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# A Review On, "Role of Regulatory Affairs in Global Pharmaceutical Sector"

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**ABSTRACT:**
In The worldwide pharmaceutical industry, regulatory affairs is essential because it makes sure that medications and medical supplies fulfil the safety, effectiveness, and quality requirements set by regulatory bodies. In a variety of worldwide markets, regulatory affairs experts manage the Preparation, Licensing and marketed phase compliance from pharmaceutical items by serving as a liaison between pharmaceutical corporations and regulatory bodies including the FDA, EMA, and WHO. Their duties encompass draughting and submitting regulatory dossiers, handling correspondence with regulators, negotiating intricate and dynamic regulatory environments, and guaranteeing adherence to regional and international regulations. As the sector keeps growing internationally, regulatory affairs plays a more and more important role in bringing global standards into line, speeding up access to life-saving medications, and encouraging innovation while upholding public health protections.

**KEYWORDS:** Regulatory Affairs, Regulatory Agencies , WHO (World Health Organization), Global Standards

## I. INTRODUCTION:

Medical products and pharmaceutical are two highly controlled sectors where regulatory affairs operates. It include gathering, evaluating, and disseminating data to authorities and the general public regarding the security and advantages of medical items. To guarantee the effectiveness, safety, and quality of pharmaceuticals, gadgets, cosmetics, and associated goods, authorities established Drug Regulatory Authorities. The interpretation, application, and social and corporate communication of regulations are critical to their achievement.[1]

Every medication has to conform to its safety, efficacy, and quality requirements. The ethical and technical facets of the Investigational New Drug, New Drug Application, Marketing Authorization Application, and Regulatory Authority procedures that aid in the production and promotion of pharmaceuticals are covered by regulatory affairs. Acceptance management is aided by international governing options like eCTD/eDMS systems. The FDA, CDSCO, TGA, and EMA are important regulatory agencies. When creating medications, biologics, medical devices, herbal items, and skincare products for humans as well as animals, pharmaceutical companies must adhere to stringent global standards.[2]

When checks, international regulatory policy experts guarantee adherence to regulatory structures. As the healthcare industry develops, their function becomes more crucial. They assist capacity checks, make ensuring Good Manufacturing Practices happen, and handle any violation concerns following checks in collaboration with organizations including the FDA, WHO, and EMA.[3]

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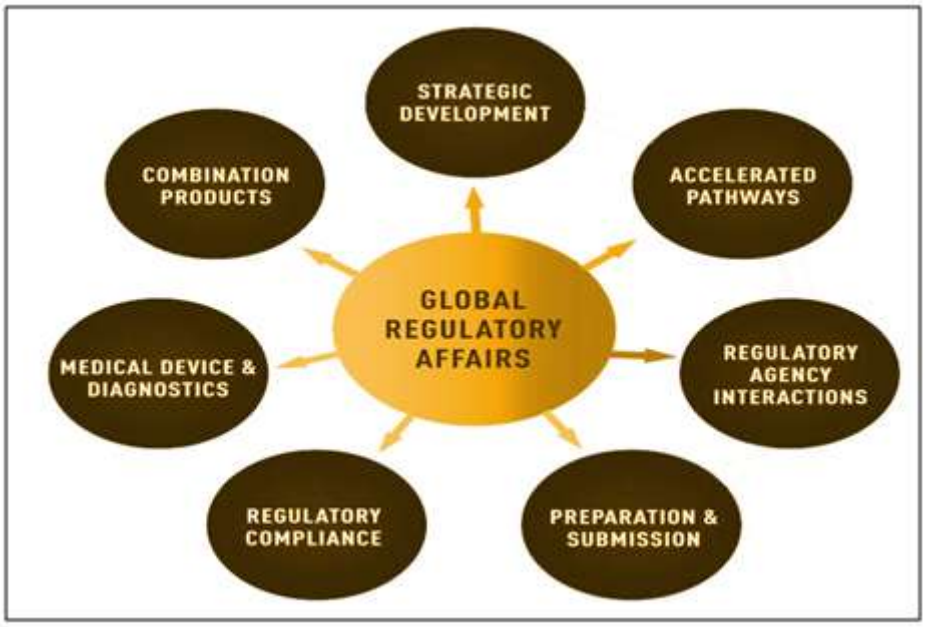


**Fig. 1 Global Regulatory Affairs**

**Advantage of Global Regulatory Affairs:**

1. Harmonization of Standards: Guarantees uniformity in efficacy, safety, and quality throughout the global market.
2. Faster Market Access: Product launches worldwide are made possible by streamlined approval procedures
3. Better Compliance: Lowers the possibility of fines by assisting businesses in adhering to international rules.
4. Improved Patient Safety: Promotes post-marketing surveillance and worldwide pharmacovigilance.
5. Enhanced Competitiveness: Makes it possible for pharmaceutical businesses to effectively enter new markets.

**Disadvantage:**

1. Complex Regulatory Requirements: Rules and paperwork requirements may still vary by location.
2. High Cost and Time Investment: The preparation and upkeep of global submissions demand substantial resources.
3. Regular Regulatory Updates: It might be difficult to stay on top of evolving international rules.
4. Data Confidentiality Issues: There may be security hazards when sharing manufacturing and clinical data internationally.
5. Language and Cultural Barriers: Misunderstandings or delays may result from differences in communication and interpretation.[4, 5]

**OBJECTIVE OF REGULATORY AFFAIRS :**

The main objective of regulatory affairs is to lay the good work for the assurance of premium food products, which can spark consumer passion in ensuring their efficacy, safety, and good quality.

1. The functions of regulatory affairs experts in medical organizations and pharmaceutical companies.
2. Laws pertaining to pharmaceuticals.
3. Research studies.
4. The Pharmaceutical Industry's Regulatory Affairs Network.
5. The evolution of the Indian pharmaceutical industry and drug regulations over time.
6. The Indian Act and Major Rules.
7. Drug Regulatory Affairs or the International, State, or National Government System[6]

**ROLES AND RESPONSIBILITY OF REGULATORY AFFAIRS:**

1. Regulatory agencies are required to review clinical trials for both non-registered and recently approved indications for approved drugs.
2. The legal mandate requires the regulatory agencies to ensure that the drugs that are made available in the country fulfill the necessary requirements for Security, Potency or Standard
3. It is the duty of regulatory bodies to terminate a current study if there are significant violations of Good Clinical Practice.

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4. The implementation of a regulatory system that requires registration for all clinical trials to be conducted in the nation falls under the purview of regulatory authorities.
5. The main responsibility of regulatory organizations will be to promote, ensure, and monitor compliance by a country's recognized ethical committees with relevant laws, rules, and regulations, including the country's best practices for conducting clinical trials involving human beings.
6 .To maintain the reliability as well as Protection a new medication for people, Controlling bodies must thoroughly examine all documentation (including both clinical and nonclinical data) before to allowing its commercialization in any nation.[7]
7. At the highest level of these organizations, the Regulatory Affairs section offers technical and strategic guidance. Thus, they contribute significantly for the positive outcome progress alsobusiness overall, both financially and scientifically.
8. Early to late phase clinical phases are started to further investigate protection also Therapeutic effect in lead molecule after drug discovery phase, which tests potentially intriguing compounds for their non-clinical features. A medicinal product must submit a marketing authorization for marketing approval following successful clinical trials.
9. After the marketing authorization is approved by the appropriate authorities, the pharmaceutical product can be commercized.[8]

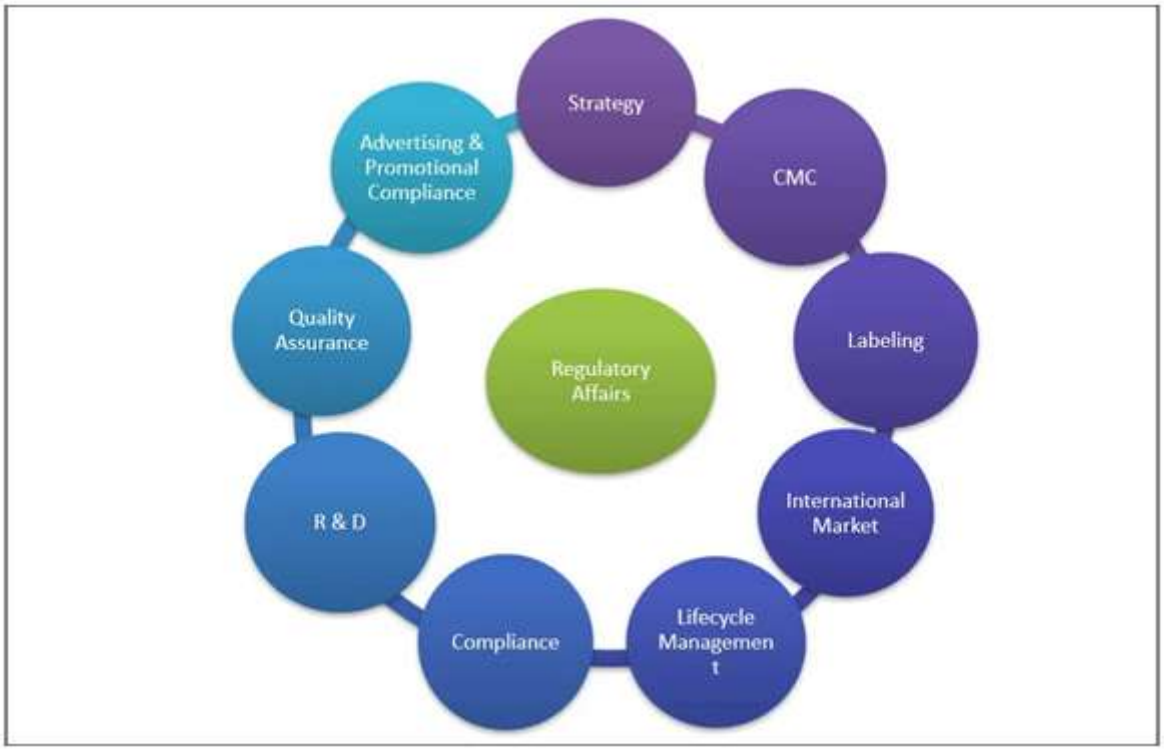


**Fig. 2 Roles of Regulatory Affairs department**

**GLOBAL REGULATORY AGENCIES:**

- **Central Drug Standard Control Organization (CDSCO)**
- **United State Food and Drug Administration (USFDA)**
- **European Medicine Agency (EMA)**
- **Therapeutic Good Administration (TGA)**
- **JAPAN**
- **Health Canda**
- **Medicine And Health care product of Regulatory Agencies (MHRA)**

**1.CDSCO**

The Ministry of Health&Family Welfare oversees the Central Drugs Standard Control Organization, which is India's National Governing Agency. Its main office is situated in New Delhi's FDA Bhawan. With nine regional offices, seven sub-zonal offices, eighteen port offices, seven

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central laboratories, and six small laboratories nationwide, CDSCO is in charge of pharmaceutical management.[9]


**Fig. 3 Organization chart of CDSCO**

Regional and the government are tasked with regulating cosmetics and drugs under the pharmaceuticals & Cosmetics Act, 1940 and Rules, 1945. Their objective is to provide consistent application for the security and welfare of clients. CDSCO promotes responsibility, openness, and uniformity in its offerings in order to guarantee the effectiveness, security, and efficacy of all medical products manufactured, brought in, and marketed in India.[10]

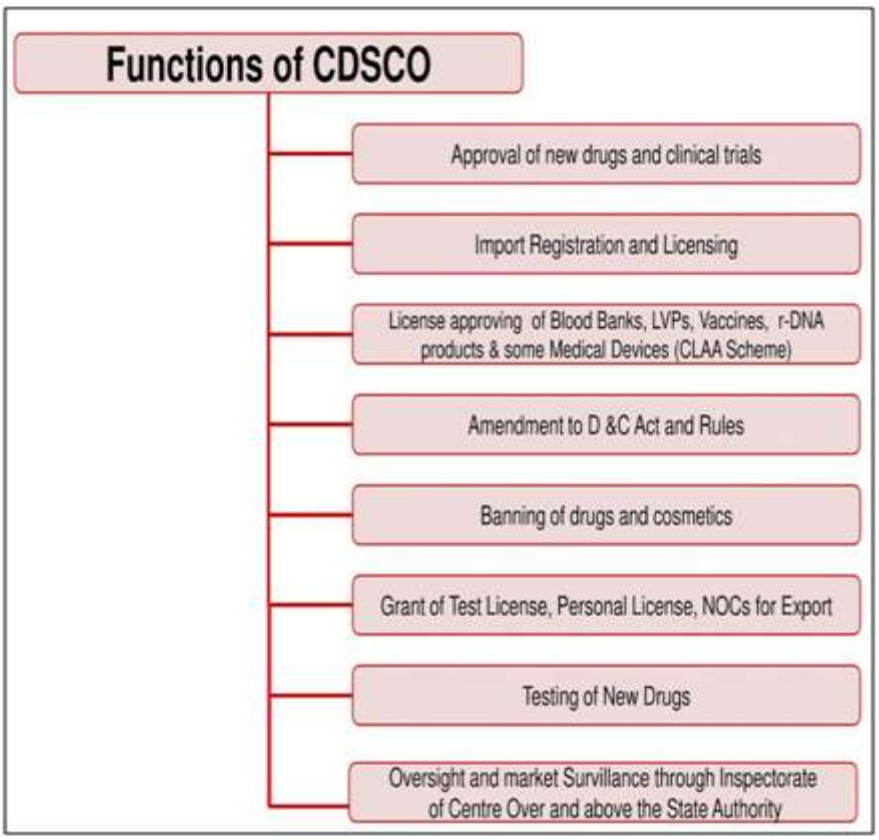


**Fig. 4 Function of CDSCO**

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**2. USFDA**

Food and Drug Administration is a governmental organisation in charge of monitoring, authorising, as well as validating healthcare goods, such as medicines with prescriptions and surgical instruments . they are in charge of a large number of other things, such as food, cosmetics, tobacco, biological products, veterinary drugs, and radiation-producing objects. The agency was established by Genuine Food and Drugs Act of 1906, a law intended to stop mismanagement in the consumer product industry. The official name in FDA was adopted in 1930. In addition to working with manufacturers to recall faulty products, the FDA is also responsible for collecting data on adverse events, or injury or side effects caused by drugs, medical devices, and vaccine.[11]

**Roles and Responsibility :**

1. Maintaining its healthfulness, effectiveness along with integrity in medications, devices used in medicine, vaccines also biologics for individuals as well as animals are vital to safeguard the health of society.
2. provide in public with precise, scientifically supported information to guarantee the proper and safe use of foods and medicinal items.
3. Ensuring food safety and appropriate labeling.
4. Regulating tobacco product production, marketing, and distribution .
5. PHS licenses facilities, inspects enterprises, and tests biologics for potency and purity
6. Product standards are issued. Increased scientific credibility for businesses and their goods .The law-mandated scientific infrastructure aided in the development of new product. [12]

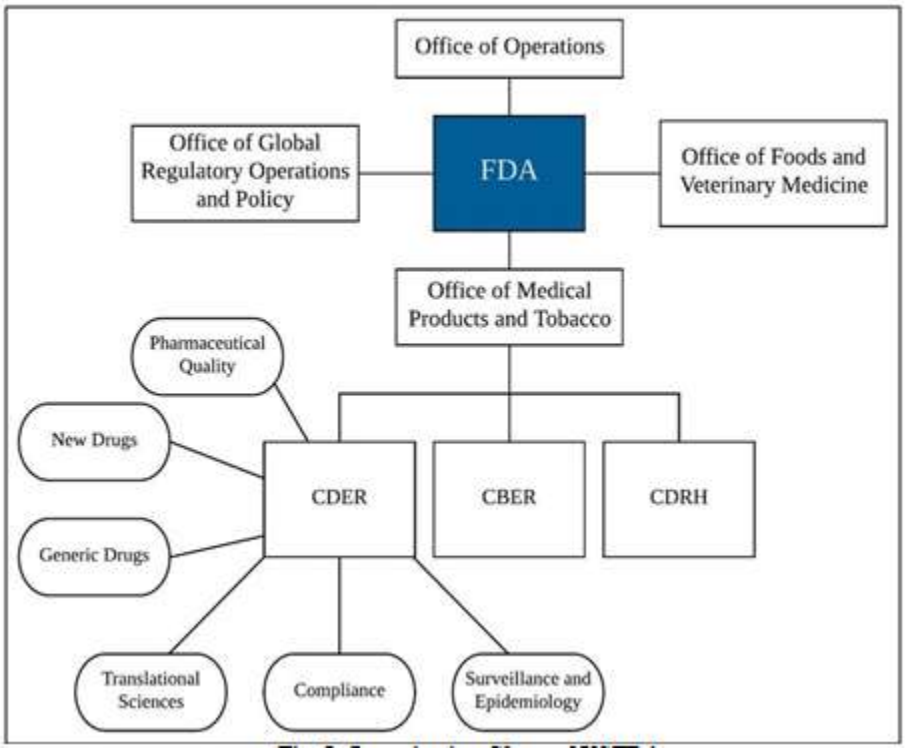


**Fig. 5 Organization Chart of USFDA**

**3.EMA**

To protect and improve human and animal health, the European Medicines Agency (EMA) regulates and assesses drugs used across the European Union also European Economic Area . It transforms breakthroughs in science into medication that genuinely enhance health for individuals by supporting the creation of and investigation into new pharmaceuticals through its professional standards, technical counselling scheme & awards.. The development of drugs and therapies for children to treat rare diseases is specifically encouraged.

**Responsibility of EMA**

1.promoting the creation of medications and their accessibility

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2.Assessing marketing authorization applications and tracking the safety of medications during their whole lifecycle Providing patients and healthcare professionals with information creating policies and standards.

3.Updating citizens of drug security and taking involvement in international monitoring initiatives that involve non-EU bodies[13]

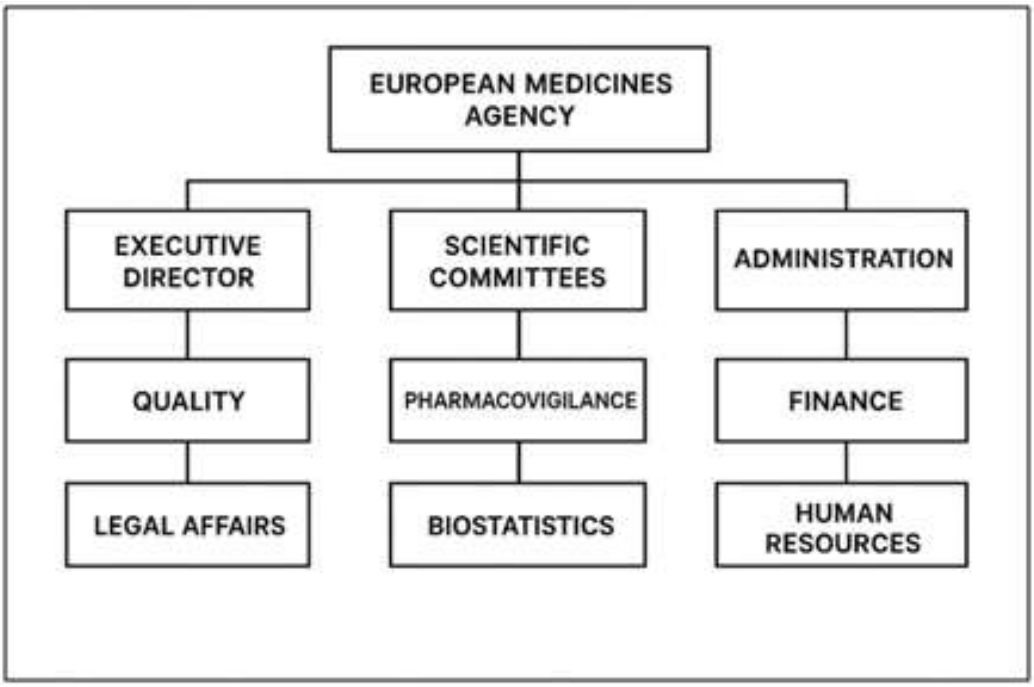


**Fig. 6 Organization chart of EMA**

**4.TGA**

The Therapeutic Goods Administration (TGA), a division of the Australian Bureau of Healthcare, is in charge of regulating therapeutic items, which include blood-derived medications, vaccines, and medical equipment. Before being sold, the majority of products with therapeutic claims need to be submitted to the Australian Register of Therapeutic Goods .[14]

**Roles and Responsibility:**

1. Control of Pharmaceuticals Before therapeutic products are supplied in the Australian market, the TGA evaluates and approves them.
2. Permitting and Examining Manufacturing licenses are granted by the TGA to guarantee adherence to Good Manufacturing Practice (GMP) regulations.
3 .Control of Pharmaceuticals Before therapeutic products are supplied in the Australian market, the TGA evaluates and approves them.
4. Post-Market Observation The TGA uses pharmacovigilance and post-marketing monitoring methods to keep an eye on goods' performance and safety after they are put on the market.
5. Compliance and Enforcement Manufacturers or distributors who fail to comply may be subject to legal and administrative action by the TGA.
6. Development of Policies and Guidance To assist industry stakeholders in adhering to regulatory obligations, the TGA offers guidelines, regulations, and education.[15]

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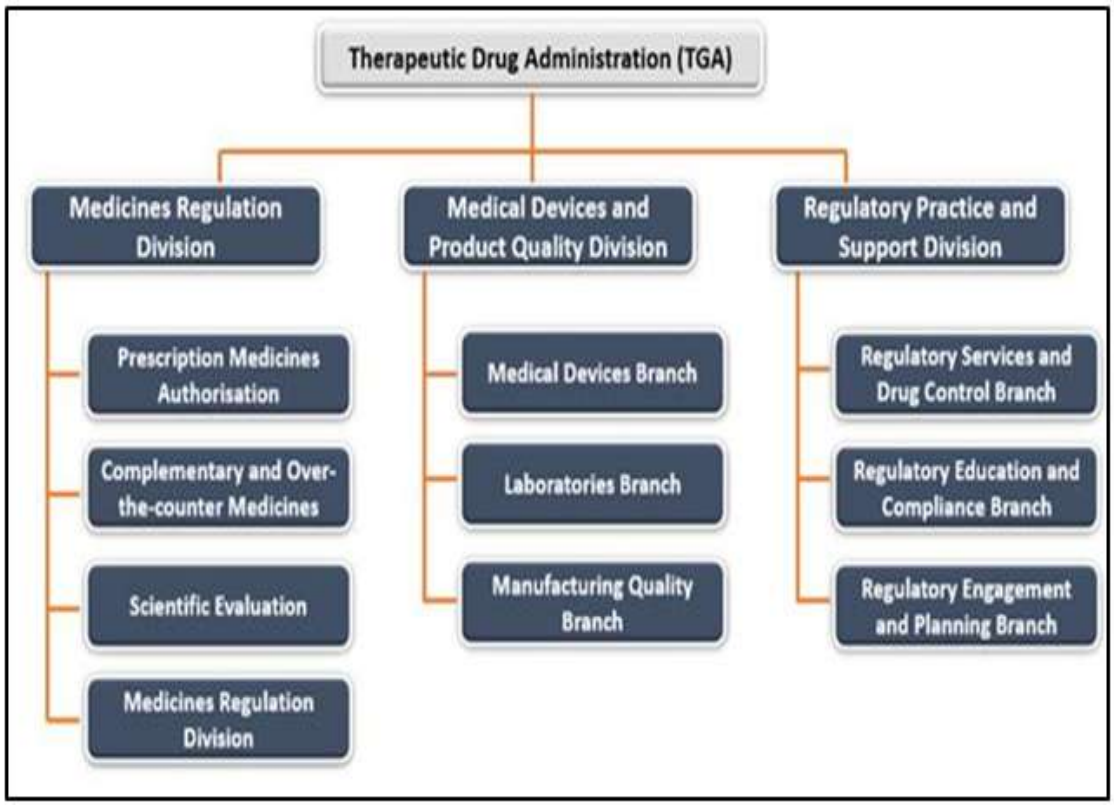


**Fig. 7 Organization chart of TGA**

**5.JAPAN**

The Ministry of Health, Welfare, and Labour (MHLW) and the PMDA oversee health products in Japan. The MHLW controls important regulations arising from the PMD Act, such as product approval requirements, and decides whether a product qualifies as a medical device.[16]

**Roles and responsibility of JAPAN**

1. Regulatory Strategy Development: In order to successfully register and approve products, RA specialists create strategies that adhere to PMDA guidelines and Japanese pharmaceutical laws.
2. Product Registration and Licensing: Under the PMD Act, they create, submit, and oversee applications for new drug approvals (NDA), generic pharmaceuticals (GDA), and medical devices.
3. Communication with PMDA and MHLW: RA facilitates pre-submission consultations, answers questions, and guarantees adherence to regulatory functions as the company's regulatory communication link organizations.
4. Labelling and package adherence: Making sure that all product labelling, package inserts, and marketing collateral follow Japanese labelling laws and include approved detail.[17]

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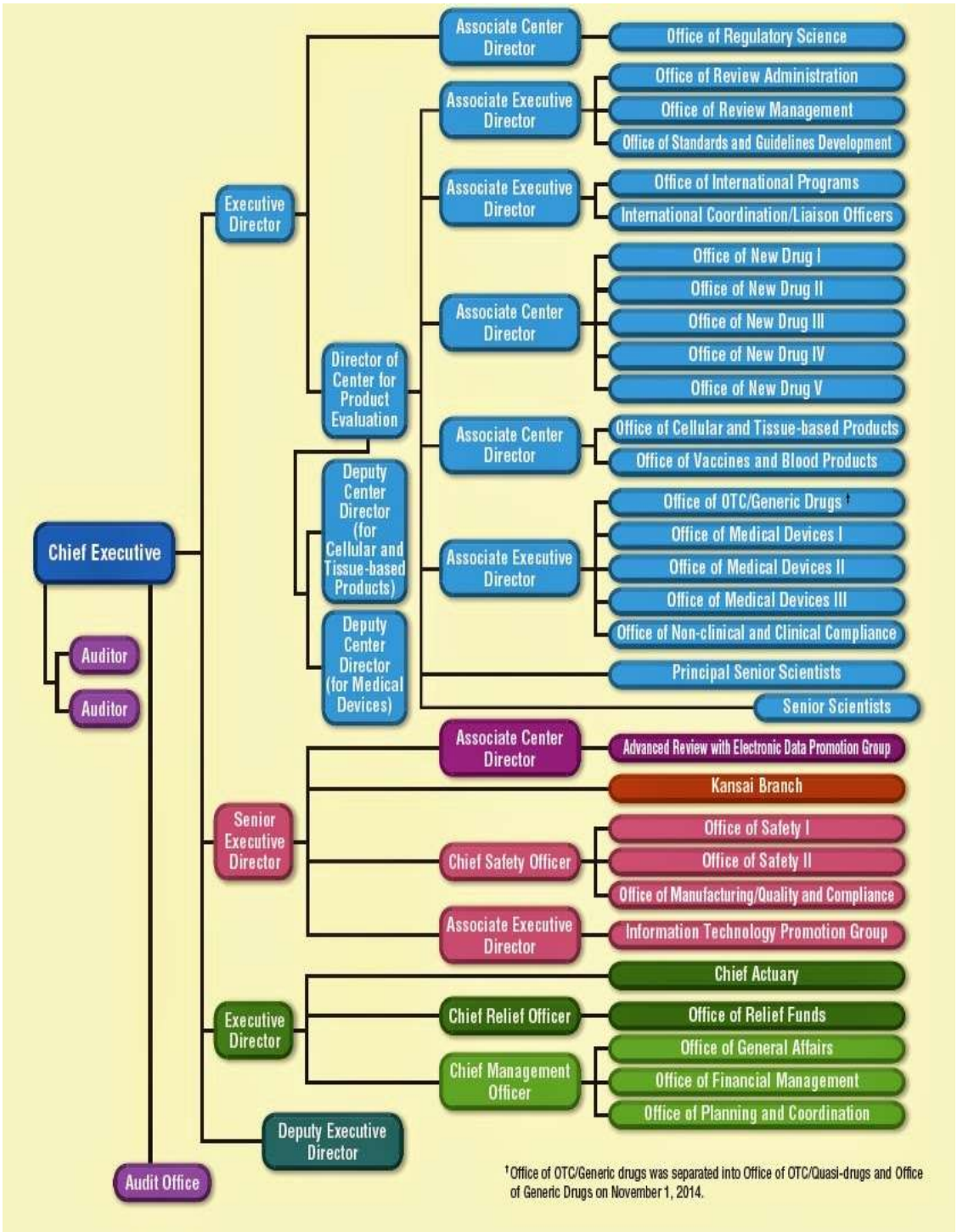


**Fig. 8 Organization chart of Japan**

**6.Health Canda**

Health Canada has jurisdiction over foods, medications, medical equipment, biologics (including goods used in cellular treatment), natural health products. While the Food and Drugs Act of 1920, as amended, gives Health Canada general regulatory authority, Part C of the Food and Drug restrictions provides restrictions specific to cellular treatment.[18]

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**Fig. 9 Organization chart of public health agencies Canda**

**Responsibility of canda**

1. Sign prolonged care partnerships with regions and states that an emphasis on enhancing mental health and home care services, as well as collaborative federal-provincial-territorial initiatives to reduce prescription medication costs and promote more creative care models. ·
2. Resolve unresolved and developing Canada Health Act issues by applying uniform interpretation and fair enforcement measures throughout the country.
3. Putting into action Health Canada's Regulatory Transparency and Openness Framework and Action Plan by educating and engaging Canadians in matters of safety and health matters, and also by boosting client trust by offering more details so that Canadians can observe which the agency supports business compliance and maintains regulatory requirements.
4. Collaborate with the The people Welfare, Legal Services, the Emergency Management agencies to legalize strictly regulate cannabis in order prevent young people from obtaining it and to prevent criminals from profiting from it.[19]

**7.MHRA**

The Medicine and Healthcare Product of Regulatory Agenciesis the UK's agencies body for blood components, medical . It evaluates industry and medical equipment and issues advertising permits.[20]

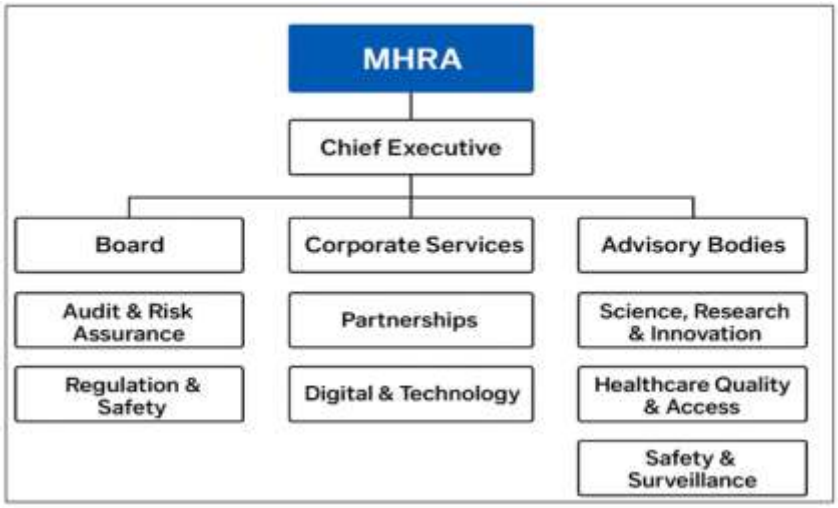


**Fig. 10 Organization chart of MHRA**

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**INTERNATIONAL DRUG REGULATORY AUTHORITY:**

**WHO**

Setting pharmaceutical standards, guaranteeing medication quality, and offering advice on pharmaceutical laws and regulations are all global responsibilities of WHO. In aiming to increase ensure safety and effective medications worldwide, it works with national regulatory bodies.[21]

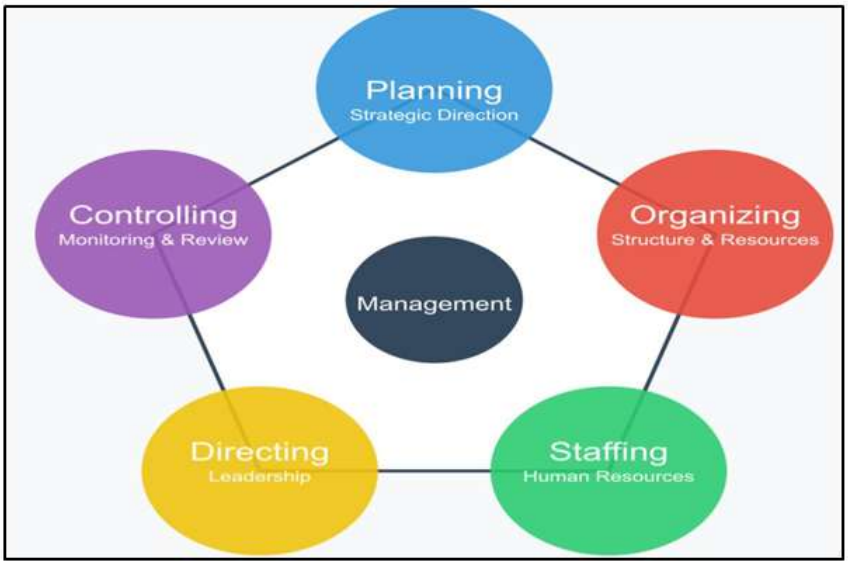


**Fig. 11 Function Of WHO**

**ICH (International Conference Harmonization) of Regulatory Affairs :**

One important international effort to enhance and harmonize medication research and registration standards is the International Council for Harmonization. The ICH, which founded in 1990, unites industrial participants and regulatory bodies from several state, as Europe, the Japan, the U.S nation & other nations should work together to establish guidelines for the pharmaceutical sector.

**Key guideline Of Regulatory Affairs :**

**1.Good Clinical Practices (GCP):** These standards guarantee clinical studies that are both morally and scientifically sound.

**2.Good Manufacturing Practices (GMP):** Ensuring that pharmaceutical items are continuously manufactured and managed in compliance with set guidelines

**3.Pharmacovigilance:** Keeping an eye on pharmaceutical safety after they are marketed in order to identify and resolve any possible hazards

**4.Quality Guidelines:** Covering stability testing, packing, and storage as well as other quality control procedures for pharmaceutical substances and products.[22]

**Goals of ICH Regulatory Affairs :**

**1.Harmonization of Regulatory Requirements:**

In order to guarantee that the medication approval process is effective and uniform, ICH works to harmonize rules across various areas. Drug developers and regulatory agencies may save time and money by reducing the need for redundant testing and regulatory processes.

**2.Facilitating Global Market Access:**

ICH makes it easier for pharmaceutical items to receive approval in several areas by standardizing technical requirements and standards. Patients all over the world now have faster access to life-saving medications because to this global alignment.

**3.Ensuring Safety and effectiveness:**

The ICH's guidelines concentrate on upholding strict standards for pharmaceutical safety, effectiveness, and quality. This contributes to the safety and efficacy of medications approved through standardized procedures in various markets.[23]

**PROCESS OF REGULATORY AFFAIRS:**

**1.Preclinical Research**

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Preclinical research is where the journey starts, as laboratory studies yield possible therapeutic possibilities. Researchers use in Preclinical in vitro and animal testing compounds for preservation, effectiveness, of mechanism of action. Strong preclinical findings are essential for future regulatory approval, although regulatory bodies like the FDA do not directly intervene at this point.

**2.IND (Investigational new drug application)**

Regulatory filing of an Investigational New Drug from is prerequisite for moving from preclinical to clinical testing. This is a crucial regulatory milestone since the application describes the goals, procedure, and preclinical data of the planned clinical investigation. Before allowing a human experiment, regulatory bodies carefully examine the IND to guarantee Ensuring subject safety and maintaining data integrity.[24]

**3.Clinical trial Phase**

**Phase 1**

First experiments to assess dose and safety. A small team of twenty–hundred healthy volunteers are usually selected for Phase I trials, where testing starts in human participants. 16–17 dosage-ranging, also known as dosage-escalation studies, are conducted during Phase I trials to determine the safest and most effective dose as well as the amount at which a substance is too hazardous for administration.

**Phase 2**

Long-term studies to assess safety and effectiveness The next objective is to assess whether the medication has any biological activity or impact after deciding on the dose or range of doses. Phase II trials continue the safety assessments from Phase I while evaluating the drug's efficacy in bigger groups of 100–300 people.

**Phase 3**

Extensive research to confirm safety and effectiveness. Phase III studies aim to provide a conclusive assessment of the drug's efficacy by carrying out selectively managed multidisciplinary research on sizable individuals (300–3,000) or higher, according upon their condition) in contrast to the current best available medication.

**Phase 4 (Post marketing Surveillance)**

Product performance is continuously evaluated. Phase IV trials, sometimes called a following marketing experiment, track a drug's effectiveness after it is put on the market. Phase IV trials cover safety monitoring (drug safety oversight) and continuing analytical assistance after medication is authorized for sale. In contrast to Phase I–III clinical studies, the safety surveillance seeks to find uncommon or persistent side effects in a much broader patient group over a longer period of time.[25, 26]

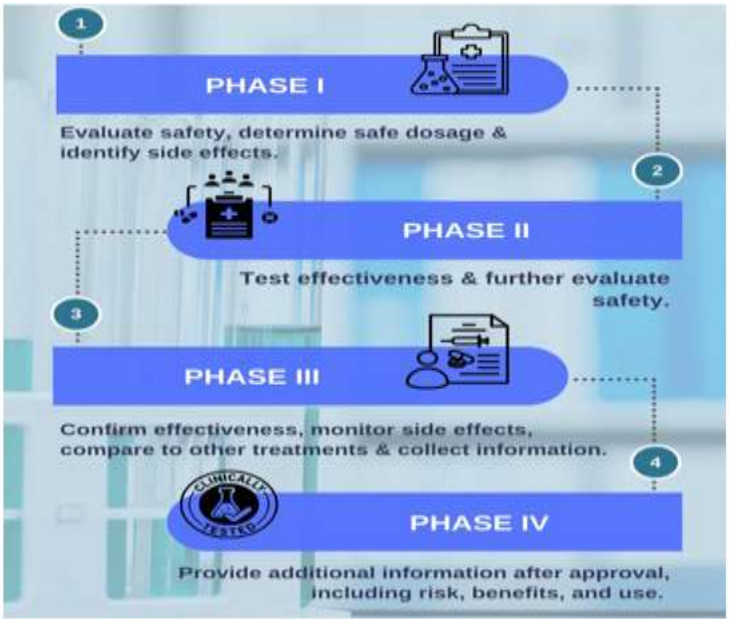


**Fig. 12 clinical trial phase**

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**4.MAA( Marketing authorization application)**

The application process for marketing authorization demonstrates notable variations in regulatory strategies. With its New Drug Application (NDA) procedure, the FDA demands extensive safety and efficacy data. On the other hand, the EMA's centralized method simplifies the process for manufacturers by An individual request for permission from every EU nation [27]

**5.Regulatory compliance**

The process of abiding laws, rules, and standards set forth by governmental agencies or business associations is known as regulatory compliance. In order to safeguard public safety, preserve product quality, and stop fraud or misbehavior, it makes sure that operations, procedures, and products comply with legal standards. Important components of adhering to regulations are:

I. **Understanding Regulations:** Professionals in regulatory compliance must possess a thorough understanding of the laws and regulations that apply to their industry, such as FDA regulations for pharmaceuticals or food safety regulations for the food industry.
II. **Documentation and Record-Keeping:** To prove compliance, thorough documentation is essential. This includes keeping records of product testing, manufacturing procedures, safety precautions, and regulatory submissions.
III. **Audits and Inspections:** In order to verify compliance, businesses must be ready for these evaluations and promptly address any non-compliance.
IV. **Reporting and Documentation:** Timely and accurate filing of regulatory paperwork, including product registrations, safety reports, and adverse event reporting, is frequently necessary for compliance.
V. **Education and Training:** Maintaining compliance across a business depends on making sure that staff members are informed about and trained on regulatory standards.
VI. **Quality Management Systems (QMS)**: By creating established procedures for quality control and documentation, QMS implementation—such as ISO 9001 or ISO 13485—can help expedite compliance efforts.[28,29]

**6.Post marketing surveillance**

Post-marketing monitoring is a new phase that begins with market entry rather than its conclusion. In order to address new issues and guarantee continuous compliance, regulatory bodies continue to place eye on a drug's efficacy and security in real-world situations. Pharmacovigilance and adverse event reporting are becoming essential regulatory requirements.[30]

**CHALLENGE OF REGULATORY AFFAIRS:**

**1. Growing Regulatory Complexity:** Businesses find it difficult to remain compliant as regulations get more complicated and frequently differ by area. Pharmaceutical businesses, for instance, have to manage complex medication approval procedures, such as several stages of clinical trials and data submissions.

**2. Globalization**: Entering foreign markets requires knowledge of and adherence to various regulatory regimes. This covers cultural, linguistic, and practical factors in addition to various product safety regulations.

**3 Digital Transformation:** Industries Are transforming to quick development of Digital System. For instance, telemedicine and AI-powered diagnostic tools are becoming more common in the healthcare industry. In order to monitor these advancements and guarantee patient safety and data privacy, regulators must adjust.

**4.**Regulatory organizations are imposing strict guidelines on how personal data is handled, especially in Europe with the GDPR. This has an impact on a number of sectors where sensitive data is frequently handled, such as healthcare and financial services.

**5.Supply network Vulnerabilities:** The coronavirus crisis revealed weaknesses in international supply networks, emphasizing the necessity of regulatory supervision to guarantee product safety and quality, particularly in sectors like pharmaceuticals.

**6. Fast-Track Approvals:** At public health catastrophes such as the COVID-19 pandemic, there is a requirement for quick the approval of medicines and immunizations. . For regulators, striking a balance between safety and speed is a major task.

**7. Post-Market Surveillance:** It is difficult to maintain product safety by post-market surveillance, particularly when products get more sophisticated. In order to successfully monitor items once they are on the market, regulators must adjust.[31]

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**CURRENT TREND OF REGULATORY AFFAIRS:**

**1.Accelerated Approval Pathways:** Regulatory organizations like the FDA and EMA have developed accelerated approval pathways in response to the demand for quick access to life-saving treatments. The goal of these processes—Priority Inspection, Innovative Therapies, and Fast Track—is to expedite the assessment and approval of medications that meet unresolved medical

**2.Digital Transformation and E-Submissions:** The drug approval process has been completely transformed by the switch to digital platforms for regulatory submissions. Electronic submissions, or "e-submissions," increase the review process's overall transparency, efficiency, and error-reduction.

**3.Real-World Evidence (RWE) and Big Data Analytics:** When making decisions, regulatory bodies are increasingly using RWE, which is obtained from real-world data (RWD) such Payout request, Digital healthcare documentation, and patient registries.

**4.Advanced Therapeutic Products and Personalized Medicine:** There are particular regulatory :issues with the introduction of advanced therapeutic products, such as cell treatments, gene therapies, and personalized medicine.

**5.Artificial intelligence and machine learning in Regulatory Agencies :**Artificial By facilitating more effective data analysis, predictive modeling, and decision-making procedures, AI and ML are revolutionizing the field.

**6.Dynamic Research Trials Concepts:** These designs are gaining popularity because they allow for modifications to the research protocol based on interim results.[34]


**Fig.13 Current Trend Of RA**

## II. FUTURE DIRECTION:

**1.AI and Digital Health Technologies :**

Effect on Regulation Artificial intelligence (AI) and digital health technologies are fast changing the pharmaceutical industry by providing creative solutions for patient monitoring, drug development, and regulatory procedures. It is anticipated that these technologies will have a major influence on pharmaceutical regulation as they develop.

**2.AI in Drug Development:**

By forecasting which chemicalscould be most useful in treating particular ailments, AI might speed up the drug discovery process. Additionally, AI-driven solutions can improve patient recruitment, simplify clinical trial designs, and analyze enormous volumes of data more effectively than conventional techniques. To ensure that AI-driven drug designs and clinical trials adhere to safety and efficacy requirements, regulatory bodies will need to create new rules for incorporating these technologies into drug approval procedures.

**3.Digital health technologies:**

Wearable technology, telemedicine platforms, and mobile health apps are becoming essential to patient treatment because they enable real-time patient health monitoring. These technologies can offer information that regulatory agencies need to evaluate the long-term efficacy and security of drugs. However, new regulatory

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frameworks addressing data privacy, cybersecurity, and device safety will be necessary for the use of digital health technology.

**4.Regulation of AI in Medicine:**

As AI applications in healthcare proliferate, regulatory bodies will have to develop rules especially for AI-based medical devices, like decision-support and diagnostic algorithms. This entails dealing with issues like accountability, transparency, and making sure AI systems are trustworthy and impartial.[35, 36]

## III. CONCLUSION:

Making sure pharmaceutical products are high-quality, secure and reliable for patients worldwide is largely dependent on global regulatory affairs. The regulatory framework encourages uniformity, openness, and effectiveness in drug development and approval procedures by harmonizing worldwide criteria, such as those set forth by the ICH, WHO, EMA, US FDA, and other organizations.

Manufacturers, regulatory bodies, and other stakeholders must work closely together due to the pharmaceutical industry's growing globalization. Through efficient pharmacovigilance and post-marketing surveillance, our partnership serves to minimize effort duplication, expedite market access, and guarantee patient safety.

With the development of digital technology, artificial intelligence, and international harmonization efforts, regulatory affairs will continue to change in the future. These advancements will ultimately improve worldwide public health by increasing regulatory effectiveness and enabling prompt access to cutting-edge treatments.

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