Credits: WHO / Atul Loke / Panos Pictures

REGULATORY UPDATES

SESSION 10 – PLENARY: Thursday 30 November 2023
08:45 – 13:00

Session Chair: Hiiti Sillo, Unit Head, Regulation and Safety, WHO

WHO's journey and its regulatory functions

World Health Organization 75 HEALTH FOR ALL

WHO work
Key non-WHO work
Major diseases

Reflecting the MHP work on Vaccines & Biologicals

1947 Global disease tracking
ECBS established

1948 WHO established 7 April

1950 Int Non-proprietary Name

1968 ECSPP established

1969 International Health Regulation

1974 PV Medicines

1977 Expanded Program of Immunization
1st Essential Medicines List

1978 Uppsala Monitoring Centre

1980 Smallpox eradication
1st ICDRA

1987 GAVI Alliance
PQ Med
GACVS
PQ Vx

1990 UN SDG
Global Fund
GOARN
ICH established

1999 UN HIV/AIDS declaration

2000 CRP Vx

2001 PQ QCL Med
Revised IHR

2004 H1N1 Pandemic

2005 WHA67.20
Regulatory Syst Strengthening
Polio declaration
Ebola outbreak W Africa

2009 PQ Dx

2010 Global Benchmarking Tool
Global Network of Vx Lab
Zika outbreak

2012 ICMRA established

2014 Memb State Mechanism
CRP Med

2015 EUL Procedure

2016 PQ VCP
Incidents & SF

2017 COVID-19 Pandemic

2020 Implementing WHO Listed Authority (WLA)

2021 Mpox outbreak

2022 Good Regulatory Practices
Good Reliance Practices

2023




Agenda for this morning

Session 1: 8:45 to 10:30
The new era of WHO Listed Authorities, reliance and facilitated regulatory pathways
Updates from WHO, industry and regulators view points

Coffee/tea Break 10:30 – 11:00

Session 2: 11:00 to 13:00
Setting standards, safety monitoring and market control
Updates on Safety monitoring, Supply Chain Integrity, Nitrosamine control, and WHO Norms and Standards

Session 1: The new era of WHO Listed Authorities, reliance and facilitated regulatory pathways – Objectives

Landmark listing of first three countries as WHO-Listed regulatory Authorities

- Discuss the latest development and next steps on the WHO Listed Authorities Initiative
- Exchange on reliance implementation and facilitated regulatory pathways
- Industry and developers perspective
- Practical experience of a NRA journey to WLA

Session 1: The new era of WHO Listed Authorities, reliance and facilitated regulatory pathways – Panelists

- **Dr Alireza Khadem**, WHO Team Lead REG/Regulatory System Strengthening *(virtually)*
- **Ms. Marie Valentin**, WHO Team Lead, REG/Facilitated Product Introduction
- **Ms. Prisha Patel Prisha Patel**, Senior Manager, International Regulatory Science & Policy Global Product Development, Pfizer, UK on behalf of IFPMA
- **Mr Parag Nagarkar**, Head of International Regulatory Affairs, Serum Institute of India will join the panel on behalf of SIIPL/DCVMN *(virtually)*
- **Dr Youngjin Ahn**, Director of Pharmaceutical Policy Division, Ministry of Food and Drug Safety *(virtually)*

World Health Organization

Thank you for your attention!

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Regulation and Prequalification

THE NEW ERA OF WLA

Alireza Khadem
WHO/RPQ/REG/RSS

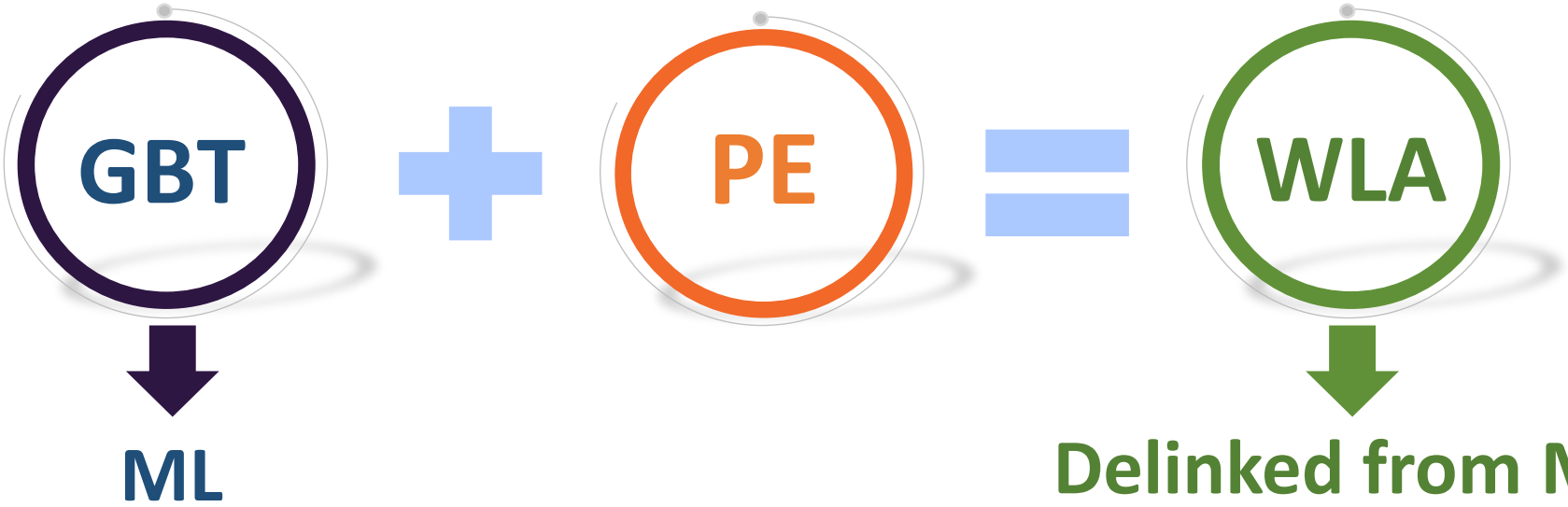
Joint UNICEF, UNFPA and WHO meeting

What is a WHO-listed authority?

WLA builds upon GBT

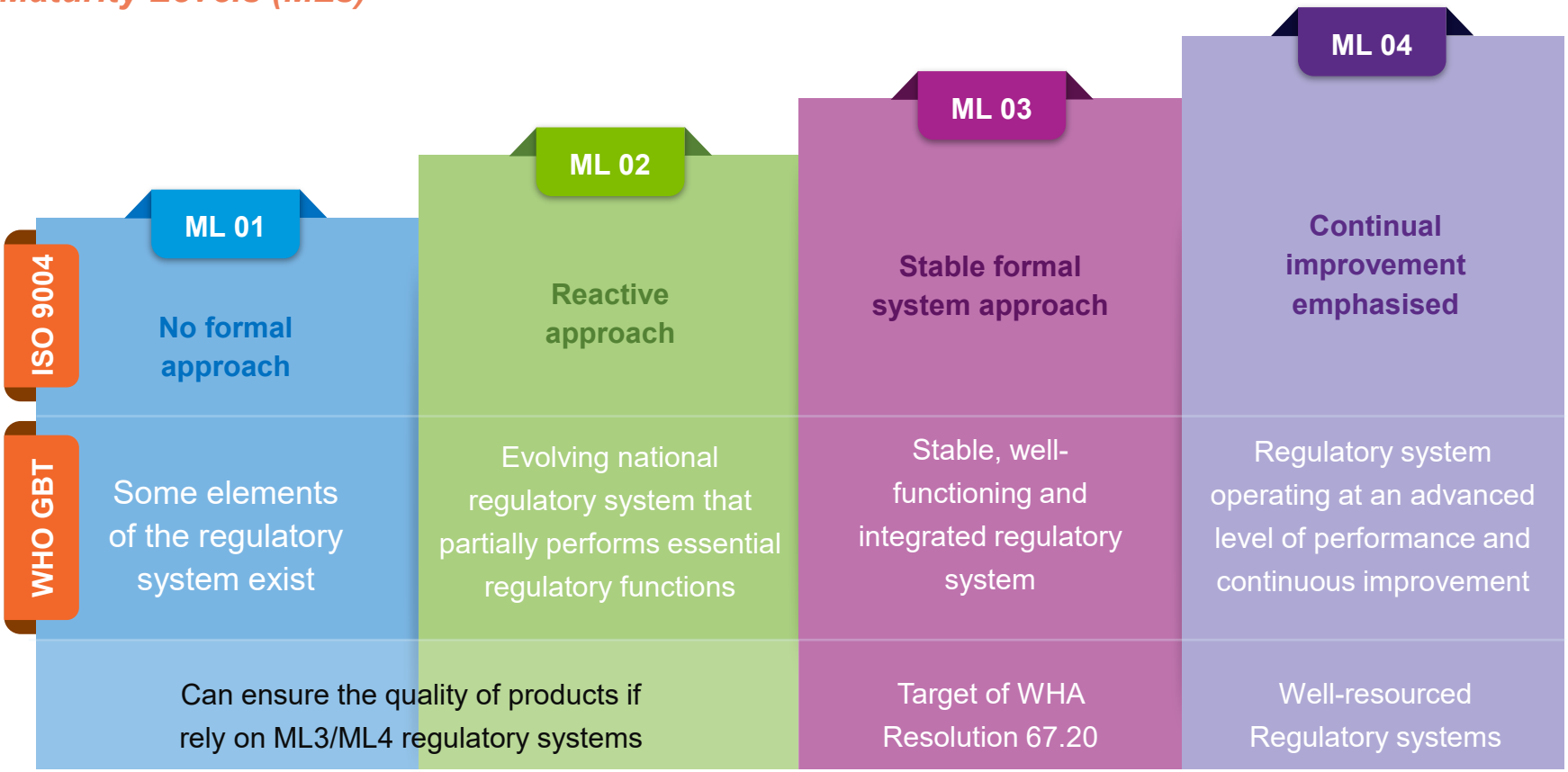
A WHO Listed Authority (WLA) is a regulatory authority or a regional regulatory system which has been documented to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an

established benchmarking (GBT) AND a **performance evaluation (PE) process**



The Global Benchmarking Tool

Maturity Levels (MLs)



What's being measured?

GBT-ML

WLA

Performance

28 sub-ind.
ML1

32 sub-ind.
ML2

151 sub-ind.
ML3

57 sub-ind.
ML4

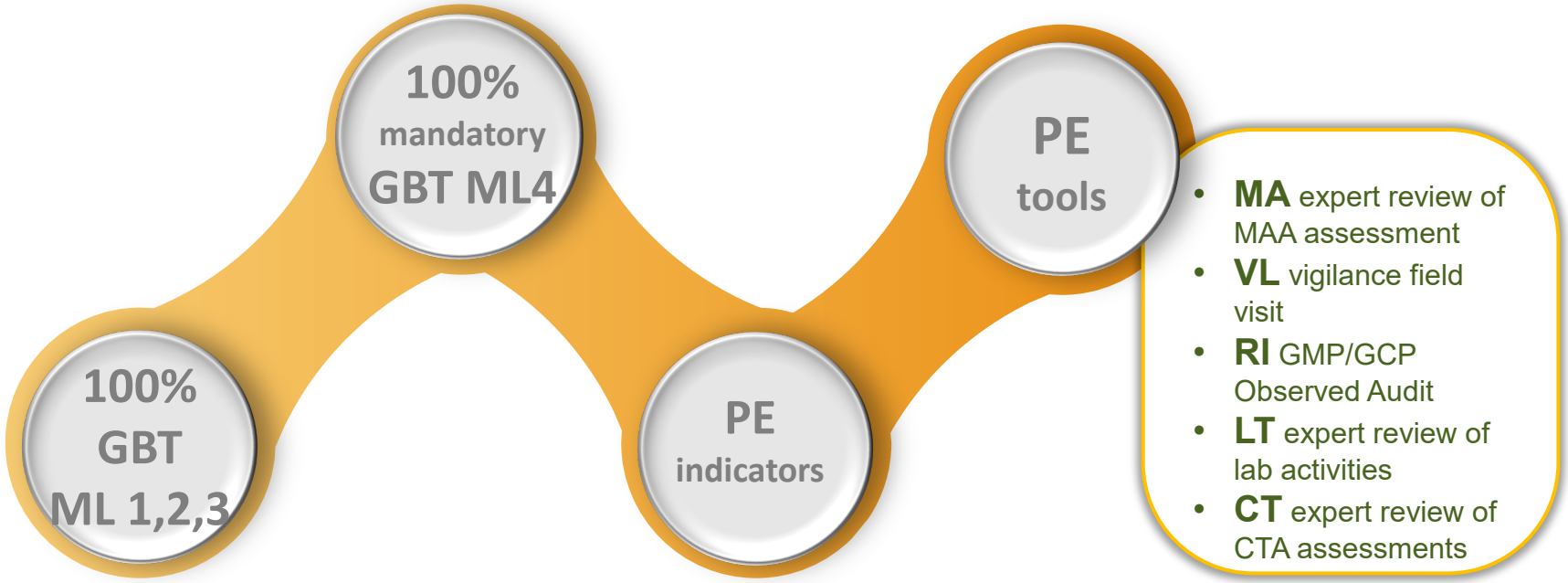
WLA Indicators and tools

How well a regulatory system is configured?

How well a regulatory system operates?

Components of the PE process towards WLA

Standard stepwise approach



If any of these 4 components fails, WHO listing is not achieved

Key considerations

ML3/4 does not automatically lead to listing

GBT-ML

Represents primary means by which the WHO objectively evaluates regulatory systems and measures their

Maturity Level

GBT benchmarking process incorporates **some elements** of performance measurement

Designed to provide a structured approach to analyzing the **inputs, regulatory processes** and intended **outputs** that together determine

how well a regulatory system is configured

Verify **establishment, appropriateness** and **implementation** of Regulations, Processes, Procedures, Plans, etc.

WLA

Nature and extent of evaluation to provide a high degree of confidence in an **authority's performance (e.g., quality of reports, scientifically sound regulatory decisions, etc.)**

Documented consistency in adherence to international regulatory requirements and best practices, procedures and in producing **outputs, outcomes reaching a more efficient regulatory system**

Expansion of performance measurement

to provide a more detailed picture of

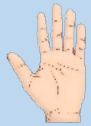
how well a regulatory system operates

Measure **performance** and **impact** of Regulations, Processes, Procedures, Plans, etc.

WLA operating principles

ELIGIBILITY

01 Voluntary process initiated by a request from a member state



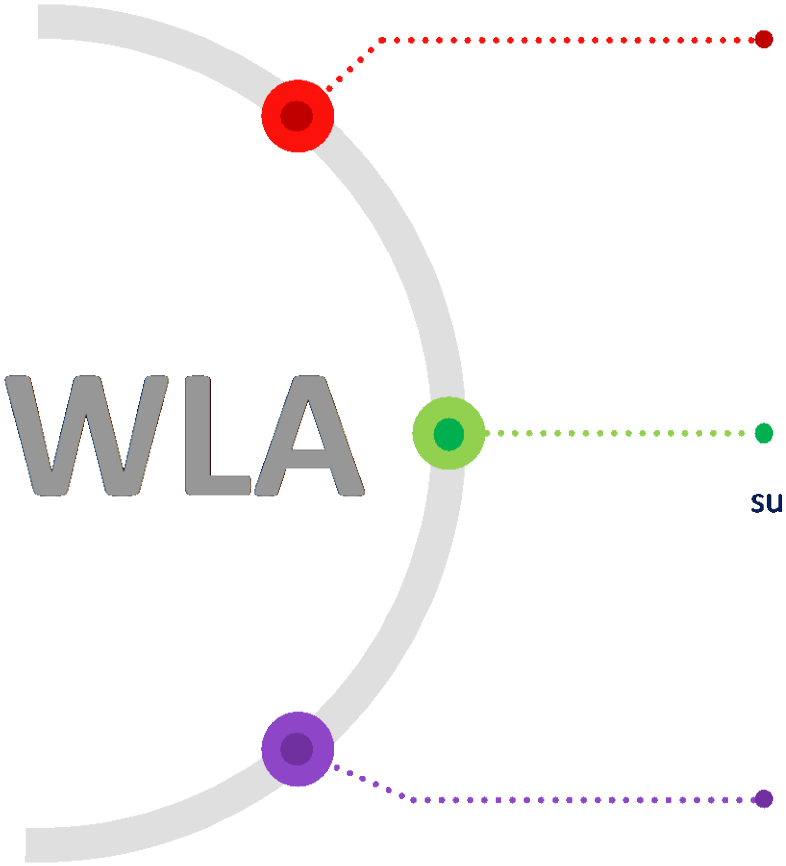
02 National Regulatory Authority (NRAs) or Regional Regulatory System (RRS) are eligible

03 Regulatory Authorities must have attained overall Maturity Level 3 to be eligible for the PE process

04 Transitional WLAs are all eligible for the PE process

Operating principles

LISTING



A **regulatory authority is publicly listed as a WLA** following successful completion of the performance evaluation process

Listing will include **scope of the designation** (functions and product streams), **evidence reviewed, process undertaken** to support the listing and period of validity of the listing

Listing will be initially valid for a **defined period of years**, provided no changes have taken place that could negatively impact the WLA listing

What is a transitional WLA (tWLA)?

1

A RA previously on the *WHO Interim list of NRAs,* published in 2019

2

The *Interim list* was composed of:

- SRAs (medicines and/or vaccines)
- functional NRAs (vaccines) with vaccine tool
- rrNRAs of AMRO (medicines and/or vaccines) with PAHO tool
- ML3/4 NRAs (medicines and/or vaccines) with GBT

3

Transition period:
- 5 years from
31 March 2022 to
31 March 2027

4

A tWLA is **NOT** a WLA, in that requirements to be met for designation as a WLA do not change

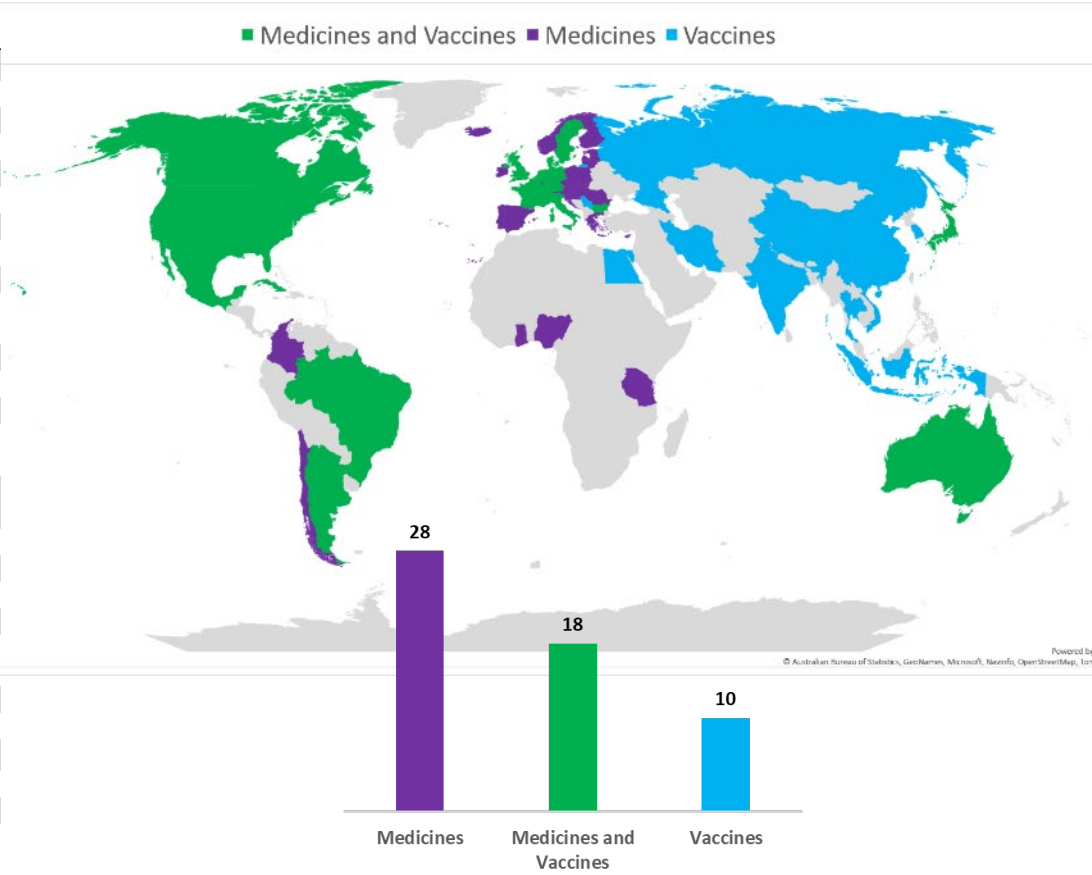
5

Transitional arrangements do **NOT** affect existing procedures for PQ of medicines and vaccines and hence the international supply of quality-assured products

https://www.who.int/publications/m/item/list-of-transitional-wlas

List of transitional WLAs as of March 2022

Country	Scope of tWLA designation
1. Argentina	Medicines Vaccines
2. Australia	Medicines Vaccines
3. Austria	Medicines
4. Belgium	Medicines Vaccines
5. Brazil	Medicines Vaccines
6. Bulgaria	Medicines Vaccines
7. Canada	Medicines Vaccines
8. Chile	Medicines
9. China	Vaccines
10. Colombia	Medicines
11. Croatia	Medicines
12. Cyprus	Medicines
13. Cuba	Medicines Vaccines
14. Czech Republic	Medicines
15. Denmark	Medicines Vaccines
16. Egypt	Vaccines
17. Estonia	Medicines
18. Finland	Medicines
19. France	Medicines Vaccines
20. Germany	Medicines Vaccines
21. Ghana	Medicines
22. Greece	Medicines
23. Hungary	Medicines
24. Iceland	Medicines
25. India	Vaccines
26. Indonesia	Vaccines
27. Iran (Islamic Republic of)	Vaccines
28. Ireland	Medicines



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization (WHO) concerning the legal status of any country, territory, city or area of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on map represent approximate border lines for which there may be not yet be full agreement.

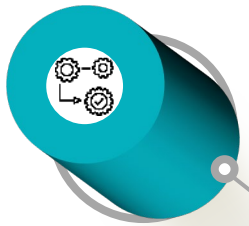
Country	Scope of tWLA designation
29. Italy	Medicines Vaccines
30. Japan	Medicines Vaccines
31. Latvia	Medicines
32. Liechtestein	Medicines
33. Lithuania	Medicines
34. Luxembourg	Medicines
35. Malta	Medicines
36. Mexico	Medicines Vaccines
37. Netherlands	Medicines Vaccines
38. Nigeria	Medicines
39. Norway	Medicines
40. Poland	Medicines
41. Portugal	Medicines
42. Republic of Korea	Vaccines
43. Romania	Medicines
44. Russian Federation	Vaccines
45. Serbia	Vaccines
46. Singapore	Medicines
47. Slovakia	Medicines
48. Slovenia	Medicines
49. Spain	Medicines
50. Sweden	Medicines Vaccines
51. Switzerland	Medicines Vaccines
52. Thailand	Vaccines
53. United Kingdom of Great Britain and Northern Ireland	Medicines Vaccines
54. United Republic of Tanzania	Medicines
55. United States of America	Medicines Vaccines
56. Viet Nam	Vaccines
57. EMA	Medicines Vaccines

Risk-based performance evaluation pathways

Routine arrangements

Standard
- NRAs and RRAs

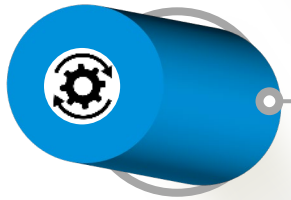
(not benchmarked)



- Full implementation of GBT ML1-3 sub-indicators
- Mandatory GBT ML4 sub-indicators
- PE indicators
- PE tools

Transitional arrangements

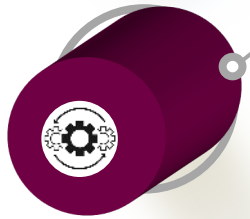
Abridged
- SRA



Abridged tool
- Pre-selected GBT and PE indicators
- No PE tools

NLA

Streamlined
- ML3/4 RA
- rRRA (AMRO)
- Functional RA



- Not previously assessed GBT Sub-indicators
- PE indicators
- Not previously assessed PE tools

Performance evaluation pathways piloted in 3 countries

Risk-based Performance Evaluation pathways

- ML4 NRA
- SRA
- tWLA

Experience from piloting informed revision of WLA documents

OPERATIONAL GUIDANCE

PE MANUAL

Published on 14 November 2023

https://www.who.int/initiatives/who-listed-authority-reg-authorities

1st TAG-WLA meeting

Technical Advisory Group on WLA (TAG-WLA) established in July 2023

1st meeting 11-12/09/23

ML4 NRA

SRA

tWLA

TAG-WLA opinion on 3 countries from piloting

WLA

listing on 31 Oct 2023

First three WLAs

31st October 2023

SRA

Switzerland

Swissmedic

Scope: Medicin and vaccine

tWLA

Republic of Korea

MFDS

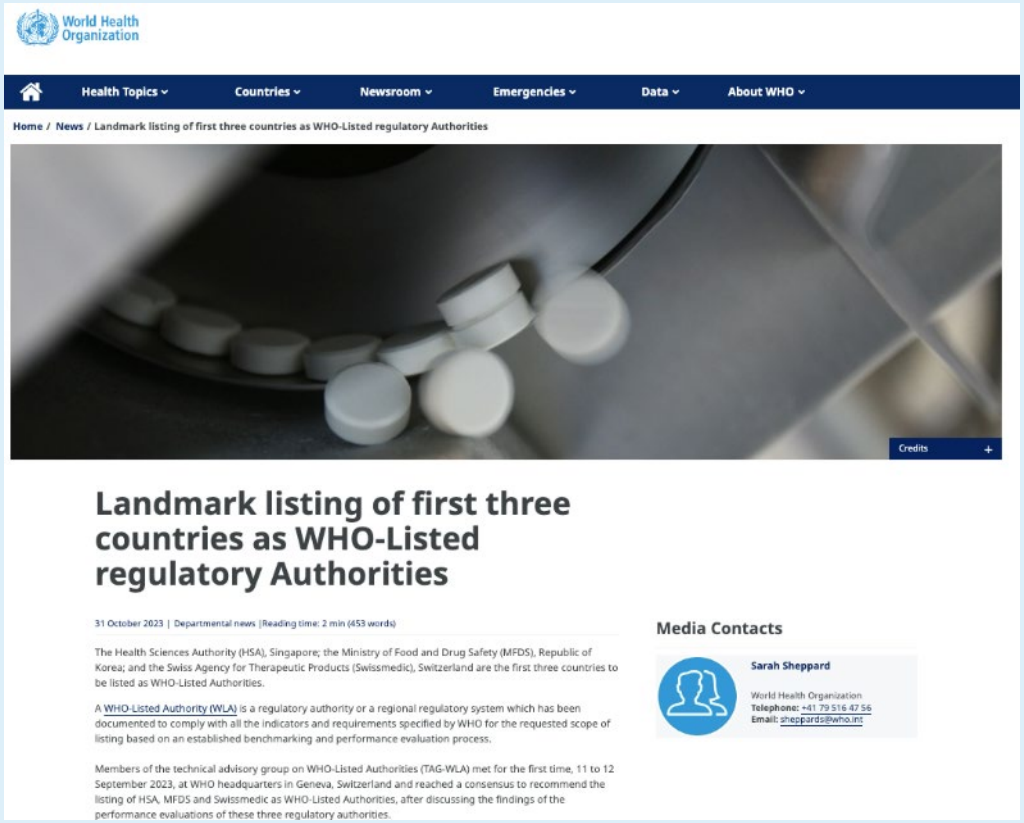
Scope: Medicine and vaccine

ML4 NRA

Singapore

HSA

Scope: Medicine



World Health Organization

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Home / News / Landmark listing of first three countries as WHO-Listed regulatory Authorities

Credits

Landmark listing of first three countries as WHO-Listed regulatory Authorities

31 October 2023 | Departmental news | Reading time: 2 min (453 words)

The Health Sciences Authority (HSA), Singapore; the Ministry of Food and Drug Safety (MFDS), Republic of Korea; and the Swiss Agency for Therapeutic Products (Swissmedic), Switzerland are the first three countries to be listed as WHO-Listed Authorities.

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

Members of the technical advisory group on WHO-Listed Authorities (TAG-WLA) met for the first time, 11 to 12 September 2023, at WHO headquarters in Geneva, Switzerland and reached a consensus to recommend the listing of HSA, MFDS and Swissmedic as WHO-Listed Authorities, after discussing the findings of the performance evaluations of these three regulatory authorities.

Media Contacts

Sarah Sheppard

World Health Organization

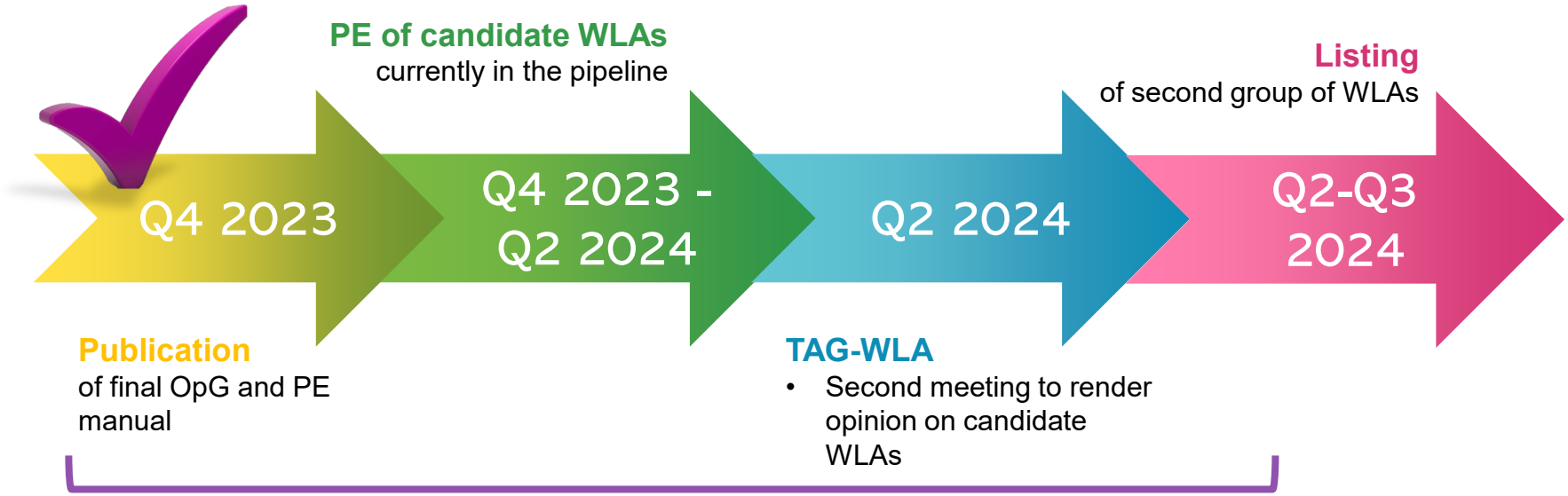
Telephone: +41 79 516 47 56

Email: sheppards@who.int

https://www.who.int/news/item/31-10-2023-landmark-listing-of-first-three-countries-as-who-listed-regulatory-authorities

The ultimate responsibility and decision for use of tWLA and WLA lists resides with the users (e.g., regulatory authorities, and procurement agencies) and will depend on the specific context of its intended use

WLA next steps in 2023-2024



https://www.who.int/initiatives/who-listed-authority-reg-authorities

Thank you

Regulatory Systems Strengthening **[RSS]** Team **LINK**

Regulation and Safety [REG] Unit

Regulation and Prequalification [RPQ] Department

Access to Medicines and Health Products [MHP] Division

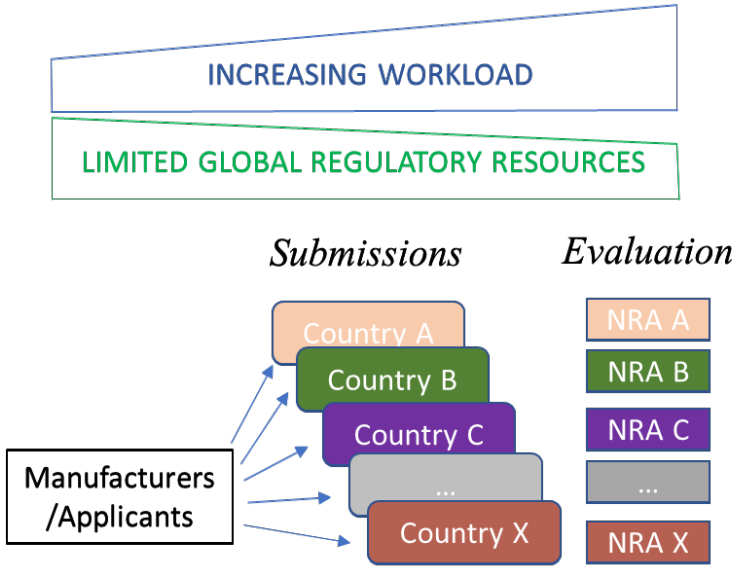
World Health Organization (Geneva, Switzerland)




Reliance and Facilitated Regulatory Pathways including WHO Collaborative Registration Procedure

Marie Valentin, Team Lead, Facilitated Product Introduction, WHO

Reliance for a more efficient use of global resources



SOLUTIONS

Work-sharing,
Joint assessment,
Abridged pathways,
Strengthened collaboration,
etc.

Implementation of reliance

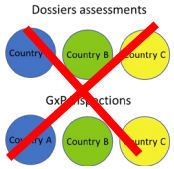
- Voluntary participation
- Change mindset
- Start small, learning by doing
- Harmonisation facilitator but not pre-requisite

Are we using the global regulatory resources as best as we can?

Reliance main principles and examples

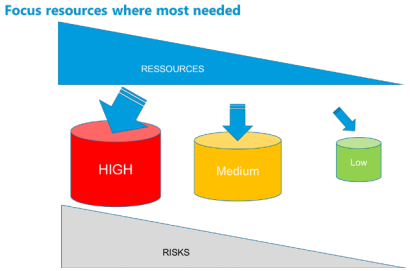
Principles

Reduce duplication



Avoid duplication where possible

Risk-based approach



Reference Authorities

WHO Listed Authorities
A transparent & evidence-based system to identify trusted authorities

Examples

Abridged and verification routes
with shortened times for quality and product labels
PACs from HSA Singapore
https://www.hsa.gov.sg/docs/default-source/hprg-tpb/guidances/guidance-on-therapeutic-product-registration-in-singapore_aug22.pdf

Regulatory Pharmaceutical Quality Knowledge Management System (PQ KMS) to Enhance the Availability of Quality Medicines
https://www.icmra.info/drupal/en/strategicinitatives/pqkms
https://www.icmra.info/drupal/strategicinitatives/pqkms/joint_reflection_paper

Many pilots for post-authorization changes

PAC: Proposed update to the Guidelines on procedures and data requirements for changes to approved vaccines, Annex 4, TRS No 993

Reliance is “implanted” in facilitated regulatory pathways

WHO PQ collaborative registration procedure

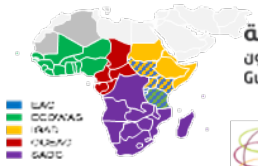
- **Vaccines:** 2004
- **Medicines:** Started in 2012
- **FDA-WHO joint pilot to accelerate access to HIV medicines (CRP-lite)**
- **Diagnostics:** Pilot 2019
- **Vector control:** Pilot 2024

“SRA” collaborative registration procedure

- Initiated in 2015
- **7 SRAs**: European Medicines Agency, MHRA UK, Dutch MEB, Swissmedic, TGA Australia, Finish Medicines Agency (FIMEA), Swedish Medical Products Agency of Sweden (MPA)

Regional regulatory harmonization initiatives and networks

African Medicines Regulatory Harmonization Initiative (AMRH)



ASEAN SIAHR Project

مجلس الصحة
لدول مجلس التعاون
Gulf Health Council

CARPHA

APEC
Asia-Pacific Economic Cooperation

SRA: Stringent Regulatory Authorities

WHO Collaborative Registration Procedure - Overview

Same principles for life cycle

Promote informed reliance

Provision of assessment and inspection reports from WHO prequalification or Stringent Regulatory Authorities (SRA)

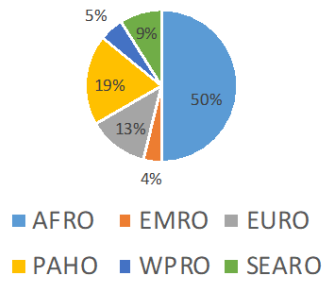
Product sameness
Quality Information Summary (QIS) validated by WHO/SRA

Aim is to facilitate in-country decision Sovereignty maintained

90 days

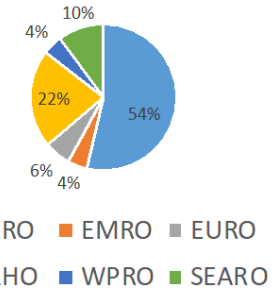
WHO Collaborative Registration Procedure – Countries

PQ CRP agreements (medicines and vaccines)



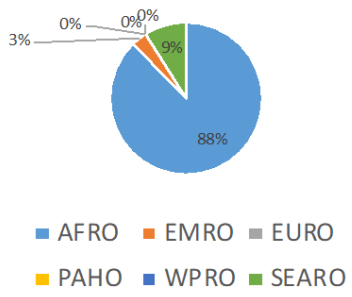
78 countries

SRA CRP agreements (medicines and vaccines)



69 countries

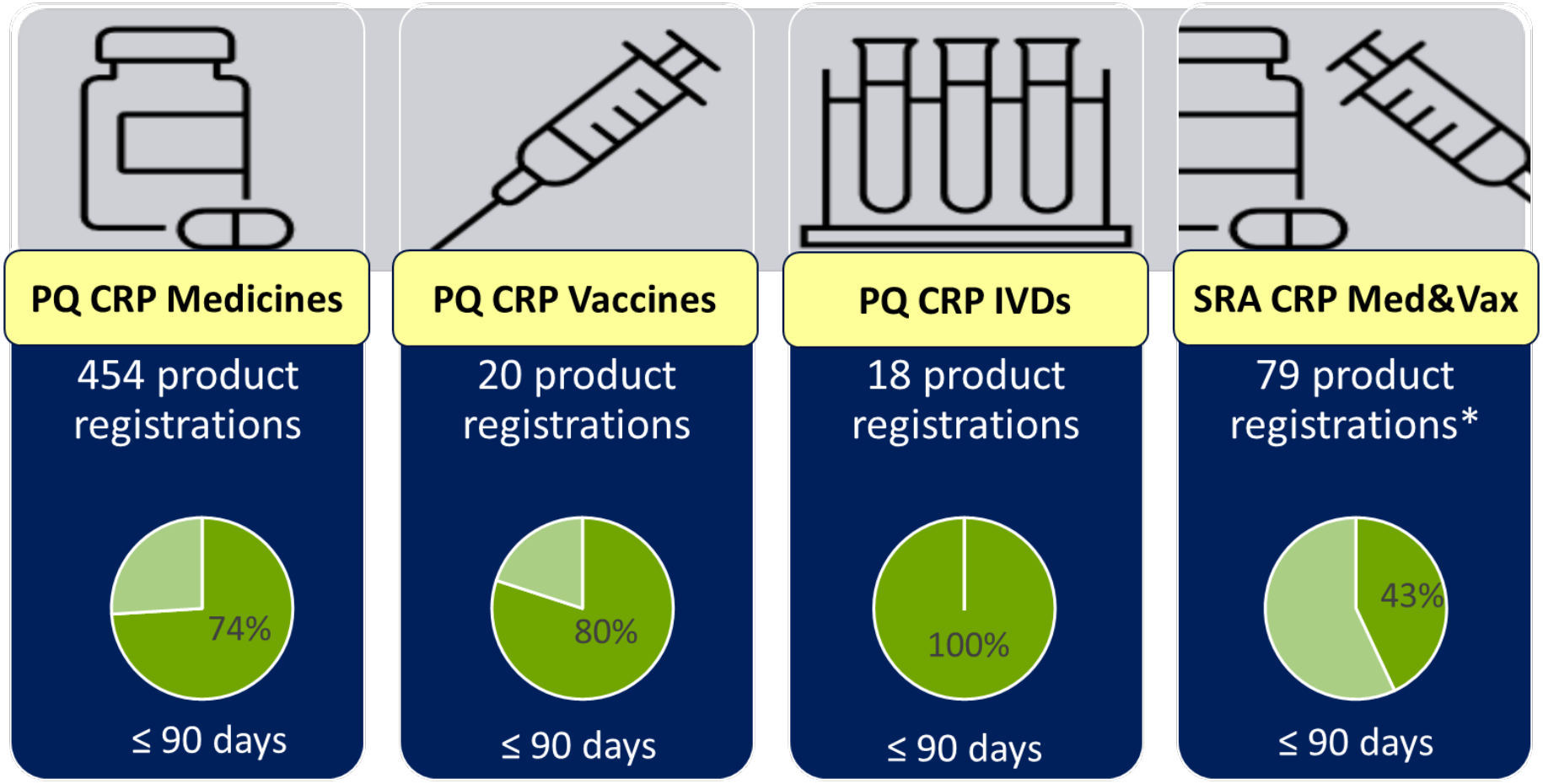
PQ CRP agreements (IVD)



31 countries

Data as per October 2023

WHO Collaborative Registration Procedure – Registrations (2018 -2022)

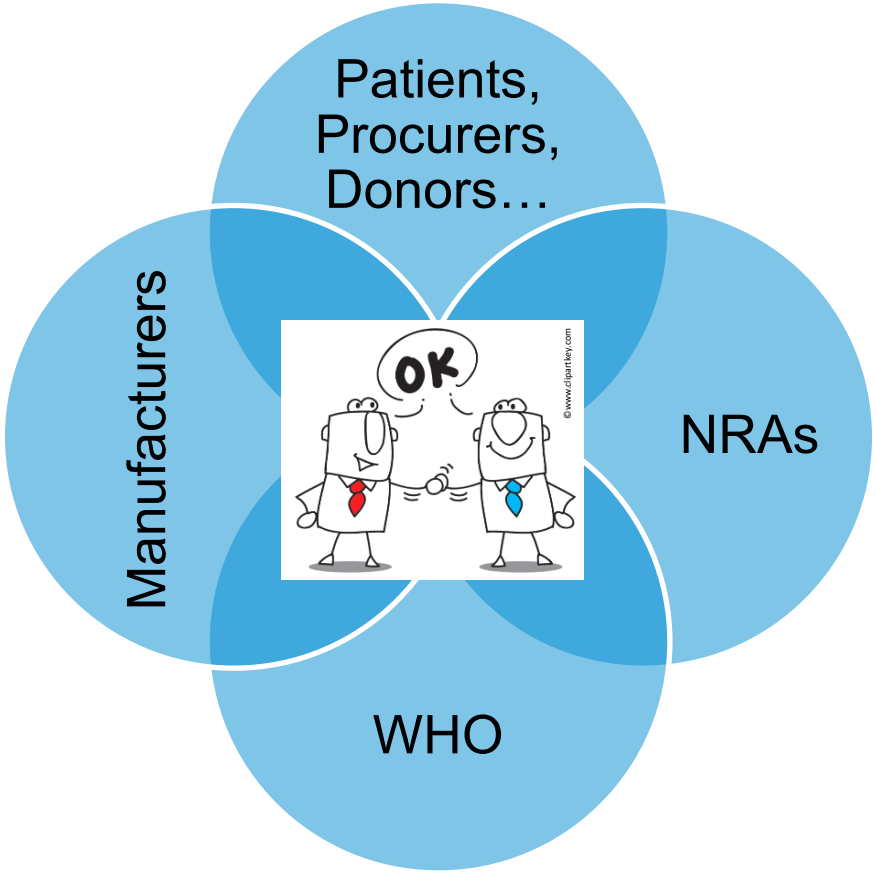


*78% within 250 days

Analysis as per RPQ impact assessment March 2023

Reliance - win-win outcomes for all concerned stakeholders - patients in the focus

- Facilitate access to quality-assured medical products
- Efficient use of available resources
- Reduce approval timelines
- Enabler for global supply



WHO Facilitated Regulatory Pathways – Conclusions

Regulatory Strategy

Manufacturers/developers to decide on the most appropriate filing strategy

FPI to clarify characteristics of the different pathways

Tools for implementation

FPI Team to help NRAs to implement the different tools, including for CRP

Advocacy and relevant trainings

Many regulatory tools in the box!

Equitable access to affordable quality medicines and other health products requires **an integrated approach** with all stakeholders

Thank You

World Health Organization

WORKING TOGETHER

Marie Valentin
Team Lead, Facilitated Product Introduction
WHO Regulation and Prequalification Department




Best use of reliance and WHO Listed Authority (WLA)

Industry point of View

Presented by Prisha Patel (Senior Manager, International Regulatory Policy, Pfizer, on behalf of IFPMA)

30 November 2023

Agenda

- WLA-Now and future status
- Best use of reliance and WLA
- Opportunities and open questions

Where are we going?

Intent is to replace current SRAs with WLAs to enhance reliance by increasing the pool of **national and regional reference agencies**

Challenge of increasing complexity – From homogeneous to heterogeneous

FROM

A few "Stringent Regulatory Authority" SRAs* + 3 WLA (Swiss Medic- former SRA, HSA and MFDS)

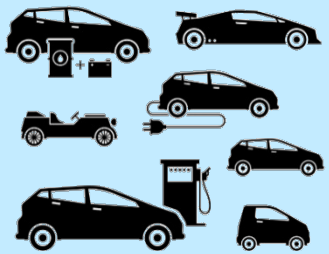
A 4x 4 jeep can navigate a variety of terrains

Similarly, SRAs have proven ability and a track record in handling complex products and all aspects of regulation for medicines and vaccines.

* historically ICH members prior geographic expansion in 2015)

TO

Up to *57 WLAs within 5 years with specific regulatory functions and product types nationally and regionally



WLAs will have specialist functions and scope, nationally and regionally, which will require careful navigation when seeking to use reliance by all stakeholders

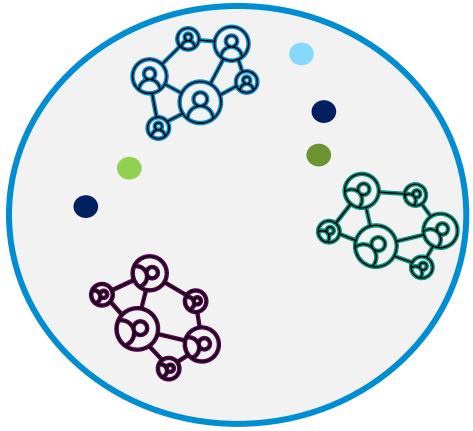
*53 NRAs plus 1 Regional Regulatory System on the tWLA list

Navigation by stakeholders requires care:

- ✓ Regulators should cite which WLAs they will rely on but WLAs are not qualified for all functions – increasing the complexity of application
- ✓ There may be some regional WLAs with specialised functions
- ✓ Continuous monitoring WLA performance to ensure they are keeping high standards

Opportunity to file earlier in countries that are currently in later stages of the filling sequence- disrupting the "sequence"

WLAs could enable networks of regulators working together and relying on one another's approvals within regions or across regions



ILLUSTRATIVE ONLY

- 5-10 years

FROM

Companies currently tend to file for approval first in jurisdictions such as the US, EU, Japan etc and subsequently file in other countries

TO

If a WLA becomes the reference agency in a region this could provide a gateway to fast approvals within that region and could move up in the filing sequence to be a reference country

If those reference WLAs also have an **expedited pathway** to shorten the approval time for innovative products that would be even more attractive for companies

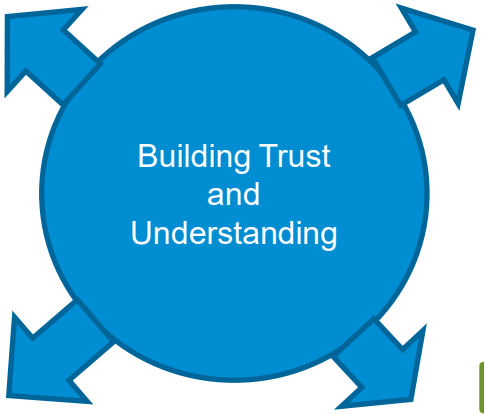
Regional WLA could also open opportunities




Industry considerations on WLAs as reference authorities in reliance

Case by case assessment (product/ region) on applicability of using a designated WLA

Acceptability of selected WLA by the relying agency



Availability of attractive pathways with set review times in WLAs to be considered as reference

Availability of scientific advice and open dialogue

Best use of reliance and WLA

*Achieving WLA status should **encourage Good Regulatory Practices (GRegP), convergence** of regulatory requirements and promote **further collaboration** via reliance and work-sharing for both **initial approvals and post approval changes (PACs)**.*

1. Greater regulatory convergence

2. NRAs to issue & share Public Assessment Reports, (PAR)* and publish timeline metrics

3. Increase efficiencies through greater collaboration

4. Applying the WLA framework MAA and for *PACs

Reliance is an exemplar of regulatory maturity

GBT encourages application of reliance and the efficient use of resources

* WHO GBT Tool sub-indicator MA05.03/04

* Assume that “MAA category” covers approval of PACs

Opportunities and Open Questions

WLAs have the potential to broaden regulatory reliance and collaboration bringing benefits to companies and patients. Whether they live up to this promise depends on how we navigate through the transition from SRAs to WLAs

Will new WLAs be incorporated into reliance frameworks in countries, or will there be a tendency to still rely on former SRAs?

How will the regional WLA listing work e.g. Africa, AMA?

How will WLAs increase transparency of decision making?

How can we encourage consistent (and ideally harmonised) use of the WLA concept?

How can the WLA concept optimize regulatory processes and reduce work duplication for industry and NRAs?

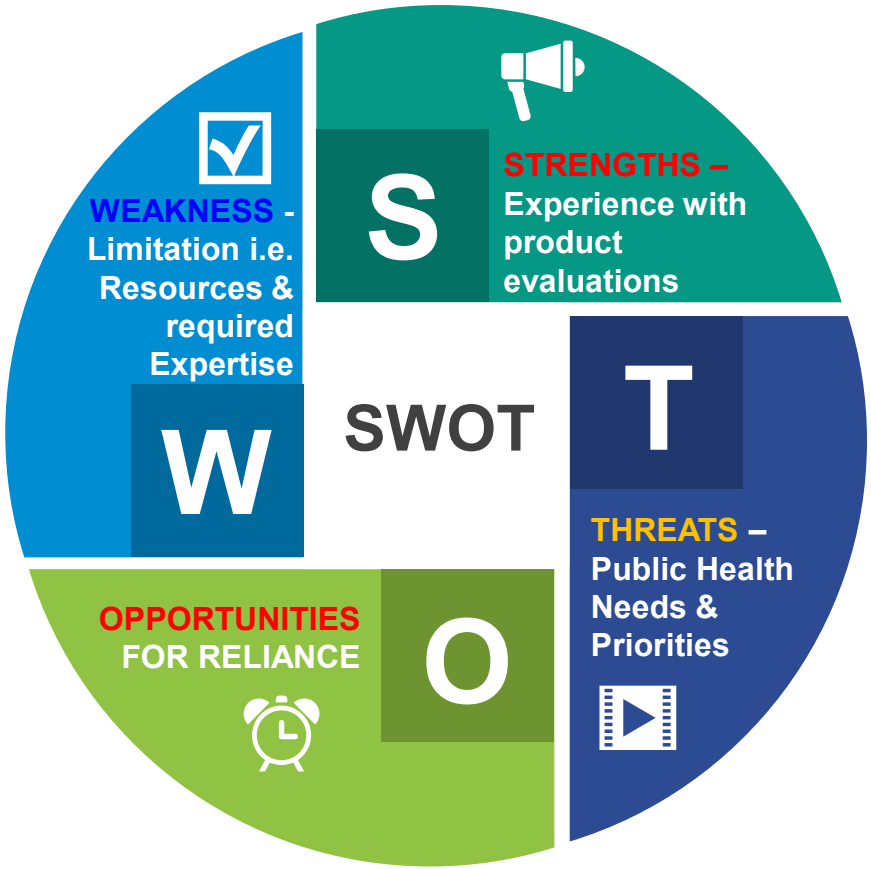
Thank you

Industry point of view – Best use of Reliance and Regulators Journey to WLA

Parag NAGARKAR
Director & Head – Regulatory Affairs
Serum Institute of India Pvt. Ltd.

DCVMN
Developing Countries Vaccine Manufacturers Network

Current scenario of regulatory reliance and examples



NRA Reliance Strategy – Not one size fits all !!

Example # 1

WHO Collaborative Registration Procedure (CRP) for Vaccine registration and life-cycle management

Example # 2

European Union & its participant countries reliance through MR-DC & CP.

Mutual Recognition Agreement (MRA) with third countries (i.e. Australia, Canada, Israel, Japan, New Zealand, Switzerland & United States)

Example # 3

US-FDA & EMA launched (15th September 2021) pilot programme for EMA-FDA parallel scientific advice for Hybrid/Complex generic products

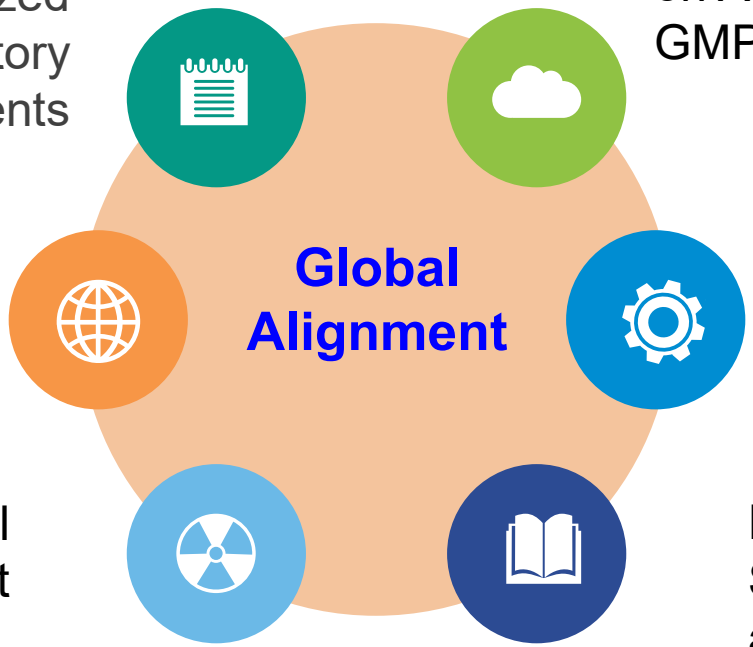
Example # 4

MHRA - European Commission (EC) Decision Reliance Procedure.

Example # 5

African Medicines Regulatory Harmonization (AMRH).

Good Reliance Practices without compromising Quality, Safety & Efficacy



Harmonized Regulatory Requirements

Regulatory Convergence on Assessment Report & GMP

Harmonizing regulatory pathways

Recognise the National Drug Testing Laboratories

Compendial alignment

Platform Knowledge, Science & risk-based approaches for Life Cycle Management

Way forward for Global Regulatory Alignment & Reliance mechanism for WLA/Regulators

Promoting Recognition/ Reference: WHO-PQ, Reference NRA/SRA.

- Support regulatory convergence through the **convincing power of WHO**.
- **Alignment with WHO regulatory** norms/requirements
- Improve efficiency, capacity and **awareness** of the Prequalification Programme (PQ) and Collaborative Registration Procedure (CRP)
- Build regulatory capacity in Member States consistent with good regulatory practices i.e. **Reliance on the functional NRA (Level 3)** may expedite review and approval of new vaccines & PAC (Post Approval Changes)
- Benchmarking of national regulatory systems and WHO Listed Authorities (WLA) i.e. **Lifting the Functional NRAs to Stringent NRA**.
- **Strengthen national regulatory capacity** to ensure quality of medical products

Way forward for Global Regulatory Alignment & Reliance mechanism for WLA/Regulators

Promoting Reliance:

- Promote **reliance and recognition** across regulatory functions
- Build **trust between NRAs**, increasing reliance and efficiency
- Implement regulation in an increasing number of countries through reliance and NRA networks, ***Implementation of WHO guideline of Good Reliance Practices (GRelP); 2021***
- **Strengthen pharmaceutical sector** capacity in countries that manufacture products for **LMICs and/or local supply**

Promoting Digitalization

- **Digitalization of administrative documents** i.e. e-CPP, e-Labelling, approval letters etc.
- **eCTD implementation**
- Information **availability on portal** i.e. Public Assessment Report / GMP etc.

Win-Win Outcome

Regulatory Reliance

Patient & End User

- Timely access to safe, effective and quality products

National Regulatory Agencies

- To reduce regulatory burden and duplication
- Promote efficient use of resources by re-allocating resources to high-risk areas/products

Manufacturers

- Streamline management of regulatory submissions & uninterrupted global supply

Implementation of Risk Based Approaches for Life-Cycle Management

- **Implementation of mechanisms ICH Q12 Principles**
  - Comparability Protocol (CP) / Post Approval Change Management Protocol (PACMP)

- **Adoption of risk-based approaches under the Pharmaceutical Quality System (PQS) aligned with ICH Q10 & ICH Q12**
  - If change is supported by FMEA analysis as per the ICH Q9, such changes can be classified under company's PQS. Such changes can be verified in next onsite Inspection.

- **WHO Collaborative Registration Procedure (CRP)**
  - Effective Life-Cycle Management by leveraging assessment and inspection outputs already produced by WHO-PQT, and thereby eliminating duplicative regulatory work


thank you
danke
謝謝
ngiyabonga
рахмат
teşekkür ederim
Баярлалаа
спасибо
faafetai lava
mersi
kia ora
barka
welalin
tack
spas
dank je
misaotra
matondo
paldies
grazzi
mahalo
tapadh leat
vinaka
спасибі
blagodaram
gracias
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asante
manana
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kiitos
dankie
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MFDS's Journey to WLA

Nov 30, 2023

Director, Youngjin Ahn

Pharmaceutical Policy Division, MFDS

CONTENTS

1. Background on WLA Registration

✓ **Announcement of WHO's "WLA Framework"**

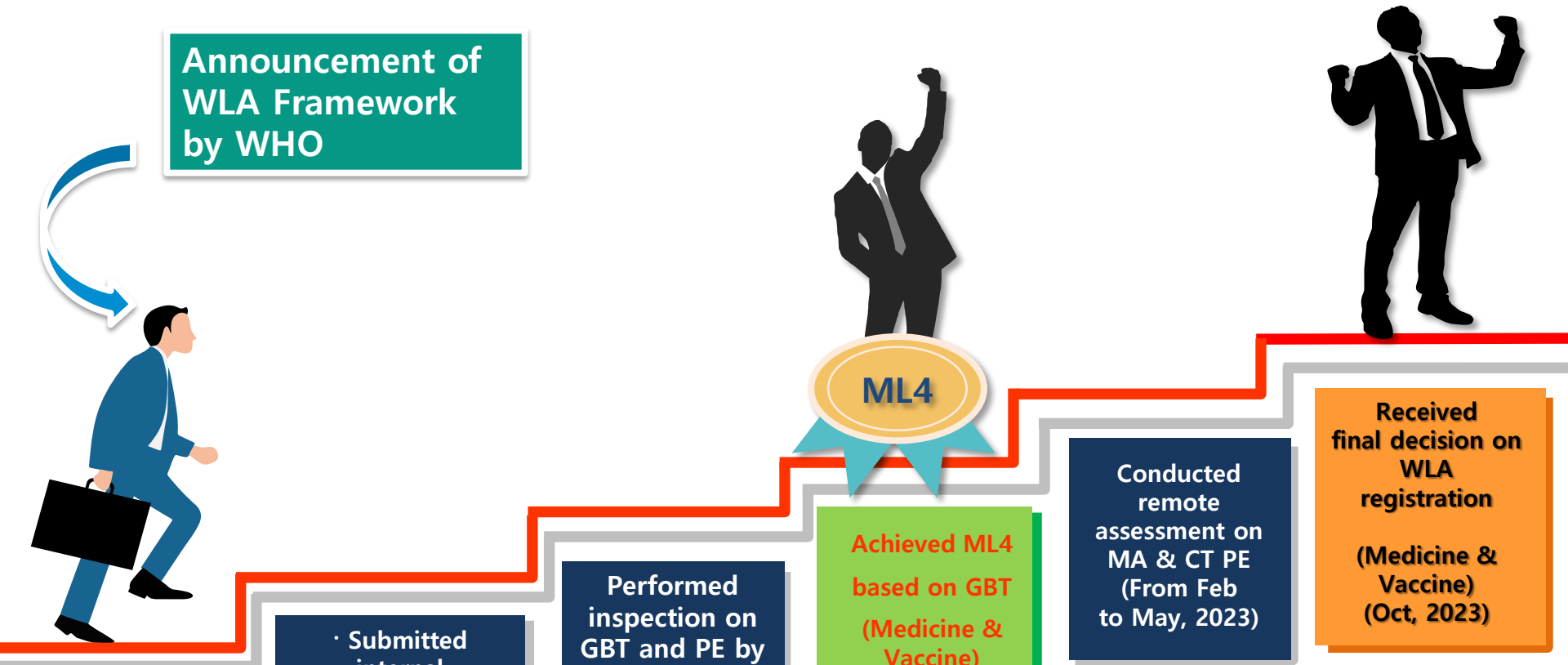
- Respond to develop a transparent and evidence-based pathway for regulatory authorities operating at an advanced level of performance to be globally recognized

- **Promote access and supply of safe, effective and quality medical products**

✓ **MFDS, supported to WLA initiative**

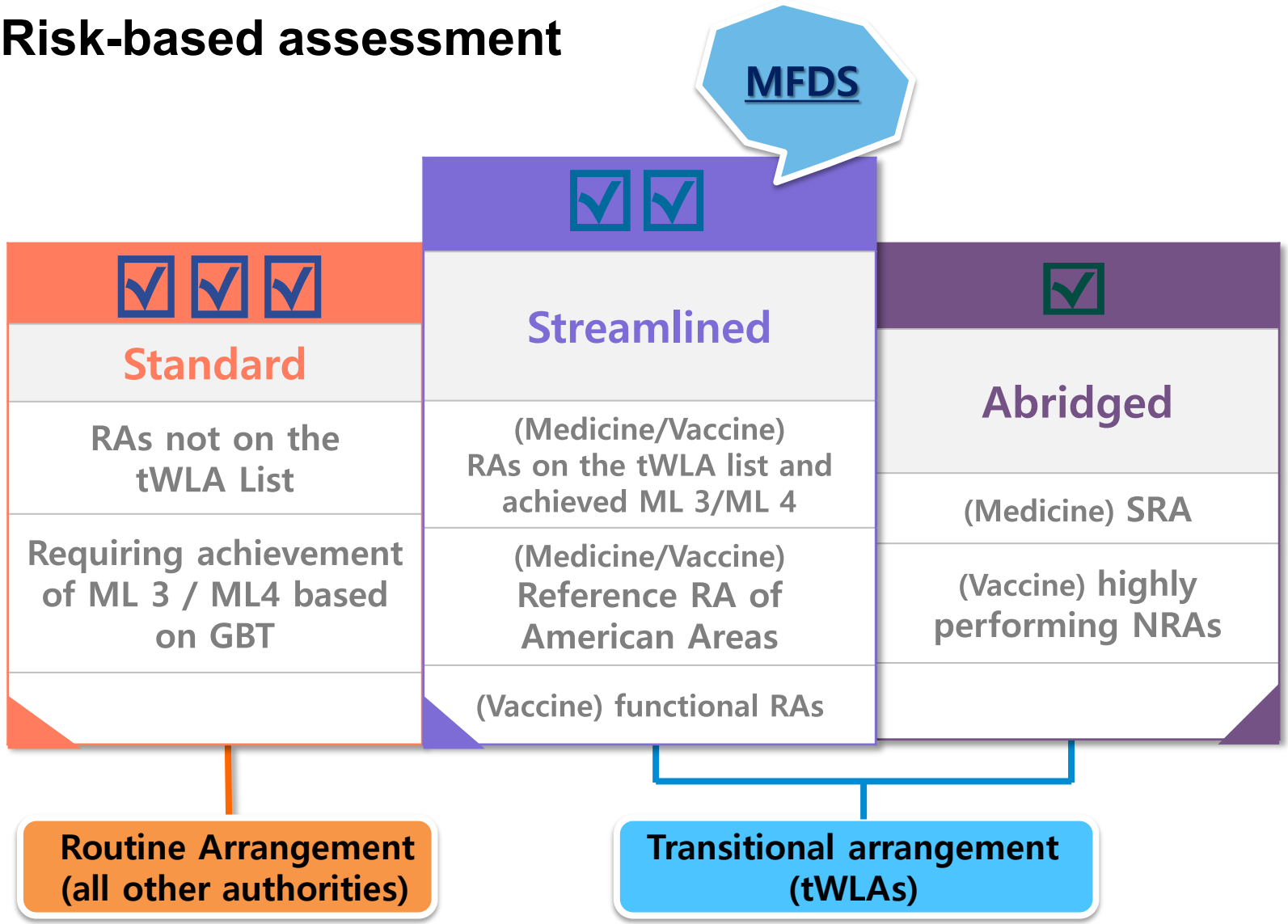
✓ **decided to preemptively pursue WLA registration,**
filed intent for registration(Nov, 2021)

2-1. WLA Registration Process



2-2. WLA Registration Process

✓ Risk-based assessment



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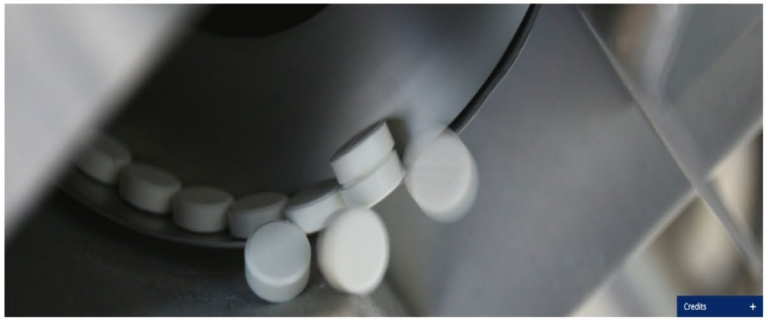
Home / News / Landmark listing of first three countries as WHO-Listed regulatory Authorities



Landmark listing of first three countries as WHO-Listed regulatory Authorities

31 October 2023 | Departmental news | Reading time: 2 min (453 words)

The Health Sciences Authority (HSA), Singapore; the Ministry of Food and Drug Safety (MFDS), Republic of Korea; and the Swiss Agency for Therapeutic Products (Swissmedic), Switzerland are the first three countries to be listed as WHO-Listed Authorities.

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

Members of the technical advisory group on WHO-Listed Authorities (TAG-WLA) met for the first time, 11 to 12 September 2023, at WHO headquarters in Geneva, Switzerland and reached a consensus to recommend the listing of HSA, MFDS and Swissmedic as WHO-Listed Authorities, after discussing the findings of the performance evaluations of these three regulatory authorities.

This represents a significant milestone for the Republic of Korea, Singapore and Switzerland, as the designation and public listing of MFDS, HSA and Swissmedic as WLAs, is a global recognition that these three regulatory authorities meet WHO and other internationally recognized regulatory standards and practices.

"This achievement is the result of investment by the Governments of the Republic of Korea, Singapore and Switzerland in the strengthening of their regulatory systems and reaffirms the collaboration between WHO and the three Governments in promoting confidence, trust and further reliance on authorities that have attained this global recognition, through the transparent and evidence-based pathway for designating and listing of WLAs", said Dr Yukiko Nakatani Assistant Director-General for Access to Medicines and Health Products.

The introduction of a framework for designating and publicly listing a regulatory authority as a WHO Listed Authority (WLA) responds to Member States' requests to develop a transparent and evidence-based pathway for regulatory authorities operating at an advanced level of performance to be globally recognized, thereby replacing the procurement-oriented concept of stringent regulatory authorities.

Implementation of the WLA framework is intended to promote access and supply of safe, effective and quality medical products. The framework also provides for the optimal use of limited resources by facilitating reliance on the work products and decisions of trusted agencies in the decision-making of regulatory authorities, the WHO Prequalification Programme and procurement agencies.

While the ultimate responsibility and decision for use of the WLA list resides with the users and depends on the specific context of its intended use, the benefits of a robust, transparent, evidence-based, global system for recognizing regulatory excellence serve the interests of a variety of stakeholders that are committed to promoting access to safe, effective, and quality medical products. It is expected that HSA, MFDS and Swissmedic will sustain this achievement, thereby enabling greater regulatory efficiencies and more informed decision-making at the national, regional and global levels.

Media Contacts

Sarah Sheppard
World Health Organization
Telephone: +41 79 516 47 56
Email: sheppards@who.int

식품의약품안전처

Press Release

다시 대한민국! 새로운 국민의 나라

For Immediate Release Release 2023. 11. 1.

< WHO Listed Authorities >

MFDS becomes the first to be WHO-Listed Regulatory Authority

- Korea's outstanding regulatory system and capabilities have been internationally recognized

- The WLA's status is expected to grant Korea favorable conditions for international procurement of pharmaceuticals and correspondingly expand exports

The Ministry of Food and Drug Safety (Minister Oh Yu-Kyoung), Republic of Korea officially stated on November 1st (KST) that WHO announced that MFDS has been listed as WHO-Listed Authority (as of October 26, 2023) on October 31, 2023 (local time in Geneva).

This makes the MFDS the first WHO-Listed Authority in the world. The following 8 regulatory functions in the field of medicines and vaccines are included.

- ① Vigilance ② Licensing Establishments ③ Regulatory Inspection ④ Laboratory Testing, ⑤ Clinical Trials oversight ⑥ NRA Lot Release ⑦ Registration and Marketing Authorization ⑧ Market Surveillance and Control

WLA is a list of excellent regulatory authorities created by WHO via evaluating regulatory systems and work performance

3-1. Organization and function

Function

Government Organization Act (Article 24)

- “In order to administer duties concerning the safety of foods and drugs, Ministry of Food and Drug Safety shall be established under the Prime Minister.”

Staff

Total 2,014 government officials as of 2023.9.

- Headquarter : **663 officials**
- NIFDS : **446 officials**
- Regional FDS : **905 officials**

Budget

Year 2023

- About 512 million USD

3-2. International Regulatory Network

The Pharmaceutical Inspection Co-operation Scheme (PIC/S)

Registered in EU White List

2014 → 2016 → 2019 → 2023

Joined PIC/S

Joined ICH

ICH harmonisation for better health

Achieved WLA Registration

World Health Organization

WHO-Listed Authority (WLA)

3-3. Lessons Learned and Next Step

Lessons

- ❖ Maintaining strength of Korea's regulatory capacity in medical products
- ❖ Awareness of international regulatory harmonization

Next Step

- ❖ Sustaining efforts to improve Reliance among regulators and harmonize international regulation
- ❖ Supporting capacity building of regulatory authorities to achieve advance in regulatory performances

Thank You

Ministry of Food and Drug Safety

Coffee/tea Break 10:30 – 11:00

Session 2: Setting standards, safety monitoring and market control – Objectives

- Ensuring efficient safety monitoring
- Supply Chain Integrity – updates on DEG / EG contamination of syrup medicines
- Nitrosamine Exchange – A Global Knowledge Base
- Updates from WHO Experts Committee activities

Session 2: Setting standards, safety monitoring and market control – Panelists

- **Dr Shanthi Pal,** Team Lead, REG/pharmacovigilance *(virtually)*
- **Mr Rutendo Kuwana,** Team Lead, REG/Incidents and Substandard/Falsified medical products *(virtually)*
- **Dr Frederick Meadows,** Sr. Technical Advisor, Product Supply Management & CMC, United States Pharmacopeia
- **Dr Steve Estevao Cordeiro,** Technical Officer, HPS/Norms and Standards for Pharmaceuticals
- **Dr Ivana Knezevic,** Team Lead, HPS/Norms and Standards for Biologicals *(virtually)*

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Thank you for your attention!

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