Extraordinary Virtual

International Conference of Drug Regulatory Authorities (ICDRA)

20-24 September 2021

Plenary 1: Progress in implementation of Recommendations of 18th ICDRA:

Consolidated report from WHO Regions and the Headquarters

THEME: Benchmarking of Regulatory Systems: towards mature regulatory systems

Recommendations to WHO

1. Continue support for regulatory systems strengthening to Member States utilizing the Global Benchmarking Tool which has proven to be effective in promoting one global standard for regulatory systems.
2. Support regulatory systems strengthening to Member States at different maturity levels in a strategic manner.
3. Further develop the process for designating WHO Listed Authorities with input from Member States.

Progress in implementation

1. WHO provided support to 54 countries trough benchmarking, IDP follow ups and implementation of recommendations. The GBT was fully integrated with the Blood Tool and will be also integrated with the Medical Device and Diagnostics indicators before end of 2021;
2. In line with WHO's five-year strategic plan to help build effective and efficient regulatory systems, **six (6) additional NRAs reached ML3 and over 40 NRAs enhanced their regulatory capacities**, with WHO support;
3. WLA definition and WLA policy document published in 2021 following endorsement by WHO Expert Committee (ECSPP) and approval by WHO, respectively. WLA Operational Guidance covering indicators and methodologies to measure the performance of regulatory systems developed and under public consultation, until 30 September 2021;
4. WHO has organized trainings to national regulatory authorities of Regional Economic Communities (RECs) in Africa on various regulatory areas based on the institutional development plans prepared to fill the gaps identified through the self-benchmarking exercises conducted.

THEME: Regulatory collaboration, convergence and harmonization

- **WHO Good Reliance Practices** and **Good Regulatory Practices** adopted by the Expert Committee on Specifications for Pharmaceutical Preparations in October 2020, published in March 2021 and a launch webinar took place on 29 June 2021.
- The importance of using reliance in the whole life-cycle of medical products (including post-authorization and vigilance) and of transparency and sharing of unredacted information is highlighted in the **Good Reliance Practice** and **Good Regulatory Practices**.
- Published WHO collaborative procedures include life-cycle management, and WHO continue to share information on post-approval changes for prequalified pharmaceuticals, in addition to initial marketing authorizations. This includes WHO PQT reliance on PAC decisions made by SRAs currently recognized by PQT;
- WHO is introducing a new online tool/platform that enables easier tracking of initial authorizations and life-cycle management outcomes for WHO-facilitated collaborative procedures for medical products.

THEME: Enabling access to innovative medical products in resource-limited settings

- Continued use of MedNet as an online platform to exchange confidential information among regulators participating in collaborative procedures and regional joint activities (assessments and inspections). In addition to facilitated registrations of prequalified products and products approved by “stringent regulatory authorities,” several regional groups use the platform for regional joint assessments and inspections;
- As part of the Evaluation Project of SRA CRP Pilot, more countries reported to start using CTD, motivated by their experience and participation in CRP procedures;
- WHO has supported Member States and Regional Economic Communities in Africa to improve knowledge of assessors on the principles and content of internationally recognized CTD format and facilitate quality assessment of medical products using CTD format.

THEME: Regulatory preparedness for public health emergencies (1)

- Expert Review Panel (ERP) has operated successfully since 2009 with several clients, notably the Global Fund but also several other clients;
- EUL guidance in place for therapeutics. Will be launched when needed and requested;
- PQTm has been conducting Annual Medicines Quality Workshop for Manufacturers since July 2018. Will shortly conduct a new workshop for Manufacturers on Biotherapeutics with a focus on insulin (1 & 2 Oct 2021);
- PQTm provides reports for approval in countries for prequalified products via CRP procedure. There are no medicines listed via the EUL procedure at present.

THEME: Regulatory preparedness for public health emergencies (2)

- RPQ developed and introduced procedure to facilitate listing/authorization of WHO EUL vaccines and in vitro diagnostics through exchange of WHO EUL assessment reports between WHO and NRAs;
- REG Supported AMRH through the its Technical working groups to form the AMDF task fore which played key role in informing and updating NRAs on listed COVID-19 assays, priority devices and PPEs by either WHO or other matured regulatory authorities and information on respective manufacturers which facilitated decision and introduction of the required products;
- WHO facilitated emergency use authorization of WHO emergency use listed (EUL) candidate vaccines during the COVID-19 pandemic. Supported member states were able to issue emergency use authorizations (EUA) in 14 days following technical workshops on COVID-19 vaccines (on the WHO EUL);
- WHO supported development of a procedure for **emergency use authorization of clinical trial applications for COVID-19 investigational products in Africa**. The procedure, facilitated by AVAREF, is an opportunity for multi-country review and approval of CTAs within 10 working days (for repurposed medicinal products) and within 15 working days for novel investigational products. To date, this procedure has been used to support 5 multi country joint reviews in Africa.

THEME: Regional regulatory networks: progress and challenges

- WHO Paediatric Regulatory Network (PRN) reactivated in December 2019 as a global paediatric working network of regulators and a platform for exchange of regulatory information on paediatric medical products and to support the availability of quality-assured medical products for children;
- In 2021 as part of ASEAN JACG, a joint assessment information management system (JAIMS) has been developed to facilitate the joint assessment between members states. It is planned to be piloted and launched in the second half of 2021;
- RPQ supports global regulatory networks, such as ICH and IPRP: leadership role in the IPRP Quality working group, ICH's Quality discussion group;
- RPQ participates in the international regulatory forum on the treatment of nitrosamine impurities.

THEME: Certification of Pharmaceutical Products (CPP)

- Revised WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce (including e-CPP) adopted by the Expert Committee on Specifications for Pharmaceutical Preparations in October 2020.
- Update: Use of e-signature for Certificates using the WHO Certification Schemes;
- Some National and Regional Regulatory Authorities have indicated that, during the COVID-19 crisis, they will no longer be in a position to issue and send paper copies of Certificates – instead they will use a secure e-signature process;
- WHO agrees with this initiative, which does not contradict the current WHO Guideline. WHO recommends other regulators issuing Certificates consider this approach too.

THEME: Regulation of clinical trials: focus on patient safety

- Development of a comprehensive training on Clinical Trial Ethics. The course, jointly developed by AVAREF and MRCT, University of Birmingham, is in first session this month, September 2021, is intended to inform and educate Ethics Committee members in Africa, harmonize the approach for ethics review of clinical trial applications within the continent to align with global ethics review considerations. In this way, the expectation is to build capacity within the continent for assessment of clinical trial applications and development of harmonized processes for monitoring and follow up on safety data.

Future direction of WHO Prequalification (PQT)

- Pilot for BTPs ongoing since 2018 (rituximab, trastuzumab). A total of 16 products have been prequalified so far;
- Pilot for Human insulin ongoing;
- Medicines for COVID 19 invited;
- First Expression of Interest (EOI) for Medicines for treatment of infections in newborn and young infants and childhood pneumonia published in March 2020;
- PQTm continues to rely on SRAs (WLAs operational guidance under development).

Implementation of recommendations in the area of IVDs

- To facilitate communication between stakeholders (manufacturers of IVDs, vaccines and therapeutics) and regulators – the pre-emergency scheme was set up in the revised WUL procedure, however it was not implemented under the current pandemic;
- To use its position in the various international regulatory harmonization fora and help promote alignment of regulatory application dossier formats – WHO works with the IMDRF and GHWP to promote alignment of submission requirements. In addition, PQDx has adopted the new IMDRF Table of Contents format for PQ applications;
- The expansion of the PQDx scope has been slowed down due to the additional workload related to EUL assessments. TB NAT assays will become eligible for PQ assessment in Q1 2022 and glucose meters and tests strips later in 2022.

Theme: Promoting medical products safely: supply chain integrity

- Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics – published June 2021, which incorporates guidance for PMS conducted by manufacturers, market surveillance conducted by regulators, and the role of other stakeholders;
- Training material: A handbook on existing training resources and reference documentation for the prevention, detection and response to SF medical products developed – published June 2019;
- Risk-based post-market surveillance:
  - E-tool and a database to automate the conduct of medical products quality surveys and enhance the quantity and quality of data captured to inform risk-based post-market surveillance programmes based on existing WHO guidance developed. Aptly called “EPIONE”, the tool is being piloted in a survey of 5 regions in the United Republic of Tanzania (2021);
  - WHO facilitated surveys of the quality of selected antimalarials, antibiotics and reproductive health products circulating in six African countries (Benin, Ghana, Nigeria, Sierra Leone, Togo and Uganda) 2019-2020. Report is being finalized in consultation with survey countries.

Pharmacovigilance (PV)

Smart Safety Surveillance

- A pilot project of six countries (Armenia, Brazil, Ethiopia, India, Peru, Thailand) was completed to demonstrate the value of risk-based prioritization, work-sharing, joint activities and reliance in PV.

Regulatory Preparedness for Public Health Emergencies

- With COVID-19 as the catalyst, WHO has developed and implemented a Vaccine Safety Surveillance Manual, for PV readiness of countries and safety surveillance of new vaccines in a pandemic
- A subcommittee of the Global Advisory Committee on Vaccine Safety has been established and routinely reviews safety signals with COVID-19 vaccines
- An Early Warning System is being piloted to gauge the value of formal and informal sources of safety information in a pandemic

Information Sharing

- The WHO Programme for International Drug Monitoring expanded to 148 Member States who share safety data in a global database (of more than 27 million case reports) for collective learning
- The WHO Vaccine Safety Network (VSN) includes 98 WHO-verified websites providing credible vaccine safety information.

Promote reliance on outputs from Quality Control Laboratories

- The WHO Network of National Control laboratories for Biological (NNB) hosts currently 43 members. The NNB serves as a platform for confidential exchange of quality and technical information on vaccines. Cooperation is increasing regulatory efficiency through greater reliance on existing data from trustworthy sources;
- Several manufacturers of prequalified vaccines have agreed to sharing the lot release data with the NNB members, hence eliminating redundant testing;
- Two Covid-19 vaccines manufacturers (Janssen J&J and Pfizer BioNTech) have signed agreements to share their lot release data with the NNB;
- Best practices and harmonized common standards were promoted through trainings.
- Annual reports from the 55 prequalified medicines QCLs were received in 2021 and have been successfully reviewed, thus ensuring the reliability of their outputs.
- In addition, two more medicines QCLs were prequalified, one QCL was audited and two QCLs received technical support.

THEME: Local Production

- World Local Production Forum: Enhancing access to medicines and other health technologies organized by the Local Production and Assistance Unit (LPA Unit)
  - High-level participation during the WLPF, including Ministers, heads of UN agencies, ambassadors, heads of NRAs, etc.
  - Delegates from > 100 Member States, together with UN agencies, international organizations, industry associations and other stakeholders, attended
  - 3 actionable recommendations resulted from the discourse
- Technical support from LPA Unit to MS in deliberations and negotiations for Resolution on Strengthening local production of medicines and other health technologies to improve access (WHA74.6)
  - Over 100 MS co-sponsored the resolution when it was adopted at 74th World Health Assembly
- Interagency Statement on Promoting Local Production
  - LPA Unit led the development and launch of the first interagency statement signed by the top leadership of 6 signatory organizations (WHO, UNCTAD, UNIDO, UNAIDS, UNICEF, The Global Fund)
  - It was launched in a Technical Briefing at the 72nd World Health Assembly in 2019

AFRO: Regulatory collaboration, convergence and harmonization

Recommendations

- Regulatory collaboration, convergence and harmonization activities should incorporate not only initial authorization but also lifecycle management and pharmacovigilance.

- WHO should provide a toolbox with all the available options for regulatory collaboration, convergence and harmonization and increase awareness to facilitate selection of the appropriate mechanisms by member states.

Progress made

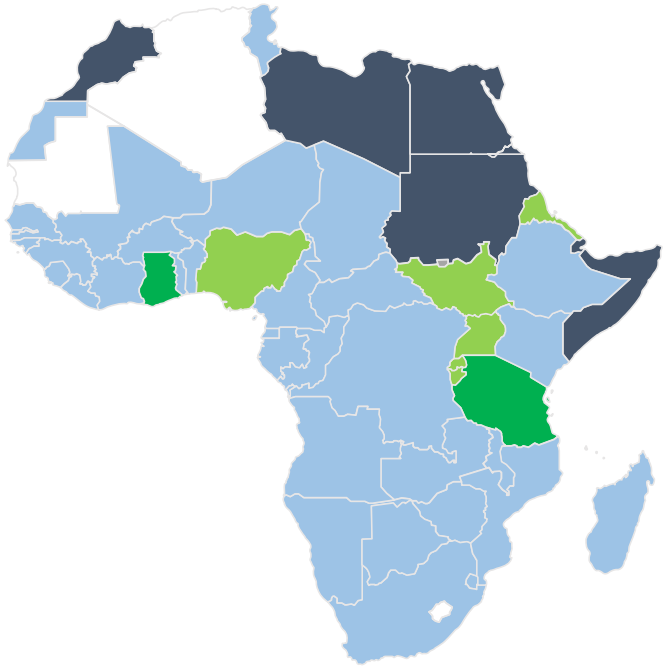
- AFRO countries participating in WHO Collaboration Procedure for Registration fo PQ'd products: **30**
- Number of products approved via CRP: **570**
- Timelines : within **90 days**
- AFRO Regulators sensitized on Facilitated registration procedures in 2019
- Treaty for Establish of AMA ratified in **15** African member states

AFRO: Benchmarking of Regulatory Systems: towards mature regulatory systems

Recommendations

- Continue support for regulatory systems strengthening to Member States utilizing the Global Benchmarking Tool which has proven to be effective in promoting one global standard for regulatory systems;
- Support regulatory systems strengthening to Member States at different maturity levels in a strategic manner;
- Further develop the process for designating WHO Listed Authorities with input from Member States;
- Further clarify the role of WHO Listed Authorities at Maturity Level 3 or Maturity Level 4 and describe how this information can be utilized by Member States to support and advance their regulatory work.

Benchmarking Type	Number of countries	Countries attaining ML3
Benchmarked	8	**2**
Self Benchmarked	35	0
Not Benchmarked	4	0



AFRO: Regulatory preparedness for public health emergencies. Enabling access to innovative medical products in resource-limited settings

Recommendations

- WHO should facilitate communication between stakeholders (manufacturers of IVDs, vaccines and therapeutics) and regulators on needs for products, development work and risk assessment work. This should be facilitated by WHO setting up a pre-Emergency Use Listing scheme.
- WHO is asked to use its position in the various international regulatory harmonization forums to help promote alignment of regulatory application dossier formats, including elimination of unnecessary differences in the national and regional CTD requirements.

Progress made

- Communication documents developed (one pager, process visualization) and disseminate to all stakeholders;
- Development of guideline for emergency review and authorizations;
- Presentation of AVAREF and its emergency process for joint-review of clinical trial applications to NRAs, ethics committees, sponsors, manufacturers;
- Clinical trial preparedness assessment conducted for 31 AFRO countries (NRAs, ethics committees, CROs/PIs) sponsors to inform on national processes, governance, HR, digital infrastructure;
- **4** countries with high preparedness, **2** with medium, **4** with low,
- 60% of responding NRAs have no reliance mechanism, 40% have reliance mechanism, 2% have adopted AVAREF templates and guidelines
- Application process is still manual, and countries need support to implement digital infrastructure;
- To address gaps in CT preparedness: further dissemination of guidelines, country support, additional guidance documents, trainings to national staff, digital platform for application review;
- Joint review of clinical trial applications.

AFRO: Regulatory preparedness for public health emergencies. Enabling access to innovative medical products in resource-limited settings

Recommendations

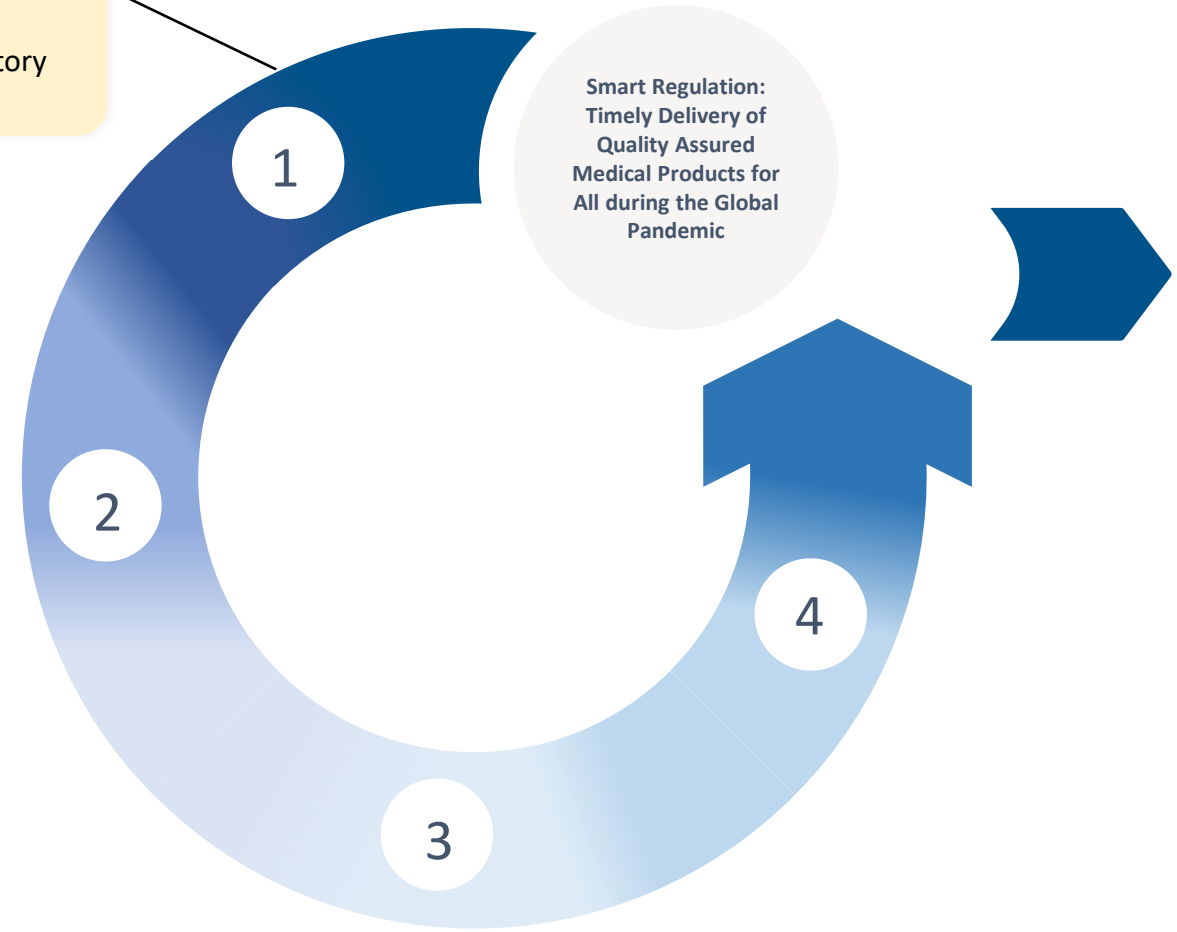
- WHO should encourage the use of regulatory networks such as ICMRA in the case of public health emergencies and should support effective transition from emergency use to in-country approval.

Progress made

- Pipeline monitoring: creation of database of over 550 product developer contacts, identification of developer associations, engagement with developers;
- Use of AVAREF for joint review and authorization of clinical trial authorizations and facilitation of emergency use authorization of Covid-19 vaccines, nOPV2, EVD vaccine;
- Positive outcomes were noted:
  - Countries were able to expedite delivering decisions relative to usual country timelines, rising to the emergency context of the global COVID-19 pandemic
  - The collaborative nature of the review allowed countries to learn from one another and collectively conduct a more thorough review of the protocol

AMRO/PAHO: Milestones on Relevant topics in the Region of the Americas

1. Benchmarking of Regulatory Systems: towards mature regulatory systems



Publications

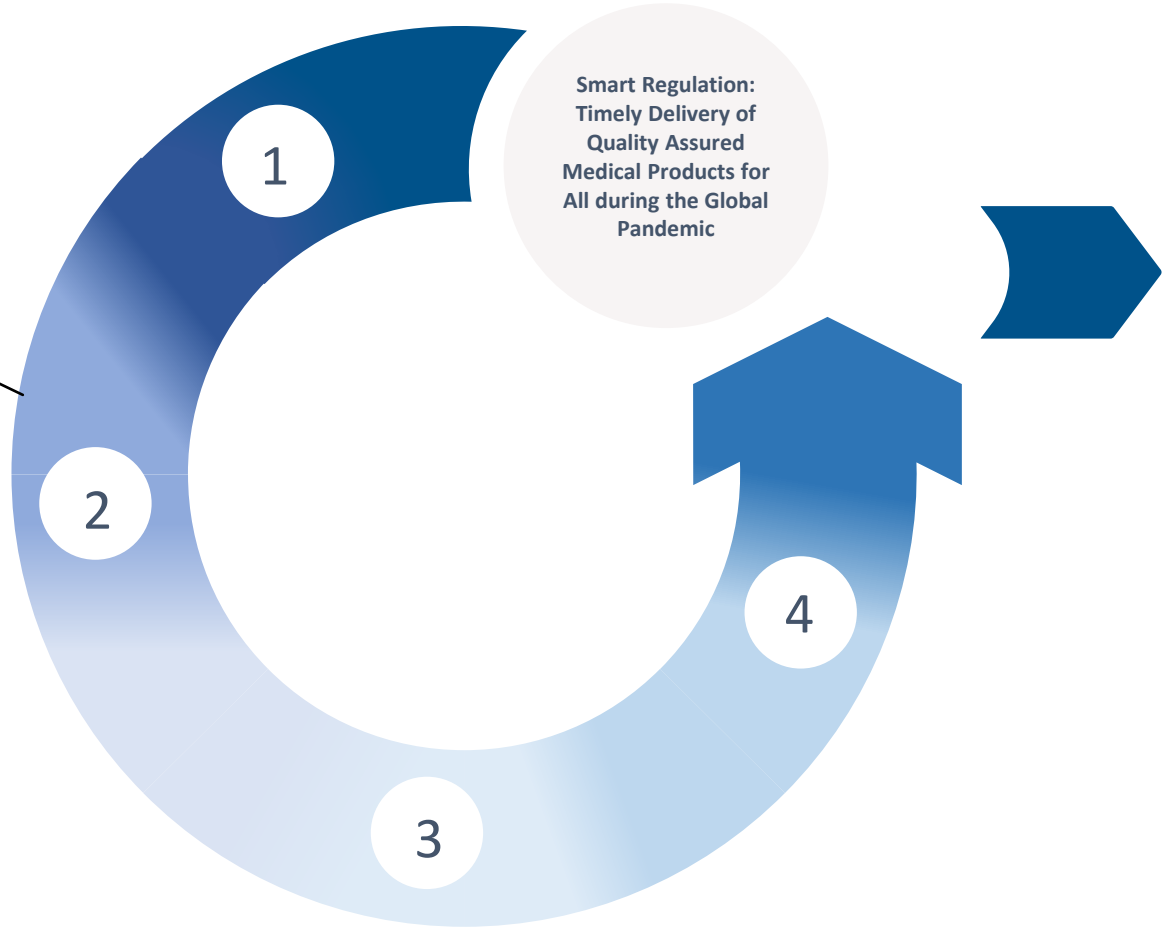
- Launching of the report Regulatory System Strengthening in the Americas. Lessons Learned from the National Regulatory Authorities of Regional Reference

- GBT Spanish publication available and its use promoted in the Region of the Americas

Coordinations

- Active participation of Regional office and PAHO Member States in the development and awareness of GBT Plus (blood products and medical devices)
- An important number of countries performing self-assessments of regulatory capacities in the Region of the Americas. Requests for supporting vigilance and market surveillance (on key selected indicators of the GBT) is being addressed.
- Active participation from the Region of the Americas in the consultation for development of WHO WLA operational principles and performance evaluation framework of WLAs.

AMRO/PAHO: Milestones on Relevant topics in the Region of the Americas



2.a. Regulatory collaboration, convergence and harmonization & Harmonization, work-sharing and reliance in several regulatory functions including pharmacovigilance
2.b. Regional regulatory networks: progress and challenges

Publications

- PANDRH publications and projects endorsed publicly available


Reliance Principles

Regulation Advanced Therapy


PANDRH Network


RS Models for Small States

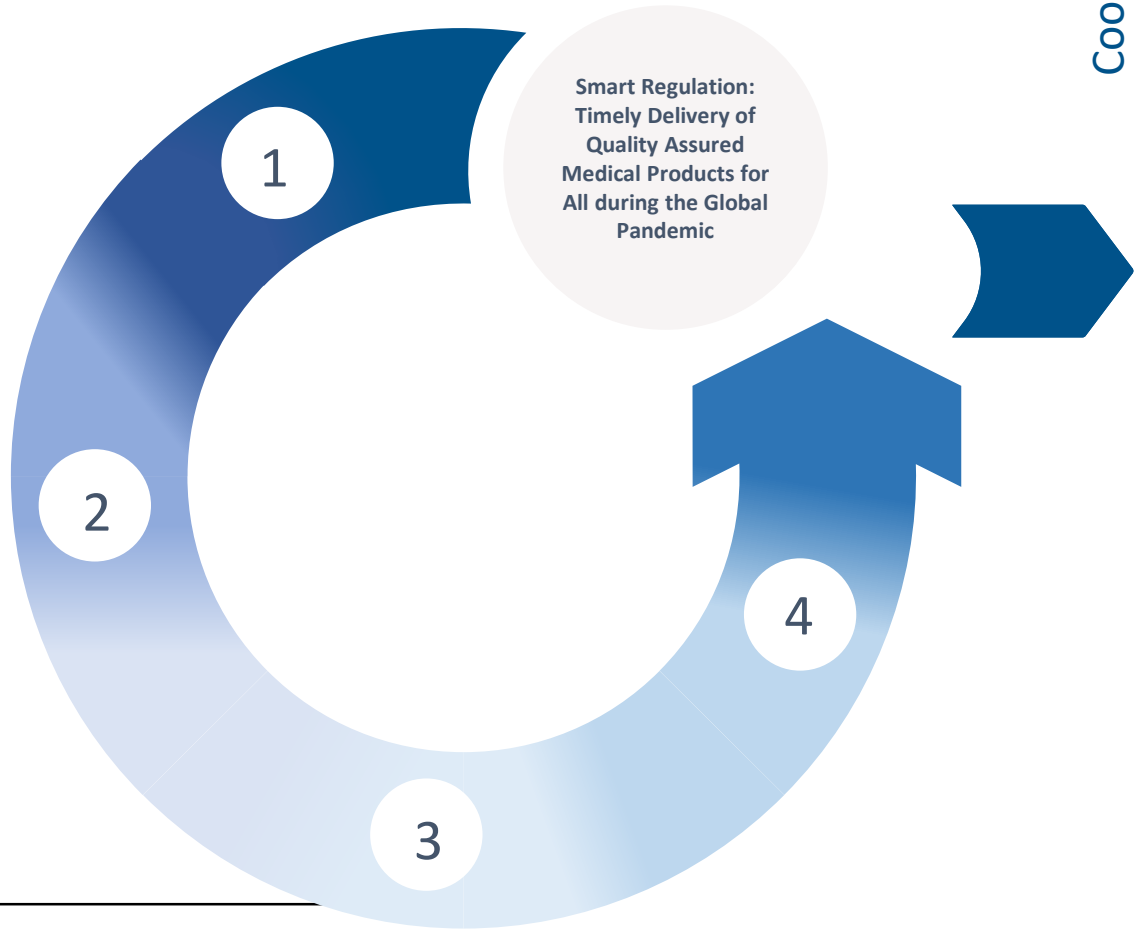

Coordinations

- Access to non-public information on WHO EUL COVID-19 vaccines granted to 25 Member States* under confidentiality agreement, to support regulatory efficiencies during pandemic situation promoting reliance practices.
- Promoting active participation of the Region in Regional and International Fora (IMDRF, ICDRA, ICH, PANDRH)
- PAHO fostered harmonization and networking in different topics related to pharmacovigilance such as improving reporting and a collaboration among countries for joint evaluation of PSURs and RMPs. (PANDRH)
- Next PANDRH Conference will be held virtually in **Dec 2021**.

- Regional networks of 1) pharmacovigilance and 2) substandard and falsified medical products and 3) working group on medical devices, have been considerably strengthened.
- IMDRF Mirror Working Groups
- Virtual courses to support RSS of MD and Biologics

*25 Member States include the CRS counted as **1 country**, the countries are: Argentina, Barbados, Belize, Bolivia, Brazil, Chile, Costa Rica, Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Guyana, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Saint Lucia, Trinidad and Tobago, Uruguay, and the CRS

AMRO/PAHO: Milestones on Relevant topics in the Region of the Americas



3.a. Promoting medical products safely: supply chain integrity & Safety of medical products throughout the product life cycle
3.b. Smart Safety Surveillance
3.c. Regulator's role in containing antimicrobial resistance
3.d. Local Production

Coordinations

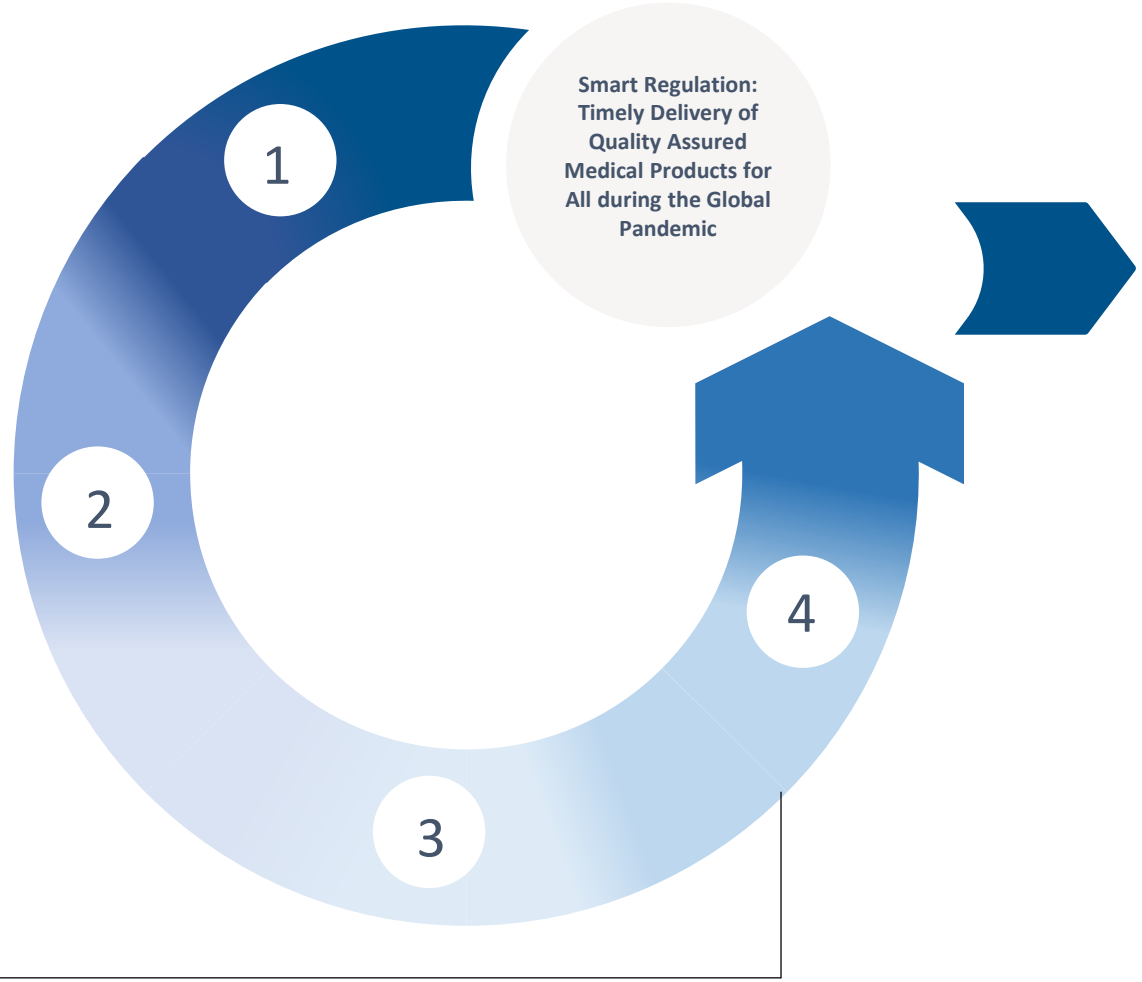
- Brazil and Colombia are leading two projects at the Member States Mechanism for SF products. A regional document on internet sales of medicines is under review.
- A Regional strategy implemented to support Member States in the supply chain management with focus on HIV, TB and Malaria.
- Increased forecasting accuracy, rationalization of TARV schemes in accordance with WHO recommendations promoted.

- 3S initiatives were supported for malaria treatments in Brazil, Peru and Colombia. A project in TB is also undergoing in Peru. A strategy for vaccines is being drafted. The Medsafety (app) reporting tool is also being implemented in countries of the region.

- Diverse lines of action have been implemented with NRAs in the region to support the national action plans on AMR (measure national and local consumption of antimicrobials, enforcing the sale of these products only with a prescription, develop awareness campaigns on AMR, among others)

- Technical cooperation on comprehensive policies and coordination
- 59° PAHO Directing Council: Resolution and policy document on "Increasing Production Capacity for Essential Medicines and Health Technologies"
- Launch of a "Regional platform to advance the manufacturing of COVID-19 vaccines and other Health Technologies in the Americas"
- Call for expression of interest to contribute to the value chain and supply of reagents for the sustainable manufacturing of a COVID-19 and other mRNA vaccines in the Americas
- Collaboration with WHO to the establishment of a COVID-19 mRNA vaccine technology transfer Hub in the Americas
- "Regional Dialogue between health, industry, science and technology sectors". Co-organized jointly by PAHO and ECLAC

AMRO/PAHO: Milestones on Relevant topics in the Region of the Americas



4. Regulatory preparedness for public health emergencies

Publications

- A network of COVID -19 NRA focal points was launched. Ongoing meetings(26 so far) have provided guidance and promoted timely exchange of information among NRAs in the Region to accelerate uptake and improve oversight of COVID-19 medical products. Publications document many of the recommendations, publicly available (ENG/SPA):

Recommendations on Regulatory Processes and Aspects related to the Introduction of Vaccines during the COVID-19 Pandemic and Other Emergencies

Post-authorization Surveillance of Medical Products during a Pandemic Emergency

Considerations for Regulatory Oversight of Clinical Trials in the COVID-19 Pandemic

Regulation of Medical Devices in the context of COVID-19

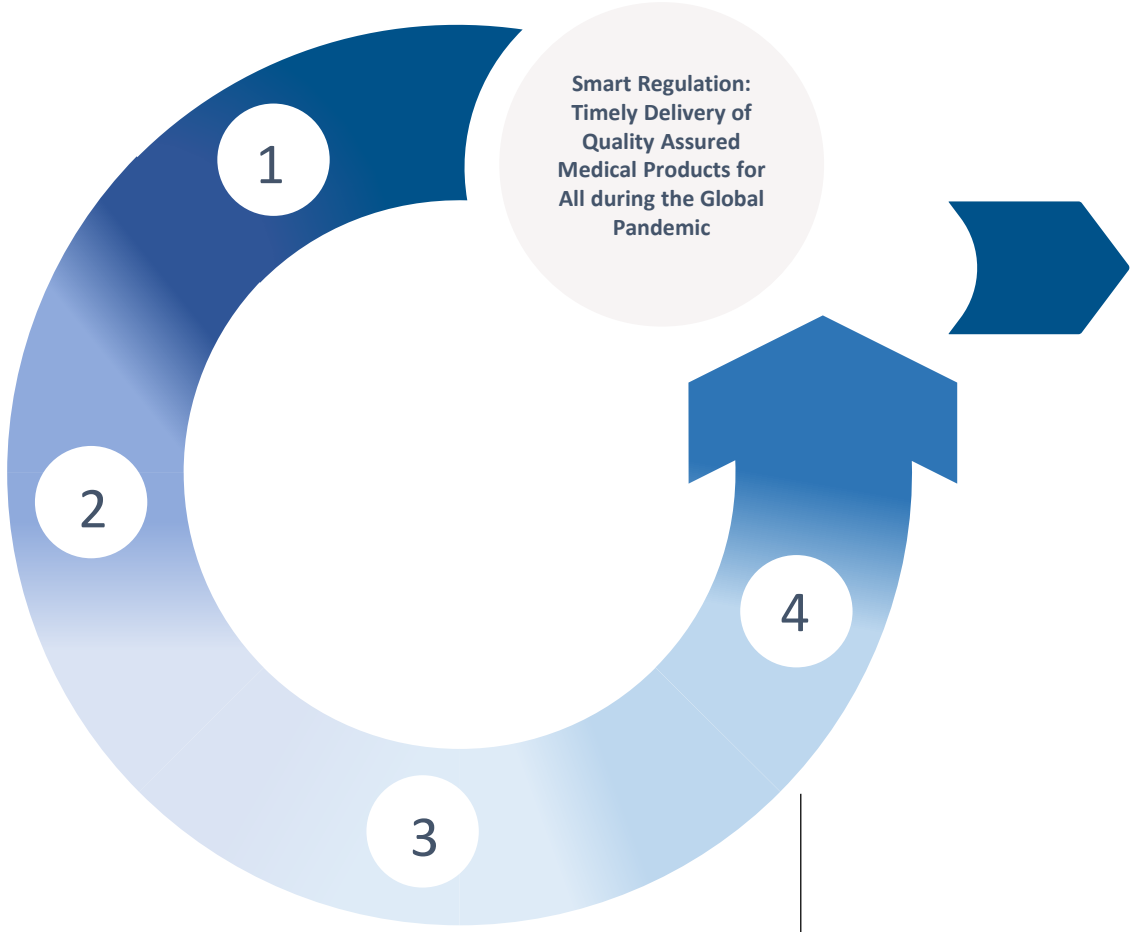
Crisis Management during an Epidemic: General guidelines for efficient response coordination by national regulatory authorities

Regulatory considerations on authorization of the use of convalescent plasma (PC) to address the COVID-19 emergency

Reliance for Emergency Use Authorization of Medicines and Other Health Technologies in a Pandemic (e.g. COVID-19)

The combined MT products are listed at PRAIS pandemic response

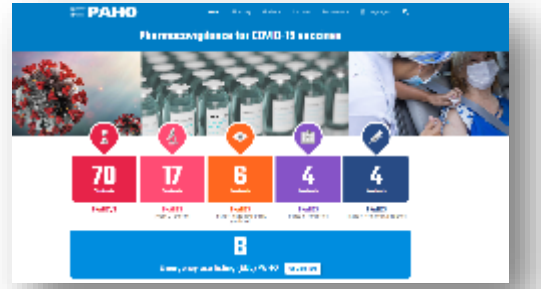
AMRO/PAHO: Milestones on Relevant topics in the Region of the Americas



4. Regulatory preparedness for public health emergencies

Tools

- Countries were supported to strengthen criteria for COVID-19 vaccines safety evaluation and **a dashboard with tools is publicly available.** Networking and permanent exchange of information were fostered, including the evaluation of reported AEFIs from the region and globally. Four documents for pharmacovigilance preparedness in the context of the COVID-19 pandemic were published. A regional system for vaccine safety is under construction.



- Additional tools for promoting information Exchange among Member States

Active Platforms: REPs, RISE and PRAIS

What is NEW?

MEDList

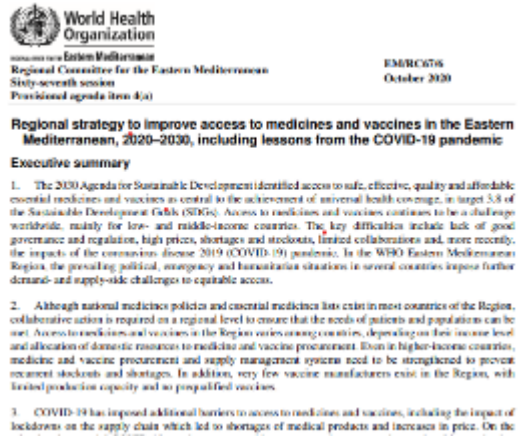
REDMA

Quantmet

EMRO Region:

WHO Strategic approaches to improving access to safe medical products

- Development of the Regional Strategy to Improve Access to Medicines and Vaccines in the Eastern Mediterranean Region (2020-2030), endorsed in the RC67, October 2020;
- Ongoing implementation of the 10-year regional strategic framework for blood safety and availability (2016-2025) with a focus on establishing an effective governance for the blood systems in the region.



World Health Organization

Eastern Mediterranean

Regional Committee for the Eastern Mediterranean
Sixty-seventh session
Provisional agenda item 4(a)

EM/RC67/6
October 2020

Regional strategy to improve access to medicines and vaccines in the Eastern Mediterranean, 2020–2030, including lessons from the COVID-19 pandemic

Executive summary

1. The 2030 Agenda for Sustainable Development identified access to safe, effective, quality and affordable essential medicines and vaccines as central to the achievement of universal health coverage, in target 3.8 of the Sustainable Development Goals (SDGs). Access to medicines and vaccines continues to be a challenge worldwide, mainly for low- and middle-income countries. The key difficulties include lack of good governance and regulation, high prices, shortages and stockouts, limited collaborations and, more recently, the impacts of the coronavirus disease 2019 (COVID-19) pandemic. In the WHO Eastern Mediterranean Region, the prevailing political, emergency and humanitarian situations in several countries impose further demand- and supply-side challenges to equitable access.

2. Although national medicines policies and essential medicines lists exist in most countries of the Region, collaborative action is required on a regional level to ensure that the needs of patients and populations can be met. Access to medicines and vaccines in the Region varies among countries, depending on their income level and allocation of domestic resources to medicine and vaccine procurement. Even in higher-income countries, medicine and vaccine procurement and supply management systems need to be strengthened to prevent recurrent stockouts and shortages. In addition, very few vaccine manufacturers exist in the Region, with limited production capacity and no prequalified vaccines.

3. COVID-19 has imposed additional barriers to access to medicines and vaccines, including the impact of lockdowns on the supply chain which led to shortages of medical products and increases in price. On the

Regulatory collaboration, convergence and harmonization and promoting regional networking

- Convene the 9th Eastern Mediterranean Drug Regulatory Authorities Conference (EMDRAC), Virtual Meeting with the Heads and Senior Staff of NRAs of Medical Products, 30-31 March 2021;
- Establish a steering committee for capacity building, collaboration, harmonization, and follow up of EMDRAC recommendations;
- Draft MOU for collaboration and information sharing on SF, PV and active Pharmaceutical ingredients/traditional medicines under review for endorsement and implementation (Afghanistan, Iran, Pakistan);
- Establishment of track and trace database across the Gulf Cooperation Council;
- Development and implementation of reliance policy for medicinal products & Vaccines (Iraq).

EMRO Region:

Regulatory preparedness for public health emergencies

- Developed Guidelines for Emergency Use Approval for unlicensed vaccines & medicines (Egypt, Jordan, Iraq)
- Developed new regulations for the fast registration of medical products (Palestine)
- Developed Guidelines on the process of reporting drug side effects in emergency situations resulting from epidemics, guidelines on remote pharmacovigilance Inspections and guidelines on the virtual regulatory inspections (Jordan)

Promoting local production

- Conducted HQ/EMRO training workshop: Key enabling factors for successful local production & supply of quality-assured medical products, October 2020;
- Regional Expert Consultation Meeting to establish a regional action plan with initial focus on COVID-19 vaccines that will take place virtually, June 2021;
- Development of a national vision, legal framework or national collaboration with different Governmental sectors for strengthening local capacity of medicines (Iraq, Afghanistan and Saudi Arabia).

EMRO Region:

Benchmarking of Regulatory Systems: towards mature regulatory systems

- Pre-visit benchmarking mission conducted: Pakistan and Afghanistan;
- Provision of technical support of NRA self-benchmarking activities (Egypt, Oman, Tunisia and Saudi Arabia);
- Self-benchmarking of blood regulatory systems conducted in two countries using GBT+Blood tool;
- Capacity building webinars conducted for strengthening blood regulation.

Regulation of Biosimilars products and other medical products

- Establishing dedicated committees for Biological and Biosimilars products evaluation (Iraq, Saudi Arabia);
- Establishment of the dedicated committee for the biosimilar applications: SAA;
- Developed/updated specific guidelines on biosimilars registration (Egypt, Iraq, Saudi Arabia);
- Capacity building of GMP inspectors specialized in the area of Biotherapeutics and biological products (Saudi Arabia);
- Enhancing the support to implement the safety of other medical products of human origin (cells, tissues, and organs);
- Regional Workshops for strengthening the regulation of medical devices including IVDs: with focus on technical files evaluation approaches and Post Market/Market Surveillance for COVID-19 assays in collaboration with the WHOCC-Saudi FDA for MD regulation (2020 and 2021).

EMRO Region:

Safety of medical products throughout the product life cycle

- Conducted Regional meeting and several In-Country training workshop to improve PV systems (Afghanistan, Egypt, Iran, Iraq, Syria, Lebanon) in collaboration with the WHO-CC-PV center of Morocco;
- Specific workshops for strengthening Covid-19 vaccine safety monitoring (Iraq, Syria, Lebanon);
- Implementation of ToT to establish a regional pool of facilitators in the area of pharmacovigilance;
- Established online system for data record of ADRs and medication errors reports and use of mobile App for ADR/AEFI reporting (Iran, Syria, Iraq and Lebanon);
- Support being provided to Member States to establish and strengthen haemovigilance systems, using the 2016 WHO guide to establishing a national haemovigilance system;
- Regional haemovigilance survey conducted that contributed to identify challenges and to support the development of haemovigilance tools.

EURO: Regulatory collaboration, convergence and harmonization

- Emergency use authorization based on WHO EUL
- aDSM and AEFI workshops:
  - A number of member states started reporting to UMC using VigiBase

Enabling access to innovative medical products in resource-limited settings

- European Programme of Work, 2020-2025 - “United Action for Better Health in Europe”;
- The Oslo Medicines Initiative – better access to effective, novel, high-priced medicines – a new vision for collaboration between the public and private sectors” is a new initiative of WHO/Europe.

EURO: Regulatory preparedness for public health emergencies

- COVID-19 regulatory updates shared timely within NRA network in the region (biweekly – ENG and RUS)
- COVID-19 related webinars and workshops (HQ supported)
- Facilitation of the national emergency authorization
- AEFI – EURO workshops (VIF&AMP)

Benchmarking of National Regulatory Authorities: towards mature regulatory systems

- Benchmarking
  - Self- Benchmarking – ALB, BIH, KGZ, MDA, MKD, MNE, TUR, UKR, UZB;
  - Benchmarking – KAZ
- Capacity – building
  - Study visit (a peer learning event) to Swissmedic – 4 visits, QMS strengthening, Vigilance / AEFI
  - GMP / GSDP support to national inspectorates

EURO:

Future direction of WHO Prequalification (PQT)

- CRP of PQed products;
- Advocacy/motivation in PQ participation.

Safety of blood and blood products

- Initiated Region-wide data collection on blood donation, blood services and regulation of blood products (GBT + Blood).

EURO:

Regulator's role in containing antimicrobial resistance (AMR)

- National antimicrobial medicines consumption monitoring ongoing and support for focused research on antibiotic use;
- NRA strengthening;
- PQ of QC laboratories in EURO.

Changing procurement models (in countries transitioning from support provided by Global Health Programmes)

- Assessment of PSM maturity (ALB, ARM, AZE, GEO, KAZ, KGZ, MDA, TJK and UZB);
- Building capacity of national procurement agencies based on GSDP, QM principles, sharing best procurement practices.

SEARO: Vaccines regulation

- WHO SEARO continues to provide technical support to member states for regulatory system strengthening based on their vaccine production status;
- Thai FDA achieved **maturity level 3** in global benchmarking this year;
- Bangladesh DGDA was also accessed for bench marking this year. DGDA has shown significant improvement in NRA functionality. The finalization of benchmarking is expected in the middle of 2021;
- WHO SEARO is in the process of creating a network of manufacturers and regulators in the region for dealing with pandemic vaccines including COVID-19 vaccine. The TORS and framework is being detailed now;
- WHO SEARO will also encourage surrogacy of NRA functions between its member states under the umbrella of SEARN.

SEARO: SEARN- Moving forward in challenging COVID-19

- **SEARN – Health Ministers Delhi Declaration 2018 provides legal mandate**
- **Steering group and Working Groups**
  - 3 members for continuity- India, Indonesia, Thailand + 2 Members nominated by consensus – Bhutan and Nepal;
- **21- 23 April 2020-** 4th Annual meeting SEARN Jakarta, Indonesia (could not be held due to COVID 19 situation):
  - SEARN Virtual Meeting on Regulatory Updates on the COVID-19 pandemic on 7 May 2020 to provide updates on regulatory parameters for access to medical products related to the pandemic.
  - Virtual meetings on 10–11 December 2020 by HQ with SEARN regulatory authorities to fast-track registration of COVID-19 vaccines in countries using the emergency use listing procedures while factoring in the COVID-19 vaccine production scales in the Region.
  - Regulatory brief and virtual session on information by HQ on vaccine clinical trial solidarity protocol on 28 August 2020.
- **22-23 April 2019** - 3rd Annual meeting of SEARN New Delhi

21 - 23 March 2018 - 2nd SEARN was held in Colombo, Sri Lanka.
11-12 April 2017 – 1st Annual meeting, South-East Asia Regulatory Network (SEARN), New Delhi, India – established Steering Group and Working Groups (WGs)

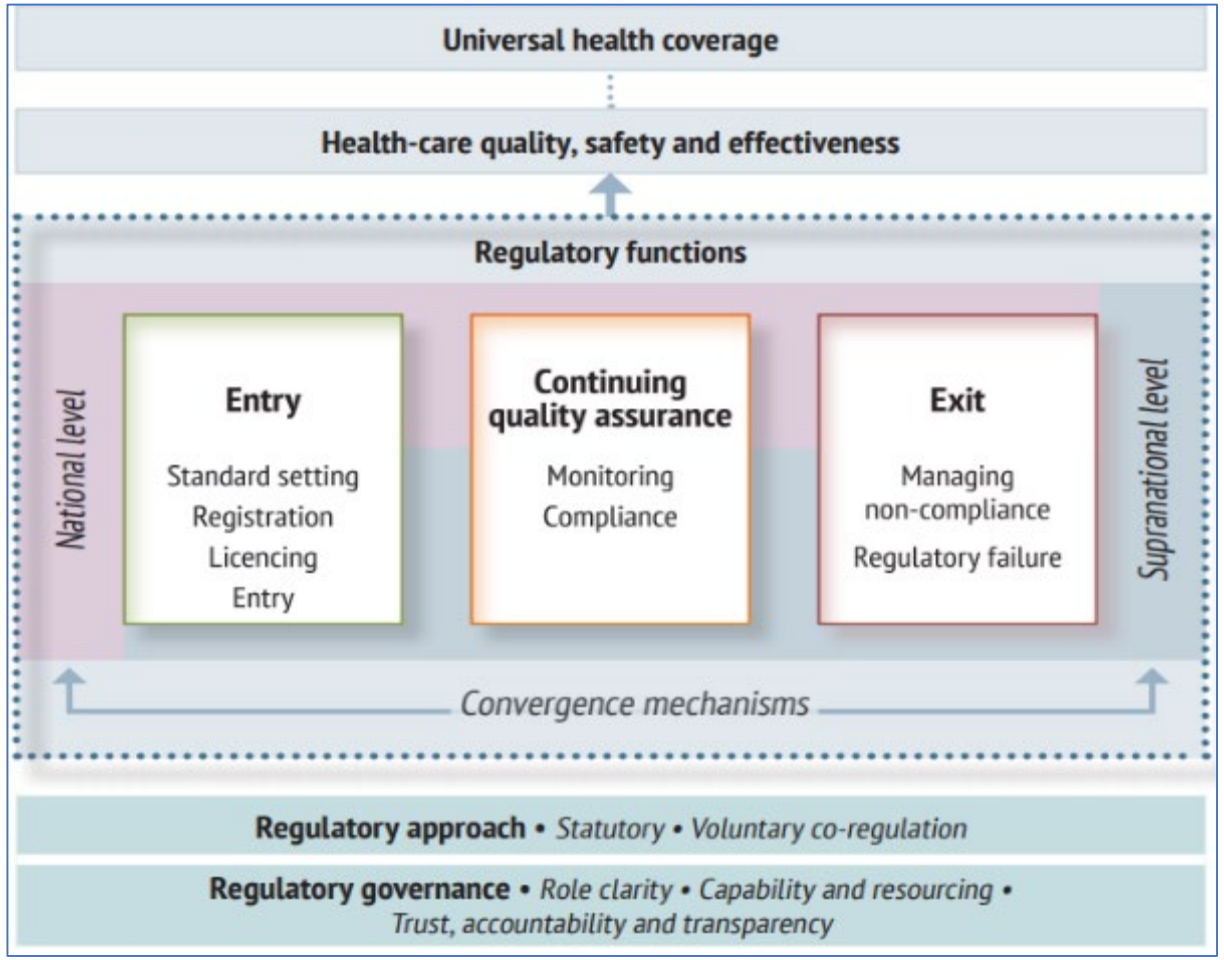
SEARO: Promoting Quality Production and Management

Virtual current good manufacturing practices (cGMP) online workshops - 2020-21

- WHO (Country office, Regional Office and HQ) organized Virtual current good manufacturing practices (cGMP) online workshops in collaboration with JSS Academy of Higher Education & Research, Mysuru, India, Ministry of Health, Indian Pharmaceutical Alliance and partners
- WHA74.6: Strengthening local production of medicines and other health technologies to improve access
- More than 38 technical subjects covered in the workshops for Active Pharmaceutical Ingredients (APIs) and Formulations.

Workshop	Category	Dates: 2020-2021	Number of Participating Units	Number of Participants	Duration (days)
Pilot	Formulation	1 -14 December	33	101	12
1	Formulation	5 May -18 May	40	143	12
2	APIs	24 May –5thJune	35	139	12
3	APIs	14 June-26thJune	49	166	12
4	Medical Devices	5 July -9 July	51	165	05
5	APIs	19 July -30 July	115	310	12
Total			**323**	**1115**	

WPRO: Regional framework for regulatory systems strengthening



https://iris.wpro.who.int/bitstream/handle/10665.1/14516/9789290618942-eng.pdf

WPRO: Regulatory Cooperation through WPRA*

Working together to strengthen regulation of medical products in Western Pacific Region

- 2011
  - 1st Workshop, Korea

- 2012
  - 1st Taskforce meeting, Australia
  - 2nd Workshop
  - 2nd Taskforce meeting
  - 1st edition of concept paper
  - 1st meeting of Steering Committee

- 2013
- 2014
  - 3rd Workshop
  - 2nd edition of Concept paper, WPRO
- 2015
  - 4th Workshop, Korea

- 2016
  - 5th Workshop, WPRO
  - Expansion to include medicines Formation of taskforce review group for the 3rd Ed Concept Paper, WPRO

- 2017
  - 6th Workshop, WPRO
  - Endorsement of Regional Action Framework Agenda
  - Development of the terms of reference of the Alliance
- 2018
  - 7th Workshop, Philippines
  - Renewal of Steering Committee Membership, WPRO

- 2019
  - 8th Workshop, Japan
- 2020
  - Monthly virtual meeting organized in response to regulatory issues during COVID-19 pandemic

- 2021
  - Virtual meeting on regulatory preparedness during public health emergencies

*WPRA: Western Pacific Regional Alliance of National Regulatory Authorities for Medical Products

WPRO: Key milestones of NRAs' benchmarking in WHO Western Pacific Region

2011
First workshop to initiate mechanism of NRA cooperation for vaccines

2013
Member States endorsed WPR Regional Alliance of NRA for Vaccines

2015
MFDS Launched Aid program

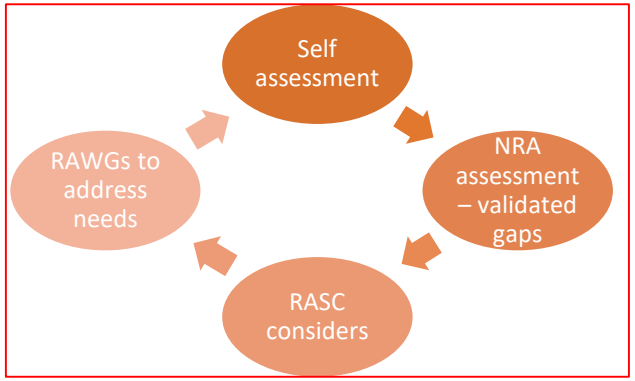
2016
WPR Regional Alliance of NRA expanded to Vaccines, Medicines;

Regional workshop on GBT

2018
TGA launched RSP 2018-22

CHALLENGES
- *GLO VQ on-hold; CIP – ring-fencing of selected countries*
- *DCVRN discontinued*

2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021



Curtesy: Dr Lisa Kerr, TGA, 3rd NRA workshop 2014

2014
China: NRA for vaccines re-certified for its functionality

Malaysia; Philippines – validation of self-assessment

2015
Cambodia self-assessment initiated

Viet Nam NRA for vaccines certified as functional

2016
Lao PDR, Mongolia; Papua New Guinea self-assessment initiated

2017
Cambodia, Lao PDR self-assessment updated

Republic of Korea, Malaysia GBT briefing & follow up

2018
Viet Nam NRA for vaccine system assessed using WHO GBT

2019
Philippines self-assessment updated using WHO GBT

Brunei Darussalam: GBT briefing

2020
Viet Nam NRA for vaccines certified "ML3"

Singapore: WLA pilot initiated

Malaysia: self assessment update

2021
Singapore: formal benchmarking for medicine and vaccine

China: interim benchmarking initiated

WPRO: Reliance and Recognition as New Normal: Regulatory preparedness & response initiatives

Countries with domestic manufacturing capability

AUS TGA:

- "Provisional Approval" pathway

KOR MFDS:

- "Considerations in COVID-19 vaccines development" [Kr] (Sep-2020, Jun-21)

CHN NMPA:

- Technical Guideline for the Development of COVID-19 Preventive Vaccines (Trial); mRNA vaccine, non-clinical study, clinical study, clinical evaluation (Aug-2020)

JPN PMDA:

- "Principles for the Evaluation of Vaccines Against the Novel Coronavirus SARS-CoV-2" (Sep-2020); "Appendix 1: Evaluation of vaccines against variants" (Apr-2021)

VNM MOH:

- MOH Decision 3659/QD-BYT "Promulgating guidelines for COVID-19 vaccine research, clinical trials, marketing authorization and use" [Vn] (Aug-2020)

Countries relying on importation

SGP HSA:

- "Pandemic Special Access Route (PSAR)"[&]
- "Special Access Route (SAR)"

MYS NPRA:

- "Guidance and Requirements on Conditional Registration for Pharmaceutical Products During Disaster (Rev 1)" (Jun-2021)

PHL FDA:

- "Guidelines on the Issuance of Emergency Use Authorization for Drugs and Vaccines for COVID-19" FDA Circular 2020-036 (Dec-2020)

LAO FDD

- Ministerial Regulation on EUA for medicines and vaccines No 0833/MoH (Feb-2021); Guideline on the issuance of EUA (Apr-2021)

MNG MMRA

- "Regulation to issue emergency authorization for SARS-CoV-2 vaccines to use"

PNG NDOH

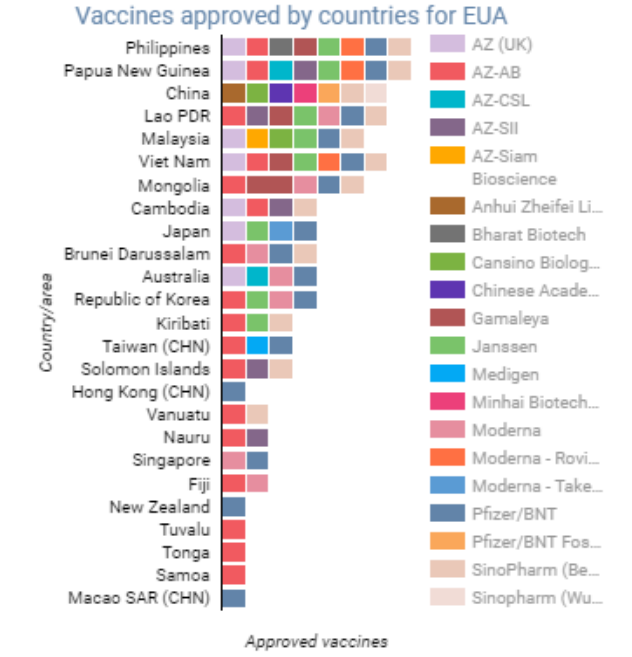
- Guidelines for emergency use authorization of in vitro diagnostics, medicines & vaccines for COVID-19"

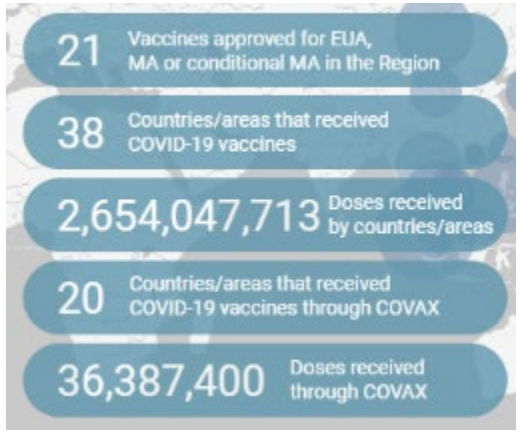
*The listed countries NRAs above are an example, but not limited to these only

[&]PSAR allows the conduct of de novo review based on a rolling submission during an emergency

WPRO: Lessons learnt from responding to public health emergencies (e.g., COVID-19 pandemic)

Regulatory preparedness that are needed in addressing challenges	• Over-all legal and regulatory framework to allow entry of products in public health emergencies and approach in managing political and public pressure to accelerate approval medical products directly related to the pandemic (e.g., vaccine applications) as well as indirectly related (e.g., to address stock shortages caused by global supply issues) • Existence of mechanisms to address mis-information based on evidence and regulatory science, while exercising independence • Existence of regulatory framework to accommodate flexibilities and variations as well as risk-based approaches to address rapid considerations on risk-benefit of new products.
Innovative/ Best Practices Identified	• A golden opportunity to demonstrate the importance of regulations and deepen public understanding of safety, efficacy and quality of products; • Virtual and desktop inspection (GMP and GCP) became a routine; • Setting up new reporting systems for AEFIs (new electronic systems); • Outdated rigid legislation became modernized (allowed fast track approvals; • Issuance of interim guidelines to address urgent need has become a routine; • Raising the value of communication in handling misinformation and continuous issuance of advisories and "talk to the media" platform to gain public understanding and trust; • Close collaboration and enhanced communication with relevant stakeholders including academia, industry, research centers and other health care professionals (NRA was part of the interagency task force, committee for COVID-19 response); • Creation of site in the webpage dedicated to COVID-19; • Creation of technical advisory group and repurposing and creation of committees/workforce focusing on COVID-19 response.





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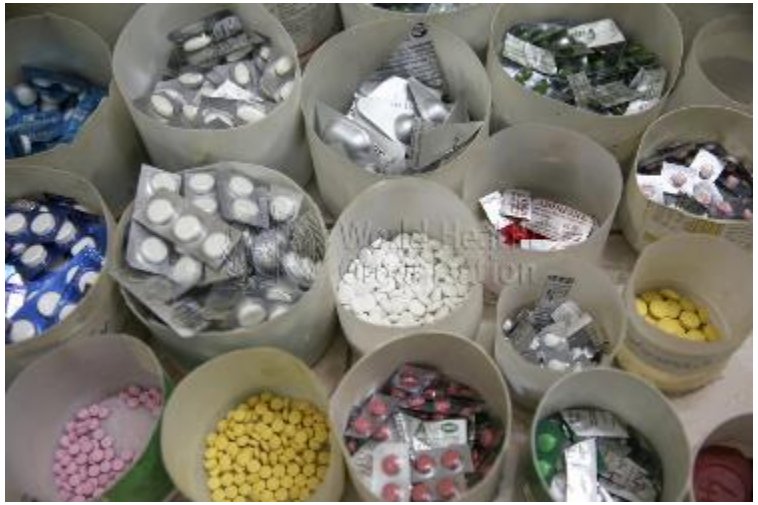

www.who.int/medicines