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Article

Ensuring Quality Medicine: A Comprehensive Overview of EMA and DGDA's History, Structure, and Functions

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Abstract: The research article provides an in-depth analysis of the European Medicines Agency (EMA) and the Directorate General of Drug Administration (DGDA), focusing on their historical development, organizational structures, and functional roles in ensuring the quality and safety of pharmaceuticals. The study highlights the origins of drug regulation, tracing back to the early 19th century in the United States with the establishment of the Food and Drug Administration (FDA), and discusses the evolution and significance of drug regulatory bodies worldwide. The EMA and DGDA are scrutinized for their efforts in maintaining high standards for drug approval, monitoring clinical trials, and managing post-marketing surveillance to prevent adverse drug reactions (ADRs). The EMA's role in coordinating with EU member states on pharmacovigilance and the DGDA's initiatives in Bangladesh, including the implementation of a nationwide drug database and pharmacovigilance system, are explored in detail. The article concludes by emphasizing the essential role of these regulatory bodies in safeguarding public health through stringent regulation and continuous monitoring of pharmaceuticals, thereby ensuring that only safe and effective medicines are available to consumers. It also provides an in-depth analysis of the roles, structures, and historical contexts of the European Medicines Agency (EMA) and the Directorate General of Drug Administration (DGDA). It outlines how these regulatory bodies ensure the safety, efficacy, and quality of medicinal products. The EMA, serving the European Union, and the DGDA, operating in Bangladesh, play critical roles in drug approval processes, pharmacovigilance, and maintaining public health standards. By setting rigorous guidelines and monitoring compliance, these agencies help safeguard the health of millions, ensuring that only safe and effective medications are available in the market. The paper underscores the importance of these regulatory bodies in promoting public health and supporting the pharmaceutical industry's development and innovation.

Keywords: EMA; DGDA; drug regulatory authorities; manufacturing guidelines; quality medicine; good laboratory practice; cGMP, GMP, GLP, IPQC, QC, QA, quality control; quality assurance; current good manufacturing practice; good manufacturing practice

Introduction:

Drug regulatory bodies are governmental organizations responsible for regulating the supply and use of drugs and medical devices within a Country. They aim to ensure that the public has access to safe, effective, and quality medicines and medical devices that have been developed and manufactured per the established standards and regulations. The purpose of establishing drug regulatory bodies is to protect public health by ensuring that medicines, medical devices, and other pharmaceutical products available in the market are safe, effective, and high-quality. This includes checking the approval of new and generic drugs and registering clinical authorizations for controlled substances. Additionally, these bodies investigate any reported adverse effects of drugs, monitor prescription practices, and control the cost of drugs. Furthermore, by determining and enforcing

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standards and regulations, drug regulatory authorities ensure that these products meet pre-established requirements for efficacy and safety.

History of Drug Regulatory Bodies:

The history of drug regulation dates back to the early 19th century in the United States. At that time, the federal government began to exert jurisdiction over specific categories of drugs – opium, cocaine, and morphine – due to the risks associated with their use. The Pure Food and Drug Act of 1906 established the first national standards for food and drugs, ultimately leading to the Food and Drug Administration (FDA) creation. The FDA is the primary drug regulatory body in the United States. It is also a member of several international organizations, such as the International Conference on Harmonization, the World Health Organization (WHO), and the Codex Alimentarius Commission.

Organizational Structure:

The organizational structure of drug regulatory bodies can vary across countries and organizations. However, most are divided into two central departments: medical, scientific, legal, and administrative. The medical, scientific, and legal department is responsible for assessing drug safety, quality, and efficacy. They evaluate the available evidence and research to determine whether a product can be approved. The administrative department is responsible for implementing policies, procedures, and regulations about the regulation of drugs.

Role and Functions of Drug Regulatory Authorities:

Drug regulatory bodies play an essential role in the world. They work to ensure that only safe and effective drugs are available in the market. Additionally, they work to control the cost of drugs and ensure that they remain affordable to consumers. Furthermore, they also promote research and development of new drugs and investigate any reported cases of adverse effects resulting from the use of drugs. These organizations ensure that medical professionals, patients, and healthcare providers have access to quality medicines and medical devices through their activities.

The primary function of drug regulatory bodies is to ensure that only safe and effective drugs and medical devices are available in the market. This includes checking the approval and registration of drugs, conducting research and development of new products, establishing standards for drug production, monitoring prescription practices, and conducting post-marketing surveillance. Additionally, they investigate any reported cases of adverse effects resulting from the use of drugs and review clinical trial applications. Furthermore, they also work to control the cost of drugs and protect the public from counterfeit medicines.

The primary benefit of drug regulatory bodies is that they ensure the safety, efficacy, and quality of medicines, medical devices, and other pharmaceutical products in the market. This helps to protect customers from dangerous and counterfeit products. Moreover, these organizations also promote research and development of new drugs, which helps to expand the availability of treatments. Additionally, by controlling the cost of drugs and reducing prescription abuse, drug regulatory bodies help make medications more accessible to the public.

The primary disadvantage of drug regulatory bodies is the amount of time and resources it may take to review medications and medical devices. Additionally, in some cases, there needs to be more transparency in the approval process, which makes it difficult for the public to understand the criteria for approval of certain drugs. Furthermore, because these organizations are heavily focused on enforcing standards, innovation may be limited due to the restrictions and delays that the approval process imposes.

Overall, drug regulatory bodies demonstrate their commitment to protecting public health and helping to make medications more accessible to the public. The pharmaceutical industry prioritizes the safety and efficacy of all medicines they develop and produces due to government regulations and guidelines set in place to ensure public health. Government agencies and pharmaceutical

 doi:10.20944/preprints202408.0031.v1

companies are dedicated to maintaining high standards in manufacturing medicines to ensure the public's safety. To ensure these standards are met, a wide range of organizations and institutions serve as curators of drug regulatory bodies.

Drug regulatory bodies are organizations, agencies, and institutions that regulate and oversee medicines' development, production, and distribution. In particular, these regulatory bodies monitor, review, and inspect aspects of the industry, such as Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP). The goal of such organizations is to guarantee the quality, safety, and efficacy of products. Regulatory bodies act as coordinators in the pharmaceutical industry by providing guidelines, standards, and policy direction, which are essential to the drug development process. They also approve clinical trials and products for marketing, placing stringent oversight and requirements on the industry, such as regulating active pharmaceutical ingredients (APIs) and container–closure systems and packaging components, inspections, and recalls.

One of the most important functions of drug regulatory bodies is to ensure compliance with GMP, a set of regulations to ensure quality and consistency throughout all stages of the production process. GMP aims to improve the quality, safety, and efficacy of medicines while also reducing costs. To achieve these goals, GMP requires strict control over the design, qualification, manufacturing, packaging, labeling, testing, and distribution of pharmaceuticals.

Drug regulatory bodies play a significant role in pharmacovigilance, which deals with assessing, understanding, and preventing adverse effects of drugs after they are administered to the general public. Drug regulatory bodies strive to ensure the safety of drugs and protect public health by rigorously monitoring the use of medication, along with the side effects of drugs. The activities of drug regulatory agencies involve active promotion of pharmacovigilance programs, assessing reports of adverse events associated with drugs, monitoring studies on drugs, educating health practitioners and the public on the safety of drugs, and actively encouraging reporting of suspected drug reactions.

These regulatory bodies also work with pharmaceutical companies to identify and investigate the risks associated with a drug and recommend ways to resolve the issues. They also develop regulations for safe drug manufacture, storage, and distribution. Drug regulatory authorities also approve drugs for sale after a complete evaluation and review of their benefits, side effects, and risks.

Furthermore, drug regulatory bodies advise and guide pharmaceutical manufacturers to ensure that drugs meet international safety standards. They also develop rules related to clinical trials, marketing research, packaging and labeling of drugs, and monitoring post-marketing surveillance. In addition, drug regulatory bodies also set guidelines for pharmaceutical research and development, the use of drugs in clinical practice, and the safety and efficacy of new drugs.

Drug regulatory bodies are essential for providing the public with safe and effective medications. They strive to monitor the use of medications and detect any potential or existing dangers that pose potential risks to public health. By performing their duties and responsibilities, drug regulatory bodies protect and improve public health through pharmacovigilance.

Several drug regulatory bodies around the world are responsible for keeping an eye on the safety and efficacy of medications. The Food and Drug Administration (FDA) is the most well-known in the United States. They regulate all medical products and ensure that drug makers have followed good manufacturing practices before releasing new drugs to the market. European countries have their agencies as well, including the European Medicines Agency (EMA) and the Pharmacovigilance and Risk Assessment Committee (PRAC), Directorate General of Drug Administration (DGDA) is the principal drug regulatory agency in Bangladesh, and it functions under the Ministry of Health and Family Welfare.

The European Medicines Agency (EMA)

The European Medicines Agency (EMA) is an agency of the European Union responsible for evaluating and supervising medicines developed for use within the European Union (EU). Established in 1995 as the European Agency for the Evaluation of Medicinal Products (EMEA), the EMA is the main body responsible for the scientific assessment of medicines developed by

 doi:10.20944/preprints202408.0031.v1

pharmaceutical companies for use in the EU. The EMA works closely with national medicines regulatory authorities, including its Medicines Evaluation Board (MEB), to evaluate and authorize new medicines.

History of The European Medicines Agency (EMA):

The history of the EMA dates back to 1970 when the European Community (EC) adopted the Pharmaceutical Directive, which directed the European System of Control of Medicines (SCM). This was subsequently replaced in the mid-1980s by a new pharmaceutical directive that set up the legal framework for the Pharmaceuticals Efficacy and Safety (PES) system, which became the basis for establishing the EMA in 1995.

The purpose of the agency's establishment was to reference the work and findings of several private and public institutions that had been providing regulatory services for medicines in the European Union for some time. The intention was to create one agency that could take responsibility for this role and create an efficient and effective system of medical regulation. However, there were also political considerations as the European Union (EU) wanted to establish a single unified system of drug regulation. The founding mission of the EMA is to protect public health through the evaluation and supervision of medicines developed and used within the Member States of the EU. The EMA focuses on evaluating and supervising medicines and works with its partners to address standard safety and quality concerns. It is responsible for developing guidelines, recommendations, and other regulatory documents related to GMP and is involved in approving pharmaceutical products for marketing in the EU.

Organizatinal Structure of The European Medicines Agency (EMA):

The European Medicines Agency (EMA) is the primary European Union (EU) medicines regulator responsible for overseeing the safety and efficacy of human and veterinary medicines produced within the EU and those imported from third countries. It is an independent body within the framework of the European Union and is accountable to the European Commission and European Parliament. The EMA manages the European Union's centralized system for assessing and monitoring medicines, and its Rules and Guidelines ensure the quality, safety, and effectiveness of medications available in the EU. The EMA is made up of four branches:

1. The Executive Directorate (ED)
2. The European Union Legal Service (ELSA)
3. The Committee for Medicinal Products for Human Use (CHMP)
4. The Pharmacovigilance Risk Assessment Committee (PRAC)

- The EMA's Executive Directorate (ED) is responsible for the agency's overall governance and management oversight, including its operational, financial, and legal activities. The ED has administrative and operational powers and is responsible for providing technical and scientific advice on the development of medicines and for implementing the recommendations of the PRAC and the CHMP. It is also responsible for ensuring legal compliance with EU law and supervising the EU's regulatory network.
- The European Medicines Evaluation System (EMEC) is the division responsible for overseeing clinical and pharmaceutical development programs, performing regulatory reviews, and monitoring the effectiveness of drugs in the EU. It comprises three distinct components: the Pre-authorization Division, the Post-authorization Division, and the Evaluation Support Unit. The Pre-authorization Division assesses medicines' quality, safety, and efficacy before they can be marketed in the EU. At the same time, the Post-authorization Division supervises the products once they are approved and is responsible for ongoing monitoring and conducting periodic reviews. The Evaluation Support Unit provides scientific and analytical support to the Pre-authorization and Post-authorization Divisions.
- The Pharmacovigilance Risk Assessment Committee (PRAC) provides scientific advice and assesses the safety and performance of medicines in the EU. The PRAC monitors the safety of medicines, evaluates reports submitted by patients and healthcare professionals, and performs

 doi:10.20944/preprints202408.0031.v1

risk management measures to ensure the safety of medicinal products. The PRAC also assesses the benefit-risk balance of medicines and provides its recommendations to the Executive Board of the EMA.

The Committee for Medicinal Products for Human Use (CHMP) is responsible for assessing and evaluating applications for the marketing authorization of medicinal products for human use. Its primary function is to evaluate medicines' quality, safety, and efficacy and to provide recommendations for their approval or rejection. The CHMP evaluates data from the pre-and post-authorization of medicines and recommends changes to the Rules and Guidelines for drug approval and marketing authorization.

A Director-General heads the EMA and has an executive team of senior officials from the Member States and the European Commission. It is supported by a Scientific Secretariat, which provides scientific advice and support to the Director-General in developing European medicines legislation. The Scientific Secretariat consists of several expertise units, including the Quality Assessment & Monitoring Section, which evaluates proposed new medicines, and the Pharmacovigilance & Risk Management Section, which monitors the safety of medicines on the market. The Director General, Executives, and Head of the European Medicines Agency (EMA) are responsible for developing, implementing, and monitoring the agency's operations. The Director General is the highest level of the management structure and is responsible for setting the agency's overall vision, mission, and strategy. The Director General is also responsible for ensuring that the agency functions effectively and efficiently per EU legislation. The Executives are the leaders of the EMA and are responsible for developing and managing the agency's day-to-day operations. They ensure the quality and safety of medicines authorized in the EU while respecting the fundamental freedoms of EU citizens. The Head of the EMA is responsible for the support and guidance of the Executives in performing their duties, as well as for providing advice to the European Commission on medical, scientific, and ethical issues related to the authorization of medicines in the EU. Together with the Executives and the European Commission, the Head of the EMA is responsible for the European Monitoring System for the Quality and Safety of Medicines (EMSFQS), an integrated approach to evaluating and monitoring medicines quality, safety, and efficacy. Additionally, the Head of the EMA ensures a high level of pharmaceutical expertise in the agency by providing advice and guidance to the Executives and ensuring the production of high-quality documents, such as guidelines and standards.

In addition to its headquarters in London, the EMA has a network of offices and research laboratories in the Member States and several countries worldwide. The agency also has access to data from some 70 countries through its International Partnerships Programme, which provides advice on the effects and safety of medicines on the global market.

Role and Functions of The European Medicines Agency (EMA):

The EMA is responsible for evaluating and supervising new medicines that may be approved in the EU. All proposed medicines must be evaluated for their safety, quality, and efficacy before being approved for sale or use in clinical trials in Europe. The agency also monitors the safety of medicines already on the market and provides advice on their use and safety to healthcare professionals, patients, and industry. The agency works closely with the European Commission, which is the central body responsible for the approval of new medicines in the EU, and with the national regulatory authorities of Member States. The EMA is responsible for assessing safety issues related to medicines and for advising the EU on safety-related matters. The EMA also works closely with the national health authorities of each Member State on issues such as pharmacovigilance, adverse event reporting, and the reporting of quality defects. The EMA also provides support to Member States in the development of national medication-related safety programs.

The work of the EMA significantly influences the drug approval process in the European Union and beyond. It aims to ensure that only safe and effective medicines are approved and the orderly supply of medicines across the EU. Ultimately, the role of the EMA is to ensure the availability of safe

 doi:10.20944/preprints202408.0031.v1

and effective medicines for the citizens of the European Union while also helping to promote innovation in the pharmaceutical industry and protect the health of citizens worldwide.

The European Medicines Agency (EMA) plays a crucial role in pharmacovigilance, which is monitoring the effects of medicines after authorization for use on the market. The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) is responsible for ensuring the safety of medicines within the EU. The PRAC assesses safety signals generated through the EU pharmacovigilance system and recommends the needed changes to risk management plans or conditions of the authorized use of medicines. PRAC also prepares opinions on new medicines and is involved in the periodic assessment of the safety of the already approved medicines.

The PRAC also provides general recommendations on pharmacovigilance to the European Commission and other EMA committees. The EMA is further responsible for the safety monitoring of clinical trials conducted in the EU through its Clinical Trials Facilitation Group (CTFG). The CTFG supports competent national authorities responsible for authorizing clinical trials and inspecting clinical trial sites.

The EMA also cooperates with various stakeholders, such as Member States, academia, and the pharmaceutical industry, to ensure medicines' safety. It supports initiatives promoting best practices in pharmacovigilance, publishes guidelines for the implementation of pharmacovigilance, and collaborates with the European Commission to implement the EU pharmacovigilance legislation. Moreover, the EMA provides technical and scientific advice to the European Commission related to the implementation of EU pharmacovigilance legislation, develops and harmonizes pharmacovigilance systems across Member States, and works with international organizations such as the World Health Organization (WHO) and the Council of Europe to share best practices and promote the exchange of pharmacovigilance information.

The EMA also operates a pharmacovigilance database, the pharmacovigilance database, which collects, analyses, and distributes information on adverse events associated with medicines. The European Commission and competent national authorities across the EU manage this database. The database collects information to monitor safety signals and identify patterns of medicine-related adverse reactions. The European Medicines Agency (EMA) database is an essential tool for pharmacovigilance. This database contains information about medicines approved in the European Union and advice on their safety, quality, and efficacy. The database also provides data for ongoing monitoring of the safety and efficacy of existing and new medicines, including the results of clinical trials and post-marketing studies. All this information is collected from the participating Member States and other sources. The EMA database includes information on adverse reactions, product recalls, and interactions with other medicines. The data is used to investigate trends and to identify potential safety and efficacy concerns. The database also stores information on product components to help improve the understanding of the quality of medicines, including the presence and level of impurities. It can be used to identify the source of counterfeit medicines. The database also provides detailed and up-to-date information on the economics of medicines and can be used to inform pricing, reimbursement, and healthcare decision-making. The database is an invaluable resource to help ensure the safety and efficacy of medicines and supports the activities of national pharmacovigilance committees. Thus, the EMA plays a key role in ensuring the safety of medicines in the EU through its complete tasks in pharmacovigilance.

The EMA also sets GMP standards for the design, safety, and efficacy of the drugs and their manufacturing processes. These standards help ensure that all medicines in the EU comply with the highest quality, safety, and efficacy standards. The EMA also has a role in the professional training of personnel manufacturing and approving medicines.

The EMA works with key stakeholders and partners, such as the European Commission, member countries, academia, industry bodies, patient organizations, and healthcare professionals, to ensure the long-term success and future of the European medicines sector. It also plays a vital role in developing new medicines and treatments by providing an independent assessment and scientific advice to support the safe and effective use of medicines.

 doi:10.20944/preprints202408.0031.v1

The EMA is responsible for the scientific evaluation of applications to authorize medicines and medical devices in the EU. For each authorized medicine, the EMA sets out the conditions and requirements that the manufacturer must comply with to ensure the medicine's safety, quality, and efficacy. The EMA also sets out guidelines and procedures for the manufacturing, storing, and distributing of medicines, which the EMA's inspectors closely supervise.

The European Medicines Agency is integral to the European Union's medicines regulatory process. It plays a vital role in ensuring that only safe and effective medicines are approved for sale or use in European clinical trials. Its influence is felt worldwide and contributes to millions of citizens' health and safety. The agency is committed to a continuous and evolving process of evaluating and supervising medicines and promoting innovation while protecting the health of citizens worldwide.

The Directorate General of Drug Administration (DGDA)

The Directorate General of Drug Administration (DGDA) is under the Ministry of Health and Family Welfare, Government of Bangladesh. DGDA was established in 1973 as an autonomous agency overseeing the regulation and control of drug production, import and export, manufacture, sales, advertisement, and distribution of all pharmaceutical products. The organization's primary purpose is to regulate and monitor the quality, efficacy, and safety of drugs entering and leaving the country and comply with international standards. The DGDA is governed by the National Drug Policy, designed to ensure that drugs are used safely and responsibly. The objectives of this policy include promoting the rational use of drugs and providing guidance to healthcare professionals; establishing standards of safety and quality of drugs; regulating the production and sale of drugs; protecting the public from counterfeit and substandard drugs; and encouraging the use of effective drugs. The DGDA also has an Ethics Committee responsible for considering ethical aspects of drug research and development.

History of The Directorate General of Drug Administration (DGDA):

DGDA was established in 1973 by the Drug Control Ordinance 1973 of Bangladesh. The Drug Control Act 1990 was passed in 1990. The latest amendment of the act was made in 2009. This amendment provided an autonomous and independent body, the Drug Administration Advisory Council (DAAC); it established the criteria for drug registration, new drugs, and clinical trials. In order to ensure quality and safe medicines are available to everyone, the Drug Administration Regulatory and Development Authority (DARDA) was created in 2010. It is mainly responsible for carrying out the following tasks:

- Formulating the rules and regulations related to importing, manufacturing, marketing, and selling drugs, vaccines, and other healthcare products.
- Assisting the Government in formulating and reviewing national policies related to drugs and other healthcare products.
- Setting up and maintaining drug safety monitoring centers to monitor drug safety, efficacy, and quality.
- Working closely with the health services department to promote rational drug use.
- Regulating the sale of over-the-counter drugs in the country.

Organizational Structure of The Directorate General of Drug Administration (DGDA):

The DGDA also works with the Ministry of Health and Family Welfare to develop national strategies for advancing public health. It is responsible for the formulation of laws and regulations related to the control and use of drugs. The DGDA educates the public on the proper and safe use of drugs and actively participates in developing healthcare policies in the country. It also provides advisory services to ensure the proper use of drugs and is responsible for licensing medical practitioners and healthcare products in Bangladesh.

Several divisions support the DGDA and work in cooperation with other organizations. These include the Bangladesh Drug Regulatory Authority, Bangladesh Pharmaceuticals Management Authority, Bangladesh Institute of Health Sciences, Ministry of Health and Family Welfare,

 doi:10.20944/preprints202408.0031.v1

Bangladesh Medical Association, and Bangladesh Pharmaceutical Association. The DGDA also cooperates with international organizations such as the World Health Organization, Food and Drug Administration, and International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

The DGDA is headed by a Chairman appointed by the Government and is assisted by an Executive Director, the day-to-day head of the organization. The DGDA is divided into four main divisions, and a Divisional Director heads for each division.

The Directorate General of Drug Administration functions under the guidance of the Chairman, who is responsible for providing overall leadership and general direction of the organization. The primary role of the Chairman is to direct, control, and monitor the activities of the Directorate General. The Chairman of the Directorate General of Drug Administration (DGDA) plays a vital role in ensuring the effectiveness, safety, and availability of medicines available in the country. The Chairman is responsible for supervising the organization and setting regulations, laws, and standards for approving and quality assurance drugs and other health-related products. The Chairman is also responsible for establishing a solid relationship with relevant stakeholders such as drug regulatory authorities of other countries and international organizations such as the World Health Organization (WHO). It is also the responsibility of the Chairman to ensure that illegal and substandard products do not compromise public health.

The Chairman is also responsible for ensuring that access to and use of medicines is enhanced through efficient supply chain networks and procurement processes. To ensure this, the Chairman should review and assess the purchasing of medicines to ensure quality and compliance with the relevant regulations. The Chairman should also collaborate with relevant stakeholders to ensure the safety and affordability of medicines in the country.

Furthermore, the Chairman oversees the drug licensing and registration process. This includes reviewing and approving applications for importing, selling, and distributing medicines in the country. The Chairman should clearly understand the drug approval protocols, national and international regulations, and ethical standards to ensure that only high-quality drugs are approved for use.

The Executive Director works closely with the Chairman by overseeing day-to-day operations and providing support in preparing reports, formulating policies, and implementing strategies. Executive directors in the Directorate General of Drug Administration play a significant role in ensuring the supply of safe and quality drugs to public health. They are responsible for developing policies and implementing plans to maintain drug safety, efficacy, and quality in the market. They also supervise the activities of drug research institutes, manufacturing and marketing establishments, laboratories, and distribution centers and ensure that they meet the relevant quality standards. These directors also set safety parameters for the drugs' sources, determining the drug's strength and purity, and packaging. They also supervise staff for inspection and monitoring and take necessary corrective measures when required.

Moreover, executive directors in the Directorate General of Drug Administration research newer prevention, assessment, and control methodologies of drug safety and usage. They are also responsible for reviewing the contraindications and adverse reactions associated with drugs and suggesting alternative modes of treatment. Besides, they ensure proper labeling and dissemination of information related to the drugs and coordinate their seamless supply.

The Divisional Directors provide the technical expertise to activities such as registering drugs and medical devices, manufacturing and control, market surveillance, pre-market assessment, post-market monitoring, and enforcement. Divisional Directors are responsible for the effective overall performance of their Directorate in the Directorate General of Drug Administration. They are expected to monitor and coordinate all the activities and functions of the Division of Drug Administration to ensure the organization's overall development and success. They are also responsible for the efficient and effective supervision of the staff assigned to their Division and for the creation, implementation, and evaluation of programs and policies in support of the mission and goals of the Directorate.

 doi:10.20944/preprints202408.0031.v1

The Divisional Director must ensure that all relevant laws, regulations, and regulations of the United Nations Drug Control Program, national laws, and Provincial laws and regulations are observed. They are also responsible for registering and licensing pharmaceutical drugs and medicines and ensuring their availability in appropriate supply and dosage levels throughout Bangladesh. In addition, they must also coordinate between various departments of the Division and its associated activities.

The Divisional Director is also responsible for developing and implementing strategies for timely and effective control and enforcement of the legal control of narcotic drugs and psychotropic substances. They must also be knowledgeable about the global narcotics problem and its associated economic and social implications. They have the responsibility of developing and implementing training and awareness programs aimed at increasing the knowledge of the public concerning the problems of illegal drugs and the efforts of the Directorate in its mission to curb the illicit trafficking of such substances. The Divisional Director must also take all necessary measures to maintain safe drug manufacturing and storage sites.

The Executive Director carries out the duties of the Chairman in his absence. At the same time, the Divisional Directors ensure the proper functioning of their respective divisions by supervising the functions of their respective departments and implementing policies and programs. Thus, the collective role of the Chairman, Executive Director, and Divisional Directors ensures that the Directorate General functions efficiently and effectively in ensuring safe and quality drugs.

The four divisions are:

1. Quality Assurance Division
2. Licensing and Registration Division
3. Drug Surveillance and Investigation Division
4. Foreign Regulatory Affairs Division

- The Quality Control (QC) Division ensures the safety, efficacy, purity, and potency of drugs and other healthcare products. Its functions include inspecting drug manufacturing sites, sample collection and testing, issuing registration certificates and licensing drug manufacturing sites, monitoring the work of drug laboratories, granting and suspending permits for manufacturing and marketing of drugs, and setting and following the prescribed standards and guidelines.
- The Drug Survey and Statistics Division is responsible for conducting surveys, collecting statistics related to drug prices and markets, and analyzing them to assess the industry's economic impact.
- The Law Enforcement Division enforces drug laws per the Drug Rules of 1945 and the Drugs Act of 1940. It also serves as an interface between the DGDA and the respective law enforcement agencies in the country.
- The Drugs Consultation, Registration & Approval Division is responsible for registering new products, approving the registration of existing drugs, and providing advice and consultation on drug-related matters.

The DGDA is fully equipped with modern laboratory equipment and technical expertise for testing and examining the quality of drugs. It also has facilities for drug registration, licensing, and certification. It also has facilities for drug manufacturing control and inspection. The DGDA has a comprehensive information system connected to Dhaka and Northeastern Sylhet offices.

The DGDA ensures the safe and effective use of pharmaceuticals and healthcare products by following good manufacturing practices and pharmacovigilance. It monitors clinical trials to ensure the safety and efficacy of trials conducted in Bangladesh. The DGDA also provides technical support to local drug regulatory authorities and other stakeholders to ensure the safety and quality of drugs.

The DGDA implements regulations and guidelines laid down by the Drug Administration Regulatory and Development Authority (DARDA) regarding drug quality, efficacy, and safety. It issues licenses, regulations, and guidelines to drug manufacturers, importers, and distributors and conducts surveillance and inspections to ensure safety and quality standards compliance. It also conducts awareness programs, directs the compilation of the national drug formulary, and conducts research on drug safety and efficacy.

 doi:10.20944/preprints202408.0031.v1

Role and Function of The Directorate General of Drug Administration (DGDA):

DGDA plays a significant role in providing quality and safe drugs in Bangladesh and abroad. It is a member of the International Council on Harmonization (ICH) of Technical Requirements for Pharmaceuticals for Human Use (ICH Q1A-R2), the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Q2(R1)), and the Regional Regulatory Conference for Drug Registration (RRDRC). It also works with international organizations like the US Food and Drug Administration (FDA) and the United Nations International Drug Control Programme (UNIDCP).

The DGDA performs various functions within Bangladesh and in the international arena. These include:

- monitoring the quality and safety of drugs in Bangladesh;
- Provide technical advice and guidance to drug manufacturers in Bangladesh;
- registering and evaluating new drugs produced in Bangladesh;
- conducting research and clinical trials on drugs;
- monitoring the quality and safety of drugs imported into Bangladesh;
- conducting inspections of drug stores and other facilities;
- participating in international conferences and other activities related to drug regulation;
- Provide training and technical assistance to other countries.

The DGDA is critical in providing quality and safe drugs in Bangladesh and internationally. It is responsible for ensuring that drugs produced, sold, and imported in Bangladesh meet the standards set out in international guidelines and that only safe and effective drugs are used by the people of Bangladesh. The DGDA works closely with other international organizations to ensure that drug quality and safety standards are raised worldwide.

The Directorate General of Drug Administration (DGDA) plays a crucial role in implementing current Good Manufacturing Practices (cGMP) in Bangladesh. cGMPs are the essential standards the World Health Organization (WHO) and other international organizations set to regulate the quality of drugs and pharmaceuticals. These standards define the design, control, and documentation of processes used to develop and manufacture quality products. The DGDA sets and enforces cGMPs under the WHO regulations. It ensures compliance through regular inspection and monitoring of pharmaceutical companies in Bangladesh. It reviews and approves the manufacturing and distribution companies' quality procedures, equipment, and processes.

The DGDA also serves as the primary point of contact for manufacturers and consumers regarding drug regulation. It works with the local regulatory authorities to ensure the drug products meet their required standards. The DGDA assists manufacturers in developing and submitting drug documentation to obtain product registration and marketing authorization. It also provides training on cGMPs to ensure compliance for manufacturers. The Directorate General of Drug Administration plays a key role in implementing current Good Manufacturing Practices (cGMP) in Bangladesh. It sets and enforces the regulations laid down by the World Health Organization and other International Organizations. It reviews, approves, and monitors manufacturing and distribution companies' quality procedures and processes. The DGDA also aids manufacturers in developing and submitting drug documentation for product registration and marketing authorization. In addition, it provides training on cGMPs to ensure compliance.

Bangladesh's Directorate General of Drug Administration (DGDA) plays a crucial role in ensuring the safety of the healthcare system by making pharmacovigilance initiatives. They are the regulatory authority responsible for monitoring and safeguarding the drug supplies in Bangladesh. In addition to regularizing and registering the manufacture, distribution, and sale of drugs in the country, the DGDA also ensures the safe and effective utilization of such drugs. The DGDA monitors the safety of drugs by employing a range of strategies and activities under pharmacovigilance. These activities range from the setting up of national pharmacovigilance centers in order to record and analyze adverse drug reactions (ADRs) to encouraging spontaneous reporting of ADRs, training human resources, and continuously assessing the safety of medications.

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The initiatives of the DGDA for pharmacovigilance have helped Bangladesh build a comprehensive system for monitoring the safety of medications. The ADR reporting system established by the DGDA is a key tool for collecting vital data on the safety of drugs in the country. The DGDA ensures that the process of ADR reporting is user-friendly and encourages healthcare professionals and consumers to report any incident. The data collected through these reports are compiled and analyzed by the national pharmacovigilance center and used to make evidence-based drug policy decisions. Further, the DGDA has undertaken initiatives to raise the awareness of healthcare providers and consumers regarding the importance of pharmacovigilance and the need to report ADRs.

Overall, the efforts of the DGDA to establish and maintain national pharmacovigilance systems have been commendable and have gone a long way in ensuring the safety of the healthcare system in Bangladesh. With its stringent regulatory activities, the DGDA has successfully protected consumers from spurious and adulterated drugs and reduced ADRs caused by medication errors.

Directorate General of Drug Administration (DGDA) has been leveraging technology to develop a nationwide drug database for pharmacovigilance. This centralized database is being implemented as part of the Drug Information System (DIS). It is expected to help public health professionals to identify any safety issues related to medicines more quickly. The system, backed by the DGDA, is expected to provide a comprehensive overview of all the pharmaceutical products that are actively marketed in the country. This information will include a comprehensive list of active ingredients, dosages, trade and brand names, labeling, frequency of use, and other information related to the drugs. Such information will help the regulatory authorities to monitor any potential risk of harm associated with marketed drugs. The system will also provide an integrated drug management platform that will help track the status of drugs registered in the country and facilitate the management of information related to monitoring, enforcement, and reporting of adverse events, providing a real-time view of any actual risks related to medicines. The Pharmacovigilance Division of the DGDA has also developed a software application for this purpose, i.e., a pharmacovigilance system, which will provide monitoring, reporting, and follow-up actions related to any side effects and other hazards identified in the products. Such data will be available on time and stored in a secure repository, allowing easy retrieval and analysis. By providing an effective and efficient drug information platform, the DIS will enable better health care for millions of people in the country.

Conclusion:

In conclusion, the role of the drug regulatory body is essential in ensuring the safety and effectiveness of drugs available to consumers. The drug regulatory body is responsible for setting standards and evaluating various drugs' safety, effectiveness, and quality prior to approval. They must monitor clinical trials conducted by drug manufacturers and keep the public informed of the results. They also monitor the distribution and use of approved drugs and respond to issues such as adverse reactions and off-label uses. The drug regulatory body is in place to protect the public from unsafe or ineffective drugs. They are an essential part of the healthcare system, and without their oversight, health risks due to unsafe drugs could be increased. The European Medicines Agency (EMA) and the Directorate General of Drug Administration (DGDA) have implemented numerous measures over the years to improve the quality of medicines and the safety of healthcare systems. They guide Member States, pharmaceutical companies, healthcare professionals, and patients in evaluating, approving, and monitoring medicines. The EMA is responsible for authorizing and supervising medicinal products for human and veterinary use in the European Union (EU). It also coordinates with the Member States on pharmacovigilance and other issues. The DGDA regulates drug safety and efficacy, standards of practice in the drug industry, and research into the effects of drugs and medical products in Bangladesh. Both agencies have worked hard to ensure that the quality and safety of medicines supplied to the patient are up to the highest standards.

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