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UNIT: V

UNIT-V

5.1. Pharmaceutical Legislations-A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee

5.2. Code of Pharmaceutical ethics: Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath

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5.4. Right to Information Act

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5.1. Pharmaceutical Legislations

History

In the early part of the 20th century, there was practically no legislative control on drugs as well as on the profession of pharmacy. Although the Opium Act-1878, the poison act-1919 and the dangerous drugs act-1930 were inforce, these were specific in nature and grossly inadequate in controlling the chaotic conditions prevailing at that time. In 1927, a resolution was passed by the council of states to recommend to the Governor General in Council to usage all Provisional Governments to take immediate steps to control indiscriminate use of drugs and to legislate for the standardization of the preparation and sale of drugs. The government of India in pursuance to the resolution appointed a committee known as the Drugs Enquiry Committee in 1928.

Government of India on 11th August 1930, appointed a committee under the chairmanship of Late Col. R.N. Chopra to see into the problems of Pharmacy in India and recommend the measures to be taken. This committee published its report in 1931. It was reported that there was no recognized specialized profession of Pharmacy. A set of people known as compounders were filling the gap. Just after the publication of the report Prof. M. L. Schroff (Prof. Mahadeva Lal Schroff) initiated pharmaceutical education at the university level in the Banaras Hindu University. In 1935 United Province Pharmaceutical Association was established which later converted into Indian Pharmaceutical Association. The Indian Journal of Pharmacy was started by Prof. M.L. Schroff in 1939. All India Pharmaceutical Congress Association was established in 1940.

The Pharmaceutical Conference held its sessions at different places to publicize Pharmacy as a whole. Govt. brought 'Drugs Bill' to regulate the import, manufacture, sale and distribution of drugs in British India. This Bill was finally adopted as 'Drugs Act of 1940. The first Drugs Technical Advisory Board (DTAB) under this act was constituted. Central Drugs Laboratory was established in Calcutta 1945 and 'Drugs Rule under the Drugs Act of 1940' was established. The Drugs Act has been modified from time to time and at presents the provisions of the Act cover Cosmetics and Ayurvedic, Unani and Homeopathic medicines in some respects.

Introduction

pharmaceutical Legislations generally includes provisions relating to the manufacturing, importing, distribution, marketing, prescribing, labeling, dispensing, and sometimes pricing of pharmaceutical products, as well as the licensing, inspection, and control of personnel and facilities. A regulatory authority is usually established for administrative control. Medicine

registration is often a major element in legislation, to ensure that individual products meet the criteria of efficacy, safety, and quality. Countries that need to introduce comprehensive legislation can seek guidance from WHO guidelines.

5.1.1. Drugs enquiry committee

The government of India appointed a committee styled as the Drug Enquiry Committee under the Chairmanship of Col. R.N. Chopra on 11th August 1930 to study the issues related to the profession of pharmacy and its various aspects in India. This Drug Enquiry Committee was later known by the name 'Chopra Committee'. The important terms of reference for the Committee were:

i) To study the details regarding the extent to which drugs and chemicals of impure quality or defective strength, particularly those recognized by the British Pharmacopoeia are imported, manufactured or sold in British India and to make necessary recommendation for controlling such activities in the interest of the public.
ii) To report how far and to what extent the above recommendations should be extended to medicinal preparations used in the indigenous systems of medicines.
iii) To study and examine the necessity of legislation for restricting the profession of pharmacy to duly qualified persons and make recommendations to that effect.

The Chopra Committee took up the challenge of studying the problems and making recommendations with all its seriousness and professional significance. They travelled various centers of the country and studied the situations. The committee submitted its report in 1931.

The committee report made it clear that till that time there was no organized and self contained profession of pharmacy in India as compared to other parts of the world. The profession is represented by a group of people known as compounders whose status, functions and duties are ill defined and improperly understood. They handle drugs and poisons with utmost ease and freedom and in many cases in ignorance of their properties. The committee also observed that no stress is laid down on the basic qualification except in the revised compounders course in Bengal and the Chemists and Druggists course in Madras made in the late 1920s. The mere ability to read the prescriptions written in English was considered sufficient to practice pharmacy.

The Drugs Enquiry Committee also recommended for the compilation of the Indian Pharmacopoeia with monographs on drugs and pharmaceuticals in common use including those of the indigenous origin.

5.1.2. Health survey and development committee

In 1946, the Health Survey and Development Committee under the chairmanship of Sir Joseph Bhore (Bhore Committee) published its report. An important recommendation of the Bhore Committee was to have an enactment (Act) with the objective of raising the interests of qualified pharmacists and thereby protect the interests of public. It was made as the committee found that incompetent people were handling drugs and doing harm to the society. The Bhore Committee also suggested that the profession of pharmacy should be reserved for the pharmacists and the pharmacists should restrict their work to the professional activities of their profession. It was also suggested that the pharmacists should not be permitted to undertake functions like prescription of medicines and administration of anaesthetics. The committee also recommended for a revision of the pharmacy education in the country as the standard of training for those entering into the practice of pharmacy was unsatisfactory. Based on the recommendations of the Chopra Committee and the interim findings of the Bhore Committee the Government of India brought forth the Pharmacy Bill in 1945 and after three years continuous efforts and discussions at various levels, it took the shape of Pharmacy Act 1948. The first Pharmacy Council of India was constituted in 1949 under the provisions of the Pharmacy Act.

It was provided in the Pharmacy Act that within three years of its coming into force, the States should constitute their Pharmacy Councils and within three years of that the Education Regulations would take effect. Hence, the first Education Regulations under the Pharmacy Act should have come in force in all states in India by 1954 and those who are not qualified to enter the profession of pharmacy as per the Education Regulations should not have been allow to enter. However the situation was different. Many states took their own time to constitute the Pharmacy Councils. Even after the Pharmacy Act the profession of pharmacy has not been able to make much headway in the country.

In 1944, a committee was appointed once again under the chairmanship of Col. R.N. Chopra to prepare the material for the list of drugs in use in India irrespective of whether or not such items are included in the British Pharmacopoeia. The Indian Pharmacopoeial list, a prelude to the Indian Pharmacopoeia, was published in 1946 under the auspices of the above committee. In 1948 a full fledged Indian Pharmacopoeia Committee was constituted under the chairmanship of Dr. B.N. Ghosh of Calcutta and several sub-committees were also set up. The committee took seven years to complete the task and in 1955 the first edition of Indian Pharmacopoeia was published.

5.1.3. Hathi committee

In the context of large-scale expansion of the drugs and pharmaceuticals industry, with a view to ensuring the regulated and rapid growth of drug manufacture and further with a view to ensuring that all essential drugs are made available to the consumers at reasonable prices, Government constituted a Committee in February, 1974. This committee consists of 15 members under the chairmanship of Mr. Jaisukhlal Hathi, which had Members of Parliament along with officials and non-officials as members, to enquire into various facets of the drugs industry in India.

The terms of reference included progress made and status achieved by the industry, role of public sector, growth of indigenous industry, including the small scale, technological requirements, quality control measures, pricing of drugs etc. Almost all the aspects of the drugs and pharmaceutical industry were critically examined by Hathi Committee with a view to achieve self-sufficiency and to serve the national interest.

After conducting various meetings, the committee had submitted its report in the year 1975. The report contained 224 recommendations spread over 8 chapters on various aspects of pharmaceutical Industry. The thrust of recommendations related to re-emphasizing the leading role for the public sector, setting up of National Drug Authority, preference to Indian Sector over the foreign sector, indigenous production of raw materials, selective price control on prices of drugs etc.

5.1.3. Mudaliar committee

This committee known as the “Health Survey and Planning Committee”, headed by Dr. A.L. Mudaliar, was set up in 1959.

Objectives

1. To assess the performance in health sector since the submission of Bhore Committee report.
2. To evaluate the progress made in the first 2 plans and
3. To make recommendation for the future path of development of health services.

The report of the committee recorded that the disease control programmes had some substantial achievements in controlling certain virulent epidemic diseases. This committee found the conditions in PHCs to be unsatisfactory. Most of the PHC's were understaffed, large numbers of them were being run by ANM's or public health nurses in-charge.

Recommendations

1. Consolidation of advances made in the first two five years plans.
2. Strengthening of the district hospitals with specialist services to serve as central base of regional services.
3. Regional organizations in each state between the headquarters organization and the district in charge of a Regional Deputy or Assistant Directors-each to supervise 2 or 3 district medical or health officers.
4. Each PHC not to serve more than 40000 populations.
5. To improve the quality of health care provided by PHC.
6. Integration of medical and health services.
7. Constitution of an All India Health service on the pattern of Indian Administrative Services.

5.2. Code of Pharmaceutical ethics

The profession of pharmacy is noble in its ideals and pious in its character. Apart from being a career for earning livelihood, it has inherent in it the attitude of service and sacrifice in the interests of the suffering humanity. In handling, selling, distributing, compounding and dispensing medical substances including poisons and potent drugs, a pharmacist is, in collaboration with medical perssonel and others, charged with the onerous responsibility of safeguarding the health of people. As such he has to uphold the interests of his patrons above all things. The lofty ideals set up by Charaka, the ancient Philosopher Physician and Pharmacist in his erunciation: “Even if your own life be in danger you should not betray or neglect the interests of your patients” should be fondly cherished by all pharmacists.

Government restricts the practice of Pharmacy to those who qualify under regulatory requirements and grant them privileges necessarily denied to others. In return, Government expects the Pharmacist to recognize his responsibilities and to fulfil his professional obligations honourably and with due regard for the well being of Society.

Standards of professional conduct for pharmacy are necessary in the public interest to ensure an efficient pharmaceutical service. Every pharmacist should not only be willing to play his part in giving such a service but should also avoid any act or omission which would prejudice the giving of the services or impair confidence in any respect for pharmacists as a body.

The nature of pharmaceutical practice is such that its demands may be beyond the capacity of the individual to carry out or to carry out as quickly or as efficiently as the needs of the public require. There should, therefore at all times, be a readiness to assist colleagues with information or advice. A Pharmacist must, above all be a good citizen and must uphold and defend the laws of the state and the Nation.

5.2.1. Pharmacist in relation to his job

When premises are registered under statutory requirements and opened as a pharmacy, a reasonably comprehensive pharmaceutical service should be provided. This involves the supply of commonly required medicines of this nature without undue delay. It also involves willingness to furnish emergency supplies at all times.

5.2.1.1. Conduct of the Pharmacy:

1. The conditions in a pharmacy should be such as to preclude avoidable risk or error or of accidental contamination in the preparation, dispensing and supply of medicines.
2. The appearance of the premises should reflect the professional character of the pharmacy.
3. It should be clear to the public that the practice of pharmacy is carried out in the establishment.
4. Signs, notices, descriptions, wording on business, stationary and related indications should be restrained in size, design and terms.
5. In every pharmacy, there should be a pharmacist in personal control of the pharmacy who will be regarded as primarily responsible for the observance of proper standards of conduct in connection with it.

5.2.1.2. Handling of Prescriptions:

1. When a prescription is presented for dispensing, it should be received by a pharmacist without any discussion or comment over it regarding the merits and demerits of its therapeutic efficiency.
2. The Pharmacist should not even show any physiognomic expression of alarm or astonishment upon the receipt of a prescription; as such things may cause anxiety in patients or their agents and may even shake their faith in their physician.
3. Any question on a prescription should be answered with caution and care.
4. It is not within the privilege of a Pharmacist to add, omit or substitute any ingredient or alter the composition of a prescription without the consent of the prescriber, unless the change is emergent or is demanded purely by the technique of the pharmaceutical art and does not cause any alteration in the therapeutic action of the recipe.

5. In case of any obvious error in it due to any ommission, incompatibility or overdosage, the prescription should be referred back to the prescriber for correction or approval of the change suggested.

5.2.1.3. Handling of Drugs:

1. All possible care should be taken to dispense a prescription correctly by weighing and measuring all ingredients in correct proportions by the help of scale and measures: visual estimations must be avoided.
2. Further, a Pharmacist should always use drugs and medicinal preparations of standard quality available.
3. He should never fill his prescriptions with spurious, sub-standard and unethical preparations.
4. A Pharmacist should be very judicious in dealing with drugs and medicinal preparations known to be poisonous or to be used for addiction or any other abusive purposes.

5.2.1.4. Apprentice Pharmacist:

1. While in-charge of a dispensary, drug store or hospital pharmacy where apprentice pharmacists are admitted for practical training, a pharmacist should see that the trainees are given full facilities for their work so that on the completion of their training, they have acquired sufficient technique and skill to make themselves dependable pharmacists.
2. No certificate or credentials should be granted unless the above criterion is attained and the recipient has proved himself worthy of the same.

5.2.2. Pharmacist in relation to his trade

Prices charged from customers should be fair and in keeping with the quality and quantity of commodity supplied and the labour and skill required in making it ready for use, so as to ensure an adequate remuneration to the pharmacist taking into consideration his knowledge, skill, the time consumed and the great responsibility involved, but at the same time without unduly taxing the purchaser.

5.2.2.1. Fair Trade Practice:

1. No attempt should be made to capture the business of a contemporary by cut-throat competition, that is, by offering any sort of prizes or gifts or any kind of allurement to patronizers or by knowingly charging lower prices for medical commodities than those charged by a fellow pharmacist if they be reasonable.
2. In case any order or prescription genuinely intended to be served by some dispensary is brought by mistake to another, the latter should be refuse to accept it and should direct the customer to the right place.
3. Labels, trademarks and other signs and symbols of contemporaries should not be imitated or copied.

5.2.2.2. Purchase of Drugs:

1. Drugs should always be purchased from genuine and reputable sources.
2. Pharmacist should always be on his guard not to aid or abet, directly or indirectly the manufacture, possession, distribution and sale of spurious or sub-standard drugs.

5.2.2.3. Hawking of Drugs:

1. Hawking of drugs and medicinals should not be encouraged nor should any attempt be made to solicit orders for such substances from door to door.
2. Self-service method of operating pharmacies and drug-stores should not be used as this practice may lead to the distribution of therapeutic substances without an expert supervision and thus would encourage self-medication, which is highly undesirable.

5.2.2.4. Advertising and Displays:

No display material either on the premises, in the press or elsewhere should be used by a pharmacist in connection with the sale to the public of medicines or medical appliances which is undignified in style or which contains:

a) Any wording design or illustration reflecting unfavorably on pharmacist collectively or upon any group or individual.
b) A disparaging reference, direct of by implication to other suppliers, products, remedies or treatments.
c) Misleading, or exaggerated statements or claims.
d) The word “Cure” in reference to an ailment or symptoms of ill-health.
e) A guarantee of therapeutic efficacy.
f) An appeal to fear,
g) An offer to refund money paid.

h) A prize**,** competition or similar scheme.

5.2.3. Pharmacist in relation to medical profession

It is expected that medical practitioners in general would not take to the practice of pharmacy by owning drug stores, as this ultimately leads to coded prescriptions and monopolistic practices detrimental to the pharmaceutical profession and also to the interest of patients. It should be made a general rule that pharmacists under no circumstances take to medical practice that is to diagnosing diseases and prescribing remedies therefore even if requested by patrons to do so. In cases of accidents and emergencies a pharmacist may, however, render First Aid to the victim. No pharmacist should recommend particular medical practitioner unless specifically asked to do so.

5.2.3.1. Clandstine Arrangements:

No pharmacist should enter into any secret arrangements or contract with a physician to offer him any commission or any advantage of any description in return for his favour of patronage by recommending his dispensary or drugstore or even his self to patients.

5.2.3.2. Liaison with public:

A pharmacist should never disclose any information which he has acquired during his professional activities to any third party or person unless required by law to do so. He should never betray the confidence which his patrons repose in him or which he has won by virtue of his eminent character and conduct.

5.2.4. Pharmacist in relation to his profession

It is not only sufficient for a pharmacist to be law-abiding and to deter from doing things detrogatory to Society and his profession, but it should be his bounden duty to make others also fulfil the provisions of the pharmaceutical and other laws and regulations. He should not be afraid of bringing or causing a miscreant to be brought to book, may be a member of his own profession. Whereas it is obligatory for a pharmacist to extend help and cooperation to a fellow member in his legitimate needs, scientific, technical or otherwise, he is to be, at the same time, vigilant to weed the undesirable out of the profession and thus help to maintain its fair name and traditions.

5.2.4. Pharmacist's oath

I swear by the code of ethics of Pharmacy Council of India, in relation to the community and shall act as an integral part of health care team.

I shall uphold the laws and standards governing my profession.

I shall strive to perfect and enlarge my knowledge to contribute to the advancement of pharmacy and public health.

I shall follow the system which I consider best for Pharmaceutical care and counseling of patients.

I shall endeavor to discover and manufacture drugs of quality to alleviate sufferings of humanity.

I shall hold in confidence the knowledge gained about the patients in connection with my professional practice and never divulge unless compelled to do so by the law.

I shall associate with organizations having their objectives for betterment of the profession of Pharmacy and make contribution to carry out the work of those organizations.

While I continue to keep this oath unviolated, May it be granted to me to enjoy life and the practice of pharmacy respected by all, at all times!

Should I trespass and violate this oath, may the reverse be my lot!

5.3. Medical Termination of Pregnancy Act

The MTP Act, 1971 preamble states "an Act to provide for the termination of certain pregnancies by registered medical practitioners and for matters connected therewith or incidental thereto".

1. **Short title, extent and commencement.-**
   i) This Act may be called the Medical Termination of Pregnancy Act, 1971.
   ii) It extends to the whole of India except the State of Jammu and Kashmir.
   iii) It shall come into force on such date1 as the Central Government may, by notification in the Official Gazette, appoint.

2. Definitions.-in this Act, unless the context otherwise requires,—

a) "guardian" means a person having the care of the person of a minor.
b) "minor" means a person who, under the provisions of the Indian Majority Act, 1875 (9 of 1875), is to be deemed not to have attained his majority.
c) "registered medical practitioner" means a medical practitioner who possesses any recognised medical qualification as defined in clause (*h*) of section 2 of the Indian Medical Council Act, 1956 (102 of 1956), whose name has been entered in a State Medical Register and who has such experience or training in gynaecology and obstetrics as may be prescribed by rules made under this Act.

3. Place where pregnancy may be terminated.—No termination of pregnancy shall be made in accordance with this Act at any place other than—

a) a hospital established or maintained by Government, or

b) a place for the time being approved for the purpose of this Act by Government or a District Level Committee constituted by that Government with the Chief Medical Officer or District Health Officer as the Chairperson of the said Committee: Provided that the District Level Committee shall consist of not less than three and not more than five members including the Chairperson, as the Government may specify from time to time.

4. Power to make rules.-

1) The Central Government may, by notification in the Official Gazette, make rules to carry out the provisions of this Act.

2) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:—

    a. the experience or training, or both, which a registered medical practitioner shall have if he intends to terminate any pregnancy under this Act; and

    b. Such other matters as are required to be or may be, provided by rules made under this Act.

3) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament while it is in session for a total period of thirty days which may be comprised in one session or in two successive sessions, and if, before the expiry of the session in which it is so laid or the session immediately following, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

5. Power to make regulations.

1) The State Government may, by regulations,—

(*a*) require any such opinion as is referred to in sub-section (*2*) of section 3 to be certified by a registered medical practitioner or practitioners concerned, in such form and at such time as may be specified in such regulations, and the preservation or disposal of such certificates;

(*b*) require any registered medical practitioner, who terminates a pregnancy, to give intimation of such termination and such other information relating to the termination as may be specified in such regulations;

(*c*) prohibit the disclosure, except to such persons and for such purposes as may be specified in such regulations, of intimations given or information furnished in pursuance of such regulations.

2) The intimation given and the information furnished in pursuance of regulations made by virtue of clause (*b*) of sub-section (*1*) shall be given or furnished, as the case may be, to the Chief Medical Officer of the State.
3) Any person who will fully contravenes or wilfully fails to comply with the requirements of any regulation made under sub-section (1) shall be liable to be punished with fine which may extend to one thousand rupees.

6. Protection of action taken in good faith.—No suit or other legal proceeding shall lie against any registered medical practitioner for any damage caused or likely to be caused by anything which is in good faith done or intended to be done under this Act.

5.4. Right to Information Act

An Act to provide for setting out the practical regime of right to information for citizens to secure access to information under the control of public authorities, in order to promote transparency and accountability in the working of every public authority, the constitution of a Central Information Commission and State Information Commissions and for matters connected therewith or incidental thereto.

1. Short title, extent and commencement.—*(1)* This Act may be called the Right to Information Act, 2005. *(2)* It extends to the whole of India. *(3)* The provisions of sub-section (1) of section 4, sub-sections *(1)* and *(2)* of section 5, sections 12, 13, 15,16, 24, 27 and 28 shall come into force at once, and the remaining provisions of this Act shall come into force on the one hundred and twentieth day of its enactment.

2. Definitions.—In this Act, unless the context otherwise requires,—

(a) "appropriate Government" means in relation to a public authority which is established, constituted, owned, controlled or substantially financed by funds provided directly or indirectly— (i) by the Central Government or the Union territory administration, the Central Government; (ii) by the State Government, the State Government;

(b) "Central Information Commission" means the Central Information Commission constituted under sub-section (1) of section 12;

(c) "Central Public Information Officer" means the Central Public Information Officer designated under sub-section (1) and includes a Central Assistant Public Information Officer designated as such under sub-section (2) of section 5;

(d) "Chief Information Commissioner" and "Information Commissioner" mean the Chief Information Commissioner and Information Commissioner appointed under sub-section (3) of section 12;

(e) "competent authority" means— (i) the Speaker in the case of the House of the People or the Legislative Assembly of a State or a Union territory having such Assembly and the Chairman in the case of the Council of States or Legislative Council of a State; (ii) the Chief Justice of India in the case of the Supreme Court; (iii) the Chief Justice of the High Court in the case of a High Court; (iv) the President or the Governor, as the case may be, in the case of other authorities established or constituted by or under the Constitution; (v) the administrator appointed under article 239 of the Constitution;

(f) "information" means any material in any form, including records, documents, memos, e-mails, opinions, advices, press releases, circulars, orders, logbooks, contracts, reports, papers, samples, models, data material held in any electronic form and information relating to any private body which can be accessed by a public authority under any other law for the time being in force;

(g) "prescribed" means prescribed by rules made under this Act by the appropriate Government or the competent authority, as the case may be;

(h) "public authority" means any authority or body or institution of self- government established or constituted— (a) by or under the Constitution; (b) by any other law made by Parliament; (c) by any other law made by State Legislature; (d) by notification issued or order made by the appropriate Government.

(i) "record" includes— (a) any document, manuscript and file; (b) any microfilm, microfiche and facsimile copy of a document; (c) any reproduction of image or images embodied in such microfilm (whether enlarged or not); and (d) any other material produced by a computer or any other device;

(j) "right to information" means the right to information accessible under this Act which is held by or under the control of any public authority and includes the right to— (i) inspection of work, documents, records; (ii) taking notes, extracts or certified copies of documents or records; (iii) taking certified samples of material; (iv) obtaining information in the form of diskettes, floppies,

tapes, video cassettes or in any other electronic mode or through printouts where such information is stored in a computer or in any other device;

(k) "State Information Commission" means the State Information Commission constituted under sub-section (1) of section 15;

(l) "State Chief Information Commissioner" and "State Information Commissioner" mean the State Chief Information Commissioner and the State Information Commissioner appointed under subsection (3) of section 15;

(m) "State Public Information Officer" means the State Public Information Officer designated under sub-section (1) and includes a State Assistant Public Information Officer designated as such under sub-section (2) of section 5;

(n) "third party" means a person other than the citizen making a request for information and includes a public authority.

3. Right to information.—Subject to the provisions of this Act, all citizens shall have the right to information.

4. Obligations of public authorities.—(1) Every public authority shall—

(a) maintain all its records duly catalogued and indexed in a manner and the form which facilitates the right to information under this Act and ensure that all records that are appropriate to be computerised are, within a reasonable time and subject to availability of resources, computerised and connected through a network all over the country on different systems so that access to such records is facilitated;

(b) Publish within one hundred and twenty days from the enactment of this Act,—

(i) the particulars of its organisation, functions and duties;

(ii) the powers and duties of its officers and employees;

(iii) the procedure followed in the decision making process, including channels of supervision and accountability;

(iv) the norms set by it for the discharge of its functions;

(v) the rules, regulations, instructions, manuals and records, held by it or under its control or used by its employees for discharging its functions;

(vi) a statement of the categories of documents that are held by it or under its control;

(vii) the particulars of any arrangement that exists for consultation with, or representation by, the members of the public in relation to the formulation of its policy or implementation thereof; (viii) a statement of the boards, councils, committees and other bodies consisting of two or more persons constituted as its part or for the purpose of its

advice, and as to whether meetings of those boards, councils, committees and other bodies are open to the public, or the minutes of such meetings are accessible for public;

(ix) a directory of its officers and employees;

(x) the monthly remuneration received by each of its officers and employees, including the system of compensation as provided in its regulations;

(xi) the budget allocated to each of its agency, indicating the particulars of all plans, proposed expenditures and reports on disbursements made;

(xii) the manner of execution of subsidy programmes, including the amounts allocated and the details of beneficiaries of such programmes;

(xiii) particulars of recipients of concessions, permits or authorisations granted by it;

(xiv) details in respect of the information, available to or held by it, reduced in an electronic form;

(xv) the particulars of facilities available to citizens for obtaining information, including the working hours of a library or reading room, if maintained for public use;

(xvi) the names, designations and other particulars of the Public Information Officers;

(xvii) such other information as may be prescribed; and thereafter update these publications every year;

(c) publish all relevant facts while formulating important policies or announcing the decisions which affect public;

(d) provide reasons for its administrative or quasi-judicial decisions to affected persons.

5. Designation of Public Information Officers.—

(1) Every public authority shall, within one hundred days of the enactment of this Act, designate as many officers as the Central Public Information Officers or State Public Information Officers, as the case may be, in all administrative units or offices under it as may be necessary to provide information to persons requesting for the information under this Act.

(2) Without prejudice to the provisions of sub-section (1), every public authority shall designate an officer, within one hundred days of the enactment of this Act, at each sub-divisional level or other subdistrict level as a Central Assistant Public Information Officer or a State Assistant Public Information Officer, as the case may be, to receive the applications for information or appeals under this Act for forwarding the same forthwith to the Central Public Information Officer or the State Public Information Officer or senior officer specified under sub-section (1) of section 19 or the Central Information Commission or the State Information Commission, as

the case may be: Provided that where an application for information or appeal is given to a Central Assistant Public Information Officer or a State Assistant Public Information Officer, as the case may be, a period of five days shall be added in computing the period for response specified under sub-section (1) of section 7.

(3) Every Central Public Information Officer or State Public Information Officer, as the case may be, shall deal with requests from persons seeking information and render reasonable assistance to the persons seeking such information.

(4) The Central Public Information Officer or State Public Information Officer, as the case may be, may seek the assistance of any other officer as he or she considers it necessary for the proper discharge of his or her duties.

(5) Any officer, whose assistance has been sought under sub-section *(4)*, shall render all assistance to the Central Public Information Officer or State Public Information Officer, as the case may be, seeking his or her assistance and for the purposes of any contravention of the provisions of this Act, such other officer shall be treated as a Central Public Information Officer or State Public Information Officer, as the case may be.

6. Request for obtaining information.—

(1) A person, who desires to obtain any information under this Act, shall make a request in writing or through electronic means in English or Hindi or in the official language of the area in which the application is being made, accompanying such fee as may be prescribed, to

(a) the Central Public Information Officer or State Public Information Officer, as the case may be, of the concerned public authority;

(b) the Central Assistant Public Information Officer or State Assistant Public Information Officer, as the case may be, specifying the particulars of the information sought by him or her: Provided that where such request cannot be made in writing, the Central Public Information Officer or State Public Information Officer, as the case may be, shall render all reasonable assistance to the person making the request orally to reduce the same in writing.

(2) An applicant making request for information shall not be required to give any reason for requesting the information or any other personal details except those that may be necessary for contacting him.

(3) Where an application is made to a public authority requesting for an information,—

(i) which is held by another public authority; or

(ii) the subject matter of which is more closely connected with the functions of another public authority,

the public authority, to which such application is made, shall transfer the application or such part of it as may be appropriate to that other public authority and inform the applicant immediately about such transfer:

Provided that the transfer of an application pursuant to this sub-section shall be made as soon as practicable but in no case later than five days from the date of receipt of the application

7. Disposal of request.—

(*1*) Subject to the proviso to sub-section (*2*) of section 5 or the proviso to sub-section (*3*) of section 6, the Central Public Information Officer or State Public Information Officer, as the case may be, on receipt of a request under section 6 shall, as expeditiously as possible, and in any case within thirty days of the receipt of the request, either provide the information on payment of such fee as may be prescribed or reject the request for any of the reasons specified in sections 8 and 9: Provided that where the information sought for concerns the life or liberty of a person, the same shall be provided within forty-eight hours of the receipt of the request.

(*2*) If the Central Public Information Officer or State Public Information Officer, as the case may be, fails to give decision on the request for information within the period specified under sub-section (1), the Central Public Information Officer or State Public Information Officer, as the case may be, shall be deemed to have refused the request.

(*3*) Where a decision is taken to provide the information on payment of any further fee representing the cost of providing the information, the Central Public Information Officer or State Public Information Officer, as the case may be, shall send an intimation to the person making the request, giving—

(a) the details of further fees representing the cost of providing the information as determined by him, together with the calculations made to arrive at the amount in accordance with fee prescribed under sub-section (1), requesting him to deposit that fees, and the period intervening between the despatch of the said intimation and payment of fees shall be excluded for the purpose of calculating the period of thirty days referred to in that sub-section;

(b) information concerning his or her right with respect to review the decision as to the amount of fees charged or the form of access provided, including the particulars of the appellate authority, time limit, process and any other forms.

(*4*) Where access to the record or a part thereof is required to be provided under this Act and the person to whom access is to be provided is sensorily disabled, the Central Public Information Officer or State Public Information Officer, as the case may be, shall provide assistance to enable access to the information, including providing such assistance as may be appropriate for the inspection.

(*5*) Where access to information is to be provided in the printed or in any electronic format, the applicant shall, subject to the provisions of sub-section (*6*), pay such fee as may be prescribed: Provided that the fee prescribed under sub-section (*1*) of section 6 and sub-sections (*1*) and (*5*) of section 7 shall be reasonable and no such fee shall be charged from the persons who are of below poverty line as may be determined by the appropriate Government.

(*6*) Notwithstanding anything contained in sub-section (*5*), the person making request for the information shall be provided the information free of charge where a public authority fails to comply with the time limits specified in sub-section (*1*).

(*7*) Before taking any decision under sub-section (*1*), the Central Public Information Officer or State Public Information Officer, as the case may be, shall take into consideration the representation made by a third party under section 11.

(*8*) Where a request has been rejected under sub-section (1), the Central Public Information Officer or State Public Information Officer, as the case may be, shall communicate to the person making the request,—

(i) the reasons for such rejection;

(ii) the period within which an appeal against such rejection may be preferred; and

(iii) the particulars of the appellate authority

(*9*) An information shall ordinarily be provided in the form in which it is sought unless it would disproportionately divert the resources of the public authority or would be detrimental to the safety or preservation of the record in question.

8. Exemption from disclosure of information—(*1*) Notwithstanding anything contained in this Act, there shall be no obligation to give any citizen,—

(a) information, disclosure of which would prejudicially affect the sovereignty and integrity of India, the security, strategic, scientific or economic interests of the State, relation with foreign State or lead to incitement of an offence;

(b) information which has been expressly forbidden to be published by any court of law or tribunal or the disclosure of which may constitute contempt of court;

(c) information, the disclosure of which would cause a breach of privilege of Parliament or the State Legislature;

(d) information including commercial confidence, trade secrets or intellectual property, the disclosure of which would harm the competitive position of a third party, unless the competent authority is satisfied that larger public interest warrants the disclosure of such information;

(e) information available to a person in his fiduciary relationship, unless the competent authority is satisfied that the larger public interest warrants the disclosure of such information;

(f) information received in confidence from foreign Government;

(g) information, the disclosure of which would endanger the life or physical safety of any person or identify the source of information or assistance given in confidence for law enforcement or security purposes;

(h) information which would impede the process of investigation or apprehension or prosecution of offenders;

(i) cabinet papers including records of deliberations of the Council of Ministers, Secretaries and other officers:

Provided that the decisions of Council of Ministers, the reasons thereof, and the material on the basis of which the decisions were taken shall be made public after the decision has been taken, and the matter is complete, or over: Provided further that those matters which come under the exemptions specified in this section shall not be disclosed;

9. Grounds for rejection to access in certain cases.—

Without prejudice to the provisions of section 8, a Central Public Information Officer or a State Public Information Officer, as the case may be, may reject a request for information where such a request for providing access would involve an infringement of copyright subsisting in a person other than the State.

10. Severability.—(*1***)** Where a request for access to information is rejected on the ground that it is in relation to information which is exempt from disclosure, then, notwithstanding anything contained in this Act, access may be provided to that part of the record which does not contain any information which is exempt from disclosure under this Act and which can reasonably be severed from any part that contains exempt information.

11. Third party information.—(*1*) Where a Central Public Information Officer or a State Public Information Officer, as the case may be, intends to disclose any information or record, or part thereof on a request made under this Act, which relates to or has been supplied by a third party and has been treated as confidential by that third party, the Central Public Information Officer or

State Public Information Officer, as the case may be, shall, within five days from the receipt of the request, give a written notice to such third party of the request and of the fact that the Central Public Information Officer or State Public Information Officer, as the case may be, intends to disclose the information or record, or part thereof, and invite the third party to make a submission in writing or orally, regarding whether the information should be disclosed, and such submission of the third party shall be kept in view while taking a decision about disclosure of information.

12. Constitution of Central Information commissions—

(*1*) The Central Government shall, by notification in the Official Gazette, constitute a body to be known as the Central Information Commission to exercise the powers conferred on, and to perform the functions assigned to, it under this Act.

(*2*) The Central Information Commission shall consist of—

(a) the Chief Information Commissioner; and

(b) such number of Central Information Commissioners, not exceeding ten, as may be deemed necessary.

(*3*) The Chief Information Commissioner and Information Commissioners shall be appointed by the President on the recommendation of a committee consisting of—

(i) the Prime Minister, who shall be the Chairperson of the committee;

(ii) the Leader of Opposition in the LokSabha; and

(iii) a Union Cabinet Minister to be nominated by the Prime Minister.

(*4*) The general superintendence, direction and management of the affairs of the Central Information Commission shall vest in the Chief Information Commissioner who shall be assisted by the Information Commissioners and may exercise all such powers and do all such acts and things which may be exercised or done by the Central Information Commission autonomously without being subjected to directions by any other authority under this Act.

(*5*) The Chief Information Commissioner and Information Commissioners shall be persons of eminence in public life with wide knowledge and experience in law, science and technology, social service, management, journalism, mass media or administration and governance.

(*6*) The Chief Information Commissioner or an Information Commissioner shall not be a Member of Parliament or Member of the Legislature of any State or Union territory, as the case may be, or hold any other office of profit or connected with any political party or carrying on any business or pursuing any profession.

(*7*) The headquarters of the Central Information Commission shall be at Delhi and the Central Information Commission may, with the previous approval of the Central Government, establish offices at other places in India.

13. Term of office and conditions of service.—

(*1*) The Chief Information Commissioner shall hold office 2 [for such term as may be prescribed by the Central Government] and shall not be eligible for reappointment: Provided that no Chief Information Commissioner shall hold office as such after he has attained the age of sixty-five years.

(*2*) Every Information Commissioner shall hold office 1 [for such term as may be prescribed by the Central Government] or till he attains the age of sixty-five years, whichever is earlier, and shall not be eligible for reappointment as such Information Commissioner: Provided that every Information Commissioner shall, on vacating his office under this sub-section be eligible for appointment as the Chief Information Commissioner in the manner specified in sub-section.

(*3*) of section 12: Provided further that where the Information Commissioner is appointed as the Chief Information Commissioner, his term of office shall not be more than five years in aggregate as the Information Commissioner and the Chief Information Commissioner.

5.5. Introduction to Intellectual Property Rights (IPR)

Intellectual Property Right is exclusive right which is granted by government of India for protecting originality of work of inventor. Simple intellectual property right is intangible creation of human mind. Intellectual Property right includes Patent, Trademark, Trades crates, Industrial design, Layout design and Copyright oriented rights. Intellectual right is important for maintaining the quality, safety, efficacy of any Pharmaceutical product and services. It is certification authority and standard authority for certification and identification of product in would wide market. This intellectual property right is the rights given to people over the creation of their minds. They usually give the creator an exclusive right over the use of his/her creations for a certain period of time. Intellectual property refers to creations of the mind, inventions in artistic, literary, scientific and industrial field. It is important application for Protection of invention of inventor and maintaining the quality as well as standard of work of inventor.

5.5.1. Objectives of IPR

1. Intellectual property Right (IPR) is a term used for various legal entitlements which attach to certain types of information, ideas, or other intangibles in their expressed form.
2. The holder of this legal entitlement is generally entitled to exercise various exclusive rights in relation to the subject matter of the Intellectual Property.
3. The term intellectual property reflects the idea that this subject matter is the product of the mind or the intellect, and that Intellectual Property rights may be protected at law in the same way as any other form of property.
4. Intellectual property laws vary from jurisdiction to jurisdiction, such that the acquisition, registration or enforcement of IP rights must be pursued or obtained separately in each territory of interest.

5.5.2. Types of IPR

- Patents
- Trademarks
- Copyrights and related rights
- Geographical indications
- Industrial designs
- Trade secrets
- Layout design for integrated circuits

5.5.2.1. Patents

1. A patent is an exclusive right granted for an invention, which is a product or a process that provides a new way of doing something, or offers a new technical solution to a problem.
2. It provides protection for the invention to the owner of the patent.
3. The protection is granted for a limited period, i.e. 20 years. Patent protection means that the invention cannot be commercially made, used, distributed or sold without the patent owner's consent.
4. A patent owner has the right to decide who may or may not use the patented invention for the period in which the invention is protected. The patent owner may give permission to, or license, other parties to use the invention on mutually agreed terms.
5. The owner may also sell the right to the invention to someone else, who will then become the new owner of the patent. Once a patent expires, the protection ends, and an invention enters the

public domain, that is the owner no longer holds exclusive rights to the invention, which becomes available to commercial exploitation by others.

6. All patent owners are obliged, in return for patent protection, to publicly disclose information on their invention in order to enrich the total body of technical knowledge in the world. Such an ever-increasing body of public knowledge promotes further creativity and innovation in others.
7. In this way, patents provide not only protection for the owner but valuable information and inspiration for future generations of researchers and inventors.

Indian Patent Act

The history of Patent law in India starts from 1911 when the Indian Patents and Designs Act, 1911 was enacted. The present Patents Act, 1970 came into force in the year 1972, amending and consolidating the existing law relating to Patents in India. The Patents Act, 1970 was again amended by the Patents (Amendment) Act, 2005, wherein product patent was extended to all fields of technology including food, drugs, chemicals and micro-organisms. After the amendment, the provisions relating to Exclusive Marketing Rights (EMRs) have been repealed, and a provision for enabling grant of compulsory license has been introduced.

An invention relating to a product or a process that is new, involving inventive step and capable of industrial application can be patented in India. However, it must not fall into the category of inventions that are non-patentable as provided under sections 3 and 4 of the (Indian) Patents Act, 1970. In India, a patent application can be filed, either alone or jointly, by true and first inventor or his assignee.

Procedure for Grant of a Patent in India

1. After filing the application for the grant of patent, a request for examination is required to be made for examination of the application in the Indian Patent Office within 48 months from the date of priority of the application or from the date of filing of the application.
2. After the first examination report is issued, the applicant is given an opportunity to meet the objections raised in the report.
3. The applicant has to comply with the requirements within 6 months from the issuance of the first examination report which may be extended for further 3 months on the request of the applicant.
4. If the requirements of the first examination report are not complied with within the prescribed period of 9 months, then the application is treated to have been abandoned by the applicant.

5. After the removal of objections and compliance of requirements, the patent is granted and notified in the Patent Office Journal. The process of the grant of patent in India can also be understood from the following flow chart (**Fig.1**).

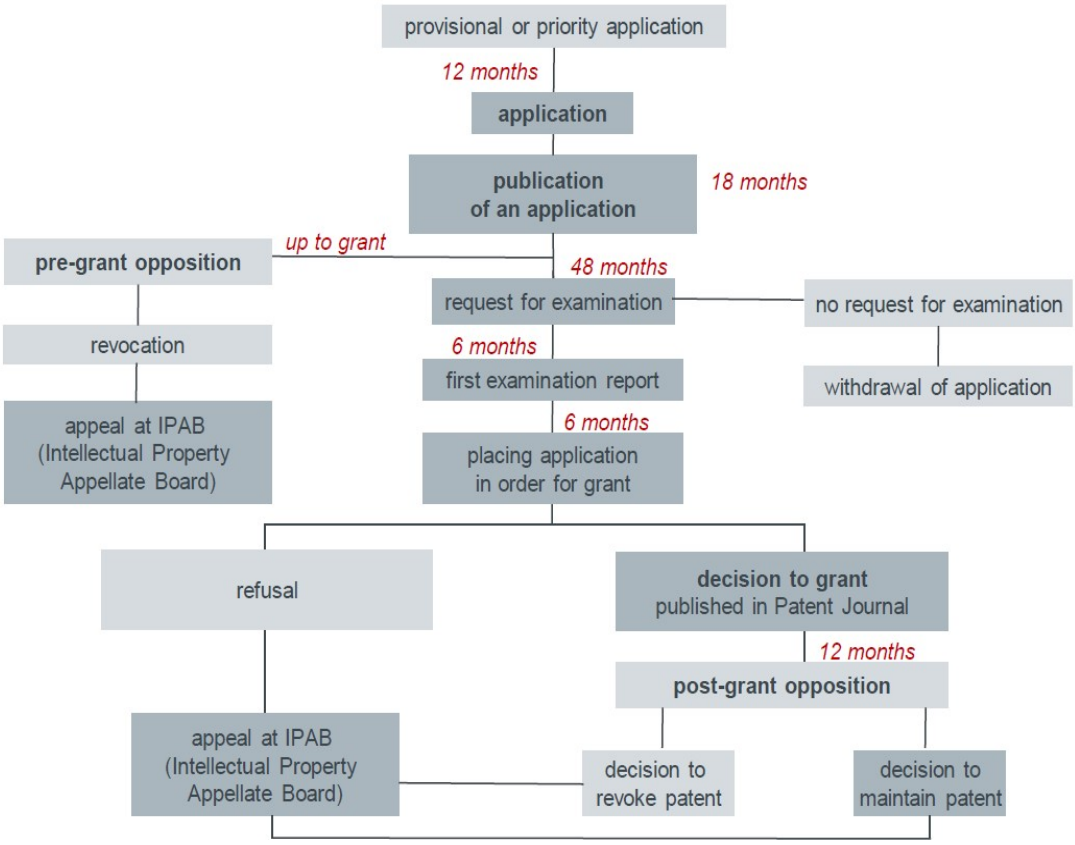

Fig.1. Patent granting procedure in India (from May 2016 onwards).

5.5.2.2. Trademarks

1. A trademark is a distinctive sign that identifies certain goods or services as those produced or provided by a specific person or enterprise.
2. It may be one or a combination of words, letters, and numerals.
3. They may consist of drawings, symbols, three- dimensional signs such as the shape and packaging of goods, audible signs such as music or vocal sounds, fragrances, or colours used as distinguishing features.
4. It provides protection to the owner of the mark by ensuring the exclusive right to use it to identify goods or services, or to authorize another to use it in return for payment.

5. It helps consumers identify and purchase a product or service because its nature and quality, indicated by its unique trademark, meets their needs.
6. Registration of trademark is prima facie proof of its ownership giving statutory right to the proprietor. Trademark rights may be held in perpetuity.
7. The initial term of registration is for 10 years; thereafter it may be renewed from time to time.

5.5.2.3. Copyrights and related rights

1. Copyright is a legal term describing rights given to creators for their literary and artistic works. The kinds of works covered by copyright include: literary works such as novels, poems, plays, reference works, newspapers and computer programs; databases; films, musical compositions, and choreography; artistic works such as paintings, drawings, photographs and sculpture; architecture; and advertisements, maps and technical drawings.
2. Copyright subsists in a work by virtue of creation; hence it‘s not mandatory to register. However, registering a copyright provides evidence that copyright subsists in the work & creator is the owner of the work. Creators often sell the rights to their works to individuals or companies best able to market the works in return for payment.
3. These payments are often made dependent on the actual use of the work, and are then referred to as royalties.
4. These economic rights have a time limit, (other than photographs) is for life of author plus sixty years after creator‘s death.

5.5.2.4. Industrial designs

1. Industrial designs refer to creative activity, which result in the ornamental or formal appearance of a product, and design right refers to a novel or original design that is accorded to the proprietor of a validly registered design. Industrial designs are an element of intellectual property.
2. Under the TRIPS Agreement, minimum standards of protection of industrial designs have been provided for. As a developing country, India has already amended its national legislation to provide for these minimal standards.
3. The essential purpose of design law it to promote and protect the design element of industrial production. It is also intended to promote innovative activity in the field of industries.

4. The existing legislation on industrial designs in India is contained in the New Designs Act, 2000 and this Act will serve its purpose well in the rapid changes in technology and international developments.
5. India has also achieved a mature status in the field of industrial designs and in view of globalization of the economy, the present legislation is aligned with the changed technical and commercial scenario and made to conform to international trends in design administration.
6. This replacement Act is also aimed to enact a more detailed classification of design to conform to the international system and to take care of the proliferation of design related activities in various fields.

5.5.2.5. Trade secrets

1. It may be confidential business information that provides an enterprise a competitive edge may be considered a trade secret. Usually these are manufacturing or industrial secrets and commercial secrets.
2. These include sales methods, distribution methods, consumer profiles, and advertising strategies, lists of suppliers and clients, and manufacturing processes. Contrary to patents, trade secrets are protected without registration.
3. A trade secret can be protected for an unlimited period of time but a substantial element of secrecy must exist, so that, except by the use of improper means, there would be difficulty in acquiring the information.
4. Considering the vast availability of traditional knowledge in the country the protection under this will be very crucial in reaping benefits from such type of knowledge.

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