



Guidelines for Reliance and Recognition on the regulatory decisions of other NRAs

Directorate General of Drug Administration
Ministry of Health and Family Welfare
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Message from the Director General, Directorate General of Drug Administration

It is a matter of great pleasure that the core functions of DGDA are now being strengthened through the regular publication of guidelines covering various classes of medical products, as well as other key regulatory areas. This ongoing initiative reflects DGDA's commitment to enhancing regulatory efficiency, transparency, and consistency in alignment with international best practices. On this aspect, "*Guidelines for Reliance on other NRAs in Bangladesh*" is one of the very important guidelines which will help the Pharmaceutical Industry, Researchers, Academicians as well as Regulators to ensure quality, efficacy and safety of medical products registered in Bangladesh.

This guideline is prepared as a supplementary guidance with WHO TRS 1033, Annex 10. So that Medical products registration would be given in Bangladesh with a high standard to get global recognition as well as protecting the health of the patients who are in dire need of these products.

I would like to express my heartfelt appreciation to the members of the working committee for their hard work and commitment.

Director General
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Acronyms and Abbreviations:

COPP	:	Certificate of Pharmaceutical Products
CPAR	:	Collaborative Procedure for Accelerated Registration
DCC	:	Drug Control Committee
DGDA	:	Directorate General of Drug Administration
EDM	:	Essential Drugs and Medicines
EMA	:	European Medicines Agency
EUA	:	Emergency Use Authorization
FDA	:	Food and Drug Administration
FSC	:	Free Sale Certificate
GMP	:	Good Manufacturing Practices
GRP	:	Good Regulatory Practices
INN	:	International Non-Proprietary Name
LDC	:	Least Developed Country
LR	:	Lot Release
MA	:	Marketing Authorization
MC	:	Market Surveillance and Control
MHRA	:	Medicines and Healthcare Products Regulatory Agency
NDCL	:	National Drug Control Laboratory
NRA	:	National Regulatory Authority
PIC	:	Pharmaceutical Inspection Convention
PIC/S	:	Pharmaceutical Inspection Co-operation Scheme
PMDA	:	Pharmaceuticals and Medical Devices Agency
RI	:	Regulatory Inspection
RRA	:	Reference Regulatory Authority
SWISSMEDIC	:	The Swiss Agency for Therapeutic Products
TGA	:	Therapeutic Goods Administration
TRS	:	Technical Report Series
USP	:	United States Pharmacopoeia
VL	:	Vigilance
WHO	:	World Health Organization
WLA	:	WHO Listed Authorities

Definitions:

Accelerated Registration: Accelerated registration is a pharmaceutical regulatory process intended to reduce the time for registration and introducing new product in the market through reducing time and burden for dossier assessment, product review, inspection and approval for medicines, vaccines, biologicals, bio-similar, medical devices and in-vitro diagnostics. The process expedites the transition from application to market authorization, guaranteeing prompt access to quality-assured, safe and effective medical products.

Collaborative Procedure: The Collaborative Procedure for Accelerated Registration (CRP) is a World Health Organization (WHO) process that helps national regulatory authorities (NRAs) expedite the national registration of WHO-prequalified pharmaceutical products and vaccines. It achieves this through improved information sharing and regulatory reliance on the WHO Prequalification Team's (PQT) scientific assessment, thus accelerating access to essential medicines and reducing duplicated effort for both manufacturers and national regulatory bodies.

Cluster: Cluster refers to an aggregation of cases grouped in place and time that are suspected to be greater than the number expected, even though the expected number may not be known.

Disease Outbreak: An Outbreak carries the same definition as an epidemic but is often used for a more limited geographic area.

Endemic: Endemic refers to the constant presence and/or usual prevalence of a disease or infectious agent in a population within a geographic area. The term endemic describes something that is constantly present or native to a specific geographic area, population or environment. Its meaning varies slightly depending on the field. A disease is considered endemic when it persists at a stable, predictable level within a certain region.

Epidemic: An epidemic is the rapid spread of disease to a large number of hosts in a given population within a short period of time. An epidemic refers to an increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area. Epidemics occur when an agent and susceptible hosts are present in adequate numbers and the agent can be effectively conveyed from a source to the susceptible hosts. More specifically, an epidemic may result from:

- A recent increase in the amount or virulence of the agent,
- The recent introduction of the agent into a setting where it has not been before,
- An enhanced mode of transmission so that more susceptible persons are exposed,
- A change in the susceptibility of the host response to the agent, and/or
- Factors that increase host exposure or involve introduction through new portals of entry.

Framework: Framework mean structural skeleton on which a system or functioning body establish and/or perform. In general, a framework is a real or conceptual structure intended to serve as a support or guide for the building or establish of something that expands the structure into something useful. A framework is the basic structure of something. It's a set of ideas or facts that provide support for something. In the case of business problems, a framework creates the basic structure that gives focus and support to the performing system.

A pharmaceutical regulatory framework is a structured system of laws, guidelines, and standards enforced by authorities (e.g., DGDA, MHRA, FDA, EMA) to ensure the safety, efficacy and quality of drugs. It governs the entire life cycle of pharmaceutical products, including development, manufacturing, testing, marketing and post-market surveillance.

INN: INN means International Non-Proprietary Name of a medicinal substance. An International Nonproprietary Name (INN) is a unique, globally recognized and non-proprietary (generic) name for an active pharmaceutical ingredient, assigned by the World Health Organization (WHO) since 1953. INNs facilitate safe prescription and dispensing by providing a universal identifier for medications,

often using consistent stems to indicate pharmacological relationships. All medicines has INN names which doesn't mean compendial or non-compendial, rather it means life-time unique name that has no specific proprietorship.

Marketing Authorization: Pharmaceutical Marketing Authorization (MA) is the official, mandatory license granted by a regulatory authority (e.g., DGDA, PMDA, TGA, MHRA, FDA) allowing a medicinal product to be registered, manufactured and sold in a specific market. It certifies that the drug has met required standards for safety, quality and efficacy based on comprehensive preclinical and clinical data.

Medical Products: Medical products are substances, instruments, apparatus, software or implants used to diagnose, prevent, monitor, treat or alleviate diseases, injuries or physiological processes in humans. These products range from pharmaceuticals (acting pharmacologically) to medical devices (acting physically). They are regulated to ensure safety and efficacy.

NRA: NRAs are national regulatory agencies responsible for ensuring that products released for public distribution (normally pharmaceuticals and biological products, such as vaccines and medical devices including test kits) are evaluated properly and meet international standards of quality, safety and efficacy. All countries need an NRA. Countries manufacturing medical products need to exercise six critical control functions and they need to exercise them in a competent and independent manner, backed up with enforcement power.

A National Regulatory Authority (NRA) is a governmental body or agency tasked with ensuring that products or services—most commonly medical products like pharmaceuticals, vaccines and devices—meet strict international standards of safety, quality and efficacy. They are responsible for market authorization, regulatory oversight and enforcing compliance to safeguard public health.

Pandemic: Pandemic refers to an epidemic that has spread over several countries or continents, usually affecting a large number of people. A pandemic is defined as “an epidemic occurring worldwide or over a very wide area, crossing international boundaries and usually affecting a large number of people”. The classical definition includes nothing about population immunity, virology or disease severity.

Public Health Emergency: A public health emergency (PHE) is an occurrence or imminent threat of an illness, injury or health condition caused by events like disease outbreaks, natural disasters or chemical/nuclear incidents. These events create widespread risks that overwhelm routine community capabilities, necessitating immediate, coordinated action by authorities to prevent or limit severe health impacts.

Reference Regulatory Authority (RRA): A Reference Regulatory Authority (RRA) is a trusted national or regional regulatory body, typically with high maturity (e.g., WHO-listed authorities) whose assessments, decisions and scientific work products are utilized by other regulatory agencies to inform their own, often accelerated, regulatory decisions. They facilitate reliance, allowing smaller authorities to leverage mature reviews for product registration. As per Drug and Cosmetics Act, 2023 Government may, by notification in the official Gazette, from time to time update Reference Regulatory Authority (RRA).

Registration: In general terms, registration is the act of enrolling or recording information in an official list or system. Pharmaceutical Registration is the process of signing up, enrolling, approval and/or authorization of a medical product. Pharmaceutical registration is the mandatory process of obtaining authorization from a national regulatory authority (NRA) to market a medicine, ensuring it meets strict standards of quality safety and efficacy. It involves evaluating a product's dossier (data on manufacturing, clinical and non-clinical studies) to permit legal sale.

Sameness of Medical Products: Sameness of medical products refers to the verification that a submitted, generic, or follow-on product has identical essential characteristics to a reference product approved by a stringent regulatory authority. It ensures the products share the same qualitative/quantitative composition, strength, dosage form, manufacturing process and intended use.

SRA: A Stringent Regulatory Authority (SRA) is a national drug regulatory body, recognized by the World Health Organization (WHO) that enforces rigorous, high-level standards for the quality, safety and efficacy of medicines and vaccines. These agencies are generally defined as members or observers of the International Council for Harmonization (ICH).

WHO Prequalification: WHO Prequalification (PQ) is a World Health Organization (WHO) program that assesses the quality, safety, and efficacy of key medical products—including medicines, vaccines and diagnostics to ensure they meet international standards. It facilitates UN and international procurement for developing countries by identifying trusted suppliers.

Background

Access to quality-assured medical products is an essential indicator for ensuring good health and better public health protection. Access to medical products is measured by the affordability, availability and reliability of medical products. An estimated two billion people have no access to essential medicines, effectively shutting them off from the benefits of advances in modern science and medicine. Reasons for limited/insufficient access are numerous, including insufficient/inadequate regulatory capacity and a lack of collaboration and work sharing between countries in the regulation of medical products. Among other Least Developed Countries (LDCs), Bangladesh made remarkable progress in being self-sufficient with locally produced medical products as it meets its 98% demand of medicines by local production. But, still 2% finished medicines are being imported. On the other hand, Bangladesh is still dependent on 85-90% imported pharmaceutical raw materials, 90-95% imported medical devices and surgical items and 98-99% dependent on imported health technologies. For the import of medical products, including finished pharmaceutical products, raw materials, medical devices, surgical items, in-vitro diagnostics and health technologies, the national regulatory authority of Bangladesh, the Directorate General of Drug Administration (DGDA), is mandated to conduct inspections of the source. But, due to limitations of resources, the Government of Bangladesh has some policy to rely on the decision of some stringent regulatory authorities (SRA) and agencies like the WHO and EMA which is known as the reliance and recognition procedure.

Reliance is a process that is “implanted” in facilitated national/international regulatory pathways. Promoting a more efficient approach to regulatory oversight, thereby improving access to quality-assured, effective and safe medical products over their entire life-cycle. According to the Drug and cosmetics Act, 2023, the DGDA may have confidence and reliance for recognition of the decision of other National Regulatory Authorities (NRAs), the European Medicines Agency (EMA) and the World Health Organization (WHO). Through the reliance mechanism, DGDA may skip regulatory inspection of the facilities from which medical products are intended to be imported. The reliance system already exists but to lay out in detail, aligning with communication and decision-making channels, up-to-date legal provisions and requirements, the guideline for reliance and recognition is essential to update.

According to the guidelines, Good Reliance Practices (GReIP) are anchored in overall good regulatory practices (GRP) (1), which provide a means for establishing sound, affordable, effective regulation of medical products as an important part of health system strengthening. If implemented effectively, GRP can result in consistent regulatory processes, sound regulatory decision-making, increased efficiency of regulatory systems and better public health outcomes.

For reliance and recognition, the DGDA first adopted the guideline as a supplementary guidance document of WHO TRS 1033, Annex 10, which was adopted by the DGDA, Bangladesh, on August 1, 2023.

Introduction

Reliance on the regulatory decision by other NRAs and recognition of other NRAs should be designed and developed, based on risk analysis considering potential threats to public health by the medical products to be imported in Bangladesh. The DGDA is mandated to conduct regulatory inspection of the source of medical products in the country of origin but the DGDA still has challenges in conducting regulatory inspection in other countries, due to limitations of resources. If regulatory inspection is essential, the DGDA may conduct regulatory inspection in other countries and in that case, the relevant business entity will cover the costs related to attending the inspection, testing of the product sample and review of the dossier.

Establishing and sustaining mature regulatory systems requires adequate resources, including skilled, capable human resources and a significant financial investment. The globalization of markets, the sophistication of health technologies, the rapid evolution of regulatory science and the increasing complexity of supply chains have shown regulators the importance of international cooperation in ensuring the safety, quality, efficacy or performance of locally used products. In view of the extent and complexity of the regulatory oversight required to address these challenges, NRAs must consider enhanced, innovative, more effective forms of collaboration to make the best use of the available resources and expertise, avoid duplication, and concentrate their regulatory efforts and resources where they are most needed. Reliance represents a smarter, more efficient way of regulating medical products in the modern world. Countries are therefore encouraged to formulate and implement strategies to strengthen their regulatory systems consistent with GRP, including pursuing regulatory cooperation and convergence as well as reliance. Reliance benefits patients and consumers, industry, national governments, the donor community and international development partners by facilitating and accelerating access to quality-assured, effective and safe medical products.

The use of reliance to enhance the efficiency of regulatory systems has a long history. The WHO Certification scheme on the quality of pharmaceutical products moving in international commerce, introduced in 1969, is a form of reliance as it provides assurance to countries that participate in the Scheme on the quality of pharmaceutical products. The European Union introduced the “mutual recognition procedure” for marketing authorizations between its member states in 1995 and the outcomes of good manufacturing practices inspections have been shared for years in the context of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) and mutual recognition agreements.

WHO investigated the use of reliance more recently in a survey conducted on behalf of the International Pharmaceutical Regulators Programme. The results showed that regulatory reliance is broadly accepted and widely practiced with regard to medical products, especially among well-resourced regulatory authorities. The responses also reflected an evolving situation, with varying experience and promise in the use of reliance-based approaches. While the use of reliance may be an emerging trend in some regions, the commonly stated goals are to increase efficiency, help to strengthen regulatory systems and optimize the use of resources. The results and suggestions from the survey were taken into account in preparation of this document. This document and the additional guidance that follows are intended to assist countries in implementing a sound, evidence-based, practical and effective approach to reliance.

Scope

This guideline shall be applicable to the reliance on the regulatory decisions made by other NRAs for the regulation of medical products. To harmonize and align the regulatory processes, the guideline will be applicable for –

- 1 Registration and Marketing Authorization of Medical Products
- 2 Vigilance of Medical Products
- 3 Market Surveillance and Control
- 4 Licensing of Premises
- 5 Regulatory Inspection
- 6 Clinical Trial Oversight
- 7 Laboratory Access and Testing & NRA Lot Release

Objective

This guideline is developed to generate a common understanding between stakeholders, counterparts, and regulators regarding the cases on which the regulatory decision of the DGDA may rely. Reliance and recognition system is an effective approach –

- a) To optimize regulatory efficiency.
- b) To reduce duplication of effort and optimize regulatory resources.
- c) To minimize costs related to the import of medical products in the country.
- d) To make the process faster toward promoting better access to medical products.
- e) To promote convergence of regulatory standards and practices.

Approaches of the DGDA toward Reliance:

For appropriate use of reliance approach in various regulatory functions, DGDA considered possible approaches keeping in view the available legal provisions, need and dynamics of the national health and regulatory system, judicious use of available resources (both human and financial) and it will ultimately lead to more evidence-based and better-quality regulatory decisions, reduce duplication of effort and eventually ensuring timely access to safe, efficacious and quality assured therapeutic goods. The following are the basic DGDA's approaches for following reliance:

This guideline serves as a comprehensive resource for both applicants and DGDA's regulators by outlining the specific requirements and processes while considering registration of medicine (pharmaceutical and biological drugs) in Bangladesh. These medicines include new (innovator), generic drug products (pharmaceuticals), and bio-similar products (biologicals) which must have already received approval from a Reference Regulatory Authority.

By adopting a reliance approach, DGDA can make the most efficient use of its resources by reducing the burden of duplication of work carried out by RRAs and minimizing redundant efforts for applicants and manufacturers.

This guideline covers the entire spectrum of the approval process i.e. assessment of registration application for safety, efficacy, and quality parameters, and also post-approval variations, pharmacovigilance and lot release procedure.

Principle of Reliance:

Reliance is practiced, making the best use of the available resources, both human and financial. This allows the allocation of resources to other areas of regulatory functions for increasing the effectiveness of the local regulatory oversight. In addition, reliance can lead to more evidence-based and better-quality decisions. Basic principle of reliance implies that regulatory work is shared by any means by reference to regulatory authorities through dossier assessment reports, GMP inspection reports, quality control reports, safety signals, etc., while DGDA considers the data of reference regulatory authorities while rendering its regulatory responsibilities according to its own scientific knowledge and regulatory procedures.

The reliance can be unilateral, mutual, or multilateral and provides a basis to arrive at a regulatory decision while considering local regulatory responsibilities and procedures. The basic aim is to gear up the evaluation process for the enlistment/registration/market authorization and surveillance of Medical products. The key principles for reliance on information or decisions of reference regulatory authorities are as follows:

Protection of Public Health: Protecting public health remains the foremost priority of the DGDA by ensuring the quality, safety and efficacy of medical products to be supplied for Medical use in Bangladesh.

Good governance and systems transparency: Ensuring open communication through proper regulatory channels and sharing of relevant information is a hallmark of the DGDA to maintain transparency. The DGDA ensures accountability by upholding the responsibility for the regulatory decisions taken.

Faster Access to Medical Products: Recognizing the regulatory decisions of Reference Regulatory Authorities (RRA) provides the DGDA with the opportunity to timely introduce new medicines in Bangladesh and make the registration process faster, robust and reliable.

Risk-Based Approach: It is regulatory best practice to implement quality risk management. For example, a product that is prequalified by WHO or approved by other reference regulatory authorities like USFDA, PMDA, TGA, UKMHRA, Swissmedic, France Regulatory Authority, German Regulatory Authority, and EMA, etc., has low risk with respect to quality, safety and efficacy compared to a product with no such prior reviews and /or their reviews could be adopted.

Optimum Use of Available Resources: DGDA allocates resources and a level of effort that is proportionate to the level of risk. DGDA believes in reliance and optimal use of available resources. This approach is undertaken to ensure that patients are provided with safe, efficacious and quality-assured Medical products. This includes removing duplication and identifying elements in the benefit-risk assessment that are critical in the domestic situation. For innovative products, this may mean bridging the benefit-risk assessment done by reference regulatory authorities to ensure the early availability of innovative treatment to the local population, and the suitability of its use with the local climatic conditions.

Ensuring the “Sameness “of Products: One of the principles for reliance is to ensure identical products with reference to regulatory authorities, or where differences exist, these are clearly stated and defined. The DGDA MA team will check the sameness of products as per Annexure-2.

Compliance with National Regulatory Requirements: Reliance on reference regulatory authorities does not substitute compliance with applicable national requirements. Submissions and documentary evidence should be consistent and comply with local regulatory and legal requirements.

Flexibility to Adapt National / Domestic Situations: DGDA may devise /adapt /revise its own national strategies or procedures that may suit national or domestic circumstances in the best public interest to ensure the availability of safe, efficacious and quality therapeutic goods.

Promoted collaboration, networking, and system harmonization: The DGDA promotes collaboration by working in partnership with Reference Regulatory Authorities to ensure consistency in regulatory standards as per international requirements

Regulatory Framework:

All of the regulatory activities of the DGDA are mandated by a Regulatory Framework, which consists of two parts: Regulatory Provisions and Legal Provisions. As part of a legal mandate, DGDA has a latest act, The Drug and cosmetics act, 2023. The reliance and recognition process is completely justified and mandated by this act.

In accordance with Chapter III, Section 17 of The Drug and cosmetics act, 2023 -

Good practice relating to the manufacture and quality control, distribution, supply, and preservation of drugs. — (1) The manufacturing or selling establishment of drugs shall follow the Good Practices (GxP) guidelines of the World Health Organization relating to manufacture, quality control, distribution, supply and preservation of drugs.

(2) The Government may prepare guidelines in respect of manufacture, quality control, distribution or supply, and preservation of drugs, following the guidelines made by The World Health Organization and other recognized international organizations.

In accordance with Chapter VII, Section 41:

(5) The Directorate may, in case of registration of importable drugs, if necessary, inspect the manufacturing premises of the manufacturing establishment for verification of the Good Manufacturing Practice (GMP).

(6) All expenses in respect of the inspection specified in sub-section (5) shall be paid by the manufacturing establishment at such rate as may be prescribed by the Government, from time to time, by rules or order.

In accordance with Chapter VII, Section 42:

(3) The Directorate may, in case of registration of importable raw materials for the manufacture of drugs or packaging materials of drugs, if necessary, inspect the manufacturing premises of the manufacturing establishment for verification of the Good Manufacturing Practice (GMP).

(4) All expenses in respect of inspection specified in sub-section (5) shall be paid by the manufacturing establishment at such rate as may be prescribed by the Government, from time to time, by rules or order.

In accordance with Chapter XII, Section 68:

Formulation of policies or guidelines, etc.—For carrying out the purposes of this Act, the Government may, by issuing administrative orders or notifications, formulate necessary policies or guidelines and determine the scope of work, including the formation of cells or committees.

In accordance with Chapter XIII, Section 73:

Following the decisions of the Authorities listed by the World Health Organization. — The Directorate may, if necessary, follow decisions of the Authorities listed by the World Health Organization in respect of decisions to be taken thereby.

Selection Criteria of Reference Regulatory Authorities for Reliance and its basis:

Criteria for selection of Reference Regulatory Authorities:

The Directorate General of Drug Administration (DGDA) shall select Reference Regulatory Authorities (RRA) based on the following criteria:

- a) In compliance with the Drug and cosmetics act, 2023, the National Drug Policy, 2016, and any amendments made thereunder.
- b) Where deemed necessary, the DGDA may consider and adopt decisions of regulatory authorities recognized or listed by the World Health Organization (WHO).
- c) Where deemed necessary, the DGDA may consider and adopt decisions of the authority is recognized as a Stringent Regulatory Authority (SRA).

- d) The authority demonstrates a high level of regulatory capacity and performance, particularly in the evaluation and approval of newly developed innovative drugs.
- e) The DGDA and/or its Expert Committee and/or the Drug Control Committee (DCC) may determine the selection of an RRA based on national interest and country-specific requirements.
- f) Where applicable, the DGDA has entered into a Memorandum of Understanding (MoU), legally binding agreement, or established harmonized regulatory frameworks (including guidelines and regulatory requirements) with the authority.
- g) Any decision of the Government in this regard shall be published through an official Gazette notification.

Legal Basis for selection of reference regulatory authorities (RRA):

According to Drug and cosmetics act, 2023, National Drug Policy 2016, DCC 248 & DCC 250, one of the Reference Regulatory Authorities, selected as mentioned above. In the Drug and cosmetics act, 2023, RRA are enlisted under Chapter III, Section 17, Chapter VII, Section 41, Chapter VII, Section 42, Chapter XII, Section 68, Chapter XIII, Section 73, the DGDA may select RRA for reliance on regulatory decision and waiver of inspection for the source manufacturers from the RRA.

Mechanism of Reliance:

Licensing authority of Drugs in Bangladesh rely on the decision of the RRA for faster it's marketing authorization process. The Government of Bangladesh (GoB) in collaboration with the DGDA, has established several committees to facilitate the selection of Reference Regulatory Authorities (RRA), with a view to relying on their regulatory decisions and enabling expedited product registration, with or without inspection, where appropriate. Especially, the GoB and DGDA established mechanisms for reliance during an emergency, pandemic, and/or epidemic outbreak. During an emergency, DGDA issues an emergency use authorization (EUA) in consultation with a public health emergency committee.

Emergency Use Authorization (EUA) for Marketing Authorization (MA):

DGDA MA Department could consider for EUA as per the gazette notification published on 17 May 2020 in section 2 and Drug and Cosmetics Act 2023 section 22 (4)

EUA could be considered on the basis of EU listing by WHO or an EUA issued by any of the DGDA reference NRAs, such as USFDA, PMDA, UKMHRA, TGA, SWISSMEDICS, EMA, Germany, and FRANCE Regulatory authority, or Medical products having EUA from the country of origin, having satisfactory clinical data (Phase-1, 2, and 3) recommended by the Public Health Emergency Committee.

In case of other regular situations, for faster registration, marketing authorization, and access, DGDA uses reliance mechanisms in the following cases -

Collaborative Procedure for Accelerated Registration (CPAR): For faster registration of Medical products and getting access to the WHO database regarding WHO Prequalified Medical products, DGDA signed an agreement with the WHO and became a participating member for CPAR.

Clinical Trial Protocol and Report: The DGDA accepts clinical trial results for new Medical products from the source/manufacturers from a country with the RRA. In addition, for the acceptance of clinical data (Phases I, II, and III), additional clinical trial reports will be required from countries with ethnic factors similar to those of Bangladesh. Reliance approaches can facilitate timely access to safe, effective, and quality-assured drug products and can help in regulatory preparedness and response, particularly during public health emergencies.

Pharmacovigilance Report: The DGDA accepts the risk benefit evaluation report of the medical products of the RRA through RMP during registration procedure as per prevailing GVP guideline.

Regulatory Inspection and Lot Release: GMP certificate for imported API source validation and Lot release certificate from the NRA of the country of origin is required. To import API, importer should

submit source validation related documents according to the DGDA checklist (SOP for Registration Vaccine & Biological Products)

Areas for Reliance in Regulatory Process and Decision-making:

The DGDA is practicing a reliance or recognition mechanism for regulating Medical products, which falls under their mandate. The areas of reliance for different types of regulatory processes of Medical products are as follows:

Marketing Authorization of Medical Products:

The MA Function of DGDA is responsible for assessment, evaluation, and registration for Medical drugs. DGDA has adopted reference regulatory authorities, which are placed at Annexure-1 for reliance on their regulatory information in consideration of application through the abridged pathway for initial approvals, as well as the post-approval changes and renewals to facilitate the supply of the medicine and timely safety information for patients.

Currently, the Authority applies a reliance procedure for granting registration/ Market Authorization in the following circumstances: -

- a. For registration of import finished medical products DGDA consider evaluation/registration/COPP of reference regulatory authorities (RRAs) in case of review of the Medical Products.
- b. For drug substances/molecules that are already registered by the reference regulatory authorities in a particular strength and dosage form, they are considered safe and efficacious, while considering the registration of new drugs for a local perspective.
- c. DGDA has participated in the World Health Organization collaborative registration process to enable early access to those Medical Products which have been evaluated and listed as pre-qualified by WHO.

The mechanism adopted for relying on information encompasses the following:

- i. Review of assessment reports (if available), summary of product characteristics, and labeling information.
- ii. Recognition of reported safety and efficacy concerns of already registered medicines.
- iii. Review of Certificate of Pharmaceutical Products (COPP).
- iv. In case information is not available on the official website, the reference regulatory authority will be contacted directly via electronic mail for a query or clarification on a particular issue under consideration.
- v. Regulatory status or any other regulatory information available in the public domain through their website.

Pharmacovigilance Activities:

The Directorate General of Drug Administration (DGDA), as the National Regulatory Authority, is responsible for ensuring the safety of marketed medicinal products through the implementation of a robust pharmacovigilance system in alignment with the World Health Organization (WHO) and the international pharmacovigilance guidelines. This includes systematic activities for signal detection, validation, assessment, and the initiation of proportionate risk minimization measures throughout the product lifecycle.

In accordance with good regulatory practices and principles of regulatory reliance, DGDA considers pharmacovigilance-related regulatory decisions and safety communications issued by Reference Regulatory Authorities (RRAs) as well as regional and international regulatory agencies/organizations and public health bodies. Where appropriate, such decisions are leveraged to support timely, evidence-based regulatory actions on pharmacovigilance issues while ensuring their relevance to national public health priorities and the local benefit–risk context as per recommendations of the Adverse Drug Reaction Advisory Committee (ADRAC).

Market Surveillance and Control:

DGDA is responsible for ensuring the quality of medical products. The reliance and recognition also enable the DGDA for better post-marketing surveillance, particularly related to safety and efficacy issues of

medical products. Reference regulatory authorities have a stronger reporting and information sharing system, which may be used by the DGDA as a useful tool for effective surveillance, evaluation of new indications or contraindications.

Regulatory Inspections (RI):

Compliance with Good Manufacturing Practices (GMP) is a mandatory consideration for registration of a Medical Product. DGDA has adopted a reliance approach for the verification of GMP of foreign manufacturing by applying a risk-based exemption approach. Importers applying for registration of imported drugs and biologicals are exempt from inspection of the manufacturing unit abroad if the criteria as defined in the “Import Policy for Inspection of Manufacturers Abroad” are fulfilled and the aforesaid policy is in place.

The reliance procedure for the exemption of GMP Inspections is applied in the following circumstances: -

- a. The applied medical product is registered or granted marketing authorization in any of the reference regulatory authorities as adopted by DGDA, and is considered for exemption from foreign inspections, or
- b. The applied medical product is exported to any EMA member state, and the manufacturing facilities within which the products are manufactured have been inspected by the EMA member's regulatory authority, or
- c. WHO pre-qualified medical products or the product registered through the WHO collaborative procedure, and the manufacturing facility is inspected by the WHO pre-qualification team.
- d. COPP issued/GMP certificate issued by DGDA reference NRAs
- e. For importing of finished product, WLAs (NRAs at least having maturity level 3) could be considered for exemption of GMP inspection on a case-by-case basis (if needed, inspection will be performed).
- f. For import of Bulk/ API / RTF from countries other than the above categories, GMP inspection will be performed on a case-by-case basis.

Clinical Trials Approval:

The mechanism of reliance in Bangladesh, the Directorate General of Drug Administration (DGDA) is the primary authority responsible for clinical trial approvals. While Bangladesh is actively modernizing its regulatory landscape to align with international standards, its reliance mechanism primarily functions through the adoption of global guidelines and specific fast-track pathways for products already approved by stringent authorities.

- Recognition of Reference Authorities: Bangladesh leverages assessments from well-resourced regulatory authorities (such as the US FDA, EMA, PMDA, UKMHRA or Health Canada) to facilitate local trials and registrations. Government of Bangladesh will decide the reliability on clinical trial data of other reference regulatory authorities.
- Multiregional Clinical Trials (MRCTs): Updated DGDA guidelines include specific provisions for multiregional clinical trials, allowing for a more streamlined review of protocols already vetted in other jurisdictions.
- The Clinical Trial Oversight department is strengthened its ability to participate in global reliance networks for quality control of clinical trial data and trial oversight.
- For expedited registration and trial pathways for vaccines and emergency-use products, particularly those with existing approvals from recognized international bodies.

Areas for reliance in the regulatory process and decision-making include the prioritization, review, authorization and monitoring of clinical trials that meet defined reliance criteria, such as multi-country trials, trials of public health importance, public health emergencies, rare diseases and emerging or re-emerging infectious diseases posing public health threats.

- In these areas, DGDA may rely on the scientific and regulatory assessments of Reference Regulatory Authorities (RRAs) to accelerate Clinical Trial Application (CTA) approval while retaining full accountability for its decisions.

- Reliance may be applied through verification, where DGDA administratively confirms an RRA-authorized clinical trial and verifies key ethical, site and administrative documents, or through an abridged review, where selected components of the submission are evaluated to ensure suitability under local regulatory requirements, including benefit–risk assessment for the Bangladeshi population, medical practice, disease patterns and nutrition.
- Reliance also extends to clinical trial oversight and monitoring where DGDA may exchange and evaluate GCP inspection outcomes, safety reports and other regulatory information from RRAs to inform timely regulatory actions and ensure continued protection of trial participants.

Licensing Establishment (LI): DGDA is responsible for licensing of establishments related with the activities such as manufacturing, distribution, storing for sale and sales of medical products. In case of the import of medical products DGDA relies on the manufacturing license issued by regulatory authority of country of origin. DGDA also relies on the regulatory decision arising from the relative NRA.

Laboratory Access and Testing & NRA Lot Release:

In Public Health Emergency, expedited Lot Release may be performed based on the ‘reliance’ mechanism. In such cases, lot release may be considered based on the lot release certificate provided by the NRA of the country of origin and/or any other responsible NRA. No vaccine is allowed for sale until a "NRA Lot Release Certificate" from the National Drug Control Laboratory, DGDA has been obtained.

- Currently, the lot release certificate for imported consignment is based on reliance on a form of summary protocol review, along with the lot release certificate of the reference national regulatory authority of the country of origin.
- NDCL will participate in lot release activity based on the principle of reliance to make the best use of available resources and expertise.
- Test results of vaccine can be accepted from any WHO Prequalified (WHO-PQ) (ML3/ML4) laboratory like Institute of Biological Products-Thailand, National Institute of Biologicals (NIB)-India, Central Drugs Laboratory (CDL)-Kasauli, India, National Institute of Food and Drug Safety Evaluation (NIFDS)-South Korea, etc. if they comply with the supplied specification or compendia.
- Imported vaccines from WHO-PQ sources are waived from any further testing for lot release unless there is any emergency situation justifying testing.
- The lot release will be based on the review of SLP, testing result (manufacturer), LRC from the country of origin. However, in rare circumstance, few vaccines Lot Release Certificate may not be issued by country of origin, in that case NDCL, DGDA will do Lot Release based on CoC/CoA provided by country of origin and issued a Certificate of Compliance instead of NRA Lot Release Certificate.

Reliance and Recognition Procedure:

Regulatory processes can be optimized, and duplication of efforts can be minimized through reliance. In addition, scientific expertise can be leveraged, leading to more fruitful and robust decision-making and enhancing the capacity of regulators. Consequently, reliance can also allow efficient utilization of resources by NRAs for other areas and improve access to quality-assured medicines. DGDA is implementing a reliance approach for qualifying product applications by complying with the following requirements: -

- Checking & verifying the sameness of products for marketing authorization.**
- To import active ingredients in Bangladesh,** an approved GMP certificate from the NRA of the country of origin is required.
- To import finished product in Bangladesh,** an approved GMP certificate or COPP from one of the 08 reference Regulatory authorities namely TGA, USFDA, PMDA, FIDMD, Swiss-medic, UKMHRA, EMA, France NRA and WHO Prequalified medical products on a case-by-case basis as per Annexure-1.
- For Emergency Use Authorization (EUA),** COPP (one of the 7 reference developed countries or EMA according to DCC and Drug policy), whether it is approved by stringent NRAs as per

Annexure-1. DGDA may accept other NRAs (Annexure-3) for EUA approval as per the decision taken by DCC.

- E. **For clinical trial approval**, authority applies Reliance and Recognition procedures in the regulation of clinical trials to expedite the review, approval and oversight of Clinical Trial Applications (CTAs) while retaining full regulatory responsibility and accountability for its decisions. Under this framework, DGDA may rely on the prior authorization and scientific assessments of Reference Regulatory Authorities (RRAs) to reduce review timelines compared to standard pathways. Reliance may be exercised through either **verification**, where administrative confirmation is undertaken based on an RRA-approved clinical trial protocol—particularly when DGDA requirements are aligned with those of the RRA or with NRAs benchmarked at WHO Maturity Level 3—or through an **abridged review** where selected elements of the submission are critically evaluated to ensure suitability under local conditions including benefit–risk in Bangladeshi population, medical practice, disease patterns and nutritional factors. For clinical trial authorization, applicants must submit the RRA-approved protocol and relevant supporting documents, including the reliance application and RRA review outcomes. Depending on the pathway applied, DGDA will either verify key administrative, ethical, and site-related documents or conduct a focused scientific and regulatory review where potential local risks are identified. In addition, DGDA will cooperate with RRAs through the exchange and evaluation of clinical trial monitoring information including GCP inspection outcomes and safety reports to inform ongoing oversight and appropriate regulatory actions.
- F. **For Pharmacovigilance**, safety variations or changes in SmPC & PIL should be approved by NRAs as per Annexure-3. An approved PSUR assessment report by the NRA of the country of origin. Serious side effects causing life-threatening cases reported by SRAs/ML03/ML04/WHO as per Annexure-3 and any signal generation/decision for risk mitigation of the SRAs/ML03/ML04/WHO will be considered as reliance by DGDA.
- G. **For Lot Release approval of imported finished product**, a summary lot protocol along with the lot release certificate of the NRA of the country of origin.

Verification and Review of Reliance Information:

MA functions of DGDA will verify that the documents and related information for the applied product for enlistment/registration/marketing authorization of any medical product or the Clinical trial in Bangladesh have been authorized by the reference regulatory authorities.

For registration, the product characteristics (use, dosage, precautions) should conform to those agreed in the authorization by the RRA, and for drug substances which are already registered by the reference regulatory authorities in a particular strength and dosage form are considered safe and efficacious while considering registration applicants of new drugs from a local perspective.

Additional Documentation:

During the review process, the applicant need to submit additional documents or CTD dossier required by DGDA to ensure the quality, safety and efficacy. Similarly, there could be circumstances when local clinical trial data is necessary. In addition to the full assessment report from the RRA, the applicant shall be required to submit a full Clinical Trial application to conduct an immuno-bridging study / a clinical trial, a full Application for Marketing Authorization and a full application for GMP and GCP inspection if DGDA deems it to be required.

Assessment based on Reliance Procedure:

The information to be used for reliance shall be evaluated according to SOP No: NRA-MA-013 (Procedure for Registration of Vaccine & Biological Products) & NRA-MA-023 (Procedure for Reliance on other NRAs).

References:

- 12.1 The Drug and cosmetics Act, 2023
- 12.2 WHO TRS 1033 Annex-10.
- 12.3 The Bengal Drug Rules, 1946.
- 12.4 National Drug Policy, 2016.
- 12.5 DCC 248.
- 12.6 DCC -250.
- 12.7 RELIANCE MECHANISM IN REGULATORY PROCESSES “A DRAP APPROACH ON GOOD RELIANCE PRACTICE” 1st edition.
- 12.8 WHO. (2020). Good reliance practices in regulatory decision-making: High-level principles and recommendations. WHO Drug Information, 34(2), 201–230.
- 12.9 WHO Technical Series 1019: WHO expert committee on specifications for Pharmaceutical Preparations, Appendix-2.

Glossary:

Definitions are essential to ensure a common understanding of concepts and clarity in interpreting guidance on reliance. In addition to the definitions provided below, reference is made to the WHO document on good regulatory practices, which includes definitions of harmonization, convergence and other relevant terms.

International Standards and Guidelines:

For the purpose of this document, the term includes relevant WHO standards and guidelines and any other relevant internationally recognized standards (e.g. International Organization for Standardization or pharmacopeia standards) and guidelines (e.g. International Council on Harmonization of Technical Requirements for Pharmaceuticals for Human Use [ICH] or guidelines of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme [PIC/S]).

Mutual Recognition Agreement:

According to a definition issued by the Organization for Economic Co-operation and Development (OECD), a mutual recognition agreement is: a principle of international law whereby states party to mutual recognition agreements recognize and uphold legal decisions taken by competent authorities in another member state. Mutual recognition is a process which allows conformity assessments (of qualifications, product.) carried out in one country to be recognized in another country.

Recognition:

Acceptance of the regulatory decision of another regulator or trusted institution. Recognition should be based on evidence that the regulatory requirements of the reference regulatory authority are sufficient to meet the regulatory requirements of the relying authority. Recognition may be unilateral or mutual and may, in the latter case, be the subject of a mutual recognition agreement.

Reference Regulatory Authority:

For the purpose of this document, a national or regional authority or a trusted institution such as WHO prequalification (WHO PQ) whose regulatory decisions and/or regulatory work products are relied upon by another regulatory authority to inform its own regulatory decisions.

Regional Regulatory System:

A system composed of individual regulatory authorities, or a regional body composed of individual regulatory authorities, operating under a common regulatory framework but not necessarily under a common legal framework. The common framework must at least ensure equivalence among the members in terms of regulatory requirements, practices and quality assurance policies. The system or regional body may have enforcement powers to ensure compliance with the common regulatory framework.

Reliance:

The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken even when it relies on the decisions, assessments and information of others.

Annexure-1: List of Reference Regulatory Authorities for Marketing Authorization

The following are reference regulatory authorities for matters related to the registration of medical products:

SI	Country	Regulatory Authority	Registration of Medical Product
1	USA	Food and Drug Administration (FDA)	√
2	Europe	European Medicines Agency (EMA)	√
3	Australia	Therapeutic Goods Administration (TGA)	√
4	Japan	Pharmaceuticals and Medical Devices Agency (PMDA)	√
5	UK	Medicines and Healthcare Regulatory Agency (MHRA)	√
6	Germany	Federal Institute for Drugs and Medical Devices	√
7	Switzerland	Swiss medic	√
8	France	France NRA	√

And WLA, the WHO Prequalified medical products case-to-case consideration.

Annexure-2: Checklist for Sameness of Products

Note [instructions on using the template]: This template is provided for verification of products to be registered nationally through the products approved by reference stringent regulatory authorities (SRAs). National regulatory authorities (NRAs) are free to modify the template as they deem fit, to suit their specific requirements.

1. Product details	
Dossier aspects to verify	
Proprietary product name	
International Non-proprietary Name (INN) of drug substance, strength, pharmaceutical form	
Applicant	
Date of application	
Application number (assigned by NRA)	
Type of product/registration	
Reference authority	
Declaration from the applicant	

2. Product quality				
Dossier aspects to verify	Comments (including confirmatory statements of sameness)			
Marketing status in reference SRA status				
Name and complete address of the applicant				
Name and complete address (including specific unit/blocks) of drug substance manufacturer(s)				
Name(s) and complete address(es) (including specific unit/blocks) of the manufacturer(s) of the finished pharmaceutical product(s) [FPP(s)] or biological drug products(s) (DP(s)), including the final product release if different from the manufacturer				
Description (visual appearance)				
Composition	Component and quality standard	Function	Quantity per unit (mg)	%
	Total			
Specifications for the finished product				

Dossier aspects to verify	Comments
Container closure system (including pack sizes, container size or volume)	
Stability summary and conclusions (including the storage statement and shelf-life)	
Lot/batch-release documents	
Assessor's comments on the product quality	

3. Product Information	
Dossier aspects to verify	Comments
Is the information for the health-care professional provided as approved by the reference SRA?	
Is the information for the patient/user (patient information leaflet) provided as approved by the reference SRA?	
The information does not contradict national therapeutic guidelines	
Assessor's comments on the product information	
4. Labelling (The following minimum information appears on the label)	
Dossier aspects to verify	Comments
Is the labelling of outer packaging (as final packaging or mock-up presentation) provided as approved by the reference SRA?	
Additional information on outer packaging as per national requirements	
Dossier aspects to verify	Comments
Is the labelling of internal packaging (as final packaging or mock-up presentation) provided as approved by the reference SRA?	
Additional information on internal packaging as per national requirements	
Assessor's comments on the product labelling	

5. Applicant commitments to the reference stringent regulatory authority

State any commitments by the applicant to WHO or to the reference SRA that may require follow up.

Example:

“The applicant committed that three consecutive production batches would be prospectively validated and a validation report – in accordance with the details of the validation protocol provided in the dossier – would be made available as soon as possible, for evaluation by assessors.”

Comments

6. General national regulatory authority review comments

Comments

7. Assessment of responses to [request for supplementary information]

Response from the applicant
Assessment of response

Annexure-3: List of Reference Regulatory Authorities for Pharmacovigilance

Followings are reference regulatory authorities for matters related to approval of Pharmacovigilance:

SI	Country	Regulatory Authority	Pharmacovigilance
1	USA	Food and Drug Administration (FDA)	√
2	Europe	European Medicines Agency (EMA)	√
3	Australia	Therapeutic Goods Administration (TGA)	√
4	Japan	Pharmaceuticals and Medical Devices Agency (PMDA)	√
5	UK	Medicines and Health Care Regulatory Agency (MHRA)	√
6	Germany	Federal Institute for Drugs and Medical Devices	√
7	Switzerland	Swiss medic	√
8	France	France NRA	√
9	Canada	Health Canada	√
10	Norway	The Norwegian Medicines Agency	√
11	Iceland	Icelandic Medicines Agency (IMA)	√
12	China	National Medical Products Administration (NMPA)	√
13	Egypt	Egyptian Drug Authority (EDA)	√
14	Ghana	Food and Drugs Authority (FDA)	√
15	India	Central Drugs Standard Control Organization (CDSCO)	√
16	Indonesia	National Agency of Drug and Food Control (BADAN POM)	√
17	Nigeria	National Agency for Food and Drug Administration and Control (NAFDAC)	√
18	Republic of Korea	Ministry of Food and Drug Safety (MFDS)	√
19	Serbia	Medicines and Medical Devices Agency (ALIMS)	√
20	Singapore	Health Sciences Authority (HAS)	√
21	South Africa	South African Health Products Regulatory Authority (SAHPRA)	√
22	Thailand	Food and Drug Administration (FDA)	√
23	United Republic of Tanzania	Tanzania Medicines and Medical Devices Authority (TMDA)	√
24	Vietnam	A. The Drug Administration of Vietnam (DAV) B. National Institute for the Control of Medicines (NICVB)	√

And WLA, WHO Prequalified medical products case-to-case consideration.