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A Comparative Overview of Global Regulatory Authorities: Ensuring Quality, Safety, and Efficacy in Medicines

Mohammed Farhan Makrani, Dr. Anju Goyal, Shaziya Yasmeen Sayeed
Department of Pharmaceutical Quality Assurance
Bhupal Noble' College of Pharmacy, Udaipur 313001), Rajasthan, India
Email address: farhanmak556@gmail.com, Shaziya.sy@gmail.com

Abstract*—The regulation of pharmaceuticals is a critical aspect of global public health, ensuring that medicines meet stringent standards for quality, safety, and efficacy. Various regulatory authorities worldwide, such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), Japan's Pharmaceuticals and Medical Devices Agency (PMDA), and India's Central Drugs Standard Control Organization (CDSCO), oversee drug approval processes and post-market surveillance. Despite sharing a common goal, these agencies operate under distinct regulatory frameworks, leading to differences in drug approval timelines, clinical trial requirements, and post-marketing monitoring strategies. This comparative study examines the roles, processes, and regulatory pathways of major global agencies, highlighting their efforts in harmonization through organizations like the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the World Health Organization (WHO). Challenges such as regulatory divergence, delays in international drug approvals, and the need for greater transparency in decision-making are explored. By analysing regulatory similarities and differences, this paper underscores the importance of harmonization in facilitating faster access to innovative medicines while maintaining stringent safety and efficacy standards. Strengthening global regulatory alignment can enhance public health outcomes, reduce redundancies, and streamline drug development processes. The study advocates for continued cooperation between regulatory authorities to address the evolving challenges of the pharmaceutical industry, ultimately benefiting patients worldwide*.

***Keywords*—** *Regulatory Authorities, Harmonization of Drug Regulations, Post-Market Surveillance, New Drug Approval Process, FDA, EMA, WHO, CDSCO.*

I. INTRODUCTION

Regulation in medicine in modern time started in the 19th century when death of 100 people was reported with diethylene glycol poisoning following the use of a sulfanilamide elixir in the United States of America . Thalidomide disaster in the years 1958-1960 resulted in about 10,000 baby being born with phocomelia and other deformities. This made the governments think about implementing more strictly regulations for medicines. After these incidents, individual countries, especially the USA and certain European nations started work on outlining regulatory guidelines and restructuring their regulatory agencies.

Regulatory approvals were implemented for manufacturing, distribution and sales of drugs and drug products. This was done to ensure that high drugs with defined effectiveness and safety be provided to make sure patient safety. To get these approvals, pharmaceutical companies require to submit an application containing quality, efficacy, and safety data along with other data with respect to their drug product. These are presented to the regulatory authority of the area where the production and distribution of the medication will take place. Every nation has its own regulatory agency, for example, Food and Drug Administration (FDA) in the US, European Medicine Agency (EMA) in Europe, Central Drug Standard Control Organization in India, and Ministry of Health, Labour, and Welfare (MHLW) in Japan. Most of the regulatory authorities have their unique format for submitting an application requesting approval for the marketing of a drug. This approval can be for new drug application (NDA) or abbreviated NDA (ANDA). [(1)]

II. KEY REGULATORY AUTHORITIES AROUND THE WORLD

2.1 USFDA Food and Drug Administration

The Food and Drug Administration (FDA or Agency) is the administrative, scientific, public health and consumer protection agency responsible for guaranteeing all human and animal drugs, medical devices, cosmetics, foods, food additives, drugs and medicated feeds for food producing animal, tobacco, and radiation emitting devices are safe, and that all such products marketed in the United States are satisfactorily, truthfully, and informatively labelled and safely and appropriately stored, transported, manufactured, packaged, and controlled. FDA's programs are national in scope and impact, and the agency's exercises have a direct and significant affect on multibillion dollar business, in expansion to securing the wellbeing and safety of American Consumers. The work of the Agency is carried out by a staff of more than 18,000 researcher, physicians, 2 regulatory and other personnel stationed throughout the United States. [(2)]

FDA's Office of Regulatory Affairs (ORA) is the lead office for all organisation regulatory exercises. Over 5,000 ORA representative strategically located in district offices, resident posts, and research facilities throughout the United States perform assessment and examination (including criminal investigations), wharf exams, sample collections and

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analyses, and carry out enforcement exercises, education, and outreach directly to consumers, industry agents, importers, and shippers, as well as other partners across the country. ORA also works with its government, state, local, tribal, territorial, and foreign counterparts to further the agency's mission. ORA is driven by the Associate Commissioner for Regulatory Affairs (ACRA). [3]

Key Functions of the FDA:

1. Regulation of Food Products:
   - Oversees most food products, including dietary supplements, bottled water, food additives, and infant formulas.
   - Note: The U.S. Department of Agriculture regulates certain aspects of meat, poultry, and egg products.
2. Regulation of Drugs:
   - Evaluates and approves both prescription and over-the-counter drugs for human and veterinary use.
   - Ensures that drugs are safe and effective before they reach the market.
3. Regulation of Medical Devices:
   - Assesses and monitors medical devices ranging from simple items like tongue depressors to complex technologies such as pacemakers.
   - Oversees the safety and effectiveness of devices that emit radiation, including X-ray machines and microwave ovens.
4. Regulation of Biological Products:
   - Ensures the safety and efficacy of biological products, including vaccines, blood and blood products, and gene therapies.
   - Monitors the production and distribution of these products to protect public health.
5. Regulation of Cosmetics:
   - Oversees the safety of cosmetics, ensuring they do not contain harmful ingredients and are properly labelled.
   - Takes action against products that are adulterated or misbranded.
6. Regulation of Tobacco Products:
   - Regulates the manufacturing, distribution, and marketing of tobacco products to protect public health.
   - Implements measures to reduce tobacco use, especially among minors. [4]
7. Advancement of Public Health:
   - Facilitates innovations that make medical products safer and more effective.
   - Provides the public with accurate, science-based information to improve health. [5]
8. Ensuring Security of Products:
   - Protects the nation's food supply and medical products from intentional and unintentional contamination.
   - Collaborates with other agencies to safeguard against bioterrorism and other public health threats.[6]

FDA Approval: What it means

FDA approval of a drug means that data on the drug's impact have been reviewed by CDER, and the drug is determined to give benefits that exceed its known and potential dangers for the intended population. The drug approval process takes place within a organized framework that includes:

- Analysis of the target condition and available treatments—FDA reviewers analyse the condition or sickness for which the drug is aiming and evaluate the current treatment landscape, which give the context for weighing the drug's risks and benefits. For example, a drug intended to treat patients with a life-threatening disease for which no other treatment exists may be considered to have benefits that outweigh the risks even if those risks would be considered unsatisfactory for a condition that is not life threatening.

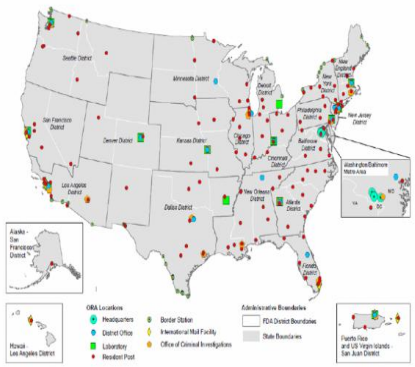

Figure 1: Map showing FDA offices across the country [21]

- Evaluation of benefits and risks from clinical data—FDA reviewers evaluate clinical advantages and risk data submitted by the drug producer, taking into account any uncertainties that may result from imperfect or incomplete data. Generally, the agency expects that the drug maker will submit results from two well-designed clinical trials, to be sure that the results from the first trial are not the result of chance or bias. In certain cases, particularly if the disease is uncommon and multiple trials may not be feasible, convincing evidence from one clinical trial may be sufficient. Evidence that the drug will advantage the target population should outweigh any risks and uncertainties.
- Strategies for managing risks—All drugs have risks. Risk management methodologies incorporate an FDA-approved drug label, which clearly describes the drug's benefits and risks, and how the risks can be detected and managed. Some of the times, more effort is required to manage risks. In these cases, a drug maker may require to implement a Risk Management and Mitigation Strategy (REMS). [7]

2.2 Australian Medicines Regulatory Agency: TGA

The Therapeutic Goods Administration (TGA) is a division of the Australian Government Department of Health and Ageing, and is responsible for directing therapeutic products including medicines, medical devices, blood and blood products. Therapeutic goods are evaluated before they are marketed by TGA. Therapeutic goods manufacturing unit is also regulated by TGA to ensure they meet acceptable standards of manufacturing quality. A group of manufacturing inspectors that audit manufacturing facilities around the world to ensure that products provided in Australia are of high

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quality. TGA administers the Therapeutic Goods Act 1989. This legislation gives a framework for a risk management approach that permits the Australian community to have timely access to therapeutic goods which are consistently safe, effective and of high quality. [8]

Role of TGA

The TGA is responsible for ensuring that therapeutic goods accessible for supply in Australia are safe and fit for their intended purpose. These include goods Australians depends on every day, such as vitamin tablets and sunscreens, through to goods used to treat serious conditions, such as prescription medicines, vaccines, blood products and surgical implants.

The TGA regulates the supply of:

- medicines prescribed by a physician or dentist
- medicine available from behind the pharmacy counter
- medicine available in the general pharmacy
- medicine available from supermarkets
- complementary medicine, these include vitamins, herbal and conventional medicines
- medical devices, from basic devices like bandages to complex technologies like heart pacemakers
- products utilized to test for different diseases or conditions (in vitro diagnostic devices), such as blood tests; and
- vaccines, blood products, and other biologics. and the manufacturing and advertising of these products. [9]

TGA Organisational Structure

The TGA regulatory offices consisting of three core groups:

1. The Market Authorisation Group is accountable for the assessment and authorisation of therapeutic goods to ensure they meet appropriate standards of quality, safety and efficacy or performance, consistent with their risk.
2. The Monitoring and Compliance Group is accountable for monitoring of therapeutic goods on the Australian market to ensure that they comply with required standards of quality, safety, efficacy and performance.
3. The Regulatory Support Group provides the business framework and support services that enable the TGA to undertake its regulatory responsibilities.

An organisation chart that details the offices within these groups follows. [10]

Drug Approval Process in Australia - Overview

The drug approval process in Australia rely upon the classification of medicinal goods by the TGA. Manufacturers must consider the TGA's categorization of medicines during TGA's new product registration. The TGA has a two-tier framework for regulating medicines, including complementary medicines:

Tier 1: Categorization Based on the Risk Level of the Medicine

- High-risk Medicines: These must be enlisted on the Australian Register of Therapeutic Goods (ARTG), requiring particular evaluation of the product's quality, safety, and effectiveness.
- Lower-risk Medicines: Medication with pre-approved, low-risk ingredients and limited claims can be recorded on the ARTG.

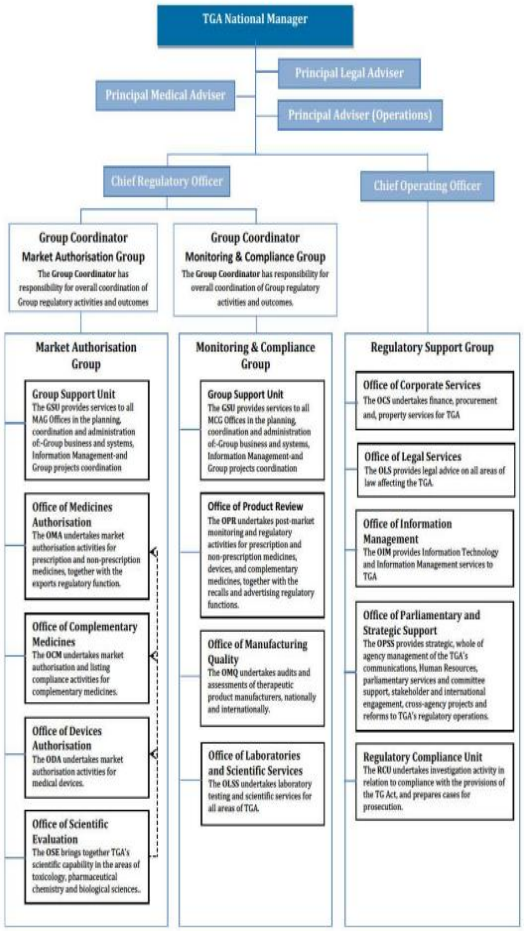

Figure 2: Organisational Structure of TGA [22]

Tier 2: Categorization Based on the Regulatory Framework

- Registered medicines: All prescription medicines, most over-the-counter (OTC) medications, and a few complementary medicines.
- Listed medicines: A few over-the-counter (OTC) medications and most complementary medicines.

The TGA enlistment process includes an 8-step market authorization procedure:

- Pre-submission: Starts with filing the Pre-submission Planning Form (PPF), which recognizes the proposed application type and incorporates general information about quality and nonclinical & clinical evidence.
- Submission of Pharma Product Registration: Processing exercises are completed in preparation for application assessment, including dossier delivery confirmation, payment verification, workflow planning, and issuing a notification letter, detailing the TGA registration requirements and any fees.
- First Round Assessment:
  Amid this stage, data in the dossier is evaluated. If issues emerge, a "Consolidated Section 31 request for information" is sent to the applicant.
- Consolidated Section 31 Request – Response:

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Candidates react to the TGA's consolidated request for data or documents.

- Second Round Assessment:
  The TGA assess the applicant's response information during the second-round assessment.
- Expert Advisory Review:
  The expert delegates consider the evaluation reports, potentially looking for independent guidance on application issues.
- Decision:
  TGA delegates conclude whether the application must be approved, adjusted, or rejected. The delegate may liaise directly with the applicant to resolve outstanding issues.
- Post-Decision:
  Regulatory and Administrative exercises are completed amid this phase.

Important Validities:

- Validity of Registration Certificate: The certificate's legitimacy is for 5 years.
- Post-approval Changes (Variations): Any registered medication changes must be recorded with the TGA and assisted with relevant documentation. [11]

2.3 Medicines Regulatory Agency in the UK: MHRA

The Medicines and Healthcare products Regulatory Agency (MHRA) is the United Kingdom's regulatory authority responsible for ensuring that medications, medicinal devices, and blood components for transfusion meet applicable guidelines of safety, quality, and efficacy. Operating as an executive agency under the Department of Health and Social Care, the MHRA plays a crucial role in safeguarding public health.

Headquarters: London

The Agency is made up of three centres [12]

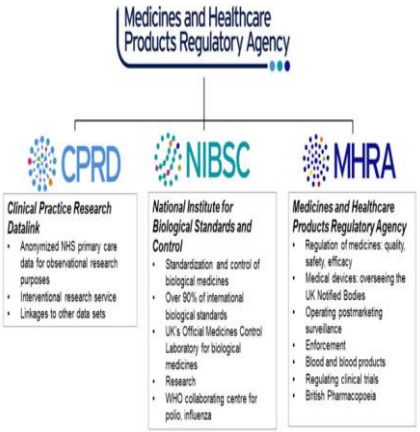

Figure 3: MHRA's Centre [23]

Role of the MHRA

- Ensure medicines, medicinal devices and blood components for transfusion meet appropriate benchmark of safety, quality and efficacy (effectiveness)
- Safe and secure supply chain for medicines, medicinal devices and blood components
- Promote international standardisation and harmonisation to ensure the effectiveness and safety of biological medications
- Educate the public and healthcare experts about the risks and benefits of medicines, medicinal devices and blood components, driving to safer and more effective use
- Empower development and research and development that is beneficial to public health
- Collaborate with partners in the UK and globally to support our mission to empower the earliest access to safe medications and medical devices and to protect public health

2.4 Japanese Medicines Regulatory Agency

PMDA (Pharmaceuticals and Medical Devices Agency) is Japanese administrative agency, working together with Ministry of Health, Labour and Welfare.

PMDA is responsible to protect the public wellbeing by assuring safety, efficacy and quality of pharmaceuticals and medicinal devices and also conduct scientific reviews of marketing authorization application of pharmaceuticals and medicinal devices, monitoring of their post-marketing safety. PMDA is also responsible for providing relief compensation for sufferers from adverse drug reaction and infections by pharmaceuticals or biological products. [13]

Services of PMDA

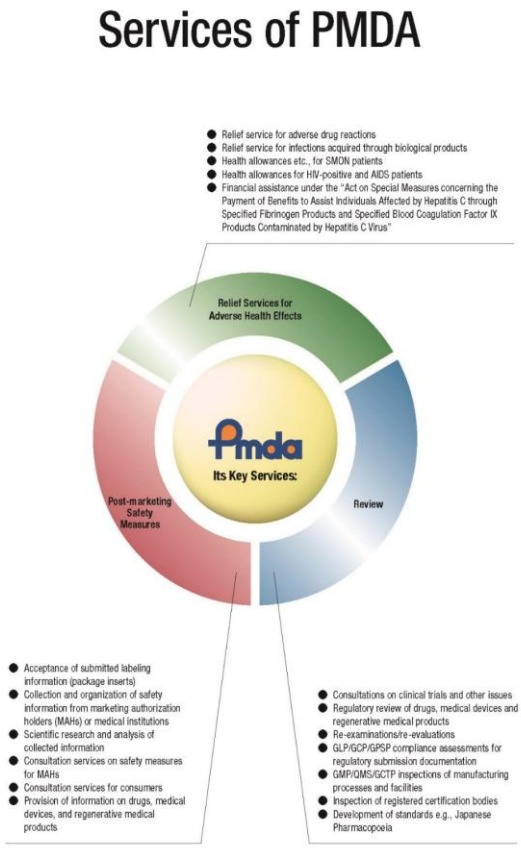

Figure 4: Services of PMDA [24]

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Organisational structure of PMDA

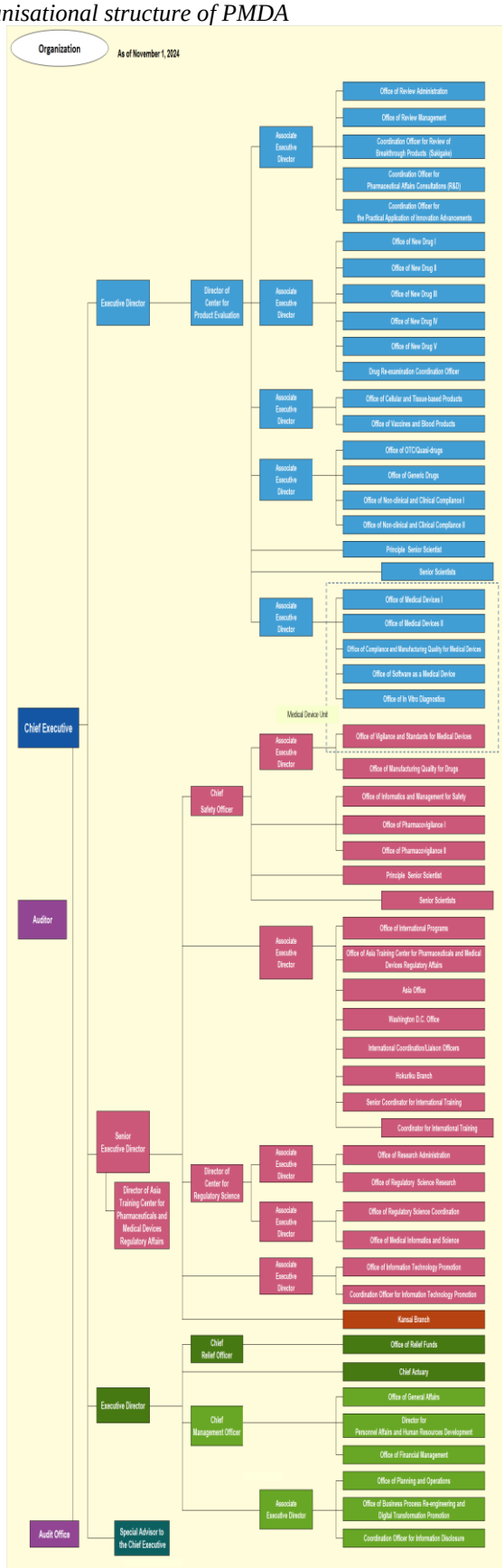

Figure 5: Organisational structure of PMDA [25]

2.5 Indian Pharmaceutical Regulatory Authority

The Central Drugs Standard Control Organisation (CDSCO) beneath Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is the National Regulatory Authority (NRA) of India. Its common headquarters is situated at FDA Bhawan, Kotla Road, New Delhi 110002 and also has six zonal offices, four sub zonal offices, thirteen harbour offices and seven laboratories spread all over the country. The Drugs & Cosmetics Act,1940 and rules 1945 have provide different responsibilities to central & state regulators for regulation of drugs & cosmetics.

Major functions of CDSCO:

1. Control of imported drugs, new drug approvals and clinical trials.
2. Drug Control Committee (DCC) and Drug Treatment Advi sory Board (DTAB) meetings
3. Central License Approving Authority. [14]

Under the Drugs and Cosmetics Act, CDSCO is accountable for approval of New Drugs, Conduct of Clinical Trials, laying down the guidelines for Drugs, control over the quality of imported drugs in the nation and coordination of the activities of State Drug Control Organizations by giving expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.

Functions of CDSCO

- Central licensing authorities are responsible for
  - New drugs approval
  - Performing clinical trials
  - Building up for drugs
  - Quality Control of imported drugs, import registration and licensing
  - Coordination of the activities of state drug control authorities by giving expert opinion to consistently enforce the D&C Act.
- State licensing authorities are responsible for
  - Regulation of production, sale and marketing of drugs.
- Other Functions
  - Legalization of the Commercialization of Blood, Vaccines, Recombinant DNA Products, and Selected Medicinal Devices.
  - Adjustments to the Rules Implementing the D&C Act
  - Issuing Export Test License, Personal License, and No Objection Certificate are.
  - Older pharmaceuticals and cosmetics should be outlawed.
  - Preclinical testing and assessment of cosmetics and medicines Functions of Drug Testing Canters Centrally. [15]

Organisational structure [16]

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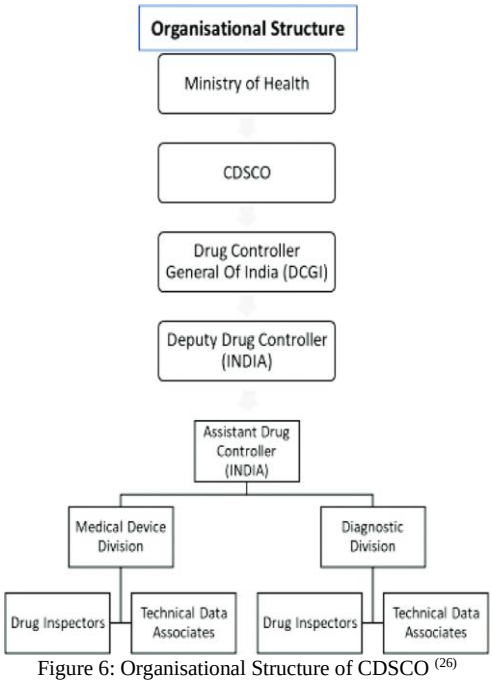

Figure 6: Organisational Structure of CDSCO [26]

2.6 European Medicines Agency (EMA)

The European Medicines Agency (EMA) is a decentralized agency of the European Union (EU) responsible for the scientific evaluation, supervision, and safety monitoring of medicines within the EU. Established in 1995 and headquartered in Amsterdam, Netherlands, the EMA plays a critical role in ensuring that medicines available in the EU market are safe, effective, and of high quality. [17]

Functions of EMA

Collaborate with the member states and the European Commission as associates in a European medicines network, the EMA

- Gives independent, science-based suggestion on the quality, safety, and efficacy of medicines, and on more common issues relevant to public and animal health that involve medicines;
- Applies effective and straightforward evaluation procedures to help bring new medicines to the market by means of a single, EU-wide marketing authorization granted by the European commission;
- Implements measures for continuously administering the quality, safety, and efficacy of authorized medicines to ensure that their benefits outweigh their risks;
- Gives scientific advice and incentives to fortify the advancement and improve the availability of innovative new medicines; [18]
- Suggest safe limits for residues of veterinary medicines used in food-producing animals for the establishment of maximum residue limits by the European commission;
- Include representatives of patients, health care experts, and other partners in its work to facilitate dialogue on issues of common interest
- Publishes data about medicines and their use and
- Develops best practices for the evaluation and supervision of medication in the EU and contributes, nearby the member states and the European Commission, to the harmonization of regulatory standards at the international level.

Organisational chart [19]

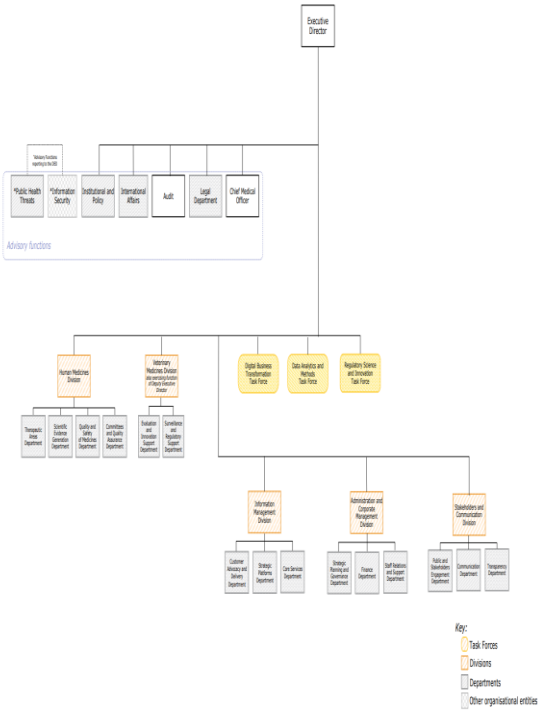

Figure 7: Organisational chart of EMA [27]

2.7 World Health Organization (WHO)

Established in 1948, WHO is the United Nations organisation that connects countries, partners and people to promote health, keep the world safe and serve the vulnerable – so everybody, everywhere can attain the highest level of health. 20

They moreover give and reinforce regulatory enforcement in unregulated regions of the world to ensure public safety regulation covers registration, manufacture, distribution, cost control, marketing, research and development and the protection of intellectual property. Pharmaceutical regulation refers to the promotion of different activities pointed at guaranteeing the efficacy, safety and quality of medicines. Medicines are accessible from a number of sources. People and governments are willing to spend money on drugs for numerous reasons. Medicines must therefore be safe, effective, of great quality and utilized appropriately. In these manner, effective drug regulation is essential to ensure the safety, efficacy and quality of drugs, as well as the accuracy and relevance of drug information provided to the public. Each nation has its own regulatory agency accountable for implementing rules and regulations and issuing guidelines for the development, licensing, registration, manufacture, marketing and labelling of drugs. The production, import, storage, circulation, sale and supply of drugs must be regulated. [20]

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III. CONCLUSION

The regulation of drug has experienced significant evolution over the century driven by historical challenges and incidents ongoing need to safeguard public health.

All around the world regulatory bodies such as the FDA, EMA, TGA, MHRA, PMDA, CDSCO, & WHO play a very crucial role in maintaining rigorous drug approval, manufacturing and post marketing surveillance of drug. While these regulatory agencies works independently global collaboration efforts which aim to harmonize regulatory process for greater efficacy and consistency of the drug. Despite efforts in aligning regulatory framework, challenges, remain, including disparities in approval timelines, clinical trial requirements and post marketing surveillance strategies.

Looking ahead, the future of pharmaceutical regulations will be shaped by advancement in AI, digital health and real world evidence, all of which can enhance decision making and streamline drug development.

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