# WHO DRUG INFORMATION

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International Nonproprietary Names for Pharmaceutical Substances

World Health Organization

# WHO Drug Information

WHO Drug Information provides an overview of topics relating to medicines development, regulation, quality and safety. The journal also publishes and reports on guidance documents and includes lists of International Nonproprietary Names for Pharmaceutical Substances (INN), ATC/DDD classification and monographs for The International Pharmacopoeia. It presents and describes WHO policies and activities while reflecting on technical and pharmaceutical topics of international and regional interest.

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### Consultation Documents



### International Nonproprietary Names (INN)



**International Conference of Drug Regulatory Authorities (ICDRA)**

19th ICDRA will take place in
New Delhi, India
28 September – 02 October 2020
https://icdra2020.in

### Abbreviations and websites

| | |
|---|---|
| CHMP | Committee for Medicinal Products for Human Use (EMA) |
| EMA | European Medicines Agency (www.ema.europa.eu) |
| EU | European Union |
| FDA | U.S. Food and Drug Administration (www.fda.gov) |
| Health Canada | Federal department responsible for health product regulation in Canada (www.hc-sc.gc.ca) |
| HPRA | Health Products Regulatory Authority, Ireland (www.hpra.ie) |
| HSA | Health Sciences Authority, Singapore (www.hsa.gov.sg) |
| ICDRA | International Conference of Drug Regulatory Authorities |
| ICH | International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (www.ich.org) |
| IGDRP | International Generic Drug Regulators Programme (https://www.igdrp.com) |
| MHLW | Ministry of Health, Labour and Welfare, Japan |
| MHRA | Medicines and Healthcare Products Regulatory Agency, United Kingdom (www.mhra.gov.uk) |
| Medsafe | New Zealand Medicines and Medical Devices Safety Authority (www.medsafe.govt.nz) |
| Ph. Int | *The International Pharmacopoeia* (http://apps.who.int/phint/) |
| PRAC | Pharmacovigilance Risk Assessment Committee (EMA) |
| PMDA | Pharmaceuticals and Medical Devices Agency, Japan (www.pmda.go.jp/english/index.htm) |
| Swissmedic | Swiss Agency for Therapeutic Products (www.swissmedic.ch) |
| TGA | Therapeutic Goods Administration, Australia (www.tga.gov.au) |
| U.S. | United States of America |
| WHO | World Health Organization (www.who.int) |
| WHO MHP | WHO Access to Medicines and Health Products Division (www.who.int/medicines/en/) |
| WHO RPQ | WHO Regulation and Prequalification Department |
| WHO PQT | WHO Prequalification Unit (https://www.who.int/topics/prequalification/en/) |
| WHO HPS | WHO Health Product Policy and Standards Department |

***Note:*** The online version of this issue (freely available at www.who.int/medicines/publications/druginformation) has

# POLICY

# EVALUATING AND PUBLICLY DESIGNATING REGULATORY AUTHORITIES AS WHO LISTED AUTHORITIES

(December 2019)

***DRAFT FOR COMMENTS***

Please send any comments you may have on this draft working document to **Mr Hiiti Sillo**, Group Lead, Country Regulatory Strengthening, Regulatory Systems Strengthening Team, email: (*silloh@who.int* ), with a copy to Yvonne Melounou (*melounouy@who.int* ) by **28 February 2020** in the format foreseen for this purpose as per below.

Working documents are sent out electronically and they will also be placed on the Medicines website for comments under "Current projects".
*http://www.who.int/medicines/areas/quality_safety/quality_assurance/guidelines/en*

If you wish to receive our draft guidelines, please send your email address to (**jonessi@who.int**) and your name will be added to our electronic mailing list.

## 1. Introduction

This policy, and related guidelines and procedures, constitute an operational framework for *WHO Listed Authorities*.

This policy was developed following broad public consultation and the review of written comments received from the publication of a concept note (1) and subsequent draft policy, as well as international consultative meetings with Member States and interested stakeholders. It also considers recommendations from the Fifty-first meeting of the World Health Organization (WHO) *Expert Committee on Specifications for Pharmaceutical Products* (ECSPP) on the replacement of the term *stringent regulatory authority* with *WHO Listed Authority* (WLA). Recommendations considered comments received on the proposed elements of a replacement definition for SRA posted by WHO for public comment in August 2017 that was intended to provide a more transparent, robust and equitable measure of regulatory capacity and performance (2).

## 2. Context

World Health Assembly Resolution 67.20 on *Regulatory system strengthening for medical products* (3) recognizes that effective regulatory systems are an essential component of health system strengthening, contribute to better public health outcomes and are necessary to the implementation of universal health coverage. The Resolution 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) (4), Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region (2005-2010) (5), and document AF/RC63/7 of the WHO Regional Office for Africa (AFRO) (6). The road map for access to medicines, vaccines and other health products (WHA72/17) 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 (7).

The World Health Organization (WHO) supports countries in strengthening regulatory systems as a means of promoting equitable access to quality assured medical products. An important area of support involves the benchmarking of regulatory systems as mandated through WHA 67.20, which calls upon the WHO to apply evaluation tools to generate and analyse evidence of regulatory system performance; facilitate the formulation and implementation of institutional development plans; and provide technical support to national regulatory authorities and governments.

The benchmarking of regulatory systems referred to in WHA 67.20 implies a structured and documented process by which Member States can assess and address gaps. The Global Benchmarking Tool (GBT) represent the primary means by which the WHO evaluates regulatory systems (8).

The objectives of the WHO regulatory system strengthening program are to:

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

These measures are intended to help ensure the availability of safe, effective and quality medical products by assisting countries reach and sustain a level of regulatory oversight that is effective, efficient and transparent.

## 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. Regulatory cooperation and reliance are built on trust and confidence, which in turn depend on greater knowledge of regulatory systems.

The introduction of a framework for designating and publicly listing a regulatory authority as a *WHO Listed Authority* provides a transparent and evidence-based pathway for regulatory authorities to be globally recognized as meeting WHO and other international recognized standards and practices, replacing the concept of a *stringent regulatory authority* (SRA) which was initially developed to guide global procurement of medicines. The concept of a stringent regulatory authority or SRA has been used by the WHO Secretariat and the Global Fund to Fight AIDS, Tuberculosis and Malaria 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) (9) but utilization of this concept has been documented since 2003.* An interim definition adopted by ECSPP in 2017 restricted eligibility to membership prior to 23 October 2015 while awaiting the development of a more suitable definition and approach based on WHO benchmarking of regulatory systems (10).

The WLA framework also replaces the concept and procedure for recognizing regulatory authorities exhibiting 'a high level of performance' in vaccine regulation based on criteria defined in WHO Technical Report Series (TRS) 978 (11).

While the GBT remains the foundation for assessing regulatory inputs, processes and outputs, the WLA framework is meant to provide a more detailed picture of how a regulatory system operates through an expanded performance evaluation process that examines key regulatory outputs and consistency in adherence to international standards.

The designation of a regulatory authority as a WLA is ultimately meant to promote access, supply and use of safe, effective and quality medical products.

## 4. Scope

This policy describes the purpose, definitions and operating principles related to the evaluation and public listing of authorities responsible for the regulation of medical products as WHO listed authorities or WLAs.

## 5. Policy statement

Efficient, effective and transparent regulatory systems are essential to 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 WHO listed authorities provides a mechanism to document and recognize well-performing regulatory systems and thereby:

- promote trust, confidence and reliance between regulatory authorities;
- encourage continuous improvement of regulatory systems and efficient use of regulatory resources;
- expand the pool of regulatory authorities contributing to the efficiency of the WHO Prequalification (PQ) programme through the increased use of abridged/streamlined procedures to PQ listing;
- promote the supply of quality assured medical products for use by UN procurement agencies and countries; and
- create an enabling environment for innovation and local production of medical