IJNRD.ORG ISSN : 2456-4184
INTERNATIONAL JOURNAL OF NOVEL RESEARCH AND DEVELOPMENT (IJNRD) | IJNRD.ORG
An International Open Access, Peer-reviewed, Refereed Journal

DESIGN AND DEVELOPMENT OF NATIONAL DRUG REGULATORY SYSTEM AND POLICIES – A Research MAHENDER

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ABSTRACT

National Drug strategy is an objective responsibilities and a direction of activity of medications. They have different need of medium objectives which is set by the states for drug areas, and recognizes them as various systems for achieving the objectives. This survey addresses and the sufficient protected and viable medications of good and better quality, so every nation ought to have a sound of National Drug Policy as an essential piece of its wellbeing strategy. In various nations there are sure standards and guideline for import and commodity of medication in different locale also it manages the law for various creating andcreated nations.This survey combines insight with drug guideline to make nonexclusive inferences from the qualities and shortcomings of various frameworks and recognize highlights influencing the presentation of medication guideline. In drug guideline, the public authority goes about as the watchman of general society by controlling confidential powers for public purposes. Guaranteeing the wellbeing, viability and nature of medications accessible to people in general is the fundamental point of medication guideline. On the off chance that administrative objectives are to be accomplished, fitting designs should be laid out and suitable exercises completed to accomplish the ideal objectives. A national drug policy involves a complex process of development, implementation and monitoring. First, the policy development process results in the formulation of the national drug policy. Second, strategies and activities aimed at achieving policy objectives are implemented by the various parties.

Keywords: Implementing anational drug policy,Formulating a national drug policy,CDSCO drug approval process,NIFP,DTAB.

I. INTRODUCTION

Introduction to drug development

Drug development is the process of bringing a new pharmaceutical drug to the market once a lead compound has been identified through the process of drug discovery.

It includes preclinical research on microorganisms and animals, filing for regulatory status, such as via the United States Food and Drug Administration for an investigational new drug to initiate clinical trials on humans, and may include the step of obtaining regulatory approval with a new drug application to market the drug.[1,2] The entire process – from concept through preclinical testing in the laboratory to clinical trial development, including Phase I–III trials – to approved vaccine or drug typically takes more than a decade.[3,1,2,4]

Clinical development, also known as clinical trials, involves testing the drug on human volunteers to provide more information about its safety and effectiveness. By the end of the clinical development phase, most of the investigational new drugs will have been eliminated on the grounds of safety and effectiveness.

The Drug Discovery Process involves many different stages and series of actions. Typically, it can be divided into five main stages:

- Step 1: Discovery and Development
- Step 2: Preclinical Research
- Step 3: Clinical Development
- Step 4: FDA Review
- Step 5: FDA Post-Market Safety monitoring

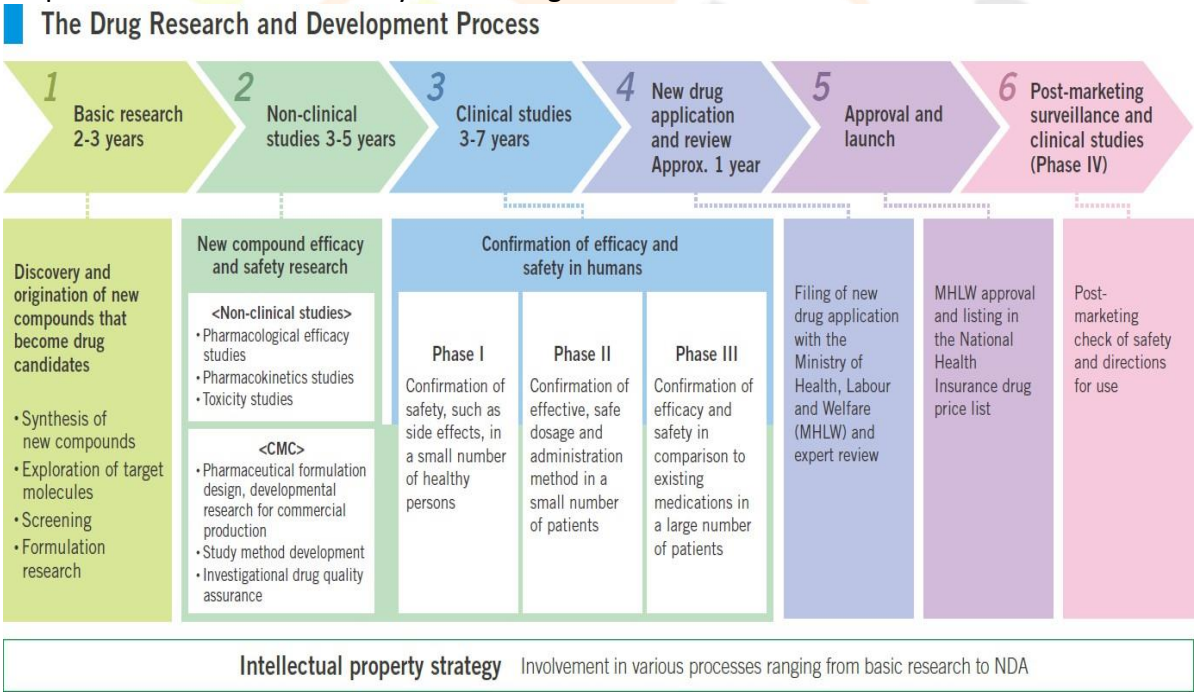


Fig 1 : Drug development process Discovery and Development

Typically, researchers discover new drugs through:

- New insights into a disease process that allow researchers to design a product to stop or reverse the effects of the disease.
- Many tests of molecular compounds to find possible beneficial effects against any of a large number of diseases.
- Existing treatments that have unanticipated effects.

New technologies, such as those that provide new ways to target medical products to specific sites within the body or to manipulate genetic material At this stage in the process, thousands of compounds may be potential candidates for development as a medical treatment. After early testing, however, only a small number of compounds look promising and call for further study.
Once researchers identify a promising compound for development, they conduct experiments to gather information on:

- How it is absorbed, distributed, metabolized, and excreted.
- Its potential benefits and mechanisms of action.
- The best dosage.
- The best way to give the drug (such as by mouth or injection).
- Side effects or adverse events that can often be referred to as toxicity.
- How it affects different groups of people (such as by gender, race, or ethnicity) differently.
- How it interacts with other drugs and treatments.

- Its effectiveness as compared with similar drugs.

Preclinical Research

Before testing a drug in people, researchers must find out whether it has the potential to cause serious harm, also called toxicity. The two types of preclinical research are:

- In Vitro
- In Vivo

FDA requires researchers to use good laboratory practices (GLP), defined in medical product development regulations, for preclinical laboratory studies.
These regulations set the minimum basic requirements for:

- study conduct
- personnel
- facilities
- equipment
- written protocols
- operating procedures
- study reports
- and a system of quality assurance oversight for each study to help assure the safety of FDA-regulated product

Usually, preclinical studies are not very large. However, these studies must provide detailed information on dosing and toxicity levels. After preclinical testing, researchers review their findings and decide whether the drug should be tested in people.

Clinical Development

Clinical research|| refers to studies, or trials, that are done in people. As the developers design the clinical study, they will consider what they want to accomplish for each of the different Clinical Research Phases and begin the Investigational New Drug Process (IND), a process they must go through before clinical research begins.

Designing Clinical Trials

Researchers design clinical trials to answer specific research questions related to a medical product. These trials follow a specific study plan, called a protocol, that is developed by the researcher or manufacturer. Before a clinical trial begins, researchers review prior information

about the drug to develop research questions and objectives. Then, they decide:

- Who qualifies to participate (selection criteria)
- How many people will be part of the study
- How long the study will last
- Whether there will be a control group and other ways to limit research bias
- How the drug will be given to patients and at what dosage
- What assessments will be conducted, when, and what data will be collected
- How the data will be reviewed and analyzed

FDA Review

If a drug developer has evidence from its early tests and preclinical and clinical research that a drug is safe and effective for its intended use, the company can file an application to market the drug. The FDA review team thoroughly examines all submitted data on the drug and makes a decision to approve or not to approve it.

New Drug Application

A New Drug Application (NDA) tells the full story of a drug. Its purpose is to demonstrate that a drug is safe and effective for its intended use in the population studied.

A drug developer must include everything about a drug—from preclinical data to Phase 3 trial data—in an NDA. Developers must include reports on all studies, data, and analyses. Along with clinical results, developers must include:

- Proposed labeling
- Safety updates
- Drug abuse information
- Patent information
- Any data from studies that may have been conducted outside the United States
- Institutional review board compliance information
- Directions for use
- FDA Review

Once FDA receives an NDA, the review team decides if it is complete. If it is not complete, the review team can refuse to file the NDA. If it is complete, the review team has 6 to 10 months to make a decision on whether to approve the drug. The process includes the following:

Each member of the review team conducts a full review of his or her section of the application. For example, the medical officer and the statistician review clinical data, while a pharmacologist reviews the data from animal studies. Within each technical discipline represented on the team, there is also a supervisory review.

FDA inspectors travel to clinical study sites to conduct a routine inspection. The Agency looks for evidence of fabrication, manipulation, or withholding of data.

The project manager assembles all individual reviews and other documents, such as the inspection report, into an ―action package.‖ This document becomes the record for FDA review. The review team issues a recommendation, and a senior FDA official makes a decision.

FDA Approval

In cases where FDA determines that a drug has been shown to be safe and effective for its intended use, it is then necessary to work with the applicant to develop and refine prescribing information. This is referred to as ―labeling.‖ Labeling accurately and objectively describes the basis for approval and how best to use the drug.

Often, though, remaining issues need to be resolved before the drug can be approved for marketing. Sometimes FDA requires the developer to address questions based on existing data. In other cases, FDA requires additional studies. At this point, the developer can decide whether or not to continue further development. If a developer disagrees with an FDA decision, there are mechanisms for formal appeal.

FDA Advisory Committees

Often, the NDA contains sufficient data for FDA to determine the safety and effectiveness of a drug. Sometimes, though, questions arise that require additional consideration. In these cases, FDA may organize a meeting of one of its Advisory Committees to get independent, expert advice and to permit the public to make comments. These Advisory Committees include a Patient Representative that provides input from the patient perspective. Learn more about FDA Advisory Committees.

FDA Post-Market Safety Monitoring

Even though clinical trials provide important information on a drug‘s efficacy and safety, it is impossible to have complete information about the safety of a drug at the time of approval. Despite the rigorous steps in the process of drug development, limitations exist. Therefore, the true picture of a product‘s safety actually evolves over the months and even years that make up a product‘s lifetime in the marketplace. FDA reviews reports of problems with prescription and over-the-counter drugs, and can decide to add cautions to the dosage or usage information, as well as other measures for more serious issues.[5]

Drug Regulation[6]

The drug regulatory authority is ―the agency that develops and implements most of the legislation and regulations on pharmaceuticals. Its main task is to ensure the quality, safety and efficacy of drugs, and the accuracy of product information.

The process of testing, developing and marketing of medicines has to regulated to protect the interests of the public. Major regulatory bodies include the Food & Drug Administration (FDA) in the US and the European Medicines Agency (EMA) in Europe. These bodies have various functions.

New drugs are given a ‗market authorisation‘ based on the evidence of quality, safety and efficacy presented by the manufacturer. The regulator will not only approve the drug but will also take great care to ensure that the accompanying information reflects the evidence that has been presented. This document is known as the Summary of Product Characteristics (SPC) or ‗label‘ provides detailed information about indications, dosage, adverse effects, warnings, monitoring etc.

Drug regulatory authorities often have other important functions including:

- Pharmacovigilance.
- Regulating clinical trials.
- Regulating herbal and homeopathic medicines.
- Inspecting and maintaining standards of drug development and manufacture.

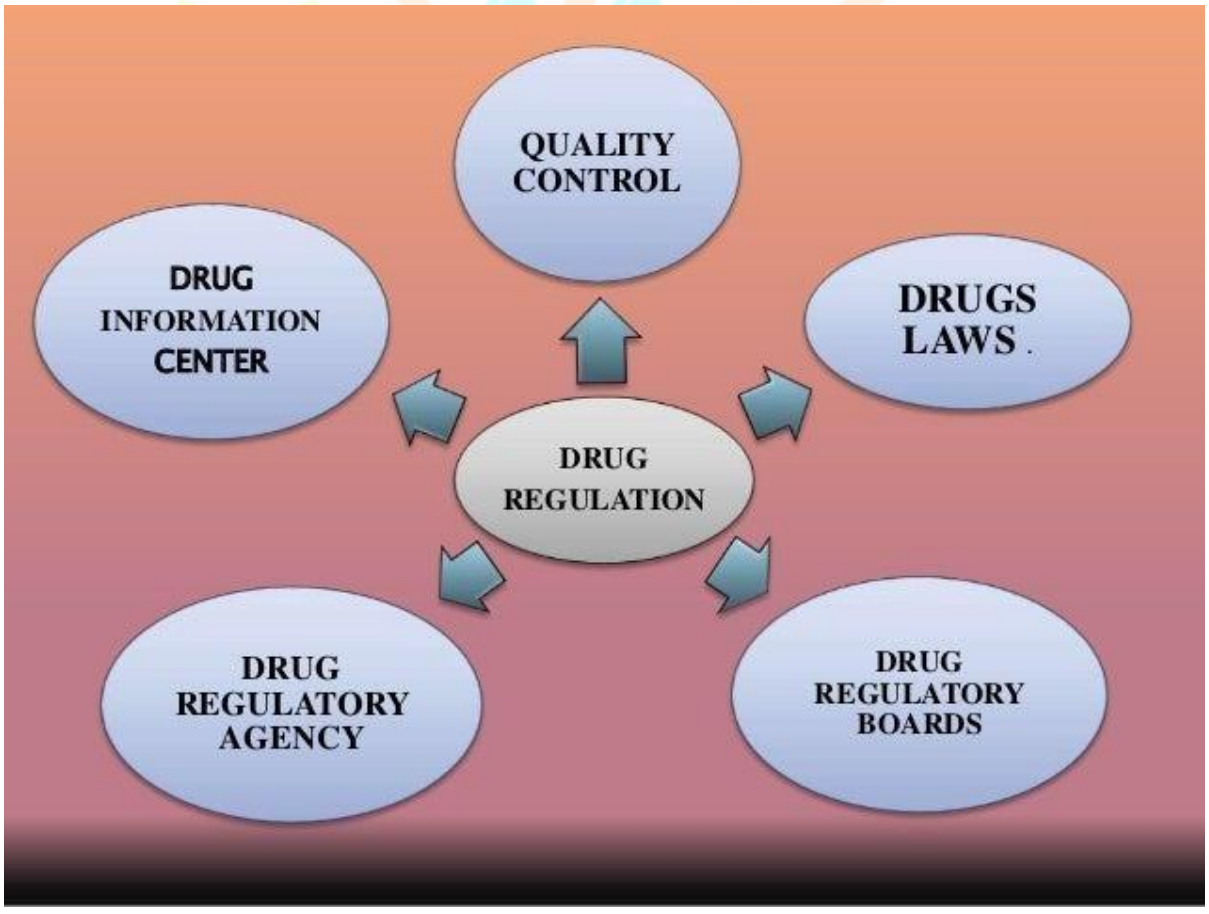
Pharmaceutical regulation is designed to ensure safety, efficacy, and quality of the drugs available to consumers. This is accomplished through a range of regulatory activities over the course of a drug's life cycle including premarket screening and evaluation of new pharmaceuticals, inspection of manufacturing facilities, regulation of drug labeling and improve drug access by lowering regulatory stringency and accelerating reviews could lead to the approval of some drugs that are either unsafe or ineffective. The trade-off between safety and access is a central one in the regulation of new pharmaceuticals. The challenge for pharmaceutical regulators is balancing an interest

for safety and efficacy with an interest for timely access. Finding the right balance, however, requires regulators to weigh the costs of unsafe or ineffective drugs against the costs of delay in the approval of beneficial drugs.

Fig 2 : Drug regulation process

Effective regulation of drug requires a variety of functions:

Guaranteeing the safety, efficacy and quality of drugs.



- Licensing of premises, persons and practices.

Inspection of manufacturing facilities and distribution channels.

- Product assessment and registration.

- Adverse drug reaction monitoring.

- Quality control.

- Control of drug promotion and advertising. Most importantly, the process of drug regulation. The drug regulation consists of:

1. Drug Laws
2. Drug Regulatory Agencies
3. Drug Regulatory Boards
4. Quality Control
5. Drug Information Centres.

Drug Regulatory Agencies In India:

India has emerged as one of the leading markets for pharmaceutical products. Increase in the private healthcare infrastructure, widening rural markets, and inclusion of newer technologies have placed healthcare as an independent sector in India. With privatization of healthcare, the medical devices sector is growing too. In order to regulate the import, manufacture, distribution and sale of drugs and cosmetics, the Drugs and Cosmetics Act, 1940 (—D&C, Act‖) was introduced in India in 1940. However, no separate regulation has been enacted for regulating the import, manufacture, distribution or sale of medical devices in India till date by the Government of India. Drugs and Health is in concurrent list of Indian Constitution. It is governed by both Centre and State Governments under the Drugs & Cosmetics Act, 1940.

Main Bodies:

- Central Drug Standard Control Organization (CDSCO)
- Ministry of Health & Family Welfare (MHFW)
- Indian Council of Medical Research (ICMR)
- Indian Pharmaceutical Association (IPA)
- Drug Technical Advisory Board (DTAB)
- Central Drug Testing Laboratory (CDTL)
- Indian Pharmacopoeia Commission (IPC)
- National Pharmaceutical Pricing Authority (NPPA)

Functions undertaken by Central Government Statutory function laying down standards of drugs, cosmetics, diagnostics and devices. Laying down regulatory measures, amendments to Acts and Rules. To regulate market authorization of new drugs. To regulate clinical research in India to approve licenses to manufacture certain categories of drugs as Central Licence Approving Authority i.e. for Blood Banks, Large Volume Parenteral and Vaccines & Sera. To regulate the standards of imported drugs. Work relating to the Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committee (DCC). Testing of drugs by Central Drugs Labs. Publication of Indian Pharmacopoeia.[7,8]

The Central Drugs Standard Control Organisation (CDSCO)[9]

CDSCO is India's national regulatory body for cosmetics , pharmaceuticals and medical devices. It serves a similar function to the European Medicines Agency of the European Union, the PMDA of Japan, the Food and Drug Administration (FDA) of the United States, and the Medicines and Healthcare products Regulatory Agency of the United Kingdom, and the National Medical Products Administration (NMPA) of China. The Indian government has announced its plan to bring all medical devices, including implants and contraceptives under a review of the Central Drugs and Standard Control Organisation (CDSCO).

Within the CDSCO, the Drug Controller General of India (DCGI) regulates pharmaceutical and medical devices and is positioning within the Ministry of Health and Family Welfare.

The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC). Divided into zonal offices, each one carries out pre-licensing and post-licensing inspections, post-market surveillance, and drug recalls (where necessary). Manufacturers who deal with the authority required to name an Authorized Indian Representative (AIR) to represent them in all dealings with the CDSCO in India.

Though the CDSCO has a good track record with the World Health Organization, it has also been accused of past collusion with independent medical experts and pharmaceutical companies. CDSCO plans to open an international office in Beijing, China. International Standard Serial Number (ISSN): 2249-6807 293. The CDSCO establishes safety, efficacy, and quality standards for pharmaceuticals and medical devices. It publishes and updates the Indian Pharmacopeia, a list of regulated pharmaceuticals and devices. For all drug and device applications, the CDSCO appoints notified bodies to perform conformity assessment procedures, including testing, in order to ensure compliance with their standards. The CDSCO is also divided into several zonal offices which do pre-licensing and post-licensing inspections, post-market surveillance, and recalls when necessary. In addition to its regulatory functions, the CDSCO offers technical guidance, trains regulatory officials and analysts, and monitors adverse events. The CDSCO works with the World Health Organization to promote Good Manufacturing Practice (GMP) and international regulatory harmony.

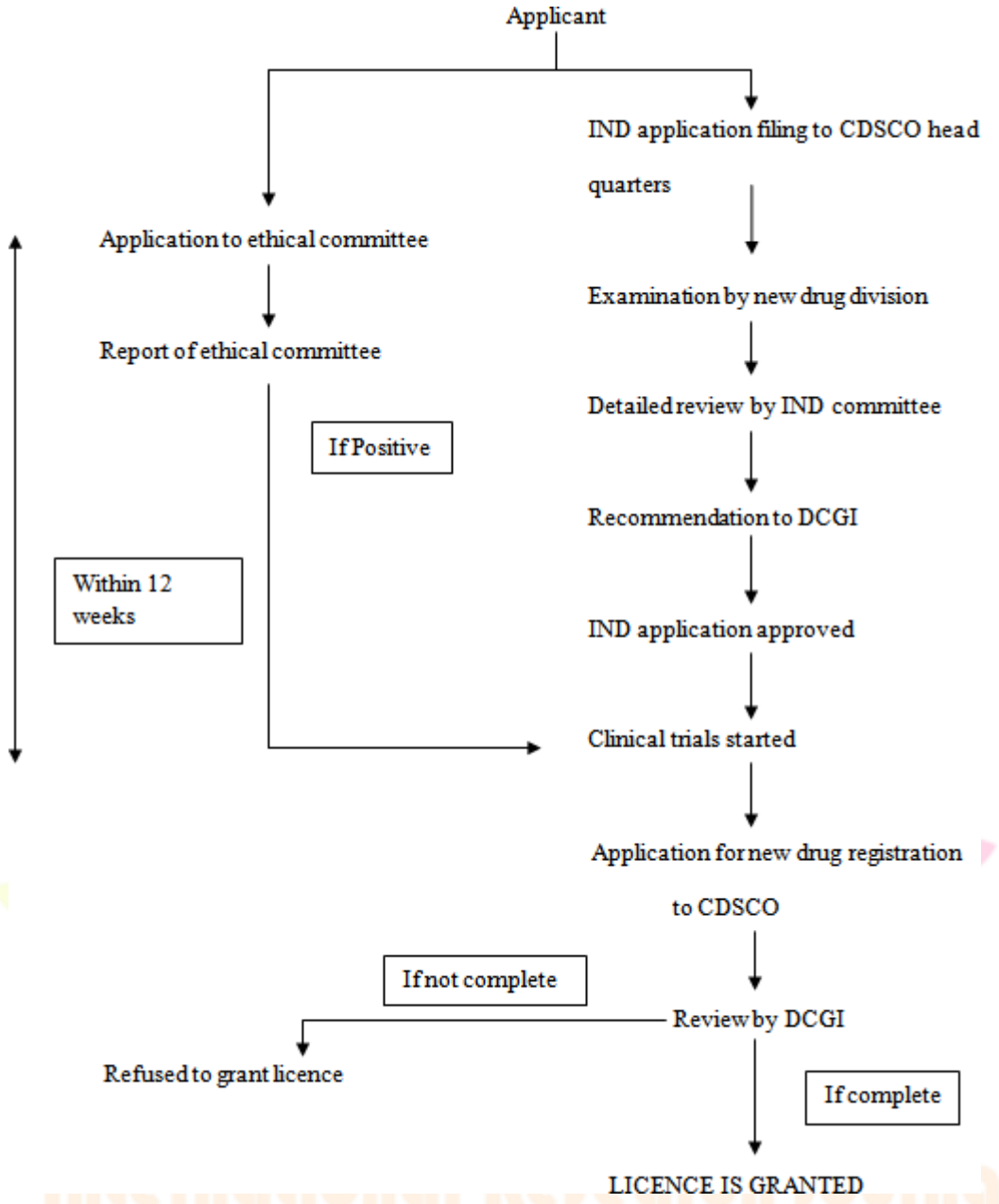


Fig 3: CDSCO drug approval process

National Institute of Health and Family Welfare (NIHFW)

NIHFW is an Apex Technical Institute, funded by Ministry of Health and Family Welfare, for promotion of health and family welfare programmers in the country through education, training, research, evaluation, consultancy and specialized services. The NIHFW was established on March 9, 1977 by a merger of the National Institute of Health Administration and Education (NIHAE) with the National Institute of Family Planning (NIFP).

List of Governing Body Members of NIHFW: 18 members 1 Chairman (ex-officio),1 Vice Chairman (ex-officio), 9 Member (ex-officio), 6 Member, 1 Member Secretary (ex-officio).

Activities And Responsibilities: Measuring weight of children to assess the nutritional status. Assessment of diseases like level of anaemia. Testing of food material like cooking salt for level iodine. To release fund on the advice of the Ministry. It is responsible for all governmental programs relating to family planning in India.

Drug Technical Advisory Board (DTAB):

The Central Government constitute a Board (to be called the Drugs Technical Advisory Board) to advise the Central Government and the State Governments on technical matters arising out of the administration of D&C, Act 1940.

List of Governing Body Members of NIHFW: 18 Members, 10 ex-officio Members, 5 Nominated Members, 5 Elected Members

Activities And Responsibilities:

It advices matter related to Drugs. The nominated and elected members of the Board shall hold office for three years, but shall be eligible for re-nomination and re-election. The Board may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure.

Central Drug Testing Laboratory (CDTL):

The central drug laboratory, Kolkata is national statutory laboratory of the government of India for quality control of drug and cosmetic and established under the D&C act, 1940.Oldest quality control laboratory of the drug control authorities in India. Function under the director general of Health Services in the Ministry of Health and Family Welfare. Composition: Indian Pharmacopoeia Commission (IPC) General Body 19 Members Governing Body 10 Members Scientific Body 23 Experts CIPL Lab IPC Secretariat Indian Pharmacopoeia was prepared by Indian Pharmacopoeia Commission (IPC)

Activities And Responsibilities: Development of comprehensive monographs. Accord priority to monographs of drugs included in the national Essential Drug List and their dosage forms. Preparation of monograph for products that have normally been in the market for not less than 2 years. Collaborate with pharmacopoeias like the BP, USP, JP and International Pharmacopoeia with a view to harmonizing with global standards.[8]

Temporal Progression of Drug Policies & Acts[10,11]

The Patents Act of 1970, Drug Price Control Order 1970 and Foreign Exchange Regulation Act 1973 assumed a critical part as far as the structure of native capacity concerning assembling of medications. The New Drug Policy of 1978 gave an additional push to native independence and accessibility of value drugs at low prices.DPCO 1987 proclaimed the expanding advancement in the business. One of the significant highlights of this demonstration was the decrease of the quantity of medications under value control to 143.

The significant goal of DPCO 1995 was to diminish imposing business model in some random market fragment, further decline the quantity of medications under value control to 74 and the incorporation of items made by limited scope makers under value control list.

In 1997, the National Pharmaceutical Pricing Authority was established to manage DPCO and manage issues identified with value update. The Pharmaceutical Policy 2002 conveyed forward before administrative drives as far as guaranteeing quality medications at sensible costs, fortifying of native ability for practical creation, decreasing exchange hindrances and giving dynamic support to in-house R&D endeavors of homegrown firms.

In 2003, the Mashelkar Committee attempted a complete assessment of the issue of fake and inadequate medications in the country and suggested a progression of rigid measures at Central and state levels. The administrative body came in for rebuff with the board of trustees taking note of that there were just 17 quality-testing research centers, of which just seven labs were completely useful.[12]

The National Pharmaceuticals Policy 2006, among different drives, has proposed a huge number of measures, for example, expanding the quantity of mass medications under guideline from 74 to 354, directing exchange edges and organizing another structure for drug value dealings in a transition to make sedates more reasonable for the Indian masses.

A medication strategy is the arrangement, generally of an administration, with respect to the control and guideline of medications considered hazardous, especially those which are addictive. Governments attempt to battle illicit drug use with approaches which address both the interest and supply of medications, too as arrangements which can moderate the damages of medication misuse, and for clinical treatment. Request decrease measures incorporate restriction, fines for drug offenses, imprisonment for people indicted for drug offenses, therapy (like willful recovery, coercive consideration, or supply on clinical solution for drug victimizers), mindfulness crusades, local area social administrations, and backing for families. Supply side decrease includes measures, for example, establishing international strategy pointed toward annihilating the worldwide development of plants used to make medications and capture attempt of medication dealing. Strategies which may help alleviate the impacts of medication misuse incorporate needle trade and medication replacement programs, just as free offices for testing a medication's immaculateness.

Medications subject to control differ from one purview to another. For instance, heroin is controlled all over; substances like qat, codeine and even Tamiflu are directed in certain spots, yet not others.

Most purviews additionally manage professionally prescribed medications, therapeutic medications not considered risky yet that must be provided to holders of a clinical remedy, and at times tranquilizes accessible without solution however just from an endorsed provider like a drug store, yet this isn't generally depicted as a "drug strategy".

Worldwide settlements

The International Opium Convention, endorsed in 1912 during the First International Opium Conference, was the primary global medication control deal. It went into power all around the world in 1919 when it was fused into the Treaty of Versailles in 1919. A modified Convention was enrolled in League of Nations Treaty Series in 1928. It likewise forced a few limitations—not all out denial—on the fare of Indian hemp (cannabis sativa forma indica). In 1961 it was supplanted by the worldwide Single Convention on Narcotic Drugs to control worldwide medication exchanging and use. The Convention prohibited nations from treating addicts by endorsing unlawful substances, permitting just logical and clinical employments of medications. It didn't detail exact medication laws and was not itself restricting on nations, which needed to pass their own enactment in conformance with the standards of the Convention.[13,14]

Drug Policy[15]

A drug policy is the policy regarding the control and regulation of psychoactive substances (commonly referred to as drugs), particularly those that are addictive or cause physical and mental dependence. While drug policies are generally implemented by governments, entities at all levels (from international organisations, national or local government, administrations, or private places) may have specific policies related to drugs.

Drug policies are usually aimed at combatting drug addiction or dependence addressing both the demand and supply of drugs, as well as mitigating the harms of drug use, and providing medical assistance and treatment. Demand reduction measures include voluntary treatment, rehabilitation, substitution therapy, overdose management, alternatives to incarceration for drug related minor offenses, medical prescription of drugs, awareness campaigns, community social services, and support for families. Supply side reduction involves measures such as enacting foreign policy aimed at eradicating the international cultivation of plants used to make drugs and interception of drug trafficking, fines for drug offenses, incarceration for persons convicted for drug offenses. Policies that help mitigate the dangers of drug use include needle syringe programs, drug substitution programs, and free facilities for testing a drug's purity.

The concept of "drugs" –a substance subject to control– varies from jurisdiction to jurisdiction. For example, heroin is regulated almost everywhere; substances such as khat, codeine, or alcohol are regulated in some places, but not others. Most jurisdictions also regulate prescription drugs, medicinal drugs not considered dangerous but that can only be supplied to holders of a medical prescription, and sometimes drugs available without prescription but only from an approved supplier such as a pharmacy, but this is not usually described as a "drug policy". There are however some international standards as to which substances are under certain controls, in particular via the three international drug control conventions.

Drug policy by country India

The major drug laws of India are the Narcotic Drugs and Psychotropic Substances Act (1985) and the Prevention of Illicit Trafficking in Narcotic Drugs and Psychotropic Substances Act (1988).

Narcotic Drugs And Psychotropic Substances Act

The Narcotic Drugs and Psychotropic Substances Bill, 1985 was introduced in the Lok Sabha on 23 August 1985. It was passed by both the Houses of Parliament and it was assented by the President on 16 September 1985. It came into force on 14 November 1985 as The Narcotic Drugs And Psychotropic Substances Act, 1985 (shortened to NDPS Act). Under the NDPS Act, it is illegal for a person to produce/manufacture/cultivate, possess, sell, purchase, transport, store, and/or consume any narcotic drug or psychotropic substance.

Under one of the provisions of the act, the Narcotics Control Bureau was set up with effect from March 1986. The Act is designed to fulfill India's treaty obligations under the Single Convention on Narcotic Drugs, Convention on Psychotropic Substances, and United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. The Act has been amended three times - in 1988, 2001, and most recently in 2014.

The 2014 Amendment recognizes the need for pain relief as an important obligation of the government. It creates a class of medicines called Essential Narcotic Drugs (ENDs). Power for legislation on ENDs has been shifted from the state governments to the central governments so that the whole country now can have a uniform law covering these medicines which are needed for pain relief.[17,18,19]

Subsequently, NDPS rules which would be applicable to all states and union territories has been announced by the government of India in May 2015.[20] It also has included 6 drugs namely Morphine, Fentanyl, Methadone, Oxycodone, Codeine and Hydrocodone.[21]According to these rules, there is a single agency - the state drug controller - who can approve recognised medical institutions (RMI) for stocking and dispensing ENDs, without the need for any other licences. The RMIs are obliged to ensure proper documentation and to submit annual consumption statistics to the drug controller of the state.

The Act extends to the whole of India and it applies also to all Indian citizens outside India and to all persons on ships and aircraft registered in India. A proposal to amend the NDPS Act via a Private Member's Bill was announced by Dr. Dharamvira Gandhi MP in November 2016. Dr. Gandhi's bill would legalise marijuana and opium.[22]

Prevention of Illicit Trafficking in Narcotic Drugs and Psychotropic Substances Act
The Prevention of Illicit Trafficking in Narcotic Drugs and Psychotropic Substances Act is a drug control law passed in 1988 by the Parliament of India. It was established to enable the full implementation and enforcement of the Narcotic Drugs and Psychotropic Substances Act of 1985.

Australia

Australian drug laws are criminal laws and mostly exist at the state and territory level, not the federal, and are therefore different, which means an analysis of trends and laws for Australia is

complicated. The federal jurisdiction has enforcement powers over national borders.In October 2016, Australia legislated for some medicinal use cannabis.[23]

Bolivia

Like Colombia, the Bolivian government signed onto the ATPA in 1991 and called for the forced eradication of the coca plant in the 1990s and early 2000s. Until 2004, the government allowed each residential family to grow 1600m2 of coca crop, enough to provide the family with a monthly minimum wage.[24] In 2005, Bolivia saw another reformist movement. The leader of a coca grower group, Evo Morales, was elected President in 2005. Morales ended any U.S. backed War on Drugs. President Morales opposed the decriminalization of drugs but saw the coca crop as an important piece of indigenous history and a pillar of the community because of the traditional use of chewing coca leaves.[24]In 2009, the Bolivian Constitution backed the legalization and industrialization of coca products.[24]

Canada

Canada's drug regulations are measures of the Food and Drug Act and the Controlled Drugs and Substances Act. In relation to controlled and restricted drug products, the Controlled Drugs and Substances Act establishes eight schedules of drugs and new penalties for the possession, trafficking, exportation and production of controlled substances as defined by the Governor-in-Council. Drug policy of Canada has traditionally favoured punishment of the smallest of offences, but this convention was partially broken in 1996 with the passing of the Controlled Drugs and Substances Act.[24]

Colombia

Under President Ronald Reagan, the United States declared War on Drugs in the late 1980s; the Colombian drug lords were widely viewed as the root of the cocaine issue in America. In the 1990s, Colombia was home to the world's two largest drug cartels: the Cali cartel and the Medellín cartel.[25] It became Colombia's priority, as well as the priority of the other countries in the Andean Region, to extinguish the cartels and drug trafficking from the region. In 1999, under President Andrés Pastrana, Colombia passed Plan Colombia. Plan Colombia funded the Andean Region's fight against the drug cartels and drug trafficking. With the implementation of Plan Colombia, the Colombian government aimed to destroy the coca crop. This prohibitionist regime has had controversial results, especially on human rights. Colombia has seen a significant decrease in coca cultivation. In 2001, there were 362,000 acres of coca crop in Colombia; by 2011, fewer than 130,000 acres remained.[25] However, farmers who cultivated the coca crop for uses other than for the creation of cocaine, such as the traditional use of chewing coca leaves, became impoverished.[25]

Since 1994, consumption of drugs has been decriminalized. However, possession and trafficking of drugs are still illegal. In 2014, Colombia further eased its prohibitionist stance on the coca crop by ceasing aerial fumigation of the coca crop and creating programs for addicts.[20] President Juan Manuel Santos (2010–present), has called for the revision of Latin American drug policy, and is open to talks about legalization.[25]

Ecuador

In the mid-1980s, under President León Febres-Cordero, Ecuador adopted the prohibitionist drug policy recommended by the United States. By cooperating with the United States, Ecuador received tariff exemptions from the United States. In February 1990, the United States held the Cartagena Drug Summit, in the hopes of continuing progress on the War on Drugs. Three of the four countries in the Andean Region were invited to the Summit: Peru, Colombia and Bolivia, with the notable absence of Ecuador. Two of those three countries— Colombia and Bolivia—joined the Andean Trade Preference Act, later called the Andean Trade Promotion and Drug Eradication Act, in 1992. Ecuador, along with Peru, would eventually join the ATPA in 1993. The Act united the region in the War on Drugs as well as stimulated their economies with tariff exemptions.

In 1991, President Rodrigo Borja Cevallos passed Law 108, a law that decriminalized drug use, while continuing to prosecute drug possession. In reality, Law 108 set a trap that snared many citizens. Citizens confused the legality of use with the illegality of carrying drugs on their person. This led to a large increase in prison populations, as 100% of drug crimes were processed.[26]In 2007, 18,000 prisoners were kept in a prison built to hold up to 7,000.[27] In urban regions of Ecuador as many as 45% of male inmates were serving time for drug charges; this prison demographic rises to 80% of female inmates.[27] In 2008, under Ecuador's new Constitution, current prisoners serving time were allowed the "smuggler pardon" if they were prosecuted for purchasing or carrying up to 2 kg of any drug, and they already served 10% of their sentence. Later, in 2009, Law 108 was replaced by the Organic Penal Code (COIP). The COIP contains many of the same rules and regulations as Law 108, but it established clear distinctions among large, medium and small drug traffickers, as well as between the mafia and rural growers, and prosecutes accordingly.[27] In 2013, the Ecuadorian government left the Andean Trade Promotion and Drug Eradication Act.

United Kingdom

Drugs considered addictive or dangerous in the United Kingdom (with the exception of tobacco and alcohol) are called "controlled substances" and regulated by law. Until 1964 the medical treatment of dependent drug users was separated from the punishment of unregulated use and supply. This arrangement was confirmed by the Rolleston Committee in 1926. This policy on drugs, known as the "British system", was maintained in Britain, and nowhere else, until the 1960s. Under this policy drug use remained low; there was relatively little recreational use and few dependent users, who were prescribed drugs by their doctors as part of their treatment. From 1964 drug use was increasingly criminalised, with the framework still in place as of 2014 largely determined by the 1971 Misuse of Drugs Act.[28]

United States

Modern US drug policy still has roots in the war on drugs started by president Richard Nixon in 1971. In the United States, illegal drugs fall into different categories and punishment for possession and dealing varies on amount and type. Punishment for marijuana possession is light in most states, but punishment for dealing and possession of hard drugs can be severe, and has contributed to the growth of the prison population.

US drug policy is also heavily invested in foreign policy, supporting military and paramilitary actions in South America, Central Asia, and other places to eradicate the growth of coca and opium. In Colombia, U.S. president Bill Clinton dispatched military and paramilitary personnel to interdict the planting of coca, as a part of the Plan Colombia. The project is often criticized for its ineffectiveness and its negative impact on local farmers, but it has been effective in destroying the once-powerful drug cartels and guerrilla groups of Colombia. President George W. Bush intensified anti-drug efforts in Mexico, initiating the Mérida Initiative, but has faced criticisms for similar reasons.

May 21, 2012 the U.S Government published an updated version of its Drug Policy[29] The director of ONDCP stated simultaneously that this policy is something different than "War on Drugs":

The U.S Government see the policy as a ―third way‖ approach to drug control one that is based on the results of a huge investment in research from some of the world‘s preeminent scholars on disease of substance abuse.

The policy does not see drug legalization as the ―silver bullet solution to drug control.It is not a policy where success is measured by the number of arrests made or prisons built.[30]

The U.S. government generates grants to develop and disseminate evidence based addiction treatments.[31] These grants have developed several practices that NIDA endorses, such as community reinforcement approach and community reinforcement and family training approach,[32] which are behavior therapy interventions.

2.LITERATURE REVIEW

Neeta Rai et al., (2022): National Drug policy is a goal commitments and a guidance of action of drugs. They have different priority of medium goals to long-term goals which is set by the governments for pharmaceutical sectors, and identifies them as different strategies for attaining the goals. This review represents and ensures the adequate supply of the safe and effective drugs of good and better quality, so that every country should have a sound of National Drug Policy as an integral part of its health policy. In different countries there are certain rules and regulation for import and export of drug in various region as well it regulates the law for different developing and developed countries.[33]

Margareth Ndomondo-Sigonda et al., (2020): An exploratory, mixed method design using both qualitative and quantitative data, was employed. Data from six NMRAs was collected through a combination of semi-structured interviews, questionnaires, and checklists for the period 2011/12-2014/15 while 2010/11 data served as baseline. Interviews were conducted with heads of NMRAs and monitoring and evaluation experts of the respective agencies. NMRA's financing was assessed using six indicators namely, funding policy, financial autonomy, the total annual budget, actual funding per annum, funds received from various sources, and the NMRA expenditure. The average total annual budget for all the EAC countries during the study period 2011–2015 ranged from USD 824,328.67 to USD 10,724,536.50. The low budget in Zanzibar may be attributed to population and pharmaceutical market size. Uganda's attainment of 98.75% (USD 10,656,704) revenue from industry fees is a result of deliberate government policy change from 100% reliance on donor funding over a period of 10 years (1995–2015). On average, the proportion of revenue against budget per annum is 54.8% (USD 458,970.11), 98.7% (USD 10,302,295.25) and 100% (USD7,375,802.08) for Zanzibar Food & Drugs Agency (ZFDA), Uganda National Drug Authority(NDA) and Tanzania Medicines and Medical Devices Authority (TMDA) respective .

Governments, industry fees and donors are the major sources of funding across all NMRAs in the EAC region, with TMDA and Uganda NDA relying more on industry fees by 73.20% (USD 4,664,777.59) and 98.25% (USD 8,077,238.20) respectively. While Burundi relies solely on government funding, ZFDA, on the other hand, received on average 50.40% (USD 252,557.22) from government and 40.60% (USD 165,303.34) from industry fees and the remaining 9% from donors and other sources. An overall contribution of funds received from donors by each NMRA was the least among other sources of financing. Observation of expenditure patterns indicated operational costs to be the major expense in the majority of the NMRAs, followed by salaries and infrastructure development. The Kenya NMRA has the highest degree of average expenditure across all three categories, with the least average expenditures being marked by Burundi NMRA. The operational costs on average increased considerably in all the NMRAs during the study period. Evidence from the EAC suggests that government and industry fees are the main sources of funding while donor contributions vary from country to country. Government policy, legal framework, and fees structure are the key enablers of NMRAs funding sustainability.[34]

Munzur E Murshid et al., (2019): Science is progressing a lot in recent years. Remarkable advances have been achieved in the field of health care technology. However, unfortunately, medicines are still the only hope for treating diseases for thousands of people in developing countries around the world. An effective National Drug Policy might be a lifesaving step for many people in these countries. Fortunately, that happened in Bangladesh after the 1982 Drug Policy. In the meantime, the country has further editions of that policy, which were National Drug Policy 2005 & 2016. In this article, this research will discuss the comparative impact scenario of these policies in Bangladesh. Readers will know the past and present of the National Drug Policy of Bangladesh and will be able to assume the future of this policy in Bangladesh.[35]

Ria Christine Siagian et al., (2019): A quantitative approach in the form of cross-sectional research using a structured survey was adopted and validated using a set of techniques involved in the calculation of a structural equation model. An independent samples t-test was used to test the significance of the differences between two views: pharmaceutical industries and the government of Indonesia. The study reveals that pharmaceutical industries and governments were highly consistent in their perceived challenges in facing the drug development. It also reveals drivers and weaknesses of drug development, including market opportunities, push-pull-regulatory pull factors and

regulation, as priorities for improvement. Gap analysis based on a structural model was borne out to address gap challenges between policy and its implementation, with the use of evidence-based policymaking.[36]

Joelle M Hebert et al., (2015): Continuous provision of appropriate medicines of assured quality, in adequate quantities, and at reasonable prices is a concern for all national governments. A national medicines policy (NMP) developed in a collaborative fashion identifies strategies needed to meet these objectives and provides a comprehensive framework to develop all components of a national pharmaceutical sector. To meet the health needs of the population, there is a general need for medicine policies based on universal principles, but nevertheless adapted to the national situation. This review aims to provide a quantitative and qualitative (describing the historical development) study of the development process and evolution of NMPs. The number of NMPs and their current status has been obtained from the results of the assessment of WHO Level I indicators. The policy formulation process is examined in more detail with case studies from four countries: Sri Lanka, Australia, former Yugoslav Republic of Macedonia and South Africa. The number of NMPs worldwide has increased in the last 25 years with the highest proportional increase in the last 5–10 years in high-income countries. Higher income countries seem to have more

NMP implementation plans available and have updated their NMP more recently. The four case studies show that the development of a NMP is a complex process that is country specific. In addition, it demonstrates that an appropriate political window is needed for the policy to be passed (for South Africa and the FYR Macedonia, a major political event acted as a trigger for initiating the policy development). Policy-making does not stop with the official adoption of a policy but should create mechanisms for implementation and monitoring. The NMPs of the FYR Macedonia and Australia provide indicators for monitoring. To date, not all countries have a NMP since political pressure by national experts or non-governmental organizations is generally needed to establish a NMP. Case studies in four countries showed that the policy process is just as important as the policy document since the process must create a mechanism by which all stakeholders are brought together and a sense of collective ownership of the final policy may be achieved.[37]

3.AIM AND OBJECTIVE

National Medicine Policy aims at promoting rational use of medicines in all aspects and areas of prescribing, dispensing, and also in private pharmacy.

- To provide an organized database of specialized information on medicines and therapeutics to meet the drug information needs of practitioners.
- To ensure the quality, safety and efficacy of drugs, and the accuracy of product information.
- To give uninterrupted supply of safe, effective and good quality Essential Medicines, and promoting the rational and safe use of medicines both in public and private sectors throughout the country.
- Encouraging R&D in the pharmaceutical sector in a manner compatible with the country's needs and with particular focus on diseases endemic or relevant to India by creating an environment conducive to channelising a higher level of investment into R&D in pharmaceuticals in India.
- Creating an incentive framework for the pharmaceutical industry which promotes new investment into pharmaceutical industry and encourages the introduction of new technologies and new drugs.

4.DISCUSSION

Overview of the national drug policy process

A national drug policy involves a complex process of development, implementation and monitoring. First, the policy development process results in the formulation of the national drug policy. Second, strategies and activities aimed at achieving policy objectives are implemented by the various parties. Finally, the effect of these activities is monitored and the programme adjusted if necessary. Throughout the process careful planning and the involvement of all parties are needed, and the political dynamics have to be considered at all times.

Planning

A drug policy without an implementation plan remains a dead document. Careful planning of the implementation steps and activities necessary to arrive at the expected outcome is important throughout the process. There are various types of plans. The first is probably the strategic plan to develop the policy itself, which should specify the various steps in the development process, and especially plan for the involvement of as many stakeholders as possible. After the policy has been adopted, an implementation plan, or master plan, is needed, which typically covers a 3–5-year period. This details the various activities for each component of the policy. The implementation plan spells out what needs to be done and who is responsible, estimates the budget and proposes a time frame. If resources are insufficient without external input, a set of priority activities should be identified that can be executed within the existing means. The master plan can be broken down into individual annual work plans for the various departments.

Involving all parties

Throughout the policy process (and not only in the development phase) there should be consultation, dialogue and negotiations with all interested groups and stakeholders. These include other ministries (higher education, trade, industry), doctors, pharmacists and nurses, local and international pharmaceutical industries, drug sellers, academia, nongovernmental organizations (NGOs), professional associations and consumer groups. It is also important to consult with provincial and district medical and administrative personnel, and to make an effort to include traditional and herbal medicine practitioners. Other government agencies (such as the drug regulatory agency), insurance companies and groups paying for health care must be involved. The media can be helpful, and support from international organizations is important. It is recommended that the national drug policy committee meets regularly to review the implementation of the policy with all interested parties in a national drug policy forum. There is likely to be some disagreement among the various stakeholders. For example, drug manufacturers may feel that their commercial interests are threatened, and doctors may fear the loss of clinical freedom. Any party that benefits from the existing situation will be worried about change. It is a real challenge to create and maintain a process that delivers the broad consensus essential to implementing the policy. In general it can be said that the more the existing pharmaceutical system needs to be improved, the more important it is to involve all interested parties in discussing the necessary reforms.

Formulating a national drug policy

By the end of 1999, 66 countries had formulated or updated their national drug policy within the previous 10 years. Very often an acute emergency or an important political change created a window of opportunity to start the policy formulation process. In some countries this was a change to a government committed to reform; in other countries it was an economic or political change, such as the sudden devaluation of the CFA (Communauté financière d'Afrique) franc, or the collapse of the Union of Soviet Socialist Republics, which created the need to harmonize and improve certain aspects of the pharmaceutical system. Other factors could be a political drive towards expansion of the local industry or the implementation of global trade agreements.

Step 1: Organize the policy process

The ministry of health is the most appropriate national authority to take the lead role in formulating a national drug policy. The first step is to decide how to organize the development process that will identify the structure of the policy, its major objectives and its priority components.

At this stage it is important to identify all the interested parties that need to be involved, the necessary resources, and how these can be obtained. The need for assistance from WHO, donors or countries with relevant experience should also be assessed. This stage can be carried out within the ministry of health with support from a small committee of selected experts.

Step 2: Identify the main problems

In order to set realistic objectives a thorough analysis and understanding of the main problems in the pharmaceutical sector are needed. There are various ways of carrying out an initial situation analysis.

One successful approach has been to bring together a small team of experts, some of whom should have performed similar analyses in other countries. These experts should come not only from the ministry of health but also from other disciplines and backgrounds. They should be asked to examine the situation systematically, to identify the main problems, to make recommendations about what needs to be done and what can be done, and to identify possible approaches. They should act as impartial advisers. Once they have formulated their recommendations, these can be discussed at one or more multidisciplinary workshops, in order to formulate consolidated advice to the government. Examples of such reports are available from the WHO Department of Essential Drugs and Medicines Policy.

Step 3: Make a detailed situation analysis

A more detailed situation analysis of the pharmaceutical sector and its components may be needed. This should further analyse the source of the problems, in order to identify potential solutions, choose the most appropriate strategies, set priorities, and serve as a baseline for future systems of monitoring and evaluation.

Step 4: Set goals and objectives for a national drug policy

Once the main problems have been defined, goals can be set and priority objectives identified. For instance, if one of the priority problems is lack of access to essential drugs, one of the priority objectives should be to improve the selection, affordability and distribution of essential drugs. The selection of appropriate strategies to achieve the objective is more complex, since it may involve choosing from among very different approaches. A workshop involving a small number of key policy-makers may be helpful. The situation analysis should justify the choices and serve as the basis for decisions. Once the main objectives and strategies have been outlined, they should be discussed with all interested parties. Broad consultation and careful consideration of conflicting interests and structural constraints are necessary to set achievable objectives and to formulate appropriate strategies to attain them.

Step 5: Draft the text of the policy

Once a thorough analysis of the situation and an outline of the main goals, objectives and approaches have been completed, a draft text of the national drug policy should be prepared. It should set out the general objectives of the policy. In most countries this will be to ensure that essential drugs are accessible to the entire population; that the drugs are safe, efficacious and of good quality; and that they are used rationally by health professionals and consumers. The specific objectives should also be described, followed in each case by the strategy to be adopted. Drafting of the policy can be done by a small group of experts who have been involved in the earlier stages of the process. Examples of national drug policy documents from other countries may be consulted.

Step 6: Circulate and revise the draft policy

The draft document should be widely circulated for comments, first within the ministry of health, then in other government ministries and departments, and finally to relevant institutions and organizations outside the government, including the private and academic sectors. Endorsement by government sectors responsible for planning, finance and education is important since the successful implementation of many elements of the policy will depend on their support as well. Once this wide consultation is complete, the draft document should be revised in the light of the comments received, and finalized.

Step 7: Secure formal endorsement of the policy

In some countries the document can then go to the cabinet or parliament for endorsement. In others it will remain an administrative document that serves as a basis for implementation plans and changes in the law and regulations. In some countries the entire national drug policy document has become law. This is a powerful demonstration of political commitment but it can also cause problems, as future adjustments to the policy may become difficult. It is therefore recommended that only certain enabling components of the policy are incorporated into law, without too many operational details.

Step 8: Launch the national drug policy

Introducing a national drug policy is much more than a technical task. To a large extent the policy's success will depend on the level of understanding of different sectors of society, and on their support for its objectives. The implications and benefits for all interested parties should therefore be stressed. The policy should be promoted through a clear and well- designed information campaign. Public endorsement by respected experts and opinion leaders can be very useful. Information should be disseminated through a variety of channels to reach different target groups. The media can play a major role in ensuring public understanding and support for the policy. Some countries have organized high profile launches.

Implementing a national drug policy

A policy, however carefully formulated, is worthless if it is not implemented. Every drug policy needs an overall implementation plan or "master plan"; each component of the policy needs a detailed strategy and specific action plans. In this section some general observations on implementation are made.

Priorities for implementation

For each country the priorities for implementation will be different. For example, when health care coverage is broad and access to drugs is not a problem, rational use and the cost of drugs are likely to be of concern. In such a situation, implementation of a drug policy will focus on regulating the market and on containing costs without decreasing sustainable access and equity. In least developed countries total spending on health and pharmaceuticals may be very low, and the private sector not geared to meeting the needs of the majority of the population. In this situation the focus of the policy will be more on increasing access to essential drugs. Priorities for implementation should be based on the severity of the problems, and on the potential for success in achieving the objective and making an impact with available resources.

Master plan and work plans

The national drug policy leads to an implementation plan or master plan, which may cover a 3–5-year period. This implementation plan spells out for each component of the policy what needs to be done and who is responsible, estimates the budget requirement and proposes a rough time frame. If resources are insufficient without external input, a set of priority activities should be identified that can be executed within existing means. Potential donor inputs should also be included, and gaps in funding can be identified as a guide for future donor support. The master plan facilitates monitoring and follow-up, and it is important that it is communicated to all parties involved.

The master plan should be broken down into annual action plans and work plans, which should be carefully developed with the various agencies involved in implementation. These plans should outline the approaches and activities for each component, specifying in detail who is responsible, listing the major tasks, and describing the target output, the detailed time frame and the exact budget.

Responsibilities in implementation

As lead agency, the ministry of health should oversee and coordinate all activities, and monitor the extent of implementation and the achievement of targets. In some countries a separate unit within the ministry, with its own budget and personnel, acts as the coordinating body. Apart from the coordinating body, it is recommended that a national consultative forum is created to oversee policy implementation. This is essential to create and maintain countrywide support for the policy, and to ensure that the major stakeholders remain informed and involved. The same could be done for some specific policy components, for example, all activities dealing with quality assurance or rational drug use. National institutions, such as the drug regulatory agency, the pharmacy department in the ministry of health, the central medical stores, and district or provincial health offices, are key players in drug policy implementation. So too are other agencies dealing with finance, trade, economic planning and education. Given the multispectral nature of pharmaceutical issues it is important not only to obtain but also to maintain consensus on the policy objectives. This can be achieved by agreement on implementation plans and through regular progress reports.

Financial resources

It is important to match the strategies and action plans with available financial resources. Allocations from government funds and revenue from drug registrations and fees are the usual funding sources. The responsible agencies should have a mechanism for actively seeking funds and be able to secure regular funding from the government. Contributions from international and local donors are also possible sources. However, there should be no conflict of interest in accepting donor contributions, for example, when donors are interested in funding activities that are of low priority in the national drug policy.

Practical aspects of policy implementation

A drug policy can be successfully implemented only if the government is committed and proactive.

Some successful strategies are:

• At an early stage, prepare the relevant legislative structure to enable the development and implementation of the national drug policy.

• Seize a window of political opportunity, such as a specific political change or developments in neighbouring countries, to advance policy development or implementation.

• Start implementing the policy in relatively easy subject areas, in order to ensure initial high visibility and success, and support for the policy at the critical early stage.

• Adopt a flexible approach; be prepared to postpone an activity if more time is needed to prepare for it, to explain it and to build consensus for it.

• Have national experts and respected political figures publicly express support for the policy and vouch for its technical soundness. It is important that the public feels confident about the policy.

• Mobilize key groups in society to support the policy. Consumer organizations, trade unions, religious organizations and the media, for example, can be important in building such support.

• Anticipate shifts in opponents' positions, and identify strategies to involve them and to win their support. For example, the pharmaceutical industry may oppose drug pricing policies and the introduction of an essential drugs list, but will usually support strategies to strengthen drug regulation and improve drug quality assurance.

• Create constituencies that support the policy both inside and outside the government. This is crucial to the policy's long-term success and sustainability.

Monitoring and evaluation

Monitoring and evaluating the impact of a national drug policy are challenging. Apart from a lack of time, human resources and budget, there is often a basic lack of understanding of the value of monitoring in the first place, and even a certain resistance to objectively or critically reviewing the effects of activities formulated in the master plan.

Monitoring is a form of continuous review which gives a picture of the implementation of planned activities and indicates whether targets are being met. It can be carried out using a combination of various methods, including supervisory visits and both routine and sentinel reporting.

Evaluation is a way of analysing progress towards meeting agreed objectives and goals. It should build on, and use, monitoring systems. At the start of a programme it is used to provide a clear needs assessment. A mid-term evaluation can provide valuable information about whether the programme is working, and if not, why not. Final evaluation allows a complete review of programme achievements from which lessons can be drawn for the future.

A system for monitoring and evaluation is a constructive management tool that enables a continuous assessment of progress, and helps to make the necessary management decisions. It also provides transparency and accountability, and creates a standard by which comparisons can be made between countries and areas and over time. All of this may produce the necessary evidence that progress is being made (or not), in order to support the policy in discussions with interested parties and policy-makers.

Indicators for monitoring national drug policies

To determine whether adequate progress is being achieved it is helpful to set realistic targets or performance standards. Indicators can be selected and used to measure changes, make comparisons and assess whether the targets are being met. If indicators are used they should be clear, useful, measurable, reliable and valid.

WHO and MSH have done a great deal of operational research to develop and refine indicators for monitoring drug policies.9,10 Currently there are four categories of drug policy indicators: background information, structural indicators, process indicators and outcome indicators. It is possible to use selected subsets of these indicators to meet the needs of countries.

WHO and MSH have also agreed on a subset of core indicators for routine use and sentinel reporting. These indicators are highly standardized so that trends can be identified. A detailed manual on their use is available.Data collection is relatively easy, so that monitoring can be done on a regular basis.

Core indicators cover the following aspects:

- access to essential drugs, and other indicators on drug financing schemes, and public supply management; these provide information on access to essential drugs;
- functions and efficiency of the drug regulatory authority, the quality control laboratory and how drugs are handled to maintain good quality; these provide information about drug quality;
- drug prescribing and dispensing, use of the list of essential drugs and clinical guidelines; these provide information about drug use patterns.

Legislation On Quality Control

Pharmaceutical legislation enforces the responsibility which is generally trusted by which is designated personals such as inspector, who inspects and authorize to inspects the manufacturing process, processing of drug as well as packaging establishments in both wholesaler and retailer. In inspection, they inspect the book and records and they take the samples which is the important function they performed. The facility for analyses the drug which ensuring the quality and safety of drug which is available in market. Some legal provision permitting their reports and certificates to be accepted as evidence and generally sufficient to dispense analysts from matters of routine. This methods followed for the analysis of drugs or the rationale underling their findings or conclusions.

Laboratories have different roles for establishing the standard .They established both by administrative and by legal measures. It is usual to assign specific statutory duties to perform them to specific duties which is performed by specific .The medication laboratory of Finland has legally empowered to obtain the samples, free of cost from manufacturer ,supplier, importers and persons which deals with drugs. To facilitate the monitoring of drug movement requires the different kinds of system is maintain and they permit its identification of any stage in its productions, storage, distribution and marketing. The Records must maintain for two-year periods. They contain the name and address of the consignee, date, sold quantity and the lot or control numbers which

identifying the batch which is sold must and be included in this records. Similar procedure is followed by India and records of batch number of their production which need to be maintained for a specified period of time.

Monitoring And Evaluation

The drug should be constantly monitored even after the drug entered in market has they gained the profit in more and more country and establishment for appropriate post market surveillance. Some national approaches towards to obtain the information related to defective

drug. The related information given by physician or drug saler and other information is obtained by voluntarily Different measures of drugs, when the defective drug has been identified in the market. Among them they are recall of the drug from the market and prohibition of further sales and suspension or cancellation of the registration and marketing license. The destruction of the defective stocks ,warnings to pharmacists, physicians and consumers for further investigation and legal actions against those responsible for contravening laws and regulations and inspections of production for quality control facilities.

5. CONCLUSION

This survey combines insight with drug guideline to make nonexclusive inferences from the qualities and shortcomings of various frameworks and recognize highlights influencing the presentation of medication guideline. In drug guideline, the public authority goes about as the watchman of general society by controlling confidential powers for public purposes. Guaranteeing the wellbeing, viability and nature of medications accessible to people in general is the fundamental point of medication guideline. On the off chance that administrative objectives are to be accomplished, fitting designs should be laid out and suitable exercises completed to accomplish the ideal objectives. Extensive and state-of-the-art regulations, bound together however autonomous association, equipped HR, independence from political and business impact, sufficient and reasonable monetary assets, clear and straightforward guidelines and strategies, result arranged execution and deliberate checking and assessment are basic parts adding to successful medication guideline.

ACKNOWLEDGEMENT

It affords us an immense Pleasure to acknowledge with gratitude the help and guidance rendered us by a host of people, to whom we owe a substantial measure for the successful completion of this project work.

We take pleasure to express our sincere thanks to our beloved **Dr. SUTHAKARAN.,Ph.D.** Principal, Vijaya College of Pharmacy for his undivided attention, Valuable and precious suggestions, and endeavor throughout the course of his investigation.

We are extremely Thankful to our Guide **Mr. BHUKYA NAGARAJU, Assistant Professor** for encouraging and galvanizing our spirit in accomplishing the project successfully with his valuable and precious suggestions and constant inspiration throughout the project work.

Special thanks to all faculty members of Vijaya college of pharmacy for their help, support and encouragement during the project work.

We are thankful to our parents and friends for their support in doing this dissertation work, which shall be remembered Forever.

Lastly, we express our sincere thanks to one and all those who have contributed directly and indirectly in bringing out this project successful.

ABBREVIATIONS

USFDA - United States Food and Drug Administration IND - Investigational New Drug Process

NDA - New Drug Application

EMA - European Medicines Agency

SPC - Summary of Product Characteristics CDSCO - Central Drug Standard Control Organization MHFW - Ministry of Health & Family Welfare

ICMR - Indian Council of Medical Research IPA
- Indian Pharmaceutical Association DTAB -
Drug Technical Advisory Board IPC - Indian
Pharmacopoeia Commission
NPPA - National Pharmaceutical Pricing Authority DCC
- Drugs Consultative Committee
AIR - Authorized Indian Representative ISSN
- International Standard Serial Number GMP
- Good Manufacturing Practice
NIHFW - National Institute of Health and Family Welfare NIFP
- National Institute of Family Planning
CDTL - Central Drug Testing Laboratory

NDPS - Narcotic Drugs And Psychotropic Substances END -
Essential Narcotic Drugs
RMI - Recognised Medical Institutions NGO -
Nongovernmental Organizations WHO - Whole
Health Organization

6.REFERENCES

1. Strovel J, Sittampalam S, Coussens NP, Hughes M, Inglese J, Kurtz A, et al. (July 1, 2016). "Early Drug Discovery and Development Guidelines: For Academic Researchers, Collaborators, and Start-up Companies". Assay Guidance Manual. Eli Lilly & Company and the National Center for Advancing Translational Sciences. PMID 22553881.
2. Taylor D (2015). "The Pharmaceutical Industry and the Future of Drug Development". Issues in Environmental Science and Technology. Royal Society of Chemistry: 1–33. doi:10.1039/9781782622345-00001. ISBN 978-1-78262-189-8.
3. Everts,Maaike;Cihlar,Tomas;Bostwick,J.Robert;Whitley,RichardJ.(6January2017)."Accelerating Drug Development: Antiviral Therapies for Emerging Viruses as a Model". Annual Review ofPharmacology andToxicology.**57**(1):155169.doi:10.1146/annurev-pharmtox-010716-104533. ISSN 0362-1642. PMID 27483339. Retrieved 2 November 2021.
4. "The Drug Development Process". U.S. Food and Drug Administration (FDA). 4 January 2018. Retrieved 21 March 2020.
5. https://www.fda.gov/patients/learn-about-drug-anddeviceapprovals/drug-development-process
6. International cooperation, convergence and Harmonization ofpharmaceutical regulations.
7. Theory and practice of industrial pharmacy by Leon Lachman Herbert A. Lieberman Joseph L. Kanig 3 RD edition.
8. An Overview on Drug Regulatory Agencies: Europe and India Patel Bhoomi B, Patel P M1, Patel N M. HOD of Quality Assurance, Shri B.M. Shah College of Pharmaceutical Education and Research, Modasa, Dist.: Sabarkantha, Gujarat, India.
9. https://en.wikipedia.org/wiki/Central_Drugs_Standard_Control_Organisation.
10. WHO. Guidelines for developing national drug policies. Geneva: World Health Organization; 1988.
11. WHO. WHO medicines strategy. Framework for action in essential drugs and medicines policy 2002–2003. Geneva: World Health Organization; 2000. WHO/EDM/2000.1.
12. WHO. Contribution to updating the WHO guidelines for developing national drug policies. Report of the WHO Expert Committee on National Drug Policies. Geneva: World Health Organization; 1995. WHO/DAP/95.9.

13. Reich M. Bangladesh pharmaceutical policy and politics. Health Policy and Planning 1994; 9(2): 130–143.
14. Lee MB. The politics of pharmaceutical reform: the case of the Philippine National Drug Policy. International Journal of Health Services 1994; 4: 477–494.
15. "Banned Drugs in Dubai and Abu Dhabi (codeine and Tamiflu are included)".

    Archived from the original on 2014-03-23. Retrieved 2014-06-25.

16. "Acts & Rules". Central Bureau of Narcotics. Retrieved 6 March 2017.

17. "NDPS Amendment Act 2014" (PDF). Central Bureau of Narcotics. Retrieved 6 March 2017.
18. "Department of Revenue Gazette Notification: NDPS Rules" (PDF). Central Bureau of Narcotics. Retrieved 6 March 2017.
19. "Department of Revenue Gazette Notification: NDPS Rules 2015" (PDF). Central Bureau of Narcotics. Retrieved 6 March 2017.

20. "Department of Revenue Gazette Notification: Essential Narcotic Drugs" (PDF).

    Central Bureau of Narcotics. Retrieved 6 March 2017.

21. "Bill for legalised supply of opium, marijuana cleared for parliament". The Hindustan Times. 2 November 2016. Retrieved 5 November 2016.
22. Timms, Penny (28 October 2016). "Medicinal marijuana to become legal to grow in Australia — but how will it work?". ABC News. Retrieved 6 January 2016.
23. Grisaffi, Thomas (2016). Drug Policies and the Politics of Drugs in the Americas.

    Springer International Publishing. pp. 149–166. ISBN 978-3-319-29080-5.

24. Timeline on Canadian Cannabis Laws Archived August 17, 2007, at the Wayback Machine. Ontario Cannabis Activist Network. Retrieved May 21, 2009.
25. Uprimny, Rodrigo; Esther Guzmán, Diana (2016). Drug Policies and the Politics of Drugs in the Americas. Springer International Publishing. pp. 87–103. ISBN 978-3- 319-29082-9.
26. Isabel Jácome, Ana; Alvarez Velasco, Carla (2016). Drug Policies and the Politics of Drugs in the Americas. Springer International Publishing. p. 79. ISBN 978-3-319- 29080-5.
27. Youngers, Coletta (June 17, 2014). "Ecuador's Pardon Laws". NACLA: North American Congress on Latin America. Retrieved 8 May 2021.
28. An Analysis of UK Drug Policy - A Monograph Prepared for the UK Drug Policy Commission, Peter Reuter, University of Maryland, Alex Stevens, University of Kent, April 2007.
29. Principles of Modern Drug Policy Archived 2017-01-23 at the Wayback Machine.

    Whitehouse.gov.

30. Statement of the Government of the United States of America World Federation Against Drugs 3rd World Forum, May 21, 2012, Stockholm, Sweden Archived January 23, 2017, at the Wayback Machine. Whitehouse.gov (September 21, 2012).
31. Milford, J.L. Austin, J.L. and Smith, J.E.(2007). Community Reinforcement and the Dissemination of Evidence-based Practice: Implications for Public Policy. International Journal of Behavioral Consultation and Therapy, 3(1), 77-87 BAO.
32. Meyers, R.J., Smith, J.E. & Lash, D.N. (2005): A Program for Engaging Treatment- Refusing Substance Abusers into Treatment: CRAFT. IJBCT, 1(2), Page 90 -100 BAO Archived 2019-05-24 at the Wayback Machine.
33. Neeta Rai, Neha Munot, Anjita Singh, Swati Mutha, Amrita Thakur, Pooonam P.Taru And Mrunalini H Kulkarni, National Drug Policies-A Systematic Review, Journal of Xi'an Shiyou University, Natural Sciences Edition, Vol: 65 Issue 04,2022.

34. Margareth Ndomondo-Sigonda ,Jacqueline Miot,Shan Naidoo,Brian Ng'andu,Nancy Ngum,Nelson E. Masota, Eliangiringa Kaale, National medicines regulatory authorities financial sustainability in the East African Community, journal.pone.0236332, 2020.
35. Munzur E Murshid, Mainul Haque, Bangladesh National Drug Policy 1982-2016 and Recommendations in Policy Aspects, Eurasian Journal Of Emergency Medicine, 2019.43765.
36. Ria Christine Siagian, Dumilah Ayuningtyas, Gap analysis for drug development policy-making: An attempt to close the gap between policy and its implementation, journal.pone.0220605,2019.

Joëlle M Hoebert, Liset van Dijk, Aukje K Mantel-Teeuwisse,corresponding author Hubert GM Leufkens, and Richard O Laing, National medicines policies – a review of the evolution and development processes, J Pharm Policy Practice,v.6; 2013.