Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline on Good Reliance Practices

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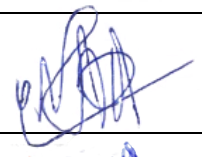
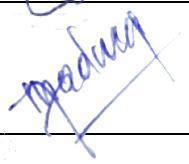
Approved By	Aishath Mohamed, Deputy Director General, Pharmaceuticals	
Authorized by	Thooma Adam, Deputy Director General, Laboratory Services (Acting Head of MFDA)	

SUMMARY OF CHANGES

Version No.	Issued Date	Section/Clause	Summary of Change	Changes Made by
1	01.09.2024	-	Creation of the document	Mohamed Fazeen, Director, Pharmaceuticals
2	24.09.2026	Overall Document	Review and update of overall guideline following the publish of new Medicine Regulation R-64/2026	Mariyam Laisa, Assistant Medicine Regulatory Officer

Contents

DEFINITIONS

Abridged Regulatory Pathways	Regulatory procedures facilitated by the use of reliance, whereby the regulatory decision is solely or widely based on the application of reliance. Usually, NRA do the limited independent assessment of specific parts or submission for suitability of use under local conditions and regulatory requirements whilst relying on prior assessment and/or inspection outcomes from reference regulatory authorities or trusted organizations. The review is based on accessible data from reference regulatory authorities including assessment reports, Good Manufacturing Practice (GMP) inspections reports and parts of the common technical document (CTD).
Assessment	Any evaluation of information for conduction of a regulatory function (e.g. evaluation for a clinical trial application, evaluation of an initial authorization for a therapeutic goods or any subsequent post-authorization changes, evaluation of safety and efficacy data, evaluation as part of an inspection, etc.).
Post Registration Variation	A change to any aspect of a registered drug product, including but not limited to a change of formulation, method, site of manufacture, specifications for the finished product and ingredients, container and container labeling, and product information.
Recognition	Recognition is a formalized acceptance of regulatory decisions made by a national regulatory authority or a trusted organization. In recognition the regulatory requirements of the reference regulatory authority are considered sufficient to meet the regulatory requirements of the relying authority. Recognition may be unilateral or mutual (may be subject to a Mutual Recognition Agreement)
Reference Regulatory Authorities (RRA)	A national or regional authority or a trusted institution as adopted by MFDA for the purpose of reliance for medicine regulation along with its scope of reliance.
Reliance	Reliance is 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. Full reliance means that the authority relies on the entire assessments/inspection and quality control reports performed by another NMRA. Partial reliance means that the authority relies on certain documents/parts of the assessments performed by another NMRA, while for the other part(s) an independent, full assessment of the documentation submitted by the Applicant is conducted. NRA remains independent, responsible and accountable regarding the

	decisions taken, even when it relies on the decisions and information of others.
Risk Management Plan	A plan to identify or characterize the safety profile of the medicinal product(s) concerned, document measures to prevent or minimize the risks associated with the medicinal product, including an assessment of the effectiveness of those interventions and document post- authorization obligations that have been imposed as a condition of the marketing authorization
Sameness of the Product	This means two products having identical essential characteristics. The product being submitted to the relying authority shall be same as the product approved by RRA.
Vigilance	It refers to the collection, assessment, reporting and identification of trends in incidents resulting from the use of medicinal products
WHO Prequalification	WHO prequalification is a service provided by WHO to assess the quality, safety, and efficacy of medicinal products for priority diseases

ABBREVIATIONS

Abbreviation	Full Term
CDA	Confidentiality Disclosure Agreement
CTD	Common Technical Document
FPP	Finished Pharmaceutical Product
GBT	Global Benchmarking Tool
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
GxP	Good Practice(s)
ICH	International Council for Harmonisation
LT	Laboratory Testing
MA	Marketing Authorization
MFDA	Maldives Food and Drug Authority
ML	Maturity Level
MoU	Memorandum of Understanding
NMRA	National Medicine Regulatory Authority
NRA	National Regulatory Authority
NPB	National Pharmaceutical Board
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PSUR	Periodic Safety Update Report
QC	Quality Control
RI	Regulatory Inspections
RMP	Risk Management Plan
RRA	Reference Regulatory Authority
RRAs	Reference Regulatory Authorities
SmPC	Summary of Product Characteristics
VL	Vigilance
WLA	WHO-Listed Authority
WHO	World Health Organization

1 INTRODUCTION

Medicine and Therapeutics Goods Division (MTG) of Maldives Food and Drug Authority (MFDA) is the National Regulatory Authority of Maldives and is responsible for the performance of all regulatory functions related to medicines. In the present-day regulatory environment, reliance is an important regulatory approach for medicinal products. This approach intended to support the efficient allocation of resources and ensure timeliness in providing safe, efficacious and quality medicines.

Through the implementation of the reliance mechanism, MTG is able to use assessments, regulatory information and decisions generated by other competent or stringent regulatory authorities and trusted institutions while reducing unnecessary duplication of regulatory work.

MFDA applies reliance with reference to relevant World Health Organization (WHO) guidance and the applicable national legal and regulatory framework. However, MTG still uses its own judgment to consider the benefit-risk balance of each product while taking into account the domestic circumstances and legislation of Maldives.

2 Purpose

This guideline is intended to establish a clear and consistent framework for the application of good reliance practices by MTG in the regulation of medicines. With the application of this guideline and the reliance mechanism MTG aims to:

a. Facilitate timely and efficient regulatory decision-making through the appropriate application of reliance, without compromising the safety, quality and efficacy of medicines.

b. Promote efficient use of regulatory resources by reducing unnecessary duplication of regulatory activities and utilizing relevant regulatory assessments and information from RRAs.

3 Scope

This guideline serves as a comprehensive resource for both applicants and MFDA's regulators by outlining the Authority's approach to adopting good reliance practices, the extent of its application, regulatory activities, criteria and selection of RRAs.

4 Concepts in Good Reliance Practices

4.1 Reliance and Recognition

4.1.1 Reliance may take many forms and be applied to varying degrees in recognizing or taking account of the assessments, decisions or other authoritative information of other authorities and institutions. Recognition may be seen as a special and more formalized approach to reliance, whereby one regulatory authority recognizes the decisions of another regulatory authority, system or institution, obviating additional regulatory assessment to reach its own decision. Recognition usually requires formal and binding legal provisions.

4.1.2 Reliance mechanism may be applied to different processes at varying degrees based on the regulatory and legal requirements of MTG and can be applicable to assessments, decisions or other authoritative information.

4.1.3 Recognition, on the other hand is a more formalized approach that may be subject to a formal and binding legal provisions.

4.1.4 The important distinction to note is in reliance approach the authority does not obviate independent assessment and decision making. While in recognition, the relying authority recognizes the decisions of a RRA, system or institution without additional regulatory assessments of its own.

4.2 Life Cycle Approach

4.2.1 Reliance may be applied to a product's life cycle from the initial regulatory assessment and through the post-authorization regulatory activities.

4.2.2 MTG applies reliance mechanism in the following activities in the products life cycle:

- Product Registration or Market Authorization including emergency use authorization
- Post registration variations
- Regulatory inspections including GMP
- Clinical Trials
- Laboratory Testing
- Lot Release
- Pharmacovigilance and Post market Surveillance

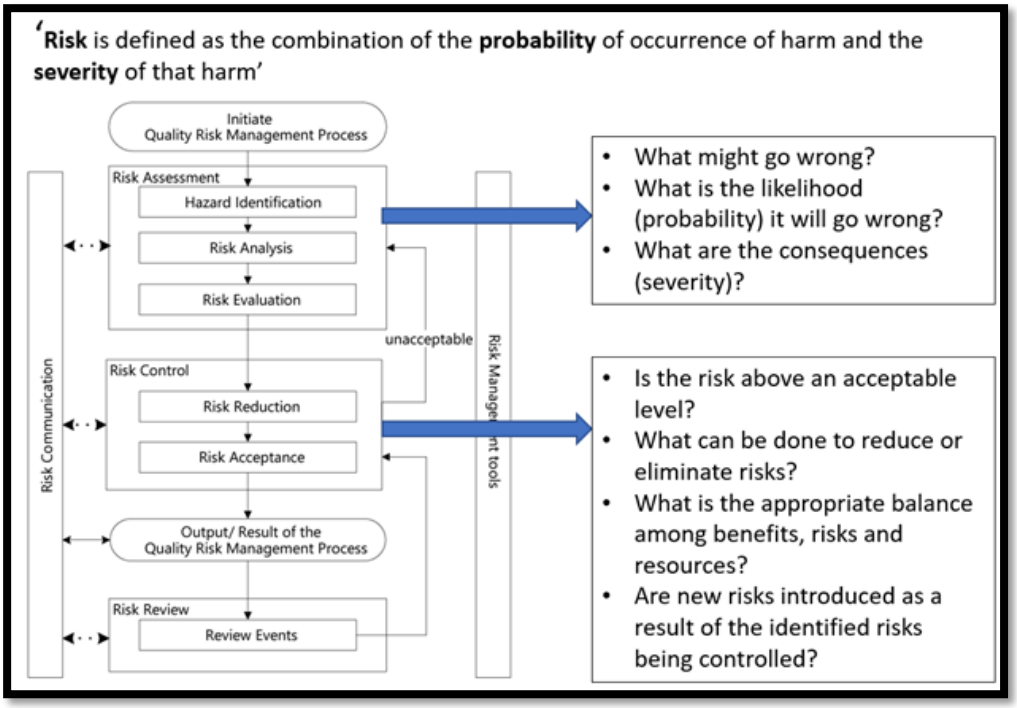
4.2.3 The degree of reliance applied may vary between the activities based on the nature of the activity, regulatory requirements and relevant information.

4.2.4 Reliance applied during one stage of the product life cycle, shall not deter MTG from undertaking additional assessment, inspection, testing and regulatory actions based on newly received information, product safety concerns and any other relevant circumstances.

4.3 Risk-Based Approach

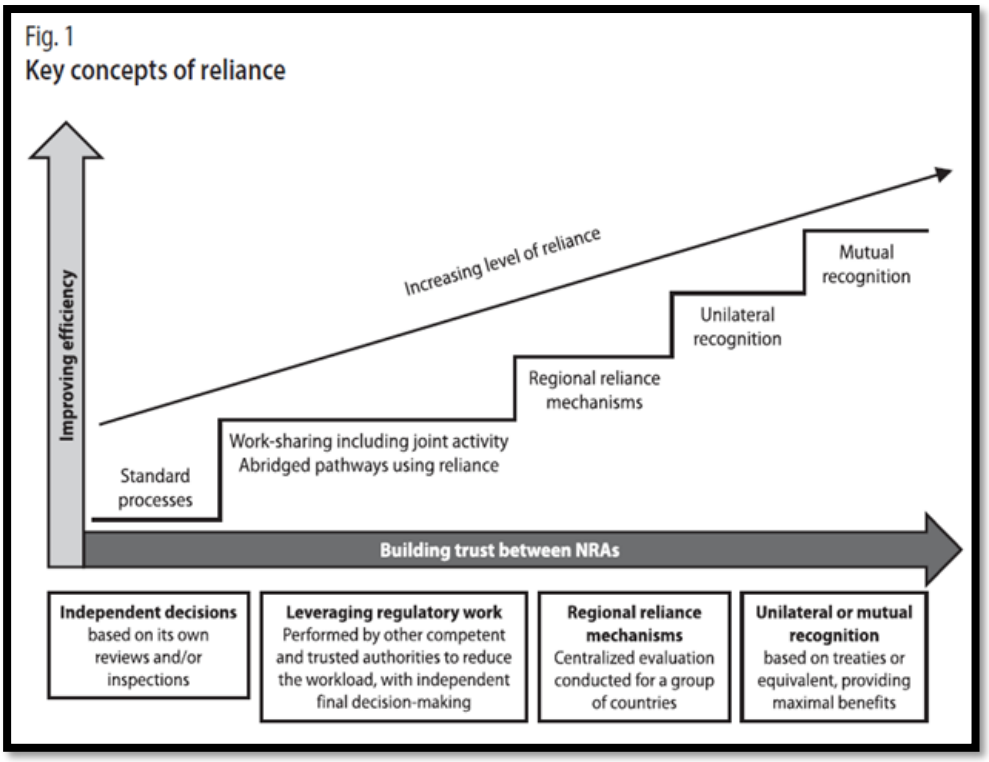
4.3.1 The degree and extent of the reliance placed on RRAs and trusted institutions shall depend on the level of risk associated with the product or the regulatory decision.

4.3.2 Factors considered can include the characteristics of the product, the availability of regulatory information and concerns related to the safety, quality and efficacy of the products.



4.3.3 The increasing levels of reliance may include:

1. verification of sameness of the medicinal product
2. confirmation of the applicability of the assessment outcomes of another authority for regulatory decision making in the national context
3. Abridged Assessments
4. Joint Assessment or Work sharing: This may entail primary review by one NRA followed by a joint assessment and finalization by the other NRA.



5 PRINCIPLES OF RELIANCE

Reliance is guided by the following basic principles in accordance with WHO GRP:

5.1 Protecting public health remains the foremost priority of MFDA by ensuring the safety and efficacy of medicines allowed to be used in Maldives.

5.2 Reliance may be applied across regulatory functions irrespective of the maturity level or available resources wherever deemed appropriate.

5.3 MTG shall promote transparency, sharing of relevant information and encourage open communication with relevant stakeholders.

5.4 MTG may rely on relevant assessments and decisions of RRAs as appropriate while maintaining its responsibility for independent assessment and decision making.

5.5 MFDA promotes collaboration with RRAs to ensure consistency in regulatory standards as per applicable international standards.

5.6 Reference Regulatory Authorities

5.6.1 Well-resourced National Regulatory Authorities, regional and international bodies having robust regulatory mechanisms are more efficient in performing their regulatory functions and are designated as Reference Regulatory Authorities (RRAs) to meet the challenges of globalization, increasingly complex technologies and growing public expectations of faster access to novel and new therapies. It is a dynamic list and is subject to change by MTG as needed like inclusion or exclusion of any NRA in World Listed Authority (WLA) list by WHO.

5.6.2 Sample RRA list is included in ANNEX 1 of this guideline. *The most recent version of the list shall be available with the relevant guidelines for individual regulatory activities.*

5.6.3 The following criteria can be applied for choosing RRAs by MTG:

Marketing Authorizations	1. Evidence of the strength of the regulatory system of the reference authority: • (t)WLA for the type of product and MA (RI may also be considered), • ML3 or ML4 for the product and MA (RI may also be considered), • Stringent Regulatory Authority definition/ICH membership • PIC/S membership (providing reassurance on the compliance of local production with cGMPs) • WHO Prequalified products, • experience (e.g. an advisory committee's recommendation, frequency of SF products identified from this country, whether another strong regulatory authority Evidence of the strength of the regulatory system of the reference authority: 2. Information on the Reference authority's decision-making system: • by whom, • is there an expert committee, etc. 3. Relative strength: does the reference regulatory authority have similar or stronger capacity for assessing this product compared to the relying

	authority? (minimum Maturity level 3 against the GBT) 4. Availability of the minimum required information from the NRA (e.g. website, MoU, CDA) or the applicant. 5. Responsiveness of the authority when contacted and ease of communication.
Vigilance	1. Evidence of the strength of the regulatory system of the reference authority: ▪ (t)WLA for the type of product and VL, ▪ ML3 or ML4 for the product and VL, ▪ Stringent Regulatory Authority definition/ICH membership, ▪ experience (e.g. an advisory committee's recommendation, robustness of previous safety decisions (has it been maintained or cancelled?), whether another strong regulatory authority relies on this authority, evidence of the performance of the reference regulatory authority etc.) 2. Information on the Reference authority's decision-making system: ▪ how the safety data is assessed, ▪ by whom, ▪ is there an expert committee, etc. 3. Relative strength: does the reference regulatory authority have similar or stronger capacity for assessing this product compared to the relying authority? 4. Availability of the minimum required information from the NRA (e.g. website, MoU, CDA) or the applicant 5. Responsiveness of the authority when contacted and ease of communication

Regulatory Inspections	1. Evidence of the strength of the regulatory system of the reference authority: ▪ (t)WLA for the type of product and RI, ▪ ML3 or ML4 for the product and RI, ▪ Stringent Regulatory Authority definition/ICH membership, ▪ PIC/S membership, ▪ experience (e.g. an advisory committee's recommendation, whether other strong regulatory authority rely on this authority, evidence of contradiction with the outcome of other regulatory authorities' inspections, evidence of the performance of the reference regulatory authority etc.) 2. Information on the Reference authority's decision-making system: A. Who can inspect B. How are inspectors trained C. Categorization of the deficiencies and follow up of the regulatory actions 3. Relative strength: does the reference regulatory authority have similar or stronger capacity for assessing this product compared to the relying authority? 4. Availability of the minimum required information from the NRA (e.g. website, MoU, CDA) or the applicant 5. Responsiveness of the authority when contacted and ease of communication
Laboratory Testing	1. Evidence of the strength of the regulatory system of the reference authority: ▪ (t)WLA for the type of product and LT,

	▪ ML3 or ML4 for the product and LT, ▪ Stringent Regulatory Authority definition/ICH membership, ▪ WHO prequalified laboratories ▪ ISO/IEC 17025: 2017 for laboratory testing ▪ ISO/IEC 17025: 2017 for laboratory instrument calibration ▪ ISO 17034:2016 for Reference Standard ▪ Recent satisfactory proficiency testing reports or inter-laboratory testing reports on the scope of interest experience (e.g.whether other strong regulatory authority rely on this NCL, evidence of the performance of the reference regulatory authority etc.) ▪ Any other international or national accreditation 2. Relative strength: does the reference regulatory authority have similar or stronger capacity for assessing this product compared to the relying authority? 3. Availability of the minimum required information from the NRA (e.g. website, MoU, CDA) or the applicant (please see section 8.4) 4. Experience (e.g. Responsiveness of the authority when contacted and ease of communication)

6 RELIANCE PATHWAYS

As mentioned in 4.3.3, MTG may apply the appropriate degree of reliance based on the product or the regulatory decision, including:

6.1 Verification

6.1.1 Verification is a process whereby regulatory decisions are made based on available information and regulatory decisions of RRAs.

6.1.2 Verification is applied where conformity with requirements of the RRAs is sufficient to meet the requirements of MTG.

6.1.3 This may include the verification of the sameness of the product, confirmation of GMP compliance in market authorization and other regulatory activities such as inspections.

6.2 Abridged/Abbreviated Review

6.2.1 Abridged/abbreviated review is the assessment of suitability of use under local conditions and regulatory requirements, while relying partly or fully on prior assessment / GMP inspection outcomes/ Quality Control (QC) laboratory reports from any RRAs for any consideration by MTG for regulatory decisions.

6.2.2 The evaluation of a certain part of the application (e.g. relevant to use under local condition) such as product quality data in relation to climatic conditions and distribution infrastructure and a benefit-risk assessment in relation to use in the local ethnic population, medical practice/culture and patterns of disease and nutrition may be necessary.

7 Regulatory Functions based on Reliance

The concept of reliance plays a pivotal role in various aspects of regulatory decision- making undertaken by Maldives Food and Drug Authority (MFDA). It ensures the efficiency and effectiveness of medicine (pharmaceutical and biological). Following are detailed procedures for each regulatory function in which reliance is applied:

7.1 Registration/ Marketing Authorization (MA) of Medicine.

7.1.1 MTG is responsible for assessment, evaluation and Registration/Marketing Authorization (MA) of Medicine, post-registration variations and renewal. Medicine Therapeutic Goods Division, MTG is responsible for processing and assessment of registration applications, followed by decision (approval or rejection) by National Pharmaceutical Board. The basic principle for registration of medicine is compliance to criteria of quality, safety, and efficacy.

7.1.2 Reliance for this activity may be applied by the aforementioned reliance pathways (Clause 6) for the following aspects of marketing authorization:

1. Initial marketing authorizations, including product information
2. Renewal of marketing authorizations
3. Variations, including e.g. new indications or changes in the posology
4. Suspension, withdrawal of a Marketing Authorization

7.1.3 Guideline for Product Registration Including Emergency Use Authorization (MTG/RE-RP/GLN-TE 001) can be referred for detailed procedure.

7.2 REGULATORY INSPECTIONS (GMP)

7.2.1 MTG has adopted reliance approach for:

- GxP compliance, including initial assessment and maintenance
- Information for risk-based planning of inspections, e.g. history of recalls

7.2.2 Importers applying for registration of imported drug products are exempted for inspection of manufacturing unit abroad, if the applied product qualifies for any of the following criterias:

a. Registered/enlisted in any of Reference Regulatory Authority (Annexure-I).
b. Registered/enlisted in minimum three of the drug regulatory authorities of former Eastern Europe.
c. Manufacturer GMP certificate (for applied dosage form facility) is available on EUDRA-GMDP website (http://eudragmdp.ema.europa,eu/inspections/gmpc/searchGMPCompliance.do)
d. WHO pre-qualified product and manufacturing facility (section) thereof.

e. The product has been approved by a PIC/S Participating Authority, and the manufacturing site/facility of the product has been inspected by a PIC/S Participating Authority and found to comply with applicable GMP requirements. (https://picscheme.org/en/members)

f. The manufacturing facility has been inspected by another NRA within the previous three years, and MTG determines, based on a review of the inspection report, that the inspection outcome provides sufficient evidence of GMP compliance. Where the report is insufficient, MTG may conduct its own inspection.

g. The registration holder shall inform MTG of any suspension, cancellation or delisting affecting the product or manufacturing facility within the specified timeline by the Authority.

7.2.3 MTG may conduct risk based GMP inspection of the manufacturing facility any time (before or after grant of approval) due to any reason as it deems fit such as repeated GMP violations, supply of substandard products, Adverse Drug Reaction due to manufacturing problem etc.

7.3 PHARMACOVIGILANCE

7.3.1 MTG collects safety information about products that it regulates, including adverse event reports, product recalls, and safety warnings and will share safety information with RRAs on a regular basis.

7.3.2 RRAs may have more extensive reporting and information sharing system and MTG may therefore consider relevant pharmacovigilance data, safety signals and regulatory assessments from RRAs as supplementary information to support its own pharmacovigilance activities and regulatory decision-making.

7.3.3 Reliance may be applied for:

- Safety signal detection and assessment
- Safety variations, including changes in the SmPC and patient information leaflet
- PSUR assessment
- Risk communication (e.g. Dear doctors' letters, Direct Healthcare professional communications)
- Risk management plans

- Benefit-Risk reviews

7.4 LABORATORY TESTING

7.4.1 To ensure the accuracy and consistency of laboratory testing data, MTG accepts testing results from RRA approved and WHO pre-qualified laboratories in line with recognized standards or any other laboratory as identified by MTG. This reliance reduces the burden on the authority in general and testing laboratory in specific and promotes efficiency in the testing process while maintaining the quality and safety of products.

7.4.2 The applicant submits laboratory testing data to the MFDA in support of a MA application, a clinical trial application, or a vigilance report.

7.4.3 The MFDA may review the laboratory testing data to ensure that it was generated by an RRA approved or WHO pre-qualified laboratory or laboratory as identified by MFDA.

7.4.4 MFDA may perform risk-based testing of drug products from its own or any other laboratory any time (before or after grant of approval) due to any reason as it deems fit like repeated GMP violations, supply of substandard products, Adverse Drug Reaction due to manufacturing problem etc.

7.5 Other Regulatory Activities

a. **Clinical Trials:** MFDA's reliance clinical trials involve accepting data from clinic trials approved by RRAs. To ensure the reliability of this data, MFDA carefully evaluates the processes, methodologies, and ethical considerations of the relevant RRA in line with international standards such as ICH- GCP. This approach expedites the approval of clinical trials while upholding the highest standards of ethical conduct, patient safety, and data integrity.

b. **Lot Release:** MTG relies on lot release testing certification issued by RRAs and mandates the submission of documented information on lot release for vaccines, biologicals and IV fluids.

c. **Market control and surveillance:** MTG considers information sharing in relation to any safety and quality concerns critical for making appropriate decisions in market control and surveillance whenever appropriate.

8 Legal Basis

a. Health Services Act 29/2015

b. Medicine Regulation R-64/2026, Clause 42 and 43

9 REFERENCES

a. Health Services Act 29/2015

b. Medicine Regulation R-64/2026, Clause 42 and 43

c. Regulations on National Pharmaceutical Board 2019/R-135

d. WHO Global Benchmarking Tool (GBT) for Evaluation of National Regulatory Systems of Medical Products, Revision VI. Geneva: World Health Organization; 2021

e. WHO, Good Reliance Practices (GReP), Annex 11, 55th report of the World Health Organization Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP), WHO Technical Report Series No. 1033, 2021.

f. WHO, Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities, Annex5.World Health Organization, WHO Technical Report Series No. 986, 2014.

g. WHO, Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products, Annex 6. World Health Organization, WHO Technical Report Series No. 1019, 2019.

h. Action Point 5 - Strategy to facilitate reliance, South-East Asia Regulatory Network (SEARN)

1 Annexure-I: List of Reference Regulatory Authorities for Reliance

Following are Reference Authorities for matters related to registration of medicine (pharmaceutical and biological drugs) and approval of clinical trials.

Note: This list is a sample list and is subject to changes. The most recent version of the list shall be available with the relevant guidelines for individual regulatory activities.

#	**Country**	**Authority**
1	Australia	Therapeutic Goods Administration
2	Austria	Austrian Agency for Health and Food Safety (AGES)
3	Belgium	Federal Agency for Medicines and Health Products (FAMHP)
4	Bulgaria	Bulgarian Drug Agency
5	Canada	Health Canada
6	Croatia	Agency for Medicinal Products and Medical Devices of Croatia (HALMED)
7	Cyprus	Ministry of Health — Pharmaceutical Services
8	Czech Republic	State Institute for Drug Control (SUKL)
9	Denmark	Danish Medicines Agency
10	Estonia	State Agency of Medicines (Ravimiamet)
11	Finland	Finnish Medicines Agency (Fimea)
12	France	National Agency for the Safety of Medicine and Health Products (ANSM)
13	Germany	Federal Institute for Drugs and Medical Devices
14	Greece	National Organization for Medicines
15	Hungary	National Institute of Pharmacy and Nutrition (OGYEI)
16	Iceland	Icelandic Medicines Agency
17	Ireland	Health Products Regulatory Authority
18	Italy	Italian Medicines Agency (AIFA)
19	Japan	Ministry of Health, Labour and Welfare/Pharmaceuticals and Medical Devices Agency
20	Latvia	State Agency of Medicines
21	Liechtenstein	Office of Health / Department of Pharmaceuticals
22	Lithuania	State Medicines Control Agency (VVKT)
23	Luxembourg	Ministry of Health
24	Malta	Medicines Authority
25	Netherlands	Health and Youth Care Inspectorate (IGZ)
26	Norway	Norwegian Medicines Agency
27	Poland	Chief Pharmaceutical Inspectorate
28	Portugal	National Authority of Medicines and Health Products (Infarmed)
29	Romania	National Agency for Medicines and Medical Devices
30	Slovakia	State Institute for Drug Control (SIDC)
31	Slovenia	Agency for Medicinal Products and Medical Devices (JAZMP)
32	Spain	Spanish Agency of Medicines and Medical Devices (AEMPS)
33	Sweden	Medical Products Agency
34	Switzerland	Swiss Agency for Therapeutic Products (Swissmedic)
35	United Kingdom	Medicines and Healthcare products Regulatory Agency (MHRA)
36	United States of America	Food and Drug Administration

37	Republic of Korea	Ministry of Food and Drug Safety (MFDS) intlpharm@korea.kr
38	Singapore	Health Sciences Authority (HSA) hsa_intl_office@hsa.gov.sg
39	Argentina	ANMAT (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica the Borrower's or National Food, Drug, and Medica Technology Administration)
40	Brazil	ANVISA (Agência Nacional de Vigilância Sanitária or National Health Surveillance Agency)
41	Chile	ISP (Public Health Institute of Chile)
42	Indonesia	BADAN POM (*Agency for Drug and Food Control*, or **Indonesian FDA)**
43	Mexico	COFEPRIS
44	Cuba	CECMED
45	Malaysia	National Pharmaceutical Regulatory Agency (NPRA)