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Regulatory Authority And Goverment Policies

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ABSTRACT
Pharmaceuticals review and assessment by regulatory bodies justifies necessity to maintain consistency, transparency, and efficiency during evaluation. Standardized approach followed during research ensures clear objective, thorough evaluation, evaluation of preformulation parameters, and hence ultimately safeguarding public health. Pharmaceutical regulatory bodies play a pivotal role in safeguarding public health by organizing the development, manufacturing, and distribution of pharmaceutical products in an effective way. Regulatory bodies are responsible for ensuring drugs standards, safety, efficacy, and quality. Regulatory bodies are responsible for guidelines enforcement and assessment of lifecycle of pharmaceuticals, which includes preclinical studies and clinical studies and then evaluation of clinical trials humans, which signifies drugs safety and efficacy. Also regulatory agencies set standards for manufacturing to ensure quality and consistency of pharmaceuticals i.e. requirements for facilities, equipment, personnel, and documentation. Adherence to Good Manufacturing Practice (GMP) guidelines is quite a crucial parameter to prevent contamination, errors, or deviations during the production. Regulatory bodies set standards for assessing ADR of drug, which involves thorough evaluation of clinical trial data, post-marketing surveillance, safety monitoring and finally labeling and packaging requirements to provide accurate information to patients. Furthermore, these bodies engage in post-marketing surveillance to monitor the safety and efficacy of pharmaceutical products. Adverse event reporting systems allow healthcare professionals and consumers to report unexpected side effects or other concerns, enabling regulatory authorities to take prompt action if necessary. Collaboration between regulatory bodies on an international level is another critical aspect of pharmaceutical regulation.
Keywords: Regulatory body, GMP, Pharmaceutical sector and government regulation,

I. INTRODUCTION

REGULATORY BODIES

1. GLOBAL REGULATORY AUTHORITIES

i. World Health Organisation (WHO)

Established on 7 April 1948, headquartered in Geneva,Switzerland, being the main directing and coordinating authority for health in United Nations., responsible for initiating plans on global health matters and concerns, from health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends. With its major role in eradication of smallpox from world, right now WHO is aiming at communicable diseases particularly HIV/AIDS, Ebola, malaria and tuberculosis, mitigation of effects of non-communicable diseases which includes sexual and reproductive health, development, aging, nutrition, food security, eating habits, occupational health, and drug abuse. Hence WHO being the major regulatory body to impact global health vision and goals, also plays a major role in requirement of medicines and vaccinations across the world, especially in the developing countries. And therefore Indian Pharmaceutical market utilizes the policies and projects supported by WHO as they have major impact on medication requirement, it's manufacturing and quantity, not only for Indian consumptions but in a major way for exports [22][1].

ii. International Conference on Harmonization (ICH)(1990)

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), comprises of regulatory authorities and pharmaceutical industry of Europe, Japan and the US to discuss scientific and technical aspects of drug registration. It focuses globally on drug development, to initiate better global health worldwide. Mission being greater harmonization to ensure development and registration of safe, effective, and high quality drugs. Since it sets standards which have crucial impact on filtering out drugs to be sold, hence being critical body for the Pharma Industry especially if organisation operates or manufacture in Europe, Japan and U.S.[25][3][1].

iii. World Trade Organisation(WTO) (1986)

It is rules of trade between nations, it agreements, negotiates and signed by the bulk of the world's trading nations and responsible for rectification. The goal is to help producers of goods and services, exporters, and importers in conducting their business. WTO dates back its work in negotiations called the Uruguay Round and earlier negotiations under the General Agreement on Tariffs and Trade (GATT). WTO currently is host to new negotiations, under the 'Doha Development Agenda' launched in 2001. Purpose being trade flow as freely as possible to ensure undesirable side effects, because this is important for economic development and well-being. WTO ensures trade rules around the world for pharmaceutical industries and governments. India has been a signatory to the WTO the day it was formed in 1995. WTO regulates exports and imports pharmaceutical products and policies and plays a major role in dispute regarding pharma trade and policies [19][2][1].

iv. Food and Drug Administration(FDA)

Being the federal agency of United States, Department of Health and Human Services, it is responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription, over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed and veterinary products.

The Center for Drug Evaluation and Research uses different requirements for the three main drug product. [13][4][1]

a. New drugs: New drugs receive extensive scrutiny before FDA approval in a process called a New Drug Application (NDA). New drugs are available only by prescription of registered medical practitioner. Drug must be approved by NDA first to claim its safety and effectiveness [23][1].

b. Generic drugs: Generic drugs are chemical equivalents brand name drugs whose patents have expired, they are less expensive than their name brand counterparts, and are manufactured and marketed by other companies. For approval of a generic drug, the U.S. Food and Drug Administration (FDA) requires scientific evidence that the generic drug is interchangeable with or therapeutically equivalent to the originally approved drug i.e. "ANDA" (Abbreviated New Drug Application) [23][19][6].

c. Over-the-counter drugs: Over-the-counter (OTC) drugs like aspirin are drugs and combinations that do not require a doctor's prescription. The FDA has a list of approximately 800 approved ingredients that are combined in various ways to create more than 100,000 OTC drug products. Many OTC drug ingredients had been previously approved prescription drugs now deemed safe enough for use without a medical practitioner's supervision like ibuprofen. Thus any organisation approval from FDA becomes mandatory for an organisation to operate and sell [13][8].

II. INDIAN REGULATORY AUTHORITIES

i. Central Drugs Standard Control Organisation

The Central Drugs Standard Control Organisation (CDSCO) being the Central Drug Authority for discharging functions assigned to the Central Government under Drugs and Cosmetics Act, has six zonal offices, four sub-zonal offices, 11 port offices and six laboratories under its control.[24][17][15]

Major functions of CDSCO:

1. Regulatory control over the import of drugs, approval of new drugs and clinical trials.
2. Meetings of Drugs Consultative Committee(DCC) and Drugs Technical Advisory board (DTAB).
3. Central License Approving Authority.

Drug Controller General of India is responsible for approval of licenses of specified categories of Drugs such as blood and blood products, I.V.fluids, vaccine and sera. Under the Drug and Cosmetics Act, the regulation of manufacture, sale and distribution of Drugs is primarily the concern of the State authorities while the Central Authorities are responsible for approval of New Drugs, Clinical Trials in the country, laying down standards for Drugs, control over the quality of imported Drugs, coordination of the activities of State Drug Control Organisations and providing expert advice with a view to bring uniformity in enforcement of Drugs and Cosmetics Act.[22][16][12]

ii. Ministry of Healthcare and Family Welfare

Ministry of Health and Family Welfare had four Departments, each of which is headed by a secretary to the government of India:

- Departments of Health & Family Welfare
- Department of AYUSH
- Department of Health Research
- Department of AIDS Control

Recently Department of AIDS Control has been merged with Department of Health & Family Welfare and now be known as National AIDS Control Organisation (NACO), hence Ministry of Health and Family Welfare comprises the following three departments, each of which is headed by a secretary to the government of India:[12][1]

- Departments of Health & Family Welfare
- Department of AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy)
- Department of Health Research

Directorate General of Health Services (DGHS) is attached office of the Department of Health & Family Welfare and has subordinate at offices spread all over the country. The DGHS renders technical advice on all medical and public health matters and is involved in the implementation of various health services.[11][2]

iii. Indian Council of Medical Research (ICMR)

The Indian Council of Medical Research (ICMR), New Delhi, the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest medical research bodies in the world.
Government of India set up the Indian Research Fund Association (IRFA) with the specific objective of sponsoring and coordinating medical research in the country, responsible for its decision on formulation of new drug, clinic trials and research, funded by the Government of India through the Department of Health Research, Ministry of Health & Family Welfare [13][9][4].

iv. Government of India – Department of Pharmaceuticals (2008)

The Department of Pharmaceuticals retrorespective of its initiation by Ministry of Chemicals & Fertilizers so as to provide greater focus for the growth of high potential Pharmaceuticals industry [24][1].
Protocols given by Ministry for catalyzing the growth of pharmaceutical industry in India:

- Drugs and Pharmaceuticals sector development except for the AYUSH sector.
- Promotion and co-ordination of basic, applied and other research in areas related to Pharmaceuticals sector.
- Development of infrastructure, manpower and skills for the Pharmaceuticals sector and management of related information.
- Education and training including high end research and grant of fellowships in India and abroad, exchange of information and technical guidance on all matters relating to pharmaceutical sector.
- Promotion of public-private-partnership in pharmaceutical related areas.
- International cooperation in pharmaceutical research, including work related to international conferences in related areas in India and abroad.
- Technical support for dealing with national hazards in pharmaceutical sector.
- All matters relating to National Pharmaceuticals Pricing Authority including related functions of price control/monitoring.
- All matters relating to National Institutes for Pharmacy Education and Research.

v. National Pharmaceutical Pricing Authority Government of India (1997)

The NPPA has been given power to implement and enforce the Drugs Price Control Order (DPCO), can fund studies regarding pricing of drugs, has the task to monitor drug shortages and take appropriate actions to rectify it. DPCO has to collect and maintain data regarding the import and export of drugs, market shares of pharmaceutical companies and their profits, handles legal disputes that arise out of policies, and advices Government in matters of drug policies and pricing.[21][3]
Function of NPPA:

1. To implement and enforce the provisions of the Drugs (Prices Control) Order.
2. To deal with legal matters arising out of decision Authority.
3. To monitor drug availability of drugs, identity shortages, especially in remedial states.
4. To collect and maintain data on production, exports and imports, market share of individual companies, profitability of companies for bulk drugs and formulation.
5. To undertake sponsor relevant studies in respect to pricing or drugs.

vi. Medical Council of India

The Medical Council of India was established in 1934 under the Indian Medical Council Act, 1933, now repealed, with the main function of establishing uniform standards of higher qualifications in medicine and recognition of medical qualifications in India and abroad.The number of medical colleges had increased steadily during the years after Independence.It was felt that the provisions of Indian Medical Council Act were not adequate to meet with the challenges posed by the very fast development and the progress of medical education

in the country.As a result, in 1956, the old Act was repealed and a new one was enacted.This was further modified in 1964, 1993 and 2001.[19][14]

The objectives of the Council are as follows:

- Maintenance of uniform standards of medical education, both undergraduate and postgraduate.
- Recommendation for recognition/de-recognition of medical qualifications of medical institutions of India or foreign countries.
- Permanent registration/provisional registration of doctors with recognised medical qualifications.
- Reciprocity with foreign countries in the matter of mutual recognition of medical qualifications.

vii. Pharmacist Council of India

Pharmacy education and profession in India graduate, post graduate and doctorate level is regulated by the PCI, a statutory body governed by the provisions of the Pharmacy Act, 1948 passed by the Parliament.[11][5][4][2][1]

Act regulates profession of pharmacy by ensuring better provision for regulation of profession and practice of pharmacy.

Objectives of PCI:

Regulation of the Pharmacy Education in the Country for the purpose of registration as a pharmacist under the Pharmacy Act.

Regulation of Profession and Practice of Pharmacy.

Functions and Duties of PCI:

- To prescribe minimum standard of education required for qualifying as a pharmacist.
- Framing of Education Regulations prescribing the conditions to be fulfilled by the institutions seeking approval of the PCI for imparting education in pharmacy.
- To ensure uniform implementation of the educational standards through out the country. Inspection of Pharmacy Institutions seeking approval under the Pharmacy Act to verify availability of the prescribed norms.
- To approve the course of study and examination for pharmacists ie, approval of the academic training institutions providing pharmacy courses.
- To withdraw approval, if the approved course of study or an approved examination does not continue to be in conformity with the educational standards prescribed by the PCI.
- To approve qualifications granted outside the territories to which the Pharmacy Act extends ie. The approval of foreign qualification.
- To maintain Central Register of Pharmacists.

viii. National Accreditation Board for Testing and Calibration Laboratories (NABL)

It is an autonomous body under the aegis of Department of Science & Technology Government of India, and is registered under the Societies Act 1860. NABL has been established with the objective to provide Government, Industry Associations and Industry in general with a scheme for third-party assessment of the quality and technical competence of testing and calibration of laboratories. Government of India has authorised NABL as the accreditation body for Testing and Calibration Laboratories [12][9][7][2].

In order to achieve this objective, NABL provides laboratory accreditation services to laboratories that are performing tests / calibrations in accordance with ISO/IEC 17025:2005 and ISO 15189:2007 for medical laboratories. These services are offered in a non-discriminatory manner and are accessible to all testing and calibration laboratories in India and abroad, regardless of their ownership, legal status, size and degree of independence.

ix. National Accreditation Board for Hospitals & Healthcare Providers (NABH)

NABH is a constituent board of Quality Council of India, set up to establish and operate accreditation programme for healthcare organisations. The board is structured to ensure desired needs of the consumers and to set benchmarks for progress of health industry. The board while being supported by all stakeholders including industry, consumers, government, have full functional autonomy in its operation.

International Linkages of NABH:

- NABH is an Institutional Member as well as a Board member of the International Society for Quality in Health Care (ISQua).
- NABH is a member of the Accreditation Council of International Society for Quality in Health Care (ISQua).
- NABH is on board of Asian Society for Quality in Healthcare (ASQua).

III. INDUSTRY ASSOCIATIONS

i. Indian Pharmaceutical Alliance (IPA)

Premier professional association of pharmacists in India, with a member base of more than 10,000. IPA operates in India through 17 state branches & more than 33 local branches the members represent various facets of pharmaceutical profession via Industry, regulatory, community pharmacy, hospital pharmacy & education. IPA is also actively associated in managing several academic programmes, as member of Drug Technical Advisory Board, India, IPA is actively involved in advising the government on matters of professional importance. IPA is affiliated with International Pharma Associations like WHO, for carrying out various collaborative professional activities which include organising training programmes for professionals from industry, academics, regulatory & practice, making representations to the authorities on matters of professional interest & working towards constantly upgrading the standards of professional services offered by the pharmacists [19][1].

ii. Bulk Drug Manufactures Association (BDMA) (1991)

The Bulk Drug Manufacturers Association (India) was formed in Hyderabad as its Head Quarters. It represents Bulk Drug Manufacturers of India, coordinates with Government and concerned departments on problems faced by Industry, updates its members on any changes in policy etc and builds capacities of its members on technical and commercials topics.

iii. Confederation of Indian Pharmaceutical Industry (CIPI) (2001)

Confederation of Indian Pharmaceutical Industry (CIPI) is the apex body of the manufacturers of drugs and pharmaceutics in the country representing small and medium scale units. All the major State level associations of the Pharmaceutical manufacturers in this segment are federating members of CIPI representing about 7000 pharmaceuticals units.[12][1]

iv. ABLE (Association of Biotechnology Led Enterprises) (2003)

It is not-for-profit pan-India forum that represents Indian Biotechnology Sector, it has over 580 members from all across India representing all verticals sector like agribiotech, bio- pharma, industrial biotech, bioinformatics, investment banks and Venture Capital firms, leading research and academic institutes and law firms and equipment suppliers. Primary focus of ABLE is to accelerate the pace of growth of the Biotechnology sector in India, through partnering with Government in their biotechnology initiatives to deliver optimal policies and create a positive regulatory environment, encouraging entrepreneurship and investment in sector, providing a platform for domestic and overseas companies to explore collaboration and partnerships, forging stronger links between academia and industry and showcasing the strengths of the indian biotech sector.[11] ABLE thus catalyses a symbiotic interface between the industry, the government, academic and research institutes and domestic and international investors.[12]

v. Association of Contract Research Organisations (ACRO) (2005)

It has been formed under aegis of Confederation of Indian Industry (CII) for bringing all CRO's operating in India on a common platform. It is used to promote quality research, uphold ethics, share best practices, promote synergies amongst members, to deliberate and act upon common concerns, specially with regards to Indian regulations and industry environment, it represents interests of Indian CROs to regional, national and international authorities and organisations.[19][1]

vi. Indian Drug Manufacturer's Association (1961)

Holding 700 Members. IDMA majorly aims to promote Drug research in all branches, including the manufacture of Drugs in India, to represent the common difficulties of the members before the various departments and local bodies (Municipality, Central & State Government, etc.) and to solve them in the best interests of the members.[1]

vii. AYUSH Medical Association

This is the association of professionals working in the space of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy.

IV. GOVERNMENT POLICIES AND SCHEMES RELATED TO PHARMACEUTICAL INDUSTRY

i. Free Drug Distribution Policy

Free Drug Distribution Policy by Government Health Ministry provides free essential medicines at all government clinics since October, 2012. Government promotes generic medicines and low-cost brands in its drive to make medicines more accessible to all those who seek treatment in public hospitals. It is being made mandatory for all doctors in the public sector to prescribe generic drugs and salt names and not brands. Affliction of domestic pharmaceutical industry is National Pricing Authority plan to roll out a text message service that will offer patients cheaper alternatives for prescribed drugs. These are big moves that could lead to a turbulent transition in the Indian pharmaceutical industry.[14][9]

India is facing growing epidemic in non-communicable diseases, like blood pressure, diabetes, obesity, stress, anxiety, depression etc., and is expected to place a significant burden on the Indian healthcare system. At present, public sector provides healthcare to 80% of the country's population. Also ministry is providing free medicines at various primary healthcare centers, community center and district hospitals. The ministry has sent the National List of Essential Medicines, 2011, (348 drugs which includes anti-AIDS, analgesics, anti-ulcers, anti-psychotic, sedatives, anesthetic agents, lipid lowering agents, steroids and anti platelet drugs) to all the states to use as reference.[18][2]

ii. The Drug (Prices Control) Order 2013

The Drug (Prices Control) Order (DPCO) 2013 was introduced in May 2013 which ensures availability of essential drugs at affordable prices for public. Act affects pricing of over 300 essential medicines based on their manufacturing cost. The Act was notified under the Essential Commodities Act, 1955, which gives power to National Pharmaceutical Pricing Authority (NPPA) to regulate prices of 348 essential drugs. Also NPPA fixes ceiling price of scheduled medicines and retail price of "new drugs" for existing manufacturers of scheduled formulations.

The Act also ensures availability of such medicines in bulk so that one may not have to switch to expensive drugs for emergency treatment.

On May 11, 2023, the Ministry of Chemicals and Fertilizers (MoCF) issued the Drugs (Prices Control) Amendment Order, 2023 to further amend the DPCO 2013 [26]

V. GOVERNMENT POLICIES AND SCHEMES RELATED TO PHARMACEUTICAL INDUSTRY:

i. Free Drug Distribution Policy:

Policy initiated and implemented by governmental health agencies and non-governmental organizations (NGOs) that involves healthcare or public health strategy that provides essential medications to public without direct cost to recipients. Policy mainly aims at government and non-profit organizations that improves access to essential drugs by lower middle class.

Merits of Free Drug Distribution Policy by government include affordability and accessibility of essential medications to broader population, that will ultimately enhance public health by ensuring timely and appropriate treatment, leading to better disease management and prevention and will finally control, eliminate, and eradicate certain harmful diseases that includes malaria, TB, and HIV/AIDS.

ii. The Drug (Prices Control) Order 2013:

This act ensure basic health care and availability of basic medicines at affordable price across India, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, notified the Drug (Prices Control) Order 2013 (DPCO 2013) in May 2013, which fluctuated the pricing of 348 essential medicines. Prior to the 2013 regime, the DPCO 1995 included 74 bulk medicines within its ambit and the pricing of the drugs were fixed on the basis of manufacturing costs declared by the drug manufacturers.[2]

As per DPCO 2013, all strengths and dosages specified in National List of Essential Medicines (NLEM) will be under price control. DPCO 2013 includes definition of various terms like -"Formulation" as 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:

- Any medicine included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines.
- Any medicine included in the Homeopathic system of medicine.
- Any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply.

As per the DPCO 2013, "Scheduled formulation" means any formulation, included in the First Schedule whether referred to by generic versions or brand name. "Nonscheduled formulation" has been defined as formulation, the dosage and strengths of which are not specified in the First Schedule.[2][1]

iii. 100% FDI Retained in Pharmaceutical Sector:

Indian government initiates policy to allow 100% foreign equity in Pharmaceutical sector. Notifying the decision, taken by the Cabinet Committee on Economic Affairs (CCEA), the department of industrial policy and promotion (DIPP) under the ministry of commerce and industry stated 100 per cent foreign direct investment (FDI) would be allowed in both Greenfield (new) and Brownfield (existing) segments. [17][12][1]

VI. GOVERNMENT ACTS:

i. Drug and Cosmetic Act:

The drug and cosmetic act drafted in 1940 and then its latest amendments on 2016. The act includes guidelines for various activities like clinical trials, sales, distribution, manufacturing, etc.[18][16][12]

Classes of drugs prohibited for sales under Drug and Cosmetic act:

1. Misbranded, spurious, adulterated and drugs not of standard quality.
2. Patent/Proprietary drugs with undisclosed formula.
3. Schedule J drugs.
4. Expired drugs.
5. Drugs used for consumption by government schemes for ex- Armed force.
6. Physician's samples.

For sale of biological (C/C1) under Drug and Cosmetic act:

1. Adequate premises, with greater than 10 m^2 area, with proper storage facility.
2. Drugs sold only to retailer having license.
3. Premises should be in charge of competent person who is Registered Pharmacist.
4. Records of purchase & sale.
5. Records preserved for 3 years from date of sale.
6. License should displayed on premises.

ii. The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954:

Acts defines guidelines for advertising drug for better clarity to customers. It deals with misleading advertisements like claim for magical remedy. The act defines magical remedies as "Anything that Includes a talisman, mantra, kavacha, and any other charm of any kind which is alleged to possess miraculous powers for or in the diagnosis, cure, mitigation, treatment or prevention of any disease in human beings or animals or for affecting or influencing in any way the structure or any organic function of the body of human beings or animals" [22][14][12].

Prohibition of Misleading Advertisements Relating to Drugs:

No person shall take any part in the publication of any advertisement relating to a drug if the advertisement contains any matter which:

- Directly or indirectly gives a false impression regarding the true character of the drug.
- Make a false claim for the drug.
- Is otherwise false or misleading in any material particular.

Prohibition of Advertisement of Magic Remedies for Treatment of Certain Diseases and Disorders:

- Publication of any advertisement referring to any magic remedy which directly or indirectly claims to be efficacious for any of the purposes.[4]

Prohibition of Import and Export from, India of Certain Advertisements:

Import or export from territories to which this act extends any document containing an advertisement of above nature.[10]

Offences and Penalties:

Whoever contravenes any of the provisions of this Act for the rules made there under) shall, on conviction, be punishable:

A) In the case of a first conviction, with imprisonment which may extend to six months, or with fine, or with both.

B) In the case of a subsequent conviction, with imprisonment which may extend to one year, or with fine, or with both.

iii. The Narcotic Drugs and Psychotropic Substances Act, 1985:
Act deals with possession, manufacturing, sales, distribution, import of narcotic drugs. This act includes following guidelines:

- The cultivation, or gathering of any portion (such cultivation or gathering being only on account of the Central Government) of coca plant, or the production, possession, sale, purchase, transport, import inter State, export inter-State, use or consumption of coca leaves.
- The cultivation (such cultivation being only on account of Central Government) of the opium poppy. The production and manufacture of opium and production of poppy straw.
- The sale of opium and opium derivatives from the Central Government factories for export from India or sale to State Government or to manufacturing chemists.
- The manufacture of manufactured drugs (other than prepared opium) but not including manufacture of medicinal opium or any preparation containing any manufactured drug from materials which the maker is lawfully entitled to possess.
- The manufacture, possession, transport, import inter-state, export inter-state, sale, purchase, consumption or use of psychotropic substances.
- The import into India and export from India and transhipment of narcotic drugs and psychotropic substances. [12][8][3]

VII. CONCLUSION:

Pharmaceutical regulatory authorities and government policies, particularly in the context of public health, underscores the critical role these entities play in ensuring the safety, efficacy, and accessibility of medicines. With objective of patient safety and efficacy it safeguards public health by ensuring that drugs are safe and effective for consumption. Quality Control, Quality Assurance and post-market surveillance are carried out by following standard regulatory bodies. Government bodies concerned with pharmaceuticals mainly aims at accessibility, pricing, generic drug availability, strategies to minimize barriers to access and affordability to general population. Pharmaceutical regulatory authorities are responsive to public health emergencies, such as pandemics. Governments has implemented policies that incentivize research and development in the area of pharmaceuticals, to encourage researchers for innovative research project . Regulatory authorities ensures strict QC and QA test and manufacturing standards to ensure required specifications. Indian government along with and Indian and International regulatory work together to share information, harmonize standards, and coordinate responses to health crises on a global scale. Also government policies initiatives to educate healthcare professionals and the public about the proper use of pharmaceuticals, potential risks, and the importance of adherence to prescribed medications that contributes to better health outcomes and reduces the risk of misuse. According to the guideline one should maintain transparency in clinical trials, disclosure of potential conflicts of interest, and fair marketing practices, integral to regulatory frameworks. Governments ensures robust system for post-market surveillance to identify and address any adverse effects promptly.

And hence pharmaceutical regulatory authority along with government policies, is quite important for public health, collaboration of both ensures innovation, accessibility, and maintains the highest standards of safety and efficacy in pharmaceutical products for population.

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