PHARMACEUTICAL JURISPRUDENCE
(Theory)

Subject code: BP 505 T.

B. Pharm – 5th Sem

Preference Unit - IV

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Contents

Study of Salient Features of Drugs and Magic Remedies Act and its rules:

Objectives:

- Under competition of marketing of any product, advertising has become a part of our life.
- Modern age is called 'advertisement' era.
- It has occupied special position in our life.
- Media (TV, Internet) and newer method for advertisement has brought massive progress.
- About fifty years ago, advertising was not appreciated but now the position is quite different. Modern methods of advertising in TV and internet have proved effective.
- Drugs and cosmetic manufactures are spending money in advertising. So, the products are reasonable high.
- Ethical advertising is never objectionable, while unethical or misuse of advertisement (for promoting sale of drugs) cause harm to the user of the advertised goods. (e.g pen or a drug for curing disease condition – lead to worse). Hence, advertisement of drugs is not directly public rather persons like physician, pharmacist and nurses.
- A common practice in India might be selling of magic remedies such as Kavachas, mantras, talishmans etc. which are claimed to be universal cure of any disease.
- Advertisement in the magazines, newspapers and on the premises of doctors, hakims or vaids claiming cure of disease.
- Innocent peoples are often trapped of such unsocial activity which leads waste of time, money, spoil their health and prematurely leave the world.
- Recent years there has been great increase in the objectionable advertisements (sexual content and muscle improving) published in newspaper and magazine and internet. This leads to self-medication with harmful drugs which cause a great harm. To stop such practice, The Drugs and Magic Remedies Act 1954, was passed.
- The act as well as rule came into force in 1st April, 1955 and amended in 1963 and extends all over India except Jammu and Kashmir.

Definitions:

Advertisement - Any notice, circular, label, wrapper, any announcement in orally of by means of producing transmitting sound and light.

Drug – any chemical substances or medicines are used for internal or external treatment of human beings or animals or used for diagnosis, cure, mitigation, treatment or prevention of disease or other than food that influence in structure or organic function of the body

Magic remedy – This includes a talisman (a ring or stone that bring luck), mantra, kavacha have miraculous power or in the cure, diagnosis, treatment or influencing any structure or organic function of the body.

Registered medical practitioner - any person who holds a qualification granted by an authority specified in, or notified under section 3 of the Indian Medical Degrees Act, 1916 (7 of 1916) specified in the Schedules to the Indian Medical Council Act, 1956.

Prohibition of advertisements:

a) Certain drugs for treatment of certain diseases and disorders:

No person shall not take part in the publication of any advertisement relating to any drug in terms which suggest

i) Miscarriage or prevention of conception in women or
ii) Maintenance or improvement of the sexual pleasure of human beings or
iii) Rectification of menstrual disorder in women or
iv) Diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule.

b) Misleading advertisements relating to drugs:

Any person shall not take any part in the publication of any advertisement relating to a drug if the advertisement contains any matters which—

i) directly or indirectly gives a false brand regarding the true character of the drug; or
ii) makes a false claim for the drug; or

c) Magic remedies for treatment of certain diseases and disorders.

Any person shall not take any part in the publication of advertisement related to any magic remedy which directly or indirectly claims to efficient for purposes of specified in section (a).

d) Import into, and export from, India of certain advertisements.

Any person shall not import into, or export from, the territories to which this Act extends any documents containing an advertisement under in section a or in section b or section c, and any document containing any such advertisements shall be deemed to be goods of which the import or export has been prohibited under section 19 of the Sea Customs Act, 1878.

Classes of Exempted advertisements:

- Any registered medical practitioner has displayed advertisement on sign board or notice his buildings showing that treatment of any disease or disorder.
- Any matter related to the disease or disorder showing on the book or treatise.
- Any advertisement relating to any drug sent confidentially (by posting) to the registered medical practitioner or whole seller or retail chemist and showing the specification "For the use only of registered medical practitioner or a hospital or a laboratory".
- Any advertisement relating to a drug printed or published by the state or central govt.
- Any advertisement, labels or sets of instruction are permitted under the Drugs and Cosmetics Act and Rules.

Classification of Advertisement:

Class	Condition
1. Leaf let or literature on packing of drugs	1. Only such information shall be shown on advertisement that required for the guidance of registered medical practitioner. The contents of the matter as follows
2. Drug advertisement in medical, pharmaceutical, scientific and technical journals	A. Therapeutic use of drugs B. Route of administration C. Dosage form D. Side effects

	E. Any precaution observed during treatment 2. Any claim made in the advertisement in respect of the drug shall not false or misleading
3. Price lists or therapeutic indexes published by manufacturers, importers or distributers of drugs under Drugs and Cosmetics Act & Rules 1940 4. Medical literature distributed by medical retailers appointed by manufacturers, importers under Drugs and Cosmetics Act & Rules 1940	1. Only such information shall be shown on advertisement that required for the guidance of registered medical practitioner. The contents of the matter as follows A. Therapeutic use of drugs B. Route of administration C. Dosage form D. Side effects E. Any precaution observed during treatment 2. The distribution of such literature is confined only to the physician, hospital, dispensaries, medical and research institution, chemist and druggists under Drugs and Cosmetics Act & Rules 1940 3. Any claim made in the advertisement in respect of the drug shall not false or misleading

Offences and Penalties:

Whoever breaks any of the provisions of this Act shall, on conviction, be punishable—

Offences	**Penalties (Imprisonment/fine)**
A. Under the Act & Rules	6 months or fine or both
1. First conviction	1 year or fine or both
2. Second conviction	As per rule
B. Offence by company	Not applicable
1. In-charge person as well as compony (with knowledge)	Forfeiture of any document, article or thing, includes its content
2. Guilty without knowledge	
C. Convict under the act	
1. Court may direct	

Powers of entry, search, etc.:

Any Gazetted Officer authorised by the State Government may, within the local limits of the area for which he/she is so authorised,—

(a) Enter and search at all reasonable times, with such assistants, if any, as he/she considers necessary, any place in which he has reason to believe that an offence under this Act has been or is being committed;

(b) seize any advertisement which he has reason to believe contravenes any of the provisions of this Act: Provided that the power of seizure under this clause may be exercised in respect of any document, article or thing which contains any such advertisement, including the contents, if any, of such document, article or thing, if the advertisement cannot be separated by reason of its being embossed or otherwise, from such document, article or thing without affecting the integrity, utility or saleable value thereof; examine any record, register, document or any other material object found in any place mentioned in clause (a) and seize the same if he has reason to believe that it may furnish evidence of the commission of any offence punishable under this Act.

(c) Where any person seizes anything under clause (b), he shall, as soon as may be, inform a Magistrate and take his orders as to the custody.

References:

Text book of Forensic Pharmacy by B.M. Mithal

A text book of Forensic Pharmacy by N.K. Jain

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 by Govt. of India publications

Prevention of Cruelty to animals Act-1960:

Objectives:

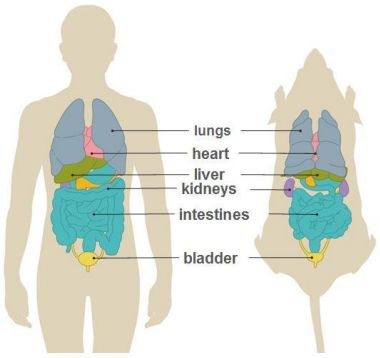

Fig 1. Physiological and anatomical level, humans and other animals are remarkably similar

- Animals are considered as important experimental subjects in modern days of research. Why???
- Although humans and animals (technically "non-human animals") may look different, at a physiological and anatomical level they are remarkably similar (**Fig.1**). Animals, from mice to monkeys, have the same organs (heart, lungs, brain etc.) and organ systems (respiratory, cardiovascular, nervous systems etc.) which perform the same functions in pretty much the same way.
- The similarity means that nearly 90% of the veterinary medicines that are used to treat animals are the same as, or very similar to, those developed to treat human patients.
- approximately 99% of our DNA is similarity with DNA of mice.
- 108 Nobel Prizes awarded for Physiology or Medicine, 96 were directly dependent on animal research.
- Addiction (monkeys), Alzheimer's Disease (mice), Diabetes – Type I (mice), Heart Damage (rats), HIV/AIDS (monkeys, mice) are Current examples of animal research in medicine for establishing for safety and therapeutic efficacy of drugs.
- Data generation on animal toxicology and animal pharmacology that clinical trials under taken the drugs and cosmetic rules are come first.
- Above facts indicates that animals may be subjected to injury, pain or suffering and even death. It explains unethical practice.
- 1890 – the first animal act was implicated to stop the cruelty towards animals.
- 1960 – The Prevention of Cruelty to animal's act was passed. This act was solely for protection of animals from unnecessary pain and suffering.
- 1998 – Control and supervision Rules were implemented. The purpose is general awareness about animal welfare, the breeding, and experiments on animals. This Act and rule was extended whole country except Jammu and Kashmir.

Definitions:

Animal- Any leaving creature other than human being

Board – Animal welfare board established under sec- 4 of the act.

Breeder – Breeds animals for the purpose of transfer to the authorized institution for performing experiments.

Committee – Control and supervision on animals under section 15 of the act.

Establishment – Any individual, company, firm, corporation, institution except college (upto PG label) performing experiments on animals.

Experiment – Use of an animal for the purpose of acquiring knowledge of a biological, psychological, ethological, physical or chemical nature.

Institutional Animals Ethics Committee- A body/committee comprising a group of persons to control and supervision on experimented animals.

Contract Research – Any research undertaken by an individual, company, firm, corporation or institution on behalf of a foreign individual, corporation or institution.

Collaborative Research – Any research undertaken between two or more research institution without any financial consideration and is meant for advancement of scientific research and human welfare.

Institutional Animal Ethics Committee (IAEC):

IAEC consist of

a) A biological scientist
b) Two scientists from different biological dept.
c) A veterinarian physician
d) A scientist from animal facility of the establishment concern
e) A scientist from outside of the institution
f) A social person
g) A representative of the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA)
h) A specialist (radioactive substance or deadly microorganisms) may be co-opted.

- An eight-member IAEC is constituted in every registered institute. All research project proposals using small animals, such as rats, mice, rabbits or guinea-pigs, have to be approved by the IAEC before initiation.
- Every member of the IAEC has the right to question/reject of a project; unapproved proposals are referred to a subcommittee of experts for scrutiny and possible approval. The IAEC cannot approve research projects on large animals, such as dogs, cats, nonhuman primates, cattle, goats and sheep.

CPCSEA

- Article 51A(g) of the Constitution of India reads that it is the fundamental duty of every citizen of India "to protect and improve the natural environment including forests, lakes, rivers and wildlife and to have compassion for living creatures".
- In 1960, the Prevention of Cruelty to Animals (Fig. 2) Act was formally made public by an act of the Indian Parliament.
- Section 15 of the Act provides for constitution, by

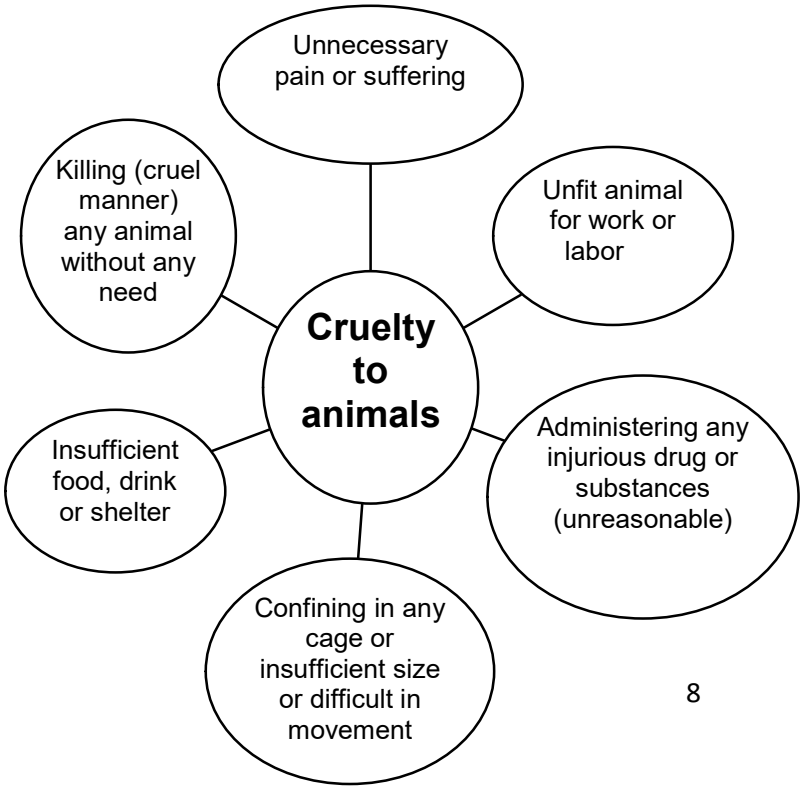

Fig.2 Cruelty to Animals

the Central Government of India, CPCSEA to supervise and control experiments on animals.

Guidelines for Breeding and Stocking of Animals

A. Breeding for business organization (Establishment):

1. Applicant must have registered and trade of animals for the purpose of experiments.
2. For registration, the applicant shall have filled in a specified format and submitted to Member- secretary or authorized person appointed by the committee.
3. They shall apply for registration within sixty days from the date of commencement of the breeding and experiments on animals under the Rules 1998.
4. Stop of breeding animals in case committee refuses to give registration.

B. Breeders for university and colleges:

1. Govt. of India has set up the "Committee" for the purpose of control and supervision of experiments on animals under the Minister of Social Justice and Empowerment, Shastri Bhavan, New Delhi. This committee shall look over registration process.
2. The applicant shall apply in prescribed format for registration to the Secretary or the authorized officer of the committee.
3. The application shall have verified information relating to premises where the experiments are to be conducted, animal housing facilities, details of breeding of animals and its trade, availability of trained manpower in handling of animals.
4. After verification, if the committee satisfied, the registration is approved for such breeder.
5. Every registered breeder shall comply all the condition at the time of registration.
6. They shall maintain a day to day register of particular animals used for conducting experiments with number of animals, the species, the age, gender, and any other related information.
7. The committee or authorized person shall examine the register during their inspection.
8. If the committee or authorized person is not satisfied during examination, they will give the opportunity to improve or may take appropriate action against breeder.

C. Guidelines for stock of the animals (by the breeder and the establishment):

1. Animal houses shall be located in a quite atmosphere
2. The premises shall keep in clean and hygienic condition.
3. Animals shall have protected from drought and extreme weather.

4. Animal cage for small and stable (firmly fixed or not likely to move or change) for large animals. So that they can live in comfort and not to be over crowded.
5. Proper care should be maintained during off-hours and on holidays.
6. The registered establishment shall stick to the detailed specification laid by the committed for housing, feeding and maintenance of various species used in animal experiment.
7. The cages and stable shall maintain the standard laid down by the Indian Standards Institution (ISI)
8. Animal attendants must be suitably trained and experienced in their duties.

Performance of Experiments:

Purpose:

- Discovery of new knowledge or chemical (or biological) active compound
- Useful for saving or establish prolonging life
- Less sever suffering of any disorder or disease
- Combating any disease in human, plant and animals.

Guidelines for performing the experiment as follows

1. The experiment shall not have performed in public demonstration except in school, college and recognized training institution for attaining purpose of manual skills.
2. Person-in-charge of the institution should take responsibility to perform on animal experiment. In case outside of the institution, the experiment should be carried out by qualified person.
3. All experiment shall be performed by or under the supervision of a duly qualified person (Diploma/Degree/PG in Pharmacy/ Medicine/ Veterinary/ Life Sciences or certificate in Laboratory animal techniques sciences).
4. Experiment performed with due care and humanity.
5. During or after experiment, the animals are not suffering unnecessary pain.
6. Before and after experiment, the animals should be under proper care or looked properly.
7. During operational procedure, anesthetic should be administered to animal by a trained person, so that, animals are not suffer pain or feeling of pain throughout the experiment.
8. Under influence of anesthesia, if animals are recovered abnormal or sever pain at any stage of continuing experiment, it shall be painlessly destroyed and discontinued the experiment.
9. Experiment with animals shall not be repeated, if experiment is already established or justified or conclusively known.
10. Pain on eye of animal by any chemical agent that should not be applied.
11. Dogs shall not have debarked (This is a surgical procedure to reduce tissue in the vocal chords) during experiment purpose.

Transfer and acquisition of animals for experiment:

Acquiring animal for conducting any experiment:

1. Every breeder has a register and shall apply for experimental activity permission directly to the Secretary or authorized person of Committee/ Institutional Animal Ethics Committee by stating name of the species and the number of animals acquired.
2. The committee shall scrutiny the application, if satisfied, may grant the permission for conducting experiments.
3. While granting permission, a condition is applied that animals are not suffering unnecessary pain during or after experiments on them.
4. Person carrying on experiments on animals should inform authority about completion of experiment for which the permission has been granted.

Contract animal experiments:

1. Contract animal experiment or research shall not permit to any establishments or educational institutional except with prior permission of the committee.
2. Collaborative research between two academic institution may be permitted for such purpose.

Transfer of animals for experiment:

1. Transfer of any animal for sale purpose to an unregistered breeder is not permitted.
2. A breeder can't acquire any animal by sale except from a registered breeder.
3. Acquired animal can't be sale except from registered breeder.
4. Experiment in production/ breed improvement programme, animals may be given out by breeder institution for domestic use.
5. Genetic experiment on rat and mice not available in India, if such, the breeder shall take the permission from Institutional Animal Ethics Committee (IAEC).
6. Import of any animal available in the country is also not allowed.

Records:

1. Every registered breeder\IAEC should maintain record of the animals and furnish them to the committee from time to time.
2. All laboratory shall inform exact number of animals used in a specified format to the Secretary or authorized person.

Power to suspend or revoke registration:

1. Rules made by the committee are not followed or not satisfied by the committee.
2. The Committee giving a reasonable opportunity for rectification, after that the registration may revoke for a specific period or indefinitely or grant the license on a special condition.
3. Failure of compliance of rule and regulation, the committee may impose pending or suspend the registration.

4. During suspension period, the breeder shall take care of animals, cease to perform any experiment or acquire or transfer of any animal is prohibited.

Offences and Penalties

If any person-

1. Breaks any order made by the Committee under section 19; or commits a break of any condition imposed by the Committee under that section: he shall be punishable with fine which may extend to two hundred rupees
2. The person in-charge of the institution has breached the condition imposed by the Committee under that section: he shall be deemed to be guilty of the offence and shall be punishable accordingly.
3. The penalty under this Act is, the offender (in the case of a first offence) will have to pay fine which shall extend to fifty rupees and if it is the case of second offence or subsequent offence committed within three years of the previous offence, he will be fined with not less than twenty-five rupees but which may extend to one hundred rupees or with the imprisonment for a term which may extend to three months or with both. Also, in the case of second offence, the offender's vehicle is seized, and he will never be allowed to keep an animal again.

Reference:

Text book of Forensic Pharmacy by B.M. Mithal

A text book of Forensic Pharmacy by N.K. Jain

Pereira S, Veeraraghavan P, Ghosh S, Gandhi M. Animal experimentation and ethics in India: the CPCSEA makes a difference. Altern Lab Anim. 2004;32 Suppl 1B:411-415. doi:10.1177/026119290403201s67

The Prevention of Cruelty Animals Act,1960 by Govt. of India publications

National Pharmaceutical Pricing Authority:

Drugs Price Control Order (DPCO)- 2013

- Drugs Price Control Order (DPCO), 1995 was introduced in India on date 6th January 1995
- This Act has abolished under sec.3 of the Essential Commodities Act 1955.
- The Central Government has changed the Drug (Prices Control) Order, 1995 and was introduce the Drugs (Prices Control) Order, 2013 on dated 15.05.2013 and this Act came into force in India on the date 22.03.2016.

Objectives:

- This Act will provide govt. control over the prices of bulk drugs as well as drug formulations.

Definitions:

"***Active pharmaceutical ingredients or bulk drug***" means any pharmaceutical, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, conforming to standards specified in the Drugs and Cosmetics Act, 1940 and which is used as such or as an ingredient in any formulation.

"***Brand***" means a name, term, design, symbol, trademark or any other feature that identifies one seller's drug as different from those of other sellers.

"Ceiling price" means a price fixed by the Government for Scheduled formulations in accordance with the provisions of this order.

"Dealer" means a person carrying on the business of purchase or sale of drugs, whether as a wholesaler or retailer.

"Distributor" means a person engaged in the work of distribution of drugs and includes an agent or a stockist for stocking drugs for sale to a dealer;

"Existing manufacturer" means manufacturer existing on the date of publication of this order in the Official Gazette.

"Form" means a form specified in the Second Schedule of the Act

"Formulation" means a medicine processed out of or containing one or more drugs with or without use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease and, but shall not include –

i) any medicine included in any genuine Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines;
ii) any medicine included in the Homeopathic system of medicine; and
iii) any substance to which the provisions of the Drugs and Cosmetics Act

"Generic version of a medicine" means a formulation sold in pharmacopeial name or the name of the active pharmaceutical ingredient contained in the formulation, without any brand name

"Import" means bringing a drug into India from a place outside India for its sale.

"Local taxes" means any tax or levy (except excise or import duty included in retail price) paid or payable to the Government or the State Government or any local body under any law for the time being in force by the manufacturer or his agent or dealer

"Manufacturer" for the purpose of this Order means any person who manufactures or imports or markets drugs for distribution or sale in the country
"Market share" means the ratio of domestic sales value (on the basis of moving annual turnover) of a brand or a generic version of a medicine and the sum of total domestic sales value of the all brands and generic versions of that medicine sold in the domestic market having same strength and dosage form
"Margin to retailer" mean a percentage of price to retailer
"Market-based data" means the data of sales related to a drug collected or obtained by the Government as deemed fit, from time to time
"Maximum retail price" means the ceiling price or the retail price plus local taxes and duties as applicable, at which the drug shall be sold to the ultimate consumer and where such price is mentioned on the pack
"Moving annual turnover" in a particular month means cumulative sales value for twelve months in domestic market, where the sales value of that month is added and the corresponding sales of the same month in the previous year are subtracted
"National List of Essential Medicines" means National List of Essential Medicines, 2011 published by the Ministry of Health and Family Welfare as updated or revised from time to time and included in the first schedule of this order by the Government through a notification in the Official Gazette
"New drug" mean a formulation launched by an existing manufacturer of a drug of specified dosages and strengths as listed in the National List of Essential Medicines by combining the drug with another drug either listed or not listed in the National List of Essential Medicines or a formulation launched by changing the strength or dosages or both
"Pharmacoeconomics" means a scientific discipline that compares the therapeutic value of one pharmaceutical drug or drug therapy to another
"Price list" means a price list referred to in paragraphs 24 and 25 and includes a supplementary price list
"Price to retailer" means the price of a drug at which it is sold to a retailer which includes duties and does not include local taxes
"Retail price" means the price fixed by the Government for a new drug under paragraph 5 of the Act
"Retailer" means a dealer carrying on the retail business of sale of drugs to customers
"Scheduled formulation" means any formulation, included in the First Schedule whether referred to by generic versions or brand name
"schedule" means a Schedule added to this Order (Drugs Price Control Order (DPCO)-2013)
"wholesaler" means a dealer or his agent or a stockist engaged in the sale of drugs to a retailer, hospital, dispensary, medical, educational or research institution or any other agency;
"wholesale price index" means annual wholesale price index of all commodities as announced by the Department of Industrial Policy and Promotion, Government of India, from time to time.

Sale prices of bulk drugs:

A. Prices of Drugs in First or Second Schedule:

- **First Schedule:** it contains the list of 74 bulk drugs
- **Second Schedule:** it contains various forms for approval or revision of prices of Scheduled formulations

- **Third Schedule:** it specifies the maximum pre-tax (of income or profits) considered or calculated before the deduction of taxes) return on sales turnover of manufacturer/importers of formulations under A, B & C categories
- The ultimate object of first & second schedule of the act to regulate the fair prices from different manufactures. Central govt. has authorized to fix the maximum sale prices of bulk drugs manufactured in the country. They have fixes more than sale price and average price in the fixation of prices in drug formulations.
- 31st January and 30th June each year, the manufacture of bulk drugs have furnished details on specified in form I. Govt. shall take into consideration, while fixing the maximum sale price of bulk drugs.
- A post tax return (An **after-tax return** is any profit made on an investment after subtracting the amount due for taxes) of 14% on net value or a return of 22% on capital employed or a new plant an internal rate of return of 12% on long term marginal costing (The increase or decrease in the total cost of a production for making one an item) depending upon the option for any of the specified rates of return that may be exercised by the manufacture of bulk drugs.
- For basic stage of production, govt. shall take consideration of a post-tax return 18% on net value or return of 26% on capital employed.
- Any person cannot sell at a price exceeding the fixed maximum price plus local taxes.
- Price option once exercised will be final and any change of price will not possible without prior approval of the govt.
- For revision of bulk drug price, the manufacture can apply the application with showing complete information to the govt. at least four months from date of receipt. The govt. may fix a revised the price or reject the application

B. Price of bulk drugs other than those specified in First or Second Schedule:

- The manufacturer can apply will all required information to the govt. within 30 days of the commencement of order, so, govt. can fix their prices.
- The manufacturer can apply for price revision to the govt. within 14 days of the commencement of manufacturer. In this case, the manufacturer/ distributor can refuse sale of drug to any dealer
- The govt. can direct the manufacturer to manufacturer formulation; as per consumption and planed growth of pharmaceutical industry
- Importer of bulk drug shall furnish price list to govt. each year, within 30 days of introduction of finance Bill. If importer fails to furnish, then govt. can fix the price based on available information.

Retail price of formulations:

Formula of retail price of any drug formulation, RP = $(M.C + C.C + P.M. + P.C) \times 1 + \frac{MAPE}{100} + E.D$

R.P = Retail Price; M.C = Materials Cost (inclusive of processing losses); C.C = Conversion Cost (combination of direct labor costs and manufacturing overhead costs) as per notified from time to time; P.M = packing material costs; P.C = Packing Charges; MAPE = maximum allowable post manufacturing expenses inclusive of trade margins (good purchased for resale (either wholesale or retail)); E.D = Excise duty

- In case of category I formulation, the MAPE shall not exceeds 70%, 100% for category II which specified in Third Schedule. If a formulation contains in both I & II category, the formulation would be deemed to be a category I formulation

- For imported formulation, the retail price may be fixed on the basis of landed costs (The landed cost includes the original price of the product, transportation fees (both inland and ocean), customs, duties, taxes, tariffs, insurance,
- currency conversion, crating (a slatted wooden box or framework for packing), handling and payment fees). The price shall not exceed 50% of the landed cost.
- Prices of category I formulation shall fix or revised by the govt. Retail prices of formulations specified in Third Schedule can also fix or revise by the govt. if, govt. cannot fix the retail prices of formulation the same cannot be sold at a price higher than that prevailing.
- New formulations in category I or II or their new packs cannot be marketed prior approval of their retail prices by the government. If, the govt does not fix the price within 4 months of their application of manufacturer or importer, he may sell them at prices not exceeding those claimed in their application to the government.
- Any formulation, not listed in the schedule, the manufacturer shall submit the detail information including fix or revise retail price to the govt. in the January and June each year. The govt. may fix or revise the retail price of nonscheduled formulation.
- The manufacturer, importer or distributor shall sell a formulation to a wholesaler at retail price not exceeding minus 20% (for ethical), 18% (for non-ethical), to a retailer at a retail price minus 15% (non-ethical)
- Display on labels of the contains with the words "Retail price not to exceed Rs……" local taxes extra.
- Every dealer shall display price lists of the product in their business house.
- Dealer can not sell loose quantity of a formulation from a container and also refuse to sale of any drug to a customer.

Retail price and ceiling price of scheduled formulations:

1. **Calculation of ceiling price of a scheduled formulation.– (1)**

The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the first schedule shall be calculated as under:

Step1. First the Average Price to Retailer of the scheduled formulation i.e. P(s) shall be calculated as below:
Average Price to Retailer, P(s) = (Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine) / (Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine.)

Step2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as below:

P(c) = P(s). (1+M/100),

where P(s) = Average Price to Retailer for the same strength and dosage of the medicine as calculated in step1 above.
M = % Margin to retailer and its value =16
(2) The ceiling price calculated as per sub-paragraph (1) and notified by the Government shall be applicable to scheduled imported formulations also.

2. **Calculation of retail price of a new drug for existing manufacturers of scheduled formulations.–**

- The price to retailer of a new drug, not available in domestic market, shall be fixed by the Government on the principles of "Pharmacoeconomics" of the new drug, on the recommendation of a Standing Committee of Experts formed under paragraph 15.
- The retail price of such new drug shall be fixed by adding sixteen percent margin to retailer on the price to retailer as fixed.

3. Ceiling price of a scheduled formulation in case of no reduction in price due to absence of competition.–

- No reduction in average price to retailer with respect to the prices to retailer of the schedule formulation; and
- There are less than five manufacturers for that formulation having one percent or more market share, the ceiling price shall be calculated as under:-
- In the event of other strengths or dosage forms of the same scheduled formulation is available in the list of scheduled formulation, the average price to retailer shall be calculated as under:

Step1: First the Average Price to Retailer of such scheduled formulation i.e. P(s) shall be calculated as under:

P(s) = Pm{1-(Pi1+Pi2+…)/(N*100)} Where,

Pm = Price to Retailer of highest priced scheduled formulation under consideration.

Pi = % reduction in Average Price to Retailer of other strengths and dosage forms (calculated as in step1 of sub-paragraph (1) of paragraph 4) in the list of schedule formulations w.r.t the highest priced formulation taken for calculating the average price to retailer of such strengths and dosage forms.

N = Number of such other strengths or dosage forms or both in the list of schedule formulations

Step2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as under:

P(c) = P(s).(1+M/100), where

P(s) = Average Price to Retailer of the scheduled formulation as calculated in step1 here in above and

M = % Margin to retailer and its value=16

(ii) in the event of other strengths or dosage forms of the scheduled formulation is not available in the schedule but there are other scheduled formulations in same sub-therapeutic category as that of the scheduled formulation, then the Ceiling Price shall be calculated as under:

Step1: First the Average Price to Retailer of such scheduled formulation i.e. P(s) shall be calculated as under:

P(s) = Pm{1-(Pi1+Pi2+…)/(N*100)}, Where,

Pm = Price of highest priced formulation taken for calculating the average price to retailer of the formulation under consideration.

Pi = % reduction in Average Price to Retailer of other schedule formulations (calculated as in step1 of sub-paragraph (1) of paragraph 4) in same sub-therapeutic category as that of the scheduled formulation under consideration w.r.t the highest priced formulation taken for calculating the average price to retailer.

N = Number of such other schedule formulations in same subtherapeutic category as that of the scheduled formulation under consideration.

Step2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as under:

P(c) = P(s)*(1+M/100), where

P(s) = Average Price to Retailer of the scheduled formulation as calculated in step1 above and
M = % Margin to retailer and its value=16

4. **Margin to retailer.–** While fixing a ceiling price of scheduled formulations and retail prices of new drugs, sixteen percent of price to retailer as a margin to retailer shall be allowed.

5. **Maximum retail price.–**
The maximum retail price of scheduled formulations shall be fixed by the manufacturers on the basis of ceiling price notified by the Government plus local taxes wherever applicable, as under:
Maximum Retail Price = Ceiling price + Local Taxes as applicable
The maximum retail price of a new drug shall be fixed by the manufacturers on the basis of retail price determined by the Government plus local taxes wherever applicable, as under:
Maximum Retail Price = Retail Price + Local Taxes as applicable

6. **Fixation of ceiling price of scheduled formulations.–**
- The Government shall fix and notify the ceiling prices of the scheduled formulations in accordance with the provisions of the paragraphs 4 and 6, as the case may be, and no manufacturer shall sell the scheduled formulations at a price higher than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government.
- Where any manufacturer sells a scheduled formulation at a price higher than the ceiling price (plus local taxes as applicable) fixed and notified by the Government, such manufacturers shall be liable to deposit the overcharged amount along with interest thereon from the date of such overcharging.

7. **Fixation of retail price of a new drug for existing manufacturers of scheduled formulations.–**
- The Government shall form a Standing Committee of such Experts, as it may deem fit, within sixty days of notification of this order with a view to recommend the retail prices of new drugs on the principles of "Pharmacoeconomics".
- Where an existing manufacturer of a drug with dosages and strengths as specified in National List of Essential Medicines launches a new drug, such existing manufacturers shall apply for prior price approval of such new drug from the Government in Form-I specified under Schedule-II of this Order.
- On receipt of the application under sub-paragraph (2), in the event of the new drug available in domestic market, the Government shall fix the retail price of the new drug in accordance with the provision of sub-paragraph(1) of paragraph 5 and in the event of the new drug not available in domestic market, the Government shall forward the same to the Standing Committee of Experts who shall examine the application on the principles of "Pharmacoeconomics" and make recommendations of retail price of the new drug to the Government within thirty days of the receipt of application.
- The Government shall, on receipt of recommendation under subparagraph (3), within thirty days, fix the retail price of such new drug and such price shall be applicable to such applicant of such new drug.
- Where existing manufacturer of scheduled formulation fails to apply for prior approval of the price of the new drug in Form-I, such manufacturer shall be liable to deposit the overcharged amount over and above such price fixed and notified by the

Government, if any, along with interest thereon from the date of launch of the new drug, in addition to the penalty.

- No existing manufacturer of a scheduled formulation shall sell such a new drug at a price higher than the retail price (plus local taxes as applicable) fixed by the Government for such new drug and in case such a manufacturer is found to sell such a new drug at a price higher than the retail price (plus local taxes as applicable) fixed by the Government, such manufacturer of the new drug shall be liable to deposit the overcharged amount along with interest from the date of overcharge, in addition to the penalty.

8. Revision of ceiling price of scheduled formulations.–

- The Government shall revise the ceiling prices of scheduled formulations as per the annual wholesale price index (WPI) for preceding calendar year on or before 1st April of every year and notify the same on the 1st day of April every year.
- The manufacturers may increase the maximum retail price (MRP) of scheduled formulations once in a year, in the month of April, on the basis of the wholesale price index with respect to previous calendar year and no prior approval of the Government in this regard shall be required.
- Information about the revision, if carried out, shall be forwarded to the Government in either electronic or physical form in Form-II within a period of fifteen days of such revision and non-submission of information under this sub-paragraph shall be construed as non revision of maximum retail price (MRP) and the concerned manufacturer shall be liable to deposit the amount charged over and above the pre-revised maximum retail price (MRP), along with interest thereon from the date of overcharging.
- In case of decline in wholesale price index, there shall be a corresponding reduction in the maximum retail price and in case of scheduled formulations produced or available in the market before the date of notification of revised ceiling price, the manufacturers shall ensure within a period of forty-five days of the date of such notification that the maximum retail price (MRP) of such scheduled formulation does not exceed the revised ceiling price (plus local taxes as applicable) and information about the revision shall be sent to the Government in either electronic or physical form in Form-II within a period of fifteen days of such revision.
- Non-submission of information under the sub-paragraph (4) shall be construed as non reduction in maximum retail price (MRP) and the concerned manufacturer shall be liable to deposit the amount charged over and above the maximum retail price revised based on decline in wholesale price index, along with interest thereon as overcharged amount from the date of overcharging.

National List of Essential Medicines 2015

(Symbols P, S and T appearing in this Schedule denote essentiality at Primary, Secondary and Tertiary levels respectively)			
Section 1-Anesthetic agents			
1.1-General Anesthetics and oxygen			
	Medicine	**Level of Healthcare**	**Dosage form and strength**
1.1.1	Halothane	S, T	Inhalation
1.1.2	Isoflurane		
1.1.3	Ketamine	P, S, T	Injection 10 mg/ml, 50 mg/ml

1.1.4	Nitrous oxide		Inhalation
1.1.5	Oxygen		Inhalation (Medicinal gas)
1.1.6	Propofol		Injection 10 mg/ml
1.1.7	Sevoflurane	T	Inhalation
1.1.8	Thiopentone	P, S, T	Powder for Injection 0.5 g & 1 g
1.2-Local anesthetics			
1.2.1	Bupivacaine	S, T	Injection 0.25% & 0.5% & Injection 0.5% with 7.5% glucose
1.2.2	Lignocaine	P, S, T	Topical forms 2-5% Injection 1% & 2% Injection 5% with 7.5% Glucose
1.2.3	Lignocaine (A) + Adrenaline (B)	P, S, T	Injection 1% (A) + 1 :200000 (5 mcg/ml) (B) Injection 2% (A) + 1 :200000 (5
1.2.4	Prilocaine (A) + Lignocaine (B)	T	Cream 2.5% (A) + 2.5% (B)
1.3-Preoperative medication and sedation for short term procedures			
1.3.1	Atropine	P, S, T	Injection 0.6 mg/ml
1.3.2	Glycopyrrolate	S, T	Injection 0.2 mg/ml
1.3.3	Midazolam	P, S, T	Tablet 7.5, 15 mg Oral liquid 2 mg/ml Injection 1 mg/ml & 5 mg/ml
1.3.4	Morphine		Injection 10 mg/ml & 15 mg/ml
Section 2- Analgesics, antipyretics, non-steroidal anti-inflammatory medicines, medicines used to treat gout and disease modifying agents used in rheumatoid disorders			
2.1- Non-opioid analgesics, antipyretics and no steroidal anti -inflammatory medicines			
2.1.1	Acetylsalicylicacid	P, S, T	Tablet 300 mg to 500 mg Effervescent/ Dispersible/ Enteric coated Tablet 300 mg to 500 mg
2.1.2	Diclofenac		Tablet 50 mg Injection 25 mg/ml
2.1.3	Ibuprofen		Tablet 200 mg & 400 mg Oral liquid 100 mg/5 ml
2.1.4	Mefenamic acid		Capsule 250 mg Capsule 500 mg Oral liquid 100 mg/5 ml
2.1.5	Paracetamol		Tablet 500 mg & 650 mg All licensed oral liquid dosage forms and strengths Injection 150 mg/ml Suppository 80 mg & 170 mg
2.2-Opioid analgesics			
2.2.1	Fentanyl	S, T	Injection 50 mcg/ml
2.2.2	Morphine	P, S, T	Tablet 10 mg Injection 10 mg/ml Injection 15 mg/ml
2.2.3	Tramadol	S, T	Capsule 50 mg Capsule 100 mg Injection 50 mg/ml
2.3-Medicines used to treat gout			

2.3.1	Allopurinol	P, S, T	Tablet 100 mg & 300 mg
2.3.2	Colchicine		Tablet 0.5 mg
2.4-Disease modifying agents used in rheumatoid disorders			
2.4.1	Azathioprine	S, T	Tablet 50 mg
2.4.2	Hydroxychloroquine		Tablet 200 mg & 400 mg
2.4.3	Leflunomide		Tablet 10 mg Tablet 20 mg
2.4.4	Methotrexate		Tablet 5 mg, 7.5 mg & 10 mg Injection 25 mg/ ml
2.4.5	Sulfasalazine		Tablet 500 mg
Section 3-Antiallergics and medicines used in anaphylaxis			
3.1	Adrenaline	P, S, T	Injection 1 mg/ml
3.2	Cetirizine		Tablet 10 mg Oral liquid 5 mg/5ml
3.3	Chlorpheniramine		Tablet 4 mg Oral liquid 2 mg/5 ml
3.4	Dexamethasone		Tablet 0.5 mg
3.5	Hydrocortisone		Powder for Injection 100 mg
3.6	Pheniramine		Injection 22.75 mg/ml
3.7	Prednisolone		Tablet 5 mg, 10 mg & 20 mg Oral liquid 5 mg/5 ml & 15 mg/5 ml
Section 4-Antidotes and other substances used in poisoning			
4.1- Nonspecific			
4.1.1	Activated charcoal	P, S, T	Powder (as licensed)
4.2-Specific			
4.2.1	Atropine	P, S, T	Injection 1 mg/ml
4.2.2	Calcium gluconate		Injection 100 mg/ml
4.2.3	Desferrioxamine	S, T	Powder for Injection 500 mg
4.2.4	Dimercaprol		Injection 50 mg/ml
4.2.5	Methylthioninium chloride (Methylene blue)		Injection 10 mg/ml
4.2.6	N-acetylcysteine	P, S, T	Sachet 200 mg Injection 200 mg/ml
4.2.7	Naloxone		Injection 0.4 mg/ml
4.2.8	Neostigmine		Injection 0.5 mg/ml
4.2.9	Penicillamine	S, T	Capsule 250 mg
4.2.10	Pralidoxime chloride (2- PAM)	P, S, T	Injection 25 mg/ml
4.2.11	Snake venom antiserum a) Soluble/ liquid polyvalent	P, S, T	Injection Powder for Injection
4.2.12	Sodium nitrite	S, T	Injection 30 mg/ml
4.2.13	Sodium	S, T	Injection 100 mg/ml
Section 5-Anticonvulsants/Antiepileptics			
5.1	Carbamazepine	P, S, T	Tablet 100 mg, 200 mg & 400 mg CR Tablet 200 mg & 400 mg Oral liquid 100 mg/5 ml & 200 mg/5 ml
5.2	Clobazam	S, T	Tablet 5 mg & 10 mg
5.3	Diazepam	P, S, T	Oral liquid 2 mg/5 ml Injection 5 mg/ml Suppository 5 mg
5.4	Levetiracetam	S, T	Tablet 250 mg, 500 mg & 750

			mg ER Tablet 750 mg Oral liquid 100 mg/ml Injection 100 mg/ml
5.5	Lorazepam	P, S, T	Tablet 1 mg, 2 mg Injection 2 mg/ml
5.6	Magnesium sulphate	S, T	Injection 500 mg/ml
5.7	Phenobarbitone	P, S, T	Tablet 30 mg, 60 mg Oral liquid 20 mg/5 ml
		S, T	Injection 200 mg/ml
5.8	Phenytoin	P, S, T	Tablet 50 mg, 100 mg & 300 mg ER Tablet 300 mg Oral liquid 20 mg/5 ml, 125mg/5ml Injection 50 mg/ml
5.9	Sodium valproate	P, S, T	Tablet 200 mg, 300 mg, 500 mg CR Tablet 300 mg, 500 mg Oral liquid 200 mg/5ml
		T	Injection 100 mg/ml
Section 6-Anti-infective medicines			
6.1-Anthelminthics			
6.1.1-Intestinal anthelminthic			
6.1.1.1	Albendazole	P, S, T	Tablet 400 mg Oral liquid 200 mg/5 ml
6.1.1.2	Mebendazole	P, S, T	Tablet 100 mg Oral liquid 100 mg/5 ml
6.1.2- Antifilarial			
6.1.2.1	Diethy lcarbamazine	P, S, T	Tablet 50 mg & 100 mg Oral liquid 120 mg/5 ml
6.1.3-Anti-schistosomal & anti-trematodal medicine			
6.1.3.1	Praziquantel	S, T	Tablet 600 mg
6.2-Antibacterials			
6.2.1-Beta lactam medicines			
6.2.1.1	Amoxicillin	P, S, T	Capsule 250 mg & 500 mg Oral liquid 250 mg/5 ml
6.2.1.2	Amoxicillin (A) + Clavulanic acid (B)		Tablet 500 mg (A) + 125 mg (B) Oral liquid 200 mg (A) + 28.5 mg (B)/5 ml Dry Syrup 125 mg (A) + 31.25 (B)/5 ml
		S, T	Powder for Injection 500 mg (A) + 100 mg (B) Powder for Injection 1 g (A) + 200 mg (B)
6.2.1.3	Ampicillin	P, S, T	Powder for Injection 500 mg Powder for Injection 1 g
6.2.1.4	Benzathine benzylpenicillin		Powder for Injection 6 lac units Powder for Injection 12 lac units
6.2.1.5	Benzyl penicillin		Powder for Injection 10 lac units
6.2.1.6	Cefadroxil		Tablet 500 mg, 1 g Oral liquid 125 mg/5 ml
6.2.1.7	Cefazolin		Powder for Injection 500 mg Powder for Injection 1 g
6.2.1.8	Cefixime	S, T	Tablet 200 mg, 400 mg Oral liquid 50 mg/5 ml Oral liquid 100 mg/5 ml

6.2.1.9	Cefotaxime		Powder for Injection 250 mg, 500 mg & 1 g
6.2.1.10	Ceftazidime		Powder for Injection 250 mg Powder for Injection 1 g
6.2.1.11	Ceftriaxone		Powder for Injection 250 mg, 500 mg, 1 g & 2 g
6.2.1.12	Cloxacillin	P, S, T	Capsule 250 mg, 500 mg Oral Liquid 125 mg/5 ml Powder for Injection 250 mg
6.2.1.13	Piperacillin (A) + Tazobactam (B)	T	Powder for Injection 1 g (A) + 125 mg (B) Powder for Injection 2 g (A) + 250 mg (B) Powder for Injection 4 g (A) + 500 mg (B)
6.2.2-Other antibacterials			
6.2.2.1	Azithromycin	P, S, T	Tablet 250 mg, 500 mg Oral liquid 200 mg/5 ml Powder for Injection 500mg
6.2.2.2	Ciprofioxacin		Tablet 250 mg, 500 mg Oral liquid 250mg/5ml Injection 200 mg/100ml
6.2.2.3	Clarithromycin	S, T	Tablet 250 mg, 500 mg Oral liquid 125mg/5ml
6.2.2.4	Co-trimoxazole [Sulphamethoxazole (A) + Trimethoprim (B)]	P, S, T	Tablet 400 mg (A) + 80 mg (B) Tablet 800 mg (A) + 160 mg (B) Oral liquid 200 mg (A) + 40 mg (B)/5 ml
6.2.2.5	Doxycycline		Capsule 100 mg Dry Syrup 50 mg/5 ml
6.2.2.6	Gentamicin		Injection 10 mg/ml, 40 mg/ml
6.2.2.7	Metronidazole		Tablet 200 mg, 400 mg Oral liquid 200 mg/5 ml Injection 500mg/100 ml
6.2.2.8	Nitrofurantoin		Tablet 100 mg Oral liquid 25 mg/5 ml
6.2.2.9	Vancomycin	T	Powder for Injection 250 mg, 500 mg & 1 g
6.2.3-Antileprosy medicines			
6.2.3.1	Clofazimine	P, S, T	Capsule 50 mg, 100 mg
6.2.3.2	Dapsone		Tablet 25 mg, 50 mg & 100 m
6.2.3.3	Rifampicin		Capsule 150 mg, 300 mg
6.2.4-Antituberculosis medicines			
6.2.4.1	Capreomycin	P, S, T	Powder for Injection 1 g
6.2.4.2	Cycloserine		Capsule 125 mg, 250 mg
6.2.4.3	Ethambutol		Tablet 200 mg. 400 mg. 600 mg & Tablet 800 mg
6.2.4.4	Ethionamide		Tablet 125 mg, 250 mg
6.2.4.5	Isoniazid		Tablet 50 mg, 100 mg, 300 mg Oral liquid 100 mg/5 ml
6.2.4.6	Kanamycin		Powder for Injection 500 mg, 750 mg & 1 g
6.2.4.7	Levofloxacin		Tablet 250 mg, 500 mg & 750 mg
6.2.4.8	Linezolid		Tablet 600 mg
6.2.4.9	Moxifloxacin		Tablet 200 mg, 400 mg
6.2.4.10	Para-amino salicylic acid		Tablet 500 mg Granules (As licensed)
6.2.4.11	Pyrazinamide		Tablet 500 mg, 750 mg, 1000 mg

			& 500 mg Oral liquid 250 mg/5 ml
6.2.4.12	Rifabutin	S, T	Capsule 150 mg
6.2.4.13	Rifampicin	P, S, T	Capsule 150 mg, 300 mg, 450 mg & Capsule 600 mg Oral liquid 100 mg/5 ml
6.2.4.14	Streptomycin	P, S, T	Powder for Injection 750 mg Powder for Injection 1 g
6.3-Antifungal medicines			
6.3.1	Amphotericin B a) Amphotericin B (conventional) b) Lipid, Liposomal Amphotericin B	S, T	Powder for Injection 50 mg

The detail list of national list of essential medicines 2015 will found in the drugs (prices control) order, 2013 which is published by Govt. of India.

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