

Working together to build **Effective and efficient regulatory systems**

From pandemic response into supporting global regulatory strengthening, a critical role to provide affordable access to quality-assured medical products



USP - Regulatory Best Practices for Global Access to Medicines, Including Anti-TB Medicines (August 16th 2022)

Access to Medicines and Health Products (MHP)



ADG - Mariângela Simão





Health Products Policy and Standard (HPS) Clive Ondari

Regulation and Prequalification (RPQ) Rogério Gaspar



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Facilitated Product Introduction Samvel Azatyan*&**

Laboratory Network and Services Gaby Vercauteren

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Incidents and SF Medical Products Rutendo Kuwana

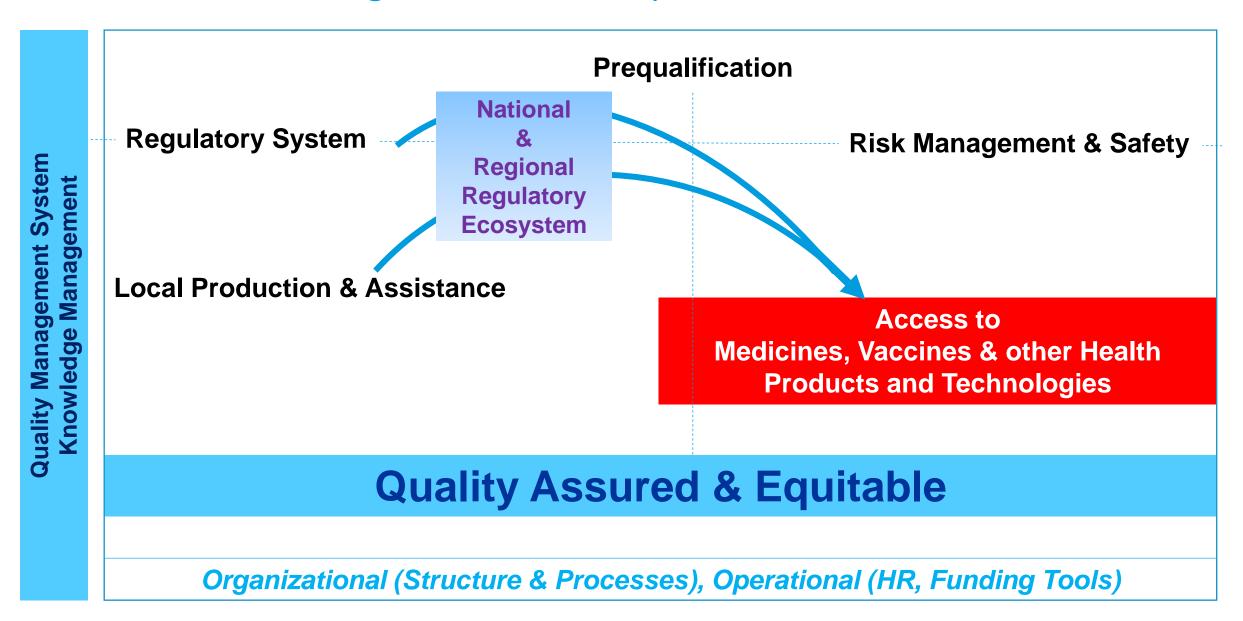
Quality Management Systems** (Jan-Anton Norder)

> Knowledge Management**

under recruitment

Regulation and Prequalification (RPQ)





WHO's Regulatory Strategic Priorities: 2019-2023





- 1 Strengthen country and regional regulatory systems
- 2 Improve regulatory preparedness for public health emergencies
- Reinforce and expand WHO prequalification & product risk assessment
- Increase the impact of WHO regulatory support activities

These strategic guide WHO regulatory activities

- ✓ Benchmarking and technical assistance to address regulatory gaps
- ✓ Promoting regulatory convergence, harmonization, work-sharing and reliance mechanisms
- ✓ Improving countries' ability to carry out risk-based post-marketing surveillance to securing supply chains against SF products
 - Includes strengthening national quality laboratories
- ✓ Broaden the prequalification programme
- ✓ Leverage political attention and commitment to advance accountability
- ✓ Promote and support sustainable and quality-assured local production through technical assistance

A reminder: WHO Regulatory Activities



Ensuring normative and technical excellence drives impact at country level

Technical Standards & Specifications

- Set global norms and standards (written & physical) and nomenclatures
- Increase common understanding on regulatory requirements by authority & manufacturer
- Standardize approach used by quality control labs

Prequalification

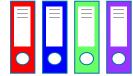
- Assure safety, quality
 efficacy & appropriateness of
 medical products used in
 LMICs, including medicines,
 vaccines, medical devices,
 cold chain equipment, vector
 control products & in vitro
 diagnostics
- Increase competition to shape the market

Regulation & Safety

- Strengthen regulatory systems in countries and regions
- Promote regulatory cooperation, convergence and transparency through networking, work-sharing and reliance
- Mitigate risks and protect against substandard / falsified products

Local production & assistance

- Provide holistic & coordinated support to strengthen local production and technology transfer
- including
 - guidance tools, situational analyses for sustainable quality local production
 - strengthening local production, capacity building and specialized technical assistance



Decreased regulatory burden







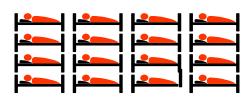


Reduced time for regulation





Decreased cost of regulation



Reduced mortality and morbidity

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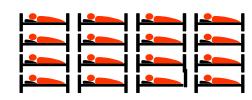


Reduced time for regulation





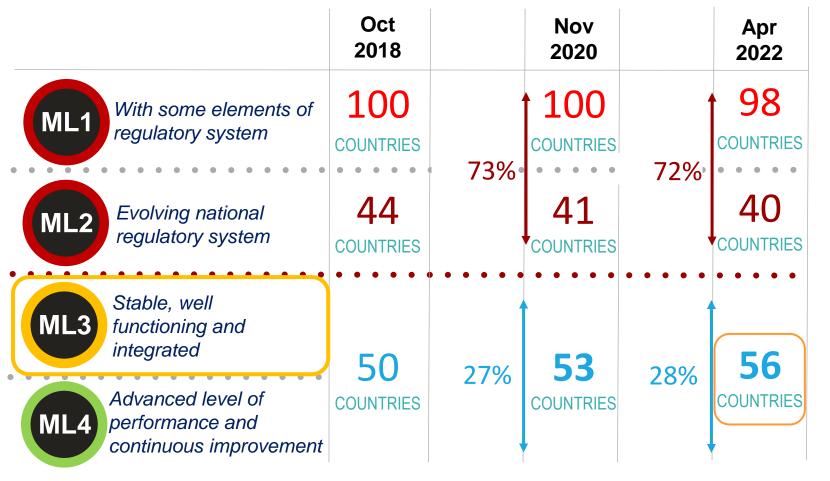
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Reduced mortality and morbidity

Global status of national regulatory systems, April 2022





Vaccines developed in countries with weak regulatory systems, i.e., ML1/ML2, are not eligible for EUL or prequalification

Singapore medicines regulator world's first to achieve the highest maturity level (ML4) following assessment (28 Feb 2022)



Timeline of events: ICMRA, COVAX RAG and R&D Blueprint Unite, Collaborate & Cooperate April 2020 initiation of ACT-Accelerator 22 Jun 2020 ICMRA workshop 10 Feb 2021 ICMRA workshop 24 Jun 2021 ICMRA workshop 12 Jan 2022 ICMRA workshop Position on Ph3 Vx trials **COVID-19 Virus Variants COVID-19 Virus Variants Omicron variants** 11 Mar 2020 Data requirements for Ph3 Vx trials WHO pandemic declaration 7-8 July 2021 ICMRA workshop 13 Jan 2021 ICMRA workshop 01-02 Dec 2021 ICMRA Summit Vx safety collaboration **Enabling manufacturing capacity** Global public health emergencies and in the COVID-19 pandemic regulatory systems - moving forward 18 Mar 2020 ICMRA workshop Data requirements for Ph1 Vx trials 06 Nov 2020 WHO-ICMRA Joint statement 07 May 2021 WHO-ICMRA Joint statement 11 Jun 2021 WHO-ICMRA Joint statement Improved regulatory alignment on Transparency and data integrity How COVID-19 vaccines are regulated for **COVID-19 medicines and vaccines** safety and effectiveness 03 Dec 2021 ICMRA Report Review of regulatory flexibilities/agilities Technical brief: COVAX RAG Technical brief: COVAX RAG Technical brief: COVAX RAG as implemented by NRAs during pandemic Synopsis from Aug - Oct 2020 Synopsis from Apr 2021 Synopsis from May 2021 **COVAX RAG meetings** COVAX RAG meeting COVAX RAG meeting Feb Mar Nov Dec Dec Apr Mav Jun Aug 23 Feb 2022 26 May 2021 11 Feb 2021 07 Dec 2020 29 Apr WHO Vx TPP Developing a framework for evaluating **COVID-19 Vx Correlates Methodological Approaches to** Human challenge model new COVID-19 vaccines of protection assess variants effect on Vx 17 Apr ToR WHO WG on Vx TPP Efficacy, Effectiveness and Impact 14 Feb 2022 12 Jan 2021 13-14 May 2021 What recent evidence do we have that omicron is New variants: Knowledge **COVID-19 Global Research** evading immunity and what are the implications? gaps & research & Innovation Forum 05 Feb 2020 SARS Vx candidates 28 Jan 2022 10 Jun 2021 2nd Global consultation 29 Mar 2021 1st Global consultation Why do we need a pan-sarbecovirus Vx? 11-12 Feb 2020 Assessing the Impact of SARS-CoV-2 Assessing the Impact of SARS-CoV-2 **Global Research & Innovation Forum** VoC on Public Health Interventions **VoC on Public Health Interventions** 15 Dec 2021 **Evidence & implications: omicron is evading immunity** ToR WHO WG on Vx Core protoco 06 Dec 2021 ToR WHO WG on Vx R&D 15 Jan 2021 Further Vx research to achieve the control of the pandemic everywhere Knowledge gaps & research priorities ToR WHO WG on Animal models 29 Nov 2021 ToR WHO WG on Assays Assays and animal models Progress summary: Assays 25 Oct 2021 Progress summary: Animal models 24 Jan X reactivity with other CoVs 05 May 2020 (18 Mar-01Apr 2020) 20 Mar 2020 (27Feb-15 Mar 2020) Emerging evidence on additional doses & their safety 27 Jan X reactivity between nCoV and SARS 04 Apr 2020 (15-26 Mar 2020) 04 Jun 2020 (26 Mar-01Jun 2020) 13 Aug 2021 30 Jan Vx Prioritization for CI trials

Can booster doses contribute to control this pandemic: what research is needed?

How can reliance help in case of public health emergency?



Authorization



Facilitate authorization or emergency use authorization

based on WHO PQ EUL or stringent regulatory authorities approvals

Encourage use of reliance and work-sharing

(e.g. WHO Covid-19 vaccines safety surveillance manual encourages reliance, review of risk management plans at regional and WHO prequalification level, pharmacovigilance inspections, etc.)

Vigilance

Reliance



Lot release

Avoid retesting through **reliance** on the batch release testing from releasing NRAs/NCLs

Emergency regulatory authorizations issued by > 150 LMI countries/territories World Health Organization



update: as of 18 May 2022

mRNA

Viral vector

Inactivated

Recombinant adjuvanted

Pfizer COMIRNATY

> 314 regulatory clearance

in 162 country/territory

Shared **EUL** reports

with 60 NRAs

4 DS sites 12 DP sites

Ref NRA:

- EMA
- US FDA

Moderna **SPIKEVAX**

506 regulatory clearance

in 78 country/territory

Shared **EUL** reports with 51 NRAs

> 2 DS sites 3 DP sites

Ref NRA:

- EMA
- US FDA
- MFDS
 - - TGA
 - DS: COFEPRIS
 - DP: ANMAT

AZ **VAXZEVRIA**

1'364 regulatory clearance

in 142 country/territory

> Shared **EUL** reports

with 81 NRAs

8 DS sites 12 DP sites

Ref NRA:

- EMA
- MFDS
- MHLW

COVISHIELD

147 regulatory clearance

SII

in 114

country/territory

Shared EUL reports

with 58 NRAs

2 DS sites 2 DP sites

Ref NRA: • DCGI

Janssen Covid-19 Vx

807 regulatory clearance

in 115

country/territory

Shared **EUL** reports with 67 NRAs

> 3 DS sites 7 DP sites

Ref NRA:

• EMA • US FDA

CanSino Convidecia

in 1

EUL granted 18 May 2022

> 1 DS sites 1 DP sites

Ref NRA:

Sinopharm

BIBP Covid-19

81

regulatory clearance

Shared

1 DS site 1 DP site

Ref NRA: NMPA

Sinovac

<u>Vx</u>

91 regulatory clearance

in 80

country/territory

EUL reports

with 60 NRAs

1 DS site 1 DP site

Ref NRA: • NMPA

Bharat Covaxin

CoronaVac

in 61

country/territory

Shared

EUL reports

ith 47 NRAs

On suspension 02 Apr 2022

17 NRAs

1 DS site 1 DP site

Ref NRA:

Novavax

Nuvaxovid

34 regulatory clearance

in 34

country/territory

Shared **EUL** reports

with 20 NRAs

2 DS sites 1 DP site

Ref NRA: • EMA

SII

Covovax

regulatory

in 1 country/territory

clearance

Shared **EUL** reports

with 9 NRAs

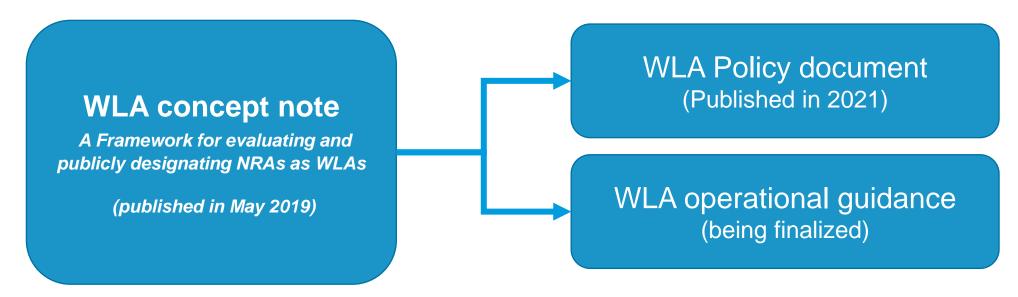
2 DS sites 2 DP sites

Ref NRA: DCGI

Operationalizing WHO Listed Authorities (WLAs)



The WLA Framework



The WLA framework is envisaged to be operational in 2022

Definition of WLA: Adopted by the ECSPP in October 2020, TRS 1033

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 and performance evaluation process

Benefits of WHO-Listed Authority (WLA) framework



Enable efficient use of regulatory resources

by providing a robust framework to promote trust, confidence and reliance

Encourage continuous improvement of regulatory systems and

regulatory convergence

Help procurement decisions

on medical products by UN and other agencies, as well as countries (especially LMICs) Contributes to WHO PQ programme

by expanding the pool of trusted regulatory authorities

Fosters health equity

by enabling an environment for innovation and local production, and accelerating access to medical products

"End-to-end" health products' management: shared responsibilities



Post market

Legislation, regulation, governance, monitoring

Access to quality-assured medicines, vaccines & other health products and technologies

- Universal health coverage
- Health emergencies
- Health and well-being



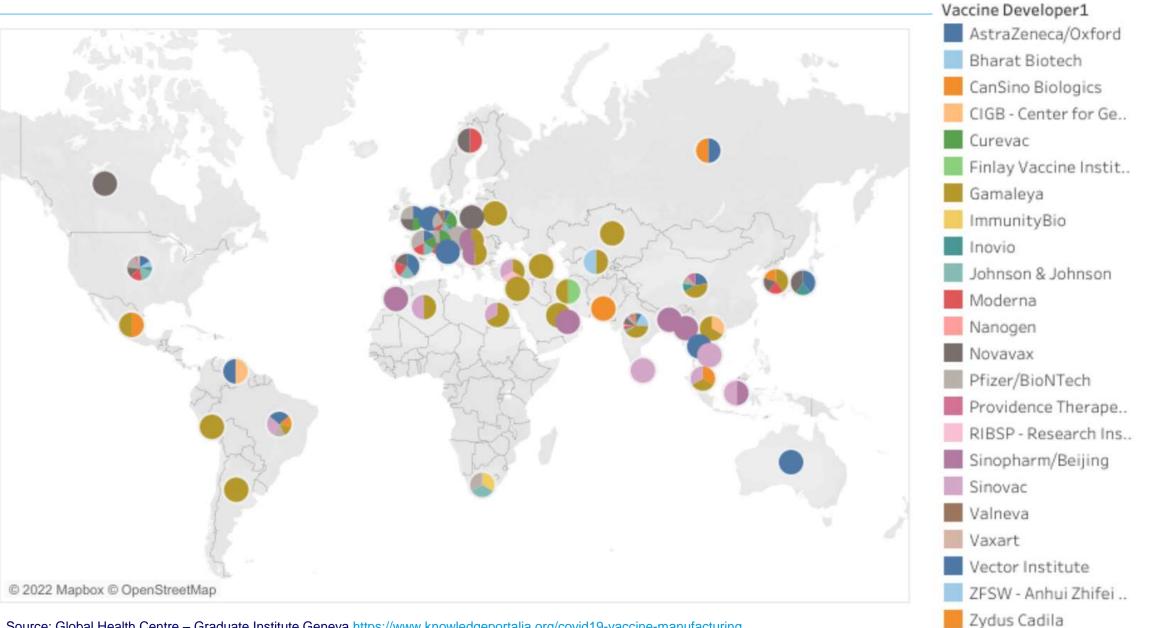
Joint reviews & assessments of clinical trials

Long term Good Regulatory Practice

Regulatory Reliance, Collaboration and Harmonization

Locations of Covid-19 Vaccine Manufacturers





Local Production and Assistance



WHO VACCINE MANUFACTURING **WORKSHOP for SOUTHEAST ASIAN** and WESTERN PACIFIC REGIONS



MEMBER STATE SUPPORT IN STRENGTHENING LOCAL PRODUCTION DZA, EUC, EGY, ETH, GHA, KAZ, NGA, SEN, SRB, etc.



ONGOING PQ/EUL-RELATED SPECIALIZED TECHNICAL ASSISTANCE



IMPLEMENTATION OF WORLD LOCAL PRODUCTION FORUM **RECOMMENDATIONS**

