

Evaluating and publicly designating regulatory authorities as WHO listed authorities

Revised policy document

Second edition



**World Health
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Evaluating and publicly designating regulatory
authorities as WHO-listed authorities
Policy document

Evaluating and publicly designating regulatory authorities as WHO listed authorities: policy document

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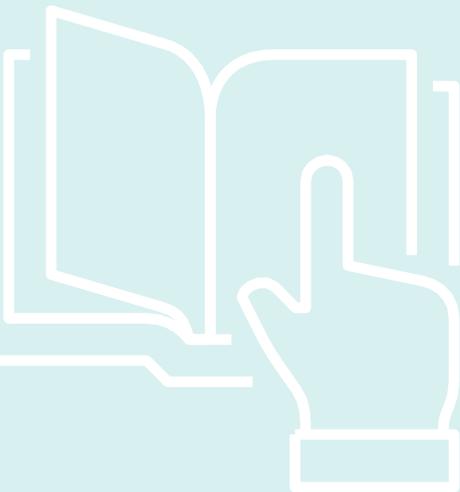
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1. Introduction

This policy on the evaluation and designation of regulatory authorities as WHO-listed authorities was developed following broad public consultation and the review of written comments received from the publication of a concept note (1), which informed the WLA policy and operational guidance, as well as international consultative meetings with Member States and interested stakeholders. It also considered recommendations from the fifty-second meeting of the World Health Organization Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) on the replacement of the term “stringent regulatory authority” with “WHO-listed authority” (2). The ECSPP recommendations were based on comments received on the proposed elements of a replacement definition for Stringent Regulatory Authorities (SRAs) posted by WHO for public comment in August 2017 that was intended to provide a more transparent, robust and equitable measure of regulatory performance (3).

This updated policy reflects that expansion and outlines the approach for integrating medical device and IVD regulation within the WLA framework.



2. Context

World Health Assembly Resolution 67.20 (WHA 67.20) on Regulatory system strengthening for medical products (4) recognizes that effective regulatory systems are an essential component of health system strengthening, necessary for the implementation of universal health coverage and, ultimately, contribute to better health outcomes. Resolution WHA 67.20 also recognizes that inefficient regulatory systems can be a barrier to access to safe, effective and quality medical products. Several WHO regional committee resolutions on regulatory system strengthening have also been adopted, including, for example, Regional Committee Resolution (CD50.R9), 2010, in the WHO Regional Office for the Americas (AMRO/PAHO) (5), *Regional strategy for improving access to essential medicines in the Western Pacific Region (2005- 2010)* (6), and document *AFIRC63/7 of the WHO Regional Office for Africa (AFRO)* (7). The road map for access to medicines, vaccines and other health products highlights regulatory system strengthening as an integral part of a health systems approach to improving access to safe and effective medical products of assured quality (8). Furthermore, WHA 76.5 (2023) “Strengthening diagnostics capacity” explicitly recalls WHA 67.20 (2014) on regulatory systems strengthening for medical products and requests WHO to prioritize support for “strengthening areas of regulation of health products that are the least developed, such as regulation of medical devices, including diagnostics”

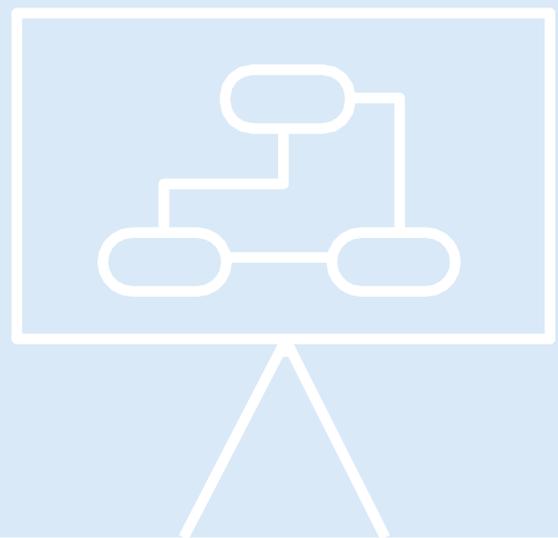
Resolution WHA 67.20 calls upon WHO to:

- a) apply evaluation tools to generate and analyze evidence of regulatory system performance;
- b) facilitate the formulation and implementation of institutional development plans (IDPs); and
- c) provide technical support to national regulatory authorities (NRAs) and governments.

The WHO supports Member States in strengthening regulatory systems as a means of promoting equitable access to and availability of quality assured medical products. WHO has implemented a regulatory system strengthening programme to assist countries in reaching and sustaining a level of medical product regulatory oversight that is effective, efficient and transparent. Its objectives are to:

- a) promote regulatory cooperation, convergence and transparency through networking, work-sharing and reliance; and
- b) build regulatory capacity in Member States consistent with good regulatory practices.

In order to reach these objectives, WHO has established the framework, principles, tools and processes to, among others, a) evaluate regulatory systems and establish maturity levels by applying the Global Benchmarking Tool (GBT) (9) as well as WHO Global Benchmarking Tool Plus (GBT+) for the evaluation of medical devices, including in-vitro diagnostics (IVDs) (10), and b) evaluate regulatory *performance* in order to designate authorities responsible for regulation of medical products as WLA.



3. Purpose

The principle of reliance is central to WHO's approach to regulatory system strengthening and effective regulation, regardless of the size and maturity of the authority (11).

WHO recognizes that reliance is often used by regulatory authorities to meet different needs. Sometimes a regulatory authority will choose to use reliance, even though it has the needed expertise, because it cannot meet immediate needs. In this case, reliance is used to add to the expertise a regulatory authority otherwise has (e.g. to increase expertise capacity – in the quantitative sense of the word). In other cases, a regulatory authority may not have the requisite expertise at all, and reliance is used to acquire expertise that is otherwise not available (e.g., to increase expertise capacity – in the qualitative sense of the word). Regulatory cooperation and reliance are built on trust and confidence which, in turn, depend on greater knowledge and transparency of the regulatory systems and the performance of the regulatory authority upon which others may rely.

The introduction of a framework for designating and publicly listing a regulatory authority as a WLA provides a transparent and evidence-based pathway for regulatory authorities to be globally recognized as meeting and applying WHO and other internationally recognized standards and guidelines, as well as good regulatory practices.

The main purpose of the introduction of the WLA designation is the replacement of the concept of an SRA which was initially developed to guide global procurement of medicines. This concept has been used by the WHO Secretariat and the Global Fund to guide medicine procurement decisions and has subsequently become widely recognized by the international regulatory and procurement community. The definition of an SRA, first published by the Global Fund in 2008, was based on membership in the International Conference (now Council) of Harmonization (ICH) (13) but the utilization of this concept has been documented since 2003. An interim definition adopted by ECSPP in 2017 restricted eligibility to ICH membership prior to 23 October 2015 while awaiting the development of a more suitable definition and approach based on the WHO benchmarking of regulatory systems (14).

The WLA framework is also replacing the concept and procedure for recognizing regulatory authorities exhibiting 'a high level of performance' in vaccine regulation based on criteria defined in the WHO Technical Report Series (TRS) 978 (13).

Similarly, the WLA designation in the field of medical devices will replace the concept of SRAs (15).

Whilst the GBT and GBT+ are and remain the foundation for assessing the regulatory systems based on inputs, processes and outputs, the WLA framework is meant to provide a comprehensive and detailed picture of how a regulatory system operates through an additional performance evaluation process after a regulatory authority has met an overall ML3 GBT regulatory systems evaluation. This regulatory performance evaluation process examines key regulatory outputs and consistency in adherence to international standards and guidelines as well as good regulatory practices.

It should be noted that in 2025, WHO estimated that two out of three of the regulatory authorities of the WHO Member States did not have a stable and well-functioning regulatory system corresponding to maturity level (ML) 3 or 4, with ML 3 being the target of Resolution WHA 67.20 (17) for regulatory oversight of medicines and vaccines. Bringing these regulatory systems to ML 3 will require significant and sustained efforts and a 'smart' regulatory approach based on reliance on other mature and trusted reference regulatory authorities with a high level of performance – the WLAs – whenever possible. The regulation of medical devices presents challenges compared to medicines and vaccines, owing to the vast number and diversity of products, the rapid pace of technological advancements, and the broad range of expertise needed for their assessment.

The designation of a regulatory authority as a WLA is intended to promote access and the supply of safe, effective and quality medical products by facilitating the use of reliance on the work products and decisions of trusted agencies in the regulatory decision-making of regulatory authorities and the procurement decisions of the United Nations (UN) and other agencies to reduce the redundancy and waste of limited regulatory and financial resources.

4. Scope

This policy provides an overarching vision for the designation of WLAs. It describes the purpose, definitions and operating principles related to the evaluation and public listing of authorities responsible for the regulation of medical products as WLAs. The scope of the WLA designation covers medicines, vaccines and, medical devices including, IVDs, with an option to expand to other categories of products in the future in line with the expansion of the scope of the GB .

Detailed descriptions and guidance on how the system will operate are provided in separate operating guidance.



5. Policy statement

Independent, efficient, science-based and transparent regulatory systems are essential to quality health care systems, access to safe, effective and quality medical products and the implementation of universal health coverage. A system for publicly designating regulatory authorities as WLAs provides an evidence-based mechanism to evaluate, recognize and transparently classify and list well-performing regulatory systems. It thereby, where appropriate, intends to:

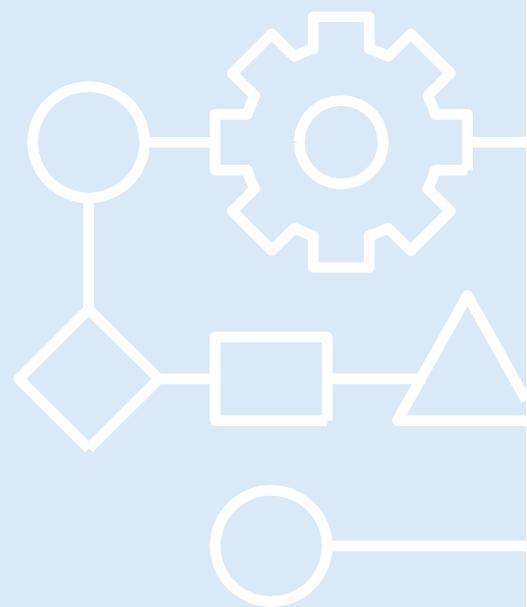
- a) promote trust, confidence and reliance between regulatory authorities;
- b) encourage continuous improvement of regulatory systems and the efficient use of regulatory resources;
- c) expand the pool of regulatory authorities beyond the previous concept of SRAs upon which users such as regulatory authorities or the WHO Prequalification (PQ) Programme can rely;
- d) promote the supply of safe, effective and quality assured medical products or use by UN procurement agencies and countries; and create an enabling environment for innovation and local production of medical products by facilitating the implementation of reliance approaches and therefore accelerating access to safe, effective and quality assured medical products.



6. Definition of a WHO Listed Authority

A WHO-Listed Authority (WLA) is a regulatory authority¹ or a regional regulatory system (RRS) which has been documented to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking and performance evaluation process.

¹ A regulatory authority is meant to cover all the institutions, working together in an integrated and effective manner, that are responsible for regulatory oversight of medical products in a given country or region.



7. Operating principles

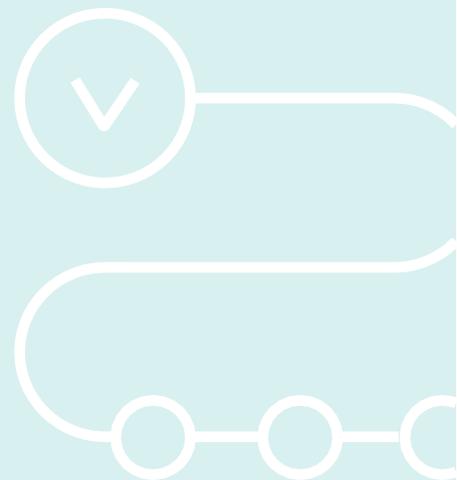
The following principles define in broad terms how the WLA framework is to be implemented. Details are provided in the *WLA Operational Guidance* and accompanying procedures.

- a) The process to establish a WLA listing is initiated by a request from the Member State; for a regional regulatory system (RRS), the request should come from a regional body, where it exists, or another institution representing the RRS, following coordination with the individual authorities that are part of the system, as appropriate.
- b) The GBT forms the basis for evaluating the ML. The WLA performance evaluation process assesses the consistent performance including adherence to international standards and guidelines, as well as good regulatory practices of the regulatory authority or RRS over time against the requirements established for the scope of listing being sought.
- c) Regulatory authorities or RRSs must at least have attained overall ML 3 as established by the GBT to be eligible for consideration as a WLA.
- d) A regulatory authority or RRS can be listed as a WLA for one or more product categories and/or for one or more regulatory functions.
- e) A WLA is expected to have the capacity and established track record of performing the regulatory functions for the product categories relevant to the requested scope of the WLA listing. A WLA can rely in a targeted way based on a defined approach on others for these functions and/or products categories, but full reliance cannot be used as a substitute for reliable performance of regulatory functions/for product categories which are assessed as part of the listing process².
- f) A regulatory authority or an RRS will need to meet the relevant GBT ML4 indicators for those regulatory functions and product categories for which it requests to be listed as a WLA (i.e., the scope of its WLA listing). If the desire is to be listed as a WLA for the full scope (i.e., it is WLA for all product categories and all regulatory functions), then it will need to meet the relevant ML4 indicators overall to be so listed.
- g) After the WHO confirms eligibility criteria to be considered for WLA listing are met, the regulatory authority or the RRS and WHO agree to a written plan of performance evaluation and commit the necessary resources to execute the plan, which may be adjusted if needed. The plan agreed, the resources involved and the time for execution of the plan will depend on the requested scope, the completeness of the documentation as well as the readiness of the regulatory authority or RRS.
- h) In considering the extent and depth of a regulatory authority's or RRS's performance evaluation process, existing evidence and track record of regulatory function and performance, including from previous benchmarking/audit exercises undertaken by WHO or other pertinent organizations recognized by WHO, should be taken into consideration when determining compliance with the requirements for designation as a WLA in order to make best use of limited resources for performance evaluation and avoid unnecessary burden and ensure optimal use of resources.
- i) The degree of integration on the basis of a common framework varies between different regional regulatory systems which should also be taken into account in the designation of these systems.
- j) All non-public information provided is kept confidential.
- k) Following the successful completion of the WLA evaluation process, a regulatory authority or RRS is publicly listed as a WLA in the list of reference authorities published on the WHO website (15). The listing as a WLA includes the scope of the designation (product categories and/or regulatory functions); evidence reviewed, and the process undertaken to support the listing; the original date and the period of validity of the initial listing.

² Note: A regulatory authority which delegates a function to another country regulatory authority based on a legal arrangement, would be considered as performing the function.

- l) A listing will initially be valid for a period of 5 years unless extended. A risk-based process will be used to renew the initial listing. Once renewed, the listing will no longer be subject to a validity period but to a continuous monitoring based on risk management principles to ensure that requirements for the listing continue to be met.
- m) Changes or events that could cause sufficient concern that the requirements for the listing are no longer met will trigger a re-evaluation of the WLA. The re-evaluation will be risk-based and will focus on the issues of concern.
- n) To ensure impartiality of the WLA process, a recommendation to list or de-list a regulatory authority or RRS is made to WHO by an advisory committee following a review of the evaluation report on the candidate WLA. This WLA advisory committee will be set up by WHO based on established and transparent criteria such as ensuring equitable geographical representation, gender balance and professional competencies in order to provide a representation of different approaches and practical experience from all regions of the world. The review process provides an additional level of assurance that due process was followed and that decisions are supported by findings.
- o) WHO may, after evaluation and subsequent discussion between the advisory committee, WHO and the regulatory authority or RRS, de-list a WLA, should it be concluded that the basis for supporting the listing is no longer valid. De-listing and the rationale for de-listing are published on the WHO website.
- p) The ultimate responsibility and decision for use of the list resides with the users (e.g. regulatory authorities, WHO Prequalification Programme, procurement agencies) and depends on the specific context of its intended use.

The designation of WLAs is accorded when a regulatory authority complies with the requirements as set out in this document. It is not intended to make any inference regarding the maturity or performance of a regulatory authority or RRS that has been evaluated by other institutions outside of WHO or through other procedures.



8. Glossary

Common regulatory framework. A common regulatory framework is a unified set of requirements, processes and controls applied in the supervision of medical products. For a common legal framework this is, in addition, underpinned by common legislation.

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. ISO or pharmacopoeial standards) and guidelines (e.g. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) or PIC/S guidelines) and IMDRFs.

Maturity level (ML). The maturity of regulatory systems is divided into four levels, characterized as follows:

- **ML1:** some elements of regulatory systems exist;
- **ML2:** evolving national regulatory systems that partially perform essential regulatory functions;
- **ML3:** stable, well-functioning and integrated regulatory systems; and
- **ML4:** regulatory systems operating at advanced level of performance and continuous improvement.

Product category(ies). Refers to “medical products” which may include the following product categories: vaccines, medicines, medical devices including in-vitro diagnostics, blood and blood products and vector control products.

Regional regulatory system (RRS). A system composed of individual regulatory authorities, or a regional body composed of individual regulatory authorities, operating under a common regulatory framework including or excluding a common legal framework. The common framework must at least ensure equivalence between the members in terms of regulatory requirements, practices and quality assurance policies. The system or regional body, where it exists, may have enforcement powers to ensure compliance with the common regulatory framework. An RRS so described may be considered a single entity and therefore eligible for listing as a WLA, as well as each of the individual authorities that are part of the system. In cases where an RRS is further underpinned by a common legal framework, it should be considered as a single entity and, as such, eligible for listing as a WLA, as well as each of the individual authorities that are part of the system.

Regulatory function(s). The term refers to the regulatory functions as components of a regulatory system for medical products defined in the GBT being national regulatory systems, registration and marketing authorization, vigilance, market surveillance and control, Post-market surveillance, market surveillance and control (applicable for GBT +) licensing establishments, regulatory inspection, laboratory testing, clinical trials oversight, and national regulatory authorities (NRA) lot release (applicable for medicines/vaccines).

Reliance. The act whereby the regulatory authority in one jurisdiction may take into account and give 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 decisions taken, even when it relies on the decisions, assessments and information of others.

Stringent regulatory authority (*interim definition ECSP*). A regulatory authority which is:

- a) a member of the ICH, being the European Commission, the United States (U.S.) Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan, also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015); or
- b) an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or
- c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015) (6).

Highly performing NRA: A regulatory authority that exhibits a high level of performance of WHO's six regulatory functions and exercises full regulatory oversight of any given vaccine (WHO-TRS-978, Annex 6).

Recognized Regulatory Authority: A National Regulatory Authority or its designated notified body that is recognized by WHO, for purposes of WHO's prequalification assessment, as applying stringent standards for quality, safety, and performance in its process of regulatory review of IVDs for marketing authorization.

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