# Guidelines for Reliance on other NRAs in Bangladesh

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 my pleasure that one of the nine functions of DGDA – "Marketing Authorization" *related guidelines are now regularly published from DGDA for different class of medical products*. On this aspect "Guidelines for Reliance on other NRAs in Bangladesh" is one of the very important guidelines which will help Vaccine and Biotech Industry, Researchers, Academicians as well as Regulators to ensure quality, efficacy and safety of Vaccine and Biological products registered in Bangladesh.

This guideline is prepared as a supplementary guidance with WHO TRS 1033, Annex 10. So that Vaccine and Biological 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 thank the members of working committee for their meticulous job which they performed.

21 AUG 2023

Major General Mohammad Yousuf
Director General
Directorate General of Drug Administration &
Licensing Authority of Drugs

DGDA MA for Vaccines-Biologics department hereby acknowledge the contribution of the following personnel for their support to consolidate this guideline.

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## 1. Introduction:

This guideline is the supplementary guidance documents of WHO TRS 1033, Annex 10 which was adopted by DGDA, Bangladesh on 31st August,2023.

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 of 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 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. In view of the increasing prevalence and importance of reliance in the regulation of medical products, Member States have requested WHO to prepare practical guidance on the topic while ensuring that the approaches meet the intended objectives. This document and additional guidance that follow are intended to assist countries in implementing a sound, evidence-based, practical, effective approach to reliance.

## 2. Scope:

This guideline shall be applicable for the reliance activities of vaccines and biologics of NRA, Bangladesh.

## 3. 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 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 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 enlistment / registration / market

authorization and surveillance of vaccines and biological products. The key principles for reliance on information or decisions of reference regulatory authorities are as follows:

**Risk Based Approach:**

It is regulatory best practice to implement quality risk management. For example, a product which 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 allocate resources and a level of effort that is proportionate with the level of risk. DGDA believes on reliance and optimal use of available resources. This approach is undertaken to ensure that patients are provided with the safe, efficacious and quality assured vaccines and biological 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, 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 regulatory authorities or where differences exist, these are clearly stated and defined. DGDA MA team will check the sameness of products as per Annexure-2.

**Compliance with Nationally Regulatory Requirements:**

Reliance on reference regulatory authorities do 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 availability of safe, efficacious and quality therapeutic goods.

**4. Selection Criteria of Reference Regulatory Authorities for Reliance:**

**Legal Basis for Marketing Authorization (MA):**

According to National Drug Policy 2016, DCC 248 & DCC 250 one of 08 reference Regulatory authority namely TGA, USFDA, PMDA, FIDMD, Swissmedic, UKMHRA, EMA, France NRA and WHO PQ vaccines/products case to case basis.

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

DGDA MA Department could consider for EUA as per 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 listed by WHO or and EUA issued by any of the DGDA reference NRAs such as USFDA, PMDA, UKMHRA, TGA, SWISSMEDICS, EMA, GERMAN AND FRANCE Regulatory authority or Vaccines or Medical products having EUA from country of origin having satisfactory clinical data (Phase-1, 2 and 3) recommended by Public Health Emergency Committee.

**Clinical Trial and Pharmacovigilance:**

**For clinical trial protocol & report**:

NRA of country of origin.

**For pharmacovigilance**:

SRAs and/or NRA having ML03 or ML04 and WHO.

**Regulatory Inspection and Lot Release:**

1. GMP certificate for imported API source validation and Lot release certificate from NRA of country of origin.
2. For imported finished product WLAs (NRAs at least having maturity level 3) case to case basis.

**Collaborative Regulatory Pathway (CRP):**

DGDA became a participated member of CRP.

## 5. Areas for Reliance in Regulatory Process and Decision-making:

Divisions of DGDA are practicing reliance or recognition mechanism for regulating vaccines and biological products falls under their mandate. The areas of reliance for different types for regulatory process of vaccines and biological products are as under:

### 5.1 Marketing Authorization of Vaccines and Biologicals Products:

MA division of DGDA is responsible for assessment, evaluation and registration for vaccines and biological drugs. DGDA has adopted reference regulatory authority which are placed at Annexure-1 for reliance on their regulatory information in consideration of application through 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 reliance procedure for granting registration/ Market Authorization in the following circumstance: -

a. Finished products of biological and vaccines which are approved by the reference regulatory authorities DGDA does not review again. On the basis of their evaluation/registration/COPP, the vaccines will be registered.
b. For drugs substance/molecules, which are already registered by the reference regulatory authorities in a particular strength and dosage form are considered as safe and efficacious, while considering registration of new drugs in local perspective.
c. DGDA has participated in World Health Organization collaborative registration process to enable early access of those vaccines and biologics, Products which have been evaluated and listed as pre-qualified by WHO.

The mechanism adopted for relying on information encompasses 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.

**5.2 Regulatory Inspections (GMP):**

Compliance to Good Manufacturing Practices is mandatory consideration for registration of a vaccine and biological drugs. DGDA has adopted reliance approach for verification of GMP of foreign manufacturing by applying risk-based exemption approach.

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

a) The applied vaccine or biological product is registered or granted marketing authorization in any of reference regulatory authority as adopted by DGDA, are considered for exemption from foreign inspections, or

b) The applied vaccine or biological product is exported to any EMA member states, and the manufacturing facilities within which the products are manufactured have been inspected by the EMA members regulatory authority, or

c) WHO pre-qualified vaccine or biological products or the product registered through WHO collaborative procedure and their manufacturing facility is inspected by 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 case to case basis (if needed inspection will be performed).

f) For import of Bulk / API / RTF from countries other than above categories GMP inspection will be performed case to case basis.

### 5.3 Clinical Trials Approval:

The mechanism adopted for reliance encompasses following:

i. Review of approval or rejection of clinical trials in reference regulatory authorities.

**ii.** In case information is not available on the official website, the reference regulatory authority is contacted directly via electronic mail for a query or clarification on a particular issue under consideration.

**iii.** Regulatory status or any other regulatory information available in the public domain through their website.

**iv.** Reports in the scientific literature and unpublished scientific papers, as well as reports from foreign regulatory authorities.

### 5.4 Pharmacovigilance Activities:

DGDA is responsible to ensure the safety of marketed products through signal detection and initiation of necessary risk minimization measures. It also relies on regulatory decisions arising due to pharmacovigilance activities of reference regulatory authorities, regional and international bodies, having public health consideration.

The reliance practices are in place for decision making of PV issues from Reference Regulatory Authorities on the basis of regulatory decisions they implemented. We translated it in our perspective having decisions taken with the support of national expert committee.

### 5.5 Lot Release of Biologics and Vaccines:

No vaccine is allowed sale until a "Lot Release Certificate" from National Control Laboratory, DGDA has been obtained.

Currently, lot release certificate for imported consignment is based on reliance in the form of summary protocol review along with lot release certificate of national regulatory authority of country of origin.

## 6. Reliance 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 reliance approach for qualifying products applications by complying the following requirements: -

A. **Checking & verifying sameness of products for marketing authorization.**
B. **To import active ingredients in Bangladesh**, approved GMP certificate from NRA of country of origin.
C. **To import finished product in Bangladesh**, approved GMP certificate or COPP from one of 08 reference Regulatory authority namely TGA, USFDA, PMDA, FIDMD, Swiss-medic, UKMHRA, EMA, France NRA and WHO PQ vaccines / products/ WLAs (NRAs at least having maturity level 3) case to case basis or as per Annexure-1.
D. **For Emergency Use Authorization (EUA)**, COPP (one of 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 decision taken by DCC.
E. **For clinical trial approval**, approved clinical trial protocol by NRA of country of origin. DGDA may ask to conduct an immuno-bridging study on few statistically reasonable Bangladeshi population.
F. **For Pharmacovigilance**, safety variations or changes in SmPC & PIL should be approved by NRAs as per Annexure-3.
G. **For Pharmacovigilance**, approved PSUR assessment report by NRA of country of origin. Serious side effects causing life threatening case 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.
H. **For Lot Release approval of imported finished product,** summary lot protocol along with lot release certificate of NRA of country of origin.

**Verification and Review of Reliance Information:**

Divisions of DGDA will verify that the documents and related information for the applied product for enlistment/registration / marketing authorization of any vaccine and biological product or the Clinical trial in Bangladesh has been authorized by reference regulatory authorities.

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

**Additional Documentations:**

During the review process, DGDA may ask the applicant to submit additional information to be included in the dossier or specific statistical / analytical requirements or sometime full application data to ensure the quality, safety and efficacy. Similarly, there could be circumstances when local clinical trial data is necessitated. In addition to the full assessment report from the RRA, the applicant shall be required to submit a full Clinical Trial application to conduct immuno-bridging study / a clinical trial, full Application for Marketing Authorization, full application for GMP inspection if DGDA deems 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 & NRA-MA-023.

## 7. References


7.1 WHO TRS 1033 Annex-10.

7.2 The Drugs Act, 1940.

7.3 The Drug Rules, 1945.

7.4 The Bengal Drug Rules, 1946.

7.5 National Drug Policy, 2016.

7.6 Drug Control Ordinance 1982.

7.7 DCC 248.

7.8 DCC -250.

7.9 RELIANCE MECHANISM IN REGULATORY PROCESSES "A DRAP APPROACH ON GOOD RELIANCE PRACTICE" 1st edition.

7.10 WHO. (2020). Good reliance practices in regulatory decision-making: High-level principles and recommendations. WHO Drug Information, 34(2), 201–230.

7.11 WHO Technical Series 1019: WHO expert committee on specifications for Pharmaceutical Preparations, Appendix-2.


## 8 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.

**8.1. 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 pharmacopeial 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]).

**8.2 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 carried out in one country to be recognized in another country.

**8.3 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.

**8.4 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

**8.5 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.

**8.6 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

Followings are reference regulatory authorities for matters related to registration of vaccines & biological products:

| Sl | Country | Regulatory Authority | Registration of Vaccine & Biological 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 | Swissmedic | √ |
| 8 | France | France NRA | √ |

And WHO PQ products/vaccines 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:

| Sl | 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 Helathcare Regulatory Agency (MHRA) | √ |
| 6 | Germany | Federal Institute for Drugs and Medical Devices | √ |
| 7 | Switzerland | Swissmedic | √ |
| 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) | √ |

| Sl | Country | Regulatory Authority | Pharmacovigilance |
|---|---|---|---|
| 17 | Nigeria | National Agency for Drug and Food 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)<br>B. National Institute for the Control of Vaccines and Biologicals (NICVB) | √ |

And WHO PQ products/vaccines case to case consideration.