WHO Listed Authorities
Consultative Meeting with Stakeholders

2 July 2020, Virtual Meeting

Hiiti Sillo

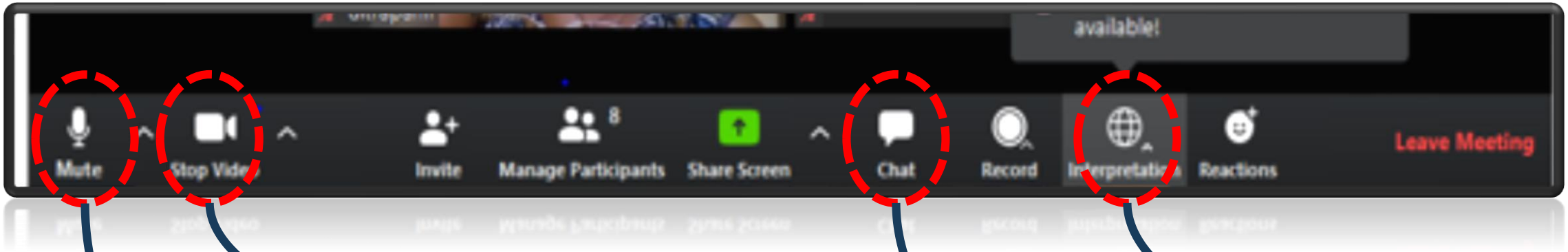
World Health Organization

Housekeeping and Agenda

Housekeeping

- Welcome and introduction
- Zoom instruction and recording of the meeting
- Confidentiality Agreement and DOIs
- Stakeholders input and questions (chat and raising hand)

Meeting controls
The toolbar at the bottom of the screen can be used to mute/unmute and turn video on/off and also to choose the language of the meeting



To turn your microphone on and off.

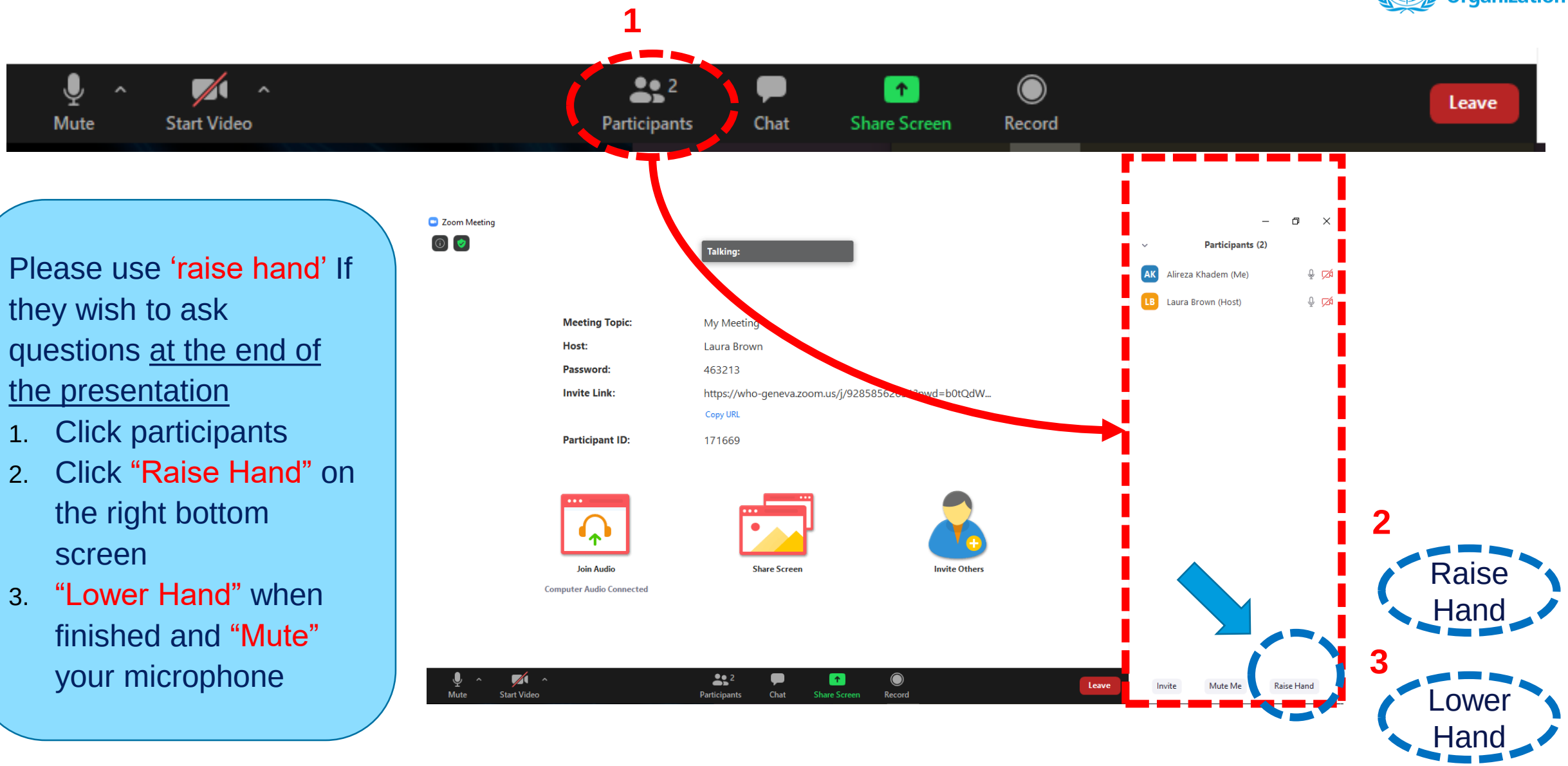
To turn your video on and off.

To write in the chat your comments and questions

To choose to listen in English or Spanish.

Please use ‘raise hand’ If they wish to ask questions <u>at the end of the presentation</u>

1. Click participants
2. Click “Raise Hand” on the right bottom screen
3. “Lower Hand” when finished and “Mute” your microphone



Agenda

Welcome remarks and introduction Objectives of the meeting	Emer Cooke, Director, Regulation and Prequalification Department (RPQ)	14.30 – 14.40
Outcome of the 2019 consultative meeting Update on development of WLA Operational Guidance	Hiiti Sillo, Team Lead, Regulatory Systems Strengthening (RSS) Alireza Khadem, Scientist, RSS	14.40 – 15.00
Overview of comments received on the WLA policy	Petra Doerr, WHO consultant	15.00 – 15.25
Outcome of consultative meeting with Member States	Hiiti Sillo	15.25 – 15.35
Break	All	15.35 – 15.50
Discussion of revised WLA policy	Chair/All	15.50 – 17.10
Next steps	Samvel Azatyan, Acting Unit Head, Regulation and Safety, RPQ	17.10 – 17.20
Conclusion and closing	Emer Cooke	17.20 – 17.30

Emer Cooke
Director, Regulation and Prequalification Department, WHO

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Welcome remarks

Introduction and objectives of the meeting

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

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

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.
- It 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.

Potential Benefits of WLAs

- 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 beyond SRAs for users such as regulatory authorities or the WHO Prequalification (PQ) Programme;
- Promote the supply of safe, effective and quality assured medical products for use by United Nations (UN) procurement agencies and countries; and
- Creation of 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.

Objectives of the consultative meeting

- Provide information on steps taken since consultative meeting in September 2019
- Provide information on outcomes of public consultation on draft WLA policy document
- Provide information on roadmap to develop WLA Operational Guidance
- Feedback on the outcome of the consultation meeting with Member States on 23 June 2020
- Discuss revised draft WLA policy

Hiiti Sillo and Alireza Khadem

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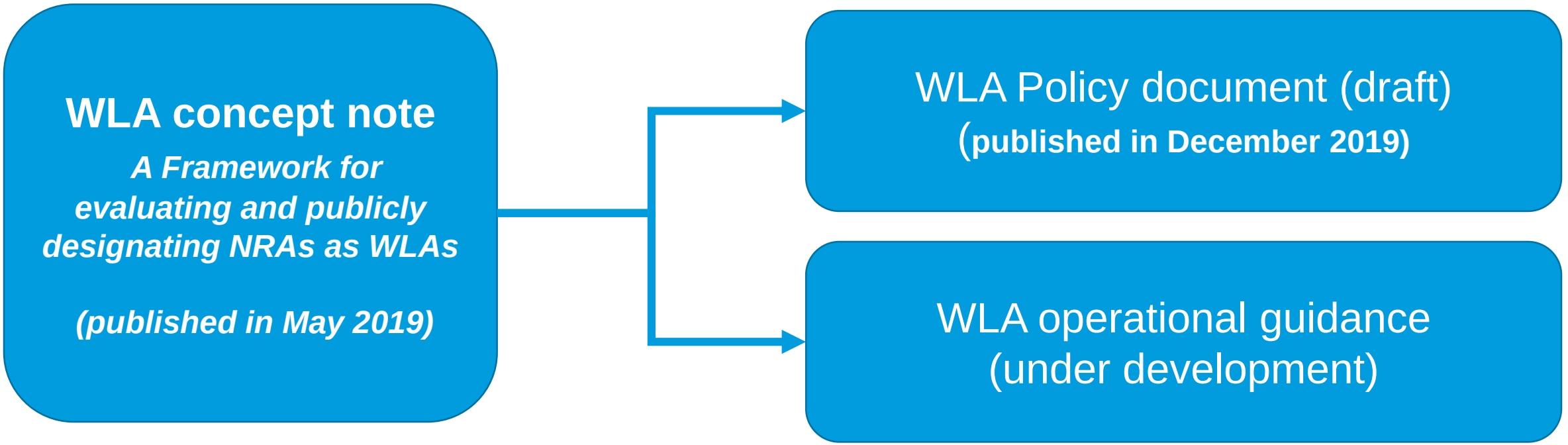
Outcome of the 2019 consultative meetings

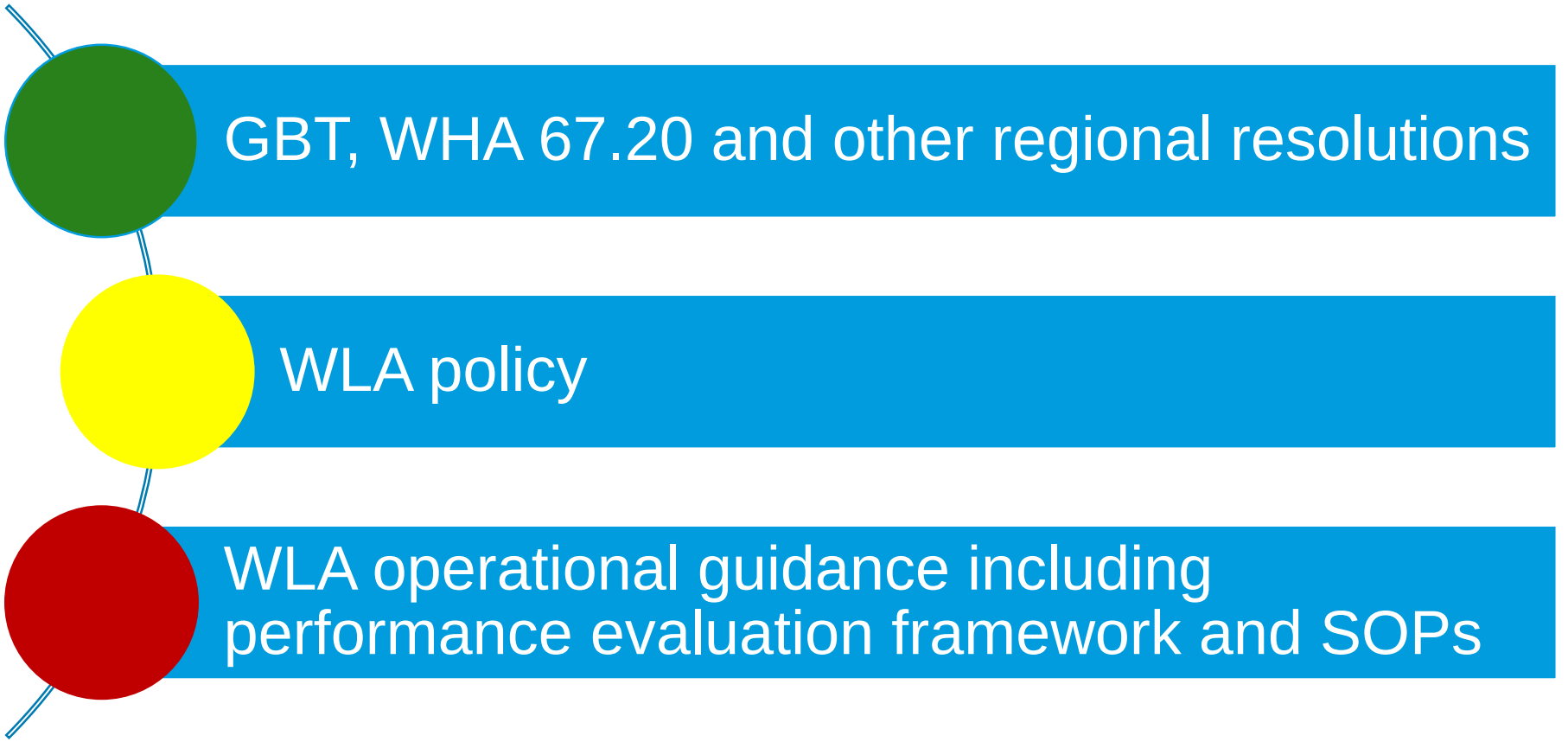
Update on development of Operational Guidance

WLA Framework



WLA policy and operational guidance envisaged to be operational in 2021

WLA framework

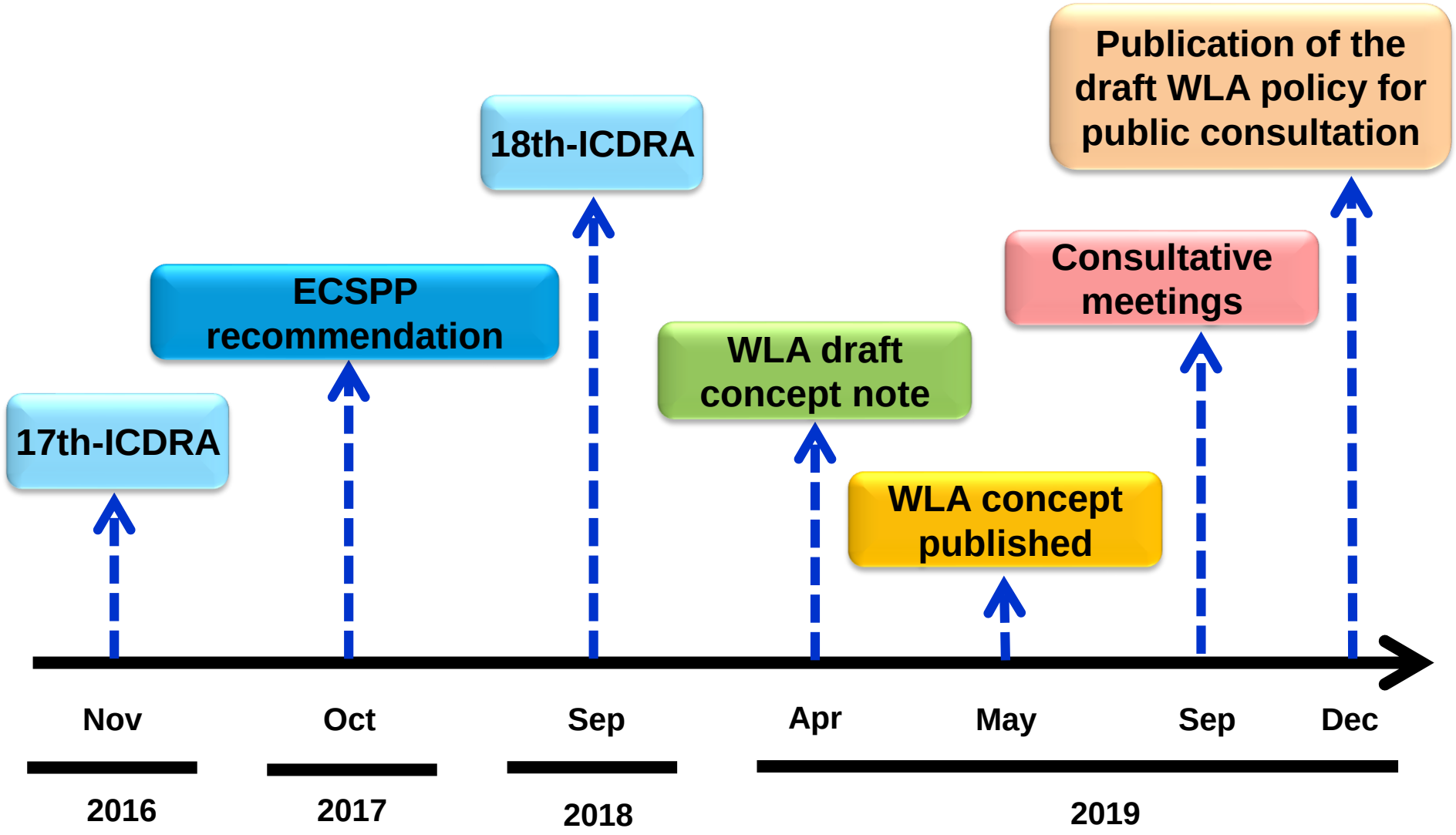


Available

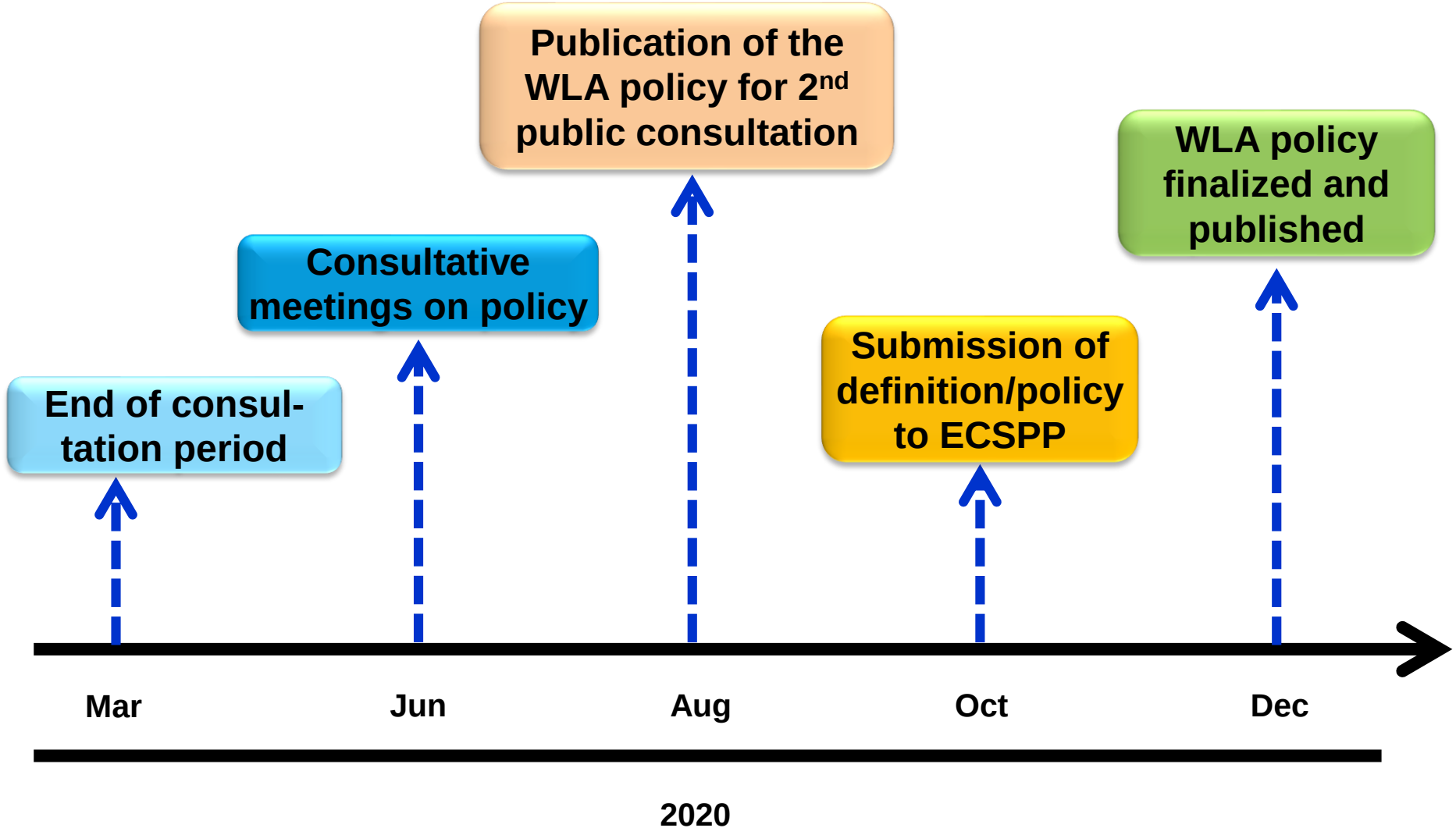
Under development

In early stages of development/ not yet developed

Where are we in the process to establish the WLA policy?



Where are we in the process to establish the WLA policy?

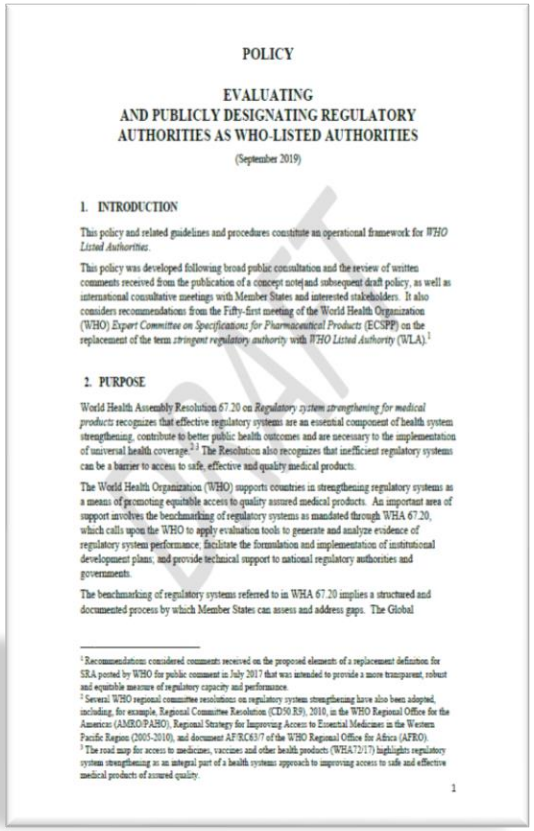


International Consultative Meetings

19 to 23 September 2019, Geneva, Switzerland

- Meetings attended by 27 Member States and 25 representatives from various stakeholder organizations.
- What was discussed?
  - Outcome of public consultation on WLA concept note
  - Draft WLA policy, including e.g.
    - Draft definitions of a WLA and a Regional Regulatory System (RRS)
    - Draft listing process
    - Transitional arrangements

Draft policy



POLICY

EVALUATING
AND PUBLICLY DESIGNATING REGULATORY
AUTHORITIES AS WHO-LISTED AUTHORITIES

(September 2019)

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).[2]

2. PURPOSE

World Health Assembly Resolution 67.20 on *Regulatory system strengthening for medical products* 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.[3,4] The Resolution also recognizes that inefficient regulatory systems can be a barrier to access to safe, effective and quality medical products.

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 analyze 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

[1] Recommendations considered comments received on the proposed elements of a replacement definition for SRA posted by WHO for public comment in July 2017 that was intended to provide a more transparent, robust and equitable measure of regulatory capacity and performance.
[2] 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), Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region (2005-2010), and document AF/RC63/7 of the WHO Regional Office for Africa (AFRO).
[3] 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.

1

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 definitions

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

5. DEFINITIONS

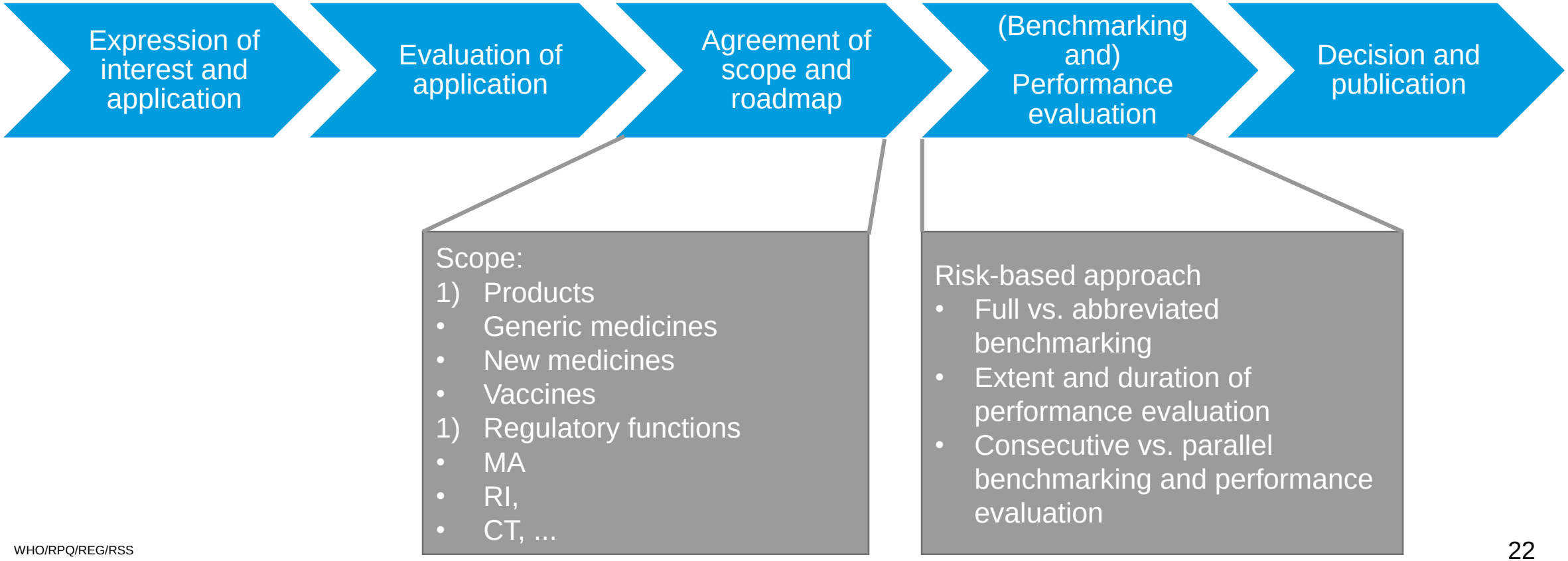
WHO Listed Authority (WLA)

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].

Draft listing process



Outcome of Consultative Meetings

19 to 23 September 2019, Geneva, Switzerland

- 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 the 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 Consultative Meetings

19 to 23 September 2019, Geneva, Switzerland

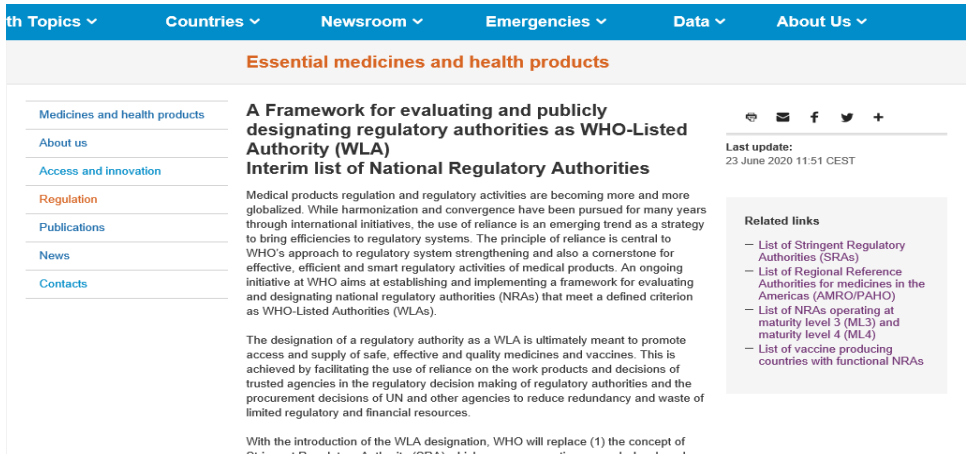
- Given diversity of views and complexity of issues agreed to extend WLA development phase and publish a WLA list in 2021 (at the earliest)
- Merits – sufficient time to :
  - ✓ properly develop the operational elements of the WLA framework & precise estimate of resource requirements
  - ✓ dialogue and 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

Outcome of Consultative Meetings

Interim list of NRAs be published on WHO website

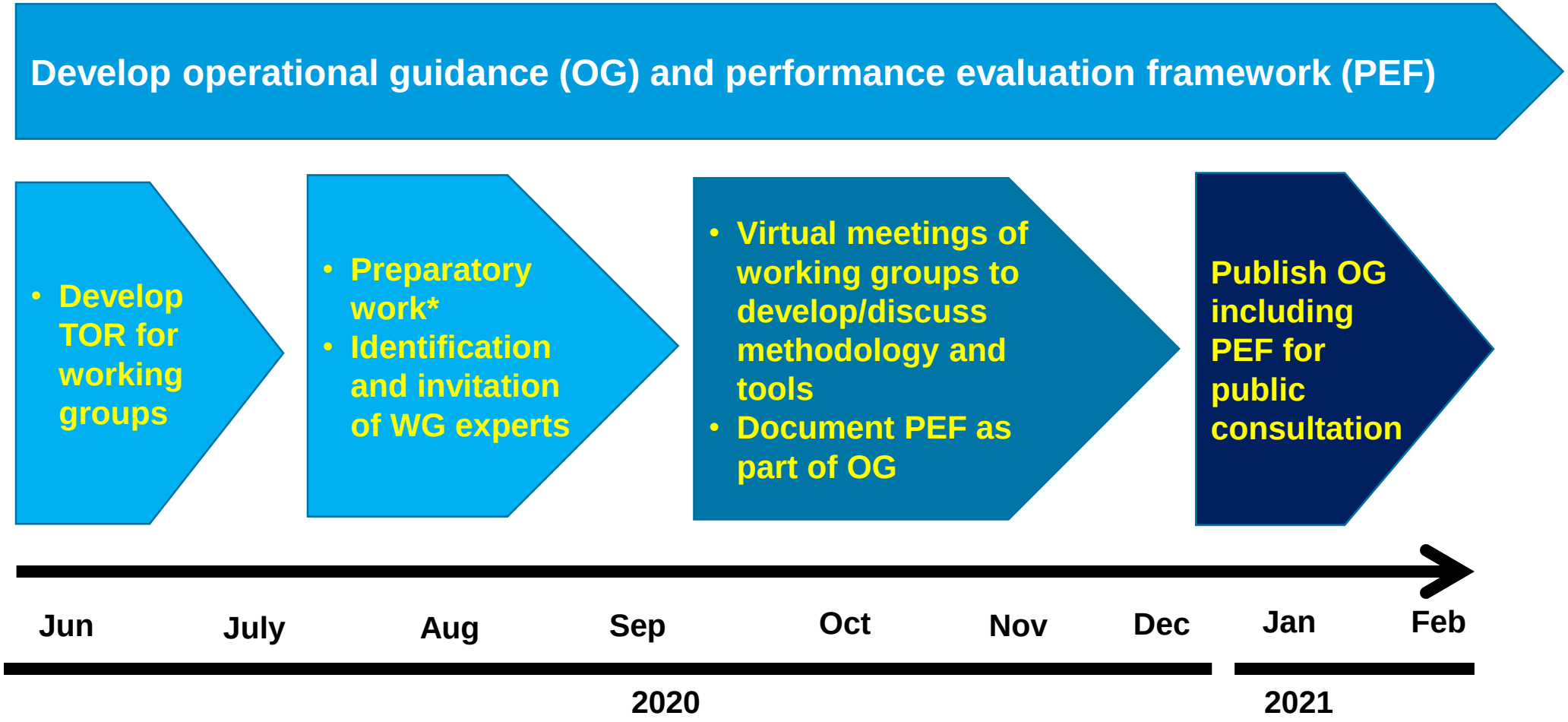
https://www.who.int/medicines/regulation/wla_introduction/en/

SRAs	NRAs of regional reference (WHO/PAHO)	WHO functional NRAs (vaccines)	NRAs at ML3 and ML4
• Based on ICH membership (2015)	• Based on WHO/PAHO tool	• Based on vaccine tool	• Based on WHO GBT (after 2016)



Proposed roadmap to develop Operational Guidance including Performance Evaluation Framework

World Health Organization



* e.g. analysis of exiting PE mechanisms, draft framework/options

Proposed roadmap to develop Operational Guidance including Performance Evaluation Framework

World Health Organization

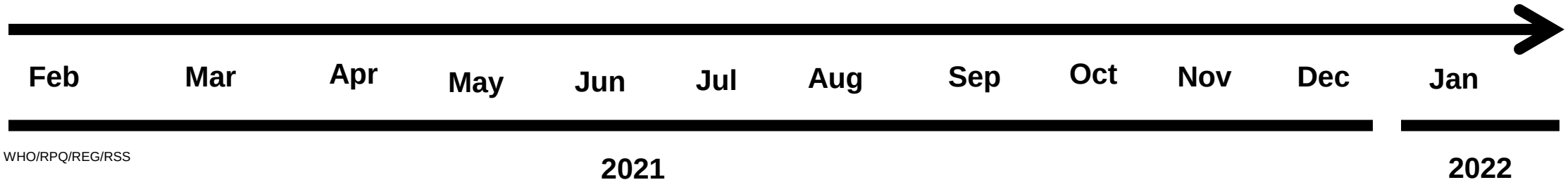
Develop operational guidance (OG) and performance evaluation framework (PEF)

Compilation, discussion and decisions on comments with involvement of WGs to produce 2nd OG/PEF

Piloting

- Consultative meetings
- Finalization and approval of OG including PEF
- Publication

- Implemenation of the WLA framework



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 analyzing the **inputs, regulatory processes** and intended **outputs** that together determine how well a regulatory authority is configured.
- Benchmarking process incorporates elements of performance measurement - but 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.
- 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.

Petra Doerr

World Health Organization

WLA policy: outcome of public consultation

(Dec 2019-Mar 2020)

Public Consultation on draft WLA policy

Organizations submitting comments

A total of 30 organizations provided comments

These included:

- 18 National and Regional Regulatory Authorities
- 4 NGOs
- 2 WHO
- 2 Individuals
- 2 Industry associations
- 1 Healthcare Professionals Organization
- 1 Individual company

Public Consultation on WLA policy

Number of comments received

A total of 241 comments have been received.

Out of these:

- 38 General comments
- 203 Detailed comments

Sections:

- 0 (Timetable) 5 comments
- 1 (Introduction) 16 comments
- 2 (Context) 13 comments
- 3 (Purpose) 30 comments
- 4 (Scope) 1 comment
- 5 (Policy statement) 21 comments
- 6 (Definitions) 23 comments
- 7 (Operating principles) 84 comments
- Annex 1 8 comments
- References 2 comments

Public Consultation on WLA policy

General support for the WLA policy but “the devil is in the detail”

Organizations voice their support in the general comments; but the large number of comments received on the operating principles shows that there is still need for clarification and further detailing on how this policy will be implemented and working in practice.

Overview of main changes

1. Regrouping of text in the “Context” (chapter 2) to have a more logical flow of information.
2. Introduction of a glossary of terms (chapter 3). The glossary includes the following terms: a) international standards (level of detail to be discussed at consultative meeting), b) Stringent Regulatory Authority, c) Common regulatory/legal framework, d) Product categories, e) Reliance
3. Adding a paragraph under “Purpose” (chapter 4) on the current situation regarding maturity levels of NRAs globally (190-195) and the importance of the WLA for the facilitation of reliance (198-201).
4. Adding the (initial) product scope being medicines and vaccines (207-209) to the “Scope” (chapter 5).

Overview of main changes

5. Revision of the “Policy statement” (chapter 6) regarding the impact of the WLA on PQ and procurement agencies (218, 223-227).
6. Shortening of the definitions of a WLA and an RRS (chapter 7).
   - The sentence “A regulatory authority can be listed for one or more product categories or for one or more regulatory functions.” has been moved from the definition to the “Operating principles” (chapter 8).
   - The sentences: “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, as well as the individual authorities that are part of the system .” has been moved from the definition to the “Operating principles” (chapter 8).

Overview of main changes

7. Add wording referring to RRS ("... A regulatory authority or RRS...") where applicable (256-257,261, 271, 278, 296, 309, 318, 321, 327, 330 in the "Operating principles" (chapter 8)
8. Inclusion of an operating principle regarding the fact that an NRA cannot be a WLA for a function or product category for which the NRA relies on others (274-277).
9. Expansion of the operating principle regarding existing evidence and track record of regulatory function (284-292)
10. Include wording to differentiate the terms "re-evaluation" (during the validity period) and "renewal" (at the end of the validity period) (299-307).

Overview of main changes

11. Two options for “renewal”: five-year validity of listing and risk-based process for renewal or no validity period with “continuous monitoring based on risk-management principles” (to be discussed at consultative meeting)
12. Adding detail on the composition of the committee of experts (311-314).
13. Adding an operating principle on the ultimate responsibility and decision for use of the list residing with the user (being e.g. RAs, WHO PQ and procurement agencies) (323-324)
14. Deletion of Annex 1 on the GBT and the concept of maturity levels (384 ff).

Examples of comments not considered

1. Amendments to the timetable referring to the Operational guidance or the interim list.
    - The Operational guidance itself will be developed following a timetable that will be incorporated in the document. The timetable in the WLA policy only refers to the steps to finalize the policy document.
2. Adding a statement on access and availability under the objectives of the WHO regulatory systems strengthening program.
    - RSS contributes to the access roadmap – it is the objective of WHO in the context of UHC.
3. Several requests were made to add detail to the policy.
    - Proposals included to add examples or detailed information on criteria and process. It is suggested that those will be addressed in the Operational guidance.

Examples of comments not considered

4. Change the definition of an RRS to say that it requires a common regulatory AND legal framework.
   - The requirement for both – a common regulatory and a common legal framework – is a criterion that only the EU would fulfill. The definition of the RRS should leave room for other approaches, e.g. AMRH and AMA in Africa, where there is no common legal framework.
5. Request to include wording on interim measures in the policy.
   - The only interim/transitional measure that was agreed at the consultative meeting in September 2019 is the publication of an “interim list”. This list has been published already.

Examples of comments not considered

6. Only NRAs with ML4 should be eligible for WLA.
    - Both NRAs with ML3 and ML4 will remain eligible to apply for the WLA designation. Both will have to demonstrate in the process that they fulfill the performance criteria of a WLA.
7. Grandfathering-in of SRAs requested.
    - It was agreed at the consultative meeting that there should be no grandfathering-in of any existing reference authorities. The process for SRAs and for other reference authorities to become WLA should consider the established track record and demonstrated performance, as outlined in the operating principles and to be detailed in the Operational guidance.

Hiiti Sillo

Outcome of consultative meeting with Members States on 23 June 2020

Consultative meeting with Member States

- > 110 participants from Member States (including WHO staff)
- Wide support of WLA policy and framework as well as the proposed roadmap for development of the operational guidance.
- Remaining uncertainties around implementation/operationalization because operational guidance is not available yet.
- Many comments raised during the meeting will be considered in the drafting of the operational guidance (e.g. ToR/role of advisory committee, process for listing/”grandfathering” of SRAs, desk-based vs. physical visits for performance evaluation, language issues).
- Discussion of level of detail to be included in policy document.

Consultative meeting with Member States

Main outcomes (1)

Comments raised

- Clarification of wording for operating principle on full reliance not being acceptable as a substitute for performance; was considered as a contradiction to WHO's efforts to promote reliance.
- Preference for continuous monitoring based on risk management principles over defined validity period (5 years); in addition, proposal to have longer validity period of 7-8 years. In any case, a risk-based approach should be applied to minimize resources needed for renewal/evaluation.
- Distinction of Regional Regulatory System with and without common legal framework.
- Include terms "maturity level" and "medicines" in glossary.

Consultative meeting with Member States

Main outcomes (2)

Comments raised

- Inclusion of reference to list of reference NRAs (see slide 25) in policy document.
- Wording around international standards and guidelines; inclusion of examples besides WHO (e.g. ICH).
- Shortening of definition of RRS (moving part of the text to operating principles) was disputed.
- Combine chapters 3 (Glossary) and 7 (Definitions)
- Reference to operational guidance in policy document should be deleted (because it is not available yet).

Emer (Moderation)

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Discussion of revised WLA policy

Discussion of revised WLA policy: Chapter 1

More specific wording

Relationship between concept note and policy/operational guidance

ECSPP did not introduce term WLA but regulatory authority “on a list”

Only refer to performance

1. Introduction

This policy, and related ~~guidelines and procedures~~documents such as the WLA operational guidance (1), constitute an operational framework for *WHO Listed Authorities (WLA)*.

This policy was developed following broad public consultation and the review of written comments received from the publication of a concept note (~~1~~2, 3), which informed the drafting of a first ~~and subsequent draft~~ version of the WLA policy and operational guidance, as well as international consultative meetings with Member States and interested stakeholders (4, 5). 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 regulatory authority~~*WHO Listed Authority* (WLA)~~ to be *“on a list”*. The ECSPP ~~R~~recommendations ~~considered~~ 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 ~~capacity and~~ performance (~~2~~6).

Discussion of revised WLA policy: Chapter 2

Part 1

Correct reference

Revised wording

2. Context

World Health Assembly Resolution 67.20 (Resolution WHA 67.20) on *Regulatory system strengthening for medical products* (~~3~~7) recognizes that effective regulatory systems are an essential component of health system strengthening, necessary for the implementation of universal health coverage ~~policy~~, and ultimately contribute to better public health outcomes~~contribute to better public health outcomes and are necessary to the implementation of universal health coverage~~. ~~The Resolution~~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) (~~4~~8), Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region (2005-2010) (~~9~~5), and document AF/RC63/7 of the WHO Regional Office for Africa (AFRO) (~~10~~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~~11).

Discussion of revised WLA policy: Chapter 2

Part 2

Text moved after the text referring to the Resolution WHA 67.20 (see below)

~~The World Health Organization (WHO) supports countries in strengthening regulatory systems as a means of promoting equitable access to~~ and availability of quality ~~assured medical products. An important area of support involves the benchmarking of regulatory systems as mandated through~~

Resolution 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.

Wording to include “and availability of”

The WHO supports Member States in strengthening regulatory systems as a means of promoting equitable access to and availability of quality assured medical products. ~~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) represents the primary means by which the WHO and Member States evaluates regulatory systems (8).~~

Discussion of revised WLA policy: Chapter 2

Part 3

RSS programme and its objectives

Implementation of the programme through e.g. GBT and WLA.

This content is now included in lines 97-98 (see previous slide)

104 To assist countries in reaching and sustaining a level of medical product regulatory oversight
105 that is effective, efficient, and transparent, WHO has implemented a regulatory system
106 strengthening programme. Its objectives~~The objectives of the WHO regulatory system~~
107 ~~strengthening program~~ are to:
108
109 • promote regulatory cooperation, convergence and transparency through networking,
110 work-sharing and reliance; and
111 • build regulatory capacity in Member States consistent with good regulatory practices.
112
113 In order to reach these objectives, WHO has established the framework, principles, tools and
114 processes to among others a) evaluate regulatory systems and establishing maturity levels by
115 applying the Global Benchmarking Tool (GBT) (812) and b) designate ~~of~~ authorities
116 responsible for regulation of medical product as WLA.
117
118 ~~These measures are intended to help ensure the availability of safe, effective and quality~~
119 ~~medical products by assisting countries reach and sustain a level of regulatory oversight that is~~
120 ~~effective, efficient and transparent.~~

Discussion of revised WLA policy: Chapter 3

Reference to international standards

Chapter 3: Glossary

122 **3. Glossary**

123 International standards: For the purpose of this document the term includes relevant WHO
124 standards~~, ICH guidelines, ISO standards~~and any other relevant internationally recognized
125 standards.

Chapter 4: Purpose

177 While the GBT remains the foundation for assessing the regulatory systems based on inputs,
178 processes and outputs, the WLA framework is meant to provide a more detailed picture of how
179 a regulatory system operates through a~~n expanded~~ performance evaluation process that
180 examines key regulatory outputs and consistency in adherence to international standards and
181 good regulatory practices.

Chapter 8: Operating principles

Discussion point:
Agree location and wording of reference to international standards

250 • The WHO Global Benchmarking Tool (GBT) and the performance evaluation process
251 form the basis for evaluating the maturity level and the consistent performance including
252 adherence to international standards and good regulatory practices of the regulatory
253 authority or RRS over time against requirements established for the scope of listing being
254 sought ~~(product category or regulatory function)~~.

Discussion of revised WLA policy: Chapter 3

Added wording on terms:

- Common regulatory/legal framework
- Regulatory function(s)
- Product category/ies

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

138 Regulatory function(s): The term refers to the regulatory functions as components of a
139 regulatory system for medical products defined in the GBT.

140 Product category(ies): The scope of the WLA policy is referring to "medical products"
141 including the following product categories: vaccines, medicines, medical devices including in-
142 vitro diagnostics, blood and blood products and vector control products.

Discussion of revised WLA policy: Chapter 4

Purpose

Introduction of a paragraph about the current status regarding maturity levels of NRAs globally, underpinning the need for reliance.

183 It should be noted that in 2019, an estimated 75% of the 194 Member States were estimated do
184 not have a stable and well-functioning regulatory system corresponding to ML 3 or 4, with ML
185 3 being the target of WHA 67.20. Bringing these regulatory systems to ML 3 will require
186 significant and sustained efforts and a 'smart' regulatory approach based on reliance on other
187 mature and trusted regulatory authorities whenever possible.
188

Introduction of wording around the relevance of the WLA to facilitate reliance.

189 The designation of a regulatory authority as a WLA is ultimately meant to promote access~~,~~ and
190 supply ~~and use~~ of safe, effective and quality medical products by facilitating the use of reliance
191 on the work products and decisions of trusted agencies in the regulatory decision making of
192 regulatory authorities and the procurement decisions of UN and other agencies to reduce
193 redundancy and waste of limited regulatory and financial resources.

Discussion of revised WLA policy: Chapter 5

Scope

Introduction of a sentence regarding the initial scope being medicines and vaccines, with the option to expand in line with the expansion of the scope of the GBT.

197 This policy describes the purpose, definitions and operating principles related to the evaluation
198 and public listing of authorities responsible for the regulation of medical products as WHO
199 listed authorities or WLAs. The initial scope of the WLA designation will be limited to
200 medicines ~~including~~and -vaccines, with an option to expand to other categories of products in
201 the future in line with the expansion of the scope of the GBT.

Discussion of revised WLA policy: Chapter 6

Policy statement

Amended wording to better reflect the voluntary nature of the WLA concept (“intends to”)

More generic wording regarding the possibility for regulatory authorities and WHO PQ to expand the pool of reference authorities beyond SRAs.

Amended wording to stress the impact of the WLA regarding the facilitation of reliance

regulatory systems. It ~~and~~ thereby, where appropriate, intends to ~~contributinge to~~:

- ~~The~~ promote~~ion of~~ trust, confidence and reliance between regulatory authorities;
- ~~The~~ encourage~~ment of~~ continuous improvement of regulatory systems and efficient use of regulatory resources;
- ~~The~~ expand~~dsion of~~ the pool of regulatory authorities beyond SRAs for users such as regulatory authorities or the WHO Prequalification (PQ) Programme~~contributing to the efficiency of the WHO Prequalification (PQ) programme as well as other pathways such as the WHO collaborative procedure; through the increased use of abridged/streamlined procedures to PQ listing~~;
- ~~The~~ promote~~ion of~~ the supply of safe, effective and quality assured medical products for use by United Nations (UN) procurement agencies and countries; and
- ~~The~~ create~~ion of~~ 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.

Discussion of revised WLA policy: Chapter 7

Definitions

The deleted sentence has been moved to chapter 8 (Operating principles).

WHO Listed Authority (WLA)

A ~~national~~ regulatory authority[1] 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.~~

The deleted sentences have been moved to chapter 8 (Operating principles).

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, as well as the individual authorities that are part of the system[2].~~

Discussion of revised WLA policy: Chapter 8

Operating principles (Part 1)

Additional wording on who should apply from an RRS.

Reference to “consistent performance” and “adherence to international standards and GRPs over time” added.

- The process to establish a WLA is initiated by a request from the Member State; for an RRS the request should come from a regional body or another institution representing the RRS.
- The WHO Global Benchmarking Tool (GBT) and the performance evaluation process form the basis for evaluating the maturity level and the consistent performance including adherence to international standards and good regulatory practices of the regulatory authority or RRS over time against requirements established for the scope of listing being sought ~~(product category or regulatory function)~~.

Discussion of revised WLA policy: Chapter 8

Operating principles (Part 2)

Wording for both definitions moved from chapter 7 (Definitions) to chapter 8 (Operating principles).

- A regulatory authority or RRS can be listed for one or more product categories and/or for one or more regulatory functions.
- For an RRS, the common framework must 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 or legal framework. A regional regulatory system so described may be considered a single entity and therefore eligible for listing as a WLA, as well as each of the individual regulatory authorities that are part of the system.

Discussion of revised WLA policy: Chapter 8

Operating principles (Part 4)

Revised wording

Additional operating principle on the fact that a WLA cannot fully rely on others in a regulatory function or for a product type that it is applying for to become a WLA.

263 • Regulatory authorities or RRSs must at least ~~meet requirements defined by WHO for a~~
264 have attained overall maturity level 3 as established by the GBT for all regulatory
265 functions ~~authority~~ to be eligible for consideration as a WLA.
266 • A WLA is expected to have the capacity and established track record of independently
267 performing all the regulatory functions relevant to the scope of the WLA listing. This
268 means that reliance cannot be used as a substitute for reliable performance of regulatory
269 functions/for products categories which are assessed as part of the listing.

Discussion point:
Add either “overall” maturity level 3 or maturity level 3 as established by the GBT “for all regulatory functions” to make it clear that it is not sufficient to have reached ML 3 in one or a few regulatory functions (and then apply to become a WLA for this/those function/s).

Discussion of revised WLA policy: Chapter 8

Operating principles (Part 5)

Additional wording to elaborate that time and resources of the listing process will depend on certain factors.

Expanded paragraph regarding the use of existing evidence or track record of performance, including examples, and the notion of avoiding unnecessary burden for applying regulatory authorities or RRS.

- ~~Once~~ After the WHO confirms eligibility criteria 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 from time to time. 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.
- In considering the extent and depth of the evaluation process, factors such as existing evidence and track record of regulatory function and performance, including from previous benchmarking/audit exercises undertaken by WHO or other organizations such as e.g. PIC/S, BEMA, ICH or ISO of the regulatory authority or RRS, 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. ~~All available evidence including from previous benchmarking/audit exercises, is taken into consideration when determining compliance with the requirements for designation as a WLA.~~

Discussion of revised WLA policy: Chapter 8

Operating principles (Part 6)

Validity of five years and risk-based process for renewal.

Distinguish terms “renewal” (at the end of the validity period) from “re-evaluation” (during the validity period)

Discussion point:
Alternatively, a listing could be granted without a validity period but with a “continuous monitoring of performance applying principles of risk management – only re-evaluating the listing when a signal is received. Discuss at consultative meeting.

291 • A listing will normally be valid for a period of ~~at least~~ 5 years. A risk-based process will
292 be used to renew the listing. ~~If no changes have taken place that could negatively impact~~
293 ~~the WLA listing, the listing can be renewed automatically.~~
294 • ~~, provided no e~~Changes or events, which have taken place during the validity period that
295 ~~that could negatively impact the WLA listing~~could cause sufficient concern that the
296 requirements for the listing are no longer met, ~~and that no event has taken place which~~
297 ~~could cause sufficient concern to~~will trigger a~~n earlier~~ re-evaluation of the WLA~~authority~~.
298 The re-evaluation will be risk-based and focus on the issues of concern~~An abbreviated,~~
299 ~~risk-based process will be used when re-evaluating a WLA~~.

Discussion of revised WLA policy: Chapter 8

Operating principles (Part 7)

Revised/additional wording around the composition of the committee.

Proposal to call it an “advisory committee” instead of “(independent) committee of experts”

Editorial changes

- To ensure impartiality of the WLA process, a recommendation to list or delist a regulatory authority or RRS is made following a review of the evaluation report ~~of~~on the candidate WLA ~~evaluation team~~ by an ~~independent~~ advisory committee ~~of experts.~~ ~~designated~~ This 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, as described in the WLA operational guidance (1), provides an additional level of assurance that due process was followed, and that decisions are supported by findings.
- WHO reserves the right to delist a ~~regulatory system~~ WLA should, upon evaluation and subsequent discussion with the regulatory authority or RRS, it ~~is~~be concluded that the basis for supporting the listing is no longer valid. Delisting and the rationale for delisting are ~~made public~~published on the WHO website. The decision to delist would follow a meeting with the regulatory authority or the RRS during which the authority would have an opportunity to present its case.

Discussion of revised WLA policy: Chapter 8

Operating principles (Part 8)

Introduction of an operating principle regarding the responsibility on if and how to use the list of WLA to reside with the user being for example regulatory authorities or WHO PQ.

Revised wording to provide more clarity.

315 • The ultimate responsibility and decision for use of the list resides with the users (e.g.
316 regulatory authorities, WHO Prequalification Programme, procurement agencies) and
317 depends on the specific context of its intended use.
318
319 The designation of WLAs is meant to substantiate the maturity level using an international
320 benchmark, as defined by the GBT and the performance of regulatory authorities and RRSs
321 ~~using an international benchmark, as defined by the GBT and~~using the WLA performance
322 evaluation process. It is not meant to make any inference regarding the maturity or
323 performance of a regulatory authority or RRS that has ~~not~~ been evaluated by ~~WHO~~other
324 institutions or through other procedures.

Discussion of revised WLA policy: Chapter 8

References and Annex 1

List of references

- Any comments?

Proposed deletion of Annex 1

- It is suggested to include the Annex in the Operational guidance

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Next steps

Next steps

- Consolidation of comments from meeting and revision of the WLA policy (July 2020)
- Second public consultation (August 2020)
- Consolidation of comments from public consultation (September 2020)
- Submission to ECSPP and ECBS (October 2020)
- Finalization of WLA policy and publication (Dec 2020)
- Development of the Operational guidance and few pilots (2020 - 2021)

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Conclusions & Closing

Thank you

World Health Organization