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Policy document

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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 drafting of a first version of the WLA policy and operational guidance, as well as international consultative meetings with Member States and interested stakeholders. It also considers 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)*.

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 AF/RC63/7 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)*.

Resolution WHA 67.20 calls upon WHO to:

a) apply evaluation tools to generate and analyse 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)* 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 *(10)*.

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 does not have enough of the expertise to 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) *(12)* 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 *(12)*.

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)*.

Whilst the GBT is and remains 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.

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