Objectives of the WHO regulatory system strengthening programme

1. Build regulatory capacity in Member States consistent with good regulatory practices

2. Promote regulatory cooperation, convergence and transparency through networking, work-sharing and reliance
Mandate

- WHA Resolution 67.20 (2014)
  Recognizes the importance of strong regulatory systems to a well-functioning healthcare system and the attainment of health-related SDGs and UHC

- SDG 3 – Target 3.8:
  Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all
Adopting a smart regulatory approach

- Strengthening regulatory systems (to ML 3) remains the primary focus of WHO efforts – the baseline for effective regulation

- However, 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
  - represents a vital strategy in confronting the challenges posed by global regulatory environment

- Regulatory cooperation and reliance are built on trust and confidence

- A framework for designating regulators as WHO Listed Authorities (WLAs) will provide a transparent and evidence-based pathway to be globally recognized
A new proposal aimed at promoting reliance - WHO Listed Authority

- WLA responds to concerns over the term *stringent regulatory authority* (SRA) and eligibility criteria based on the pre-reform membership of ICH

- Also considers feedback from two international consultations with Member States in 2015 on the WHO benchmarking policy and process and perceived limitations in measuring regulatory outputs or ‘performance’

- Extensive consultations: key principles in the Concept Note released May 2019 have been subject of public consultation, WHO Expert Committee recommendations (2017) and numerous meetings since, including 2018 ICDRA in Dublin
What’s different from current practice?

- WHO GBT represents primary means by which the WHO evaluates regulatory systems
- GBT designed to provide a structured approach to analysing the inputs, regulatory processes and intended outputs that together determine how well a regulatory authority is configured
- Benchmarking process incorporates elements of performance measurement
  - the challenge has been time required to fully evaluate consistent performance during benchmarking
- WHO intends to address this challenge through an expansion of performance measurement within the benchmarking process
- Positive outcome would result in a public listing as a WLA
Performance evaluation process

• Performance evaluation activity is expected to provide a more detailed picture of how a regulatory system operates

• Will serve to document **consistency** in adherence to procedures and in producing outputs
  
  ✓ consistent with international regulatory requirements and best practices

• WLA Framework will consider the nature and extent of evaluation required to provide a high degree of confidence in an authority’s performance

• Regulatory outputs will serve as a proxy for regulatory competencies
Operating principles (1)

- Voluntary process initiated by a request from a Member State
- Regulatory authorities must meet ML 3 requirements to be eligible for consideration as a WLA
- National regulatory authority (NRA) or a Regional Regulatory System (RRS) eligible
- All available evidence will be taken into consideration when determining compliance with WLA requirements
Operating principles (2)

• Following successful completion of the WLA evaluation process, a regulatory authority is publicly listed as a WLA

• Listing will include scope of the designation, evidence reviewed, process undertaken to support the listing and period of validity of the listing

• Listing will normally be valid for a period of X years, provided no changes have taken place that could negatively impact the WLA listing
Potential Benefits

- Provide a robust framework to promote trust, confidence and reliance and thereby enable efficient use of regulatory resources
- Encourage continuous improvement of regulatory systems
- Help guide procurement decisions on medical products by UN and other agencies, as well as countries;
- Expand the pool of regulatory authorities contributing to efficiency of WHO Prequalification programme
WLA Concept Note, Draft Policy and Operational Guidance
CONCEPT NOTE: A FRAMEWORK FOR EVALUATING AND PUBLICLY DESIGNATING REGULATORY AUTHORITIES AS WHO-LISTED AUTHORITIES

1. SUMMARY

This concept note outlines a proposed framework for evaluating and publicly designating regulatory authorities as "WHO-listed authorities", following upon recommendations from the Fifty-first meeting of the World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Products (ECOSPP) in October 2017 on the replacement of the term stringent regulatory authority with WHO-Listed Authority (WLA).

This concept note presents a proposed definition for WLA; procedures for designating a WLA; and the process for finalizing the definition and the procedures for putting the framework into place. This concept note is meant to provide sufficient information to solicit comments on proposals presented herein, not to provide details of how the framework might be implemented.

WHO intends to publish a draft WLA policy document similar in scope to this note by the end of July 2019 and draft operational guidance documents by the end of August 2019 to enable implementation of the WLA framework. Both the WLA policy document and operational guidance documents will be published for public comment.

Given the wide interest in and implications associated with the definition and framework, WHO will adopt a multi-group consultation process as outlined in this concept note.

How a framework for WLA might operate

Framework for evaluating and publicly designating WLAs

Proposed definition for WLA

Process for finalizing the definition

Procedures for putting the framework into place

Solicit comments

Concept Note, May 2019
Received comments on the Concept Note

Close to 500 comments

Number of parties/organizations providing comments: 44

Type of organizations:

• Regulatory authorities: 25
  • Africa: 3
  • Europe: 9
  • Asia: 4
  • Americas: 8
• International association representing regulatory authorities: 1
• NGO, not-for profit: 6
• Industry (individual companies, associations): 3
• Individuals: 3
• HCP association: 1
• UN organizations: 2
• WHO: 3
Comments received informed development of the draft policy (and definition) and preliminary operational guidance

Meetings attended by 27 Member States and 25 representatives from various stakeholder organizations
INTRODUCTION

• This policy document and related guidelines and procedures constitute an operational framework for WLA

PURPOSE

• Regulatory System Strengthening (WHA 67.20)
• Regulatory cooperation and reliance
• Recognizing regulatory authorities

SCOPE

• Describes the purpose, definitions and operating principles

POLICY STATEMENT

• Promote trust, confidence
• Encourage continuous improvement
• Promote the supply of quality assured medical products

DEFINITIONS

• WHO Listed Authority (WLA)
• Regional regulatory system (RRS)

OPERATING PRINCIPLES

• Principles how the WLA framework
Draft definition of WLA (and RRS)

Extracted from draft WLA policy (circulated for consultative meeting on 19 September 2019)

5. DEFINITIONS

WHO Listed Authority (WLA)

A national regulatory authority\(^8\) or a regional regulatory system which has been documented to comply with all the indicators and requirements specified by WHO for listing based on an established benchmarking and performance evaluation process. A regulatory authority can be listed for one or more product categories or for one or more regulatory functions.

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 or legal framework. The common framework must ensure equivalence between the members in terms of regulatory requirements, practices and quality assurance policies. The regional body, where it exists, may have enforcement powers to ensure compliance with the common regulatory framework. A regional regulatory system so described may be considered a single entity and therefore eligible for listing as a WLA\(^9\).
WHO listing process (Proposed)

SCOPE:
(1) PRODUCTS
- Generic medicines
- New medicines
- Vaccines
- ........

(2) REGULATORY FUNCTIONS:
- MA
- RI
- CT
- ........

RISK BASED APPROACH will be applied:
- Full vs. abbreviated benchmarking
- Extent and duration of the performance evaluation
- Consecutive vs. parallel benchmarking and performance evaluation
Outcomes of the consultative meetings

- Participants voiced overall support for the development of WLA framework, understanding the significance of WLA framework ("game changer")

- Re-affirmation of importance of regulatory system strengthening

- Need for better articulation of the benefits of framework, including with respect to WHO Prequalification

- Complex undertaking; strong support for taking the time to ‘get it right’—allocate sufficient time for consultation, development and piloting of WLA framework

- Transparency on the evaluation outcomes/classifications together with basis/rationale

- Listing as WLA for given scope without reference to maturity level
Outcome of the consultative meetings (2)

- Given diversity of views and complexity of issues
  - Agreed to extend WLA development phase and publish a positive WLA list in 2021 (at the earliest)
  - Merits – sufficient time to:
    - properly develop the operational elements of the WLA framework & precise estimate of resource requirements
    - dialogue and engage with Member States in exploring pathways to establish performance, taking account of investments and available information
    - conduct pilots that will help test and refine the framework.
  - Publish an interim listing of regulatory designations and associated evidence/criteria
Interim listing proposal - current state

- SRAs
- WHO/PAHO designated NRAs of regional reference
- WHO Functional NRAs (Vaccines)
- WHO ML3 and ML4 NRAs

Based on ICH membership (2015)
Based on PAHO/WHO tool
Vaccine tool
Global Benchmarking Tool (after 2016)
What are the next steps?

• Update draft WLA policy based on outcome of meetings and expert committee discussion (Oct 19) and publish for comment

• Develop proposed timelines, resourcing estimates and advocacy and communication plan

• Develop working draft of operational guidance, including performance evaluation framework

• Engage with experts to further develop operational guidance and publish for comment

• Conduct limited number of pilots to test and refine Framework

• Finalize WLA Framework and implement from 2021
Thank you

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