturers, the druggist is not generally liable for any injurious consequences of the use of the remedy. The injured person must look to the manufacturer of the product for redressal. With respect to such medicines, a druggist is not required to analyse the contents of each bottle or package he receives and if he delivers to the customer the article called for with the label of the proprietor or patentee upon it, he can’t be justly charged with negligence. But a druggist purchasing a proprietary preparation in bulk and selling it from the broken package may become liable to one injured as a result of the negligence of

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107 *Thomas v. Winchester*, 6 NY 597 quoted from 25 Am Jun 337 (2nd)
the manufacturer. This distinction is supported on the ground that in a sale from the broken package the vendor has an opportunity of seeking or knowing and determining the character of the drug.

**Effect of contributory negligence:**

Contributory negligence on the part of one who sustains injury from the use of drugs or medicines will defeat a recovery against a negligent druggist. In this regard a druggist is not liable to one purchasing drugs on a physicians prescription for injuries caused by violating the instruction of prescription by taking the drugs in amounts exceeding the directions of the prescription. There is a reason to support that one who has been adequately warned that the use of a drug may produce certain consequences, but who, not withstanding such warning, elects to use the drug, assumes the risk of injury.

Contributory negligence was attributed to a minor who was injured but shown to be old enough to possess a knowledge and understanding of the dangers attending the course he has pursued. In *Cullinan v. Tetrault* it was held that one who attempted to purchase a harmless extract from a plainly incompetent boy in charge of a drugstore, and who relied upon his own sense of smell to determine whether or not the article offered was what he wanted, was negligent and that he could not hold the proprietor of the store liable when he was injured by the article received. In yet another case, *Scheres v. Schlaberg*, a father permitted the administration of medicine which he knew differed in character, in dose and in frequency of dose, from that

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18 ND 421, 122 NW 1000, quoted from 25 Am Jur 338 (2nd)
which the attending physician had prescribed to a child of 3 months old who was dangerously ill. The father was held guilty of negligence, and barred from recovering for the death of the child resulting from the negligent act of a druggist in furnishing medicine other than that called for by the prescription. It may be stated that the general principle in law of torts with respect to contributory negligence where the negligence of both the parties caused the death or injury, the common law rule was that the plaintiff was to fail.\footnote{See for general principles on contributory negligence, Ratanlal & Dhirajlal, *The Law of Torts* (1992) Wadhwa & Co. Nagpur at p. 477}

In actions to recover damages for injuries allegedly caused by negligence of a druggist, the question of plaintiff’s contributory negligence is ordinarily one of fact for the court to determine in each case.

**Effect of lack of privity between druggist and injured person:**

A druggist is liable to one injured by a drug sold by him even though the injured person did not purchase the substance from the druggist, provided that the injury complained of is the direct, natural and probable consequence of the druggist’s negligence in selling, labelling or preparing the drug. The liability in such a case arises not out of any contract or privity between the druggist and the person injured but out of the duty which the law imposed on the druggist to avoid acts in their nature dangerous to the lives of others. Accordingly a dealer in drugs is responsible in damages to persons other than the immediate purchaser for injury or death resulting from the negligent sale of a poison as harmless drug. Moreover, a pharmacist who carelessly labels a poison as a harmless medicines, and sends it so labelled into the
market is liable to any person who, without fault on his part, is injured by using it as a medicine in reliance on the label, even though the preparation may have passed through many intermediate sales before reaching the person injured.\textsuperscript{111}

The sale by a druggist of a substance innocent in itself but dangerous when combined with certain other drugs does not render him liable to a third person who subsequently makes such use of it, unless the druggist at the time of the sale had knowledge of how the preparation was to be used.

**The law on sale and distribution of drugs: a critical overview:**

The foregoing discussion discloses that the legislation regulating sale and distribution of drugs in India are comprehensive and self explanatory. Except in the case of collection and distribution of blood and blood products, the existing law can protect consumers effectively if it is implemented in true spirit. What is disturbing is that machinery for enforcement is inadequate and devoid of modern devices. Training of personnel and providing infrastructural facilities may improve the situation. In the case of blood and blood products the law is not clearly laid down. It may be possible to extend rules regulating the manufacturing, storage and supply of drugs to the collection, storage and distribution of blood also till a comprehensive legislation in ture with the Supreme Court direction is enacted.