Plenary 5: Recommendations of Extraordinary Virtual International Conference of Drug Regulatory Authorities (ICDRA)
Plenary 2: Global Benchmarking Tool (GBT) and WHO-listed Authorities (WLA)

Member States:

• Regional approach to regulatory systems strengthening should be promoted through support of NRAs by stronger authorities in the region to share experiences, communicate lessons learned, and optimize use of available resources;

• The GBT can be utilized by all countries, regardless of maturity level, to enhance their regulatory capacity, better implement Good Regulatory Practices (GRP) and promote reliance and continuous improvement.

WHO:

• GBT and WLA assessment tools provide a quantifiable measure of progress and should be used to demonstrate positive impact of investment in regulatory systems on human health;

• WLA designation process should be risk- and evidence-based, simple to understand, transparent and independent. In addition, the information on the evaluation process, evidence reviewed, and time period for designation should be included in the listing.
Plenary 3: Emergency Use Listing of Medicines, Vaccines and IVDs including inspections during the COVID-19 pandemic

• Continue momentum of work and information sharing, reliance, mutual recognition and risk/benefit decisions by regulators, procurers and decision-making bodies;

• Continue using new tools such as visual presence facilitated by digital tools to allow for visibility, structure, accountability and greater operational excellence in the area of inspections;

• Continue with rolling submission and emphasis on post approval submissions and pharmacovigilance;

• Advocate frequent engagements between Regulators and Industry.
Plenary 4: Facilitated Registration of Medical Products

Member States:

• Maintain and adopt the best practices introduced during a pandemic in a post-pandemic setting, in the “new normal”, to ensure faster regulatory procedures on medicines and vaccines. New possible regulatory tools include emergency approval, rolling application submissions, remote inspections, digital submission, risk-based approaches, e-signatures, e-CPPs, e-labelling, and lot release reliance on other trusted laboratories;

• Information exchange and data sharing are the bases for reliance-based regulatory activities and decision-making. Member states should seek to promote transparency and to conclude confidentiality agreements or equivalent to efficiently exchange actionable information, documents, and data on which regulation through reliance decisions can be informed. The development and implementation of IMS, including the capacity to conduct virtual meetings, at the country, regional and continental level, aligned with international standards, is encouraged.
Plenary 4: Facilitated Registration of Medical Products

WHO:

• Collect experience of regulatory flexibilities and agilities during the pandemic and provide/share the best practices and examples to member states for the new normal and next public health emergency;

• Provide further support for capacity building (both technical and operational) of regulatory procedures to regulators in low- and middle-income countries, so that they can implement WHO’s good reliance practices as they institute their own procedures for regulation through reliance.

Member States:
- Identify regulatory flexibilities and reliance best practices that proved to be effective during the pandemic and consider adopting such practices/approaches into the national regulations, guidelines and regulatory processes;

WHO:
- Identify regulatory flexibility/agility approaches adopted at the national, regional and global level during the COVID-19 pandemic or other PHEs and share such information with MS to increase efficiency in decision making and accelerate access to the medicines and vaccines during the pandemic situation;
- Support NRAs to implement Good Regulatory Practices and Good Reliance practices principles.
Member States:

- MS NRAs to review/adjust their national regulations (if and where appropriate) so that they are not a barrier for reliance outside of emergency situations;

- NRAs to use the analysis of the COVID-19 induced agilities to further review and simplify the regulation of PACs. Further work on broader adoption and implementation of WHO’s guidance (standardized categorization) and other International guidelines on PACs (e.g., ICH Q12), should be conducted by NRAs;

- NRAs to apply more harmonized systems for all PACs throughout a medicinal product’s lifecycle and reliance models with a risk-based approach for PACs evaluations;

- NRAs to make their guidelines and procedures on PAC available to stakeholders, including reliance procedures, to encourage more use of reliance and to streamline the processes.
Workshop 2: Post-approval changes (PAC) in the overall products life cycle

**WHO:**
- To promote the use of reliance and work-sharing mechanisms for the evaluation of PACs;
- To encourage all stakeholders to participate in pilots of reliance for PACs management and create a space/forum where experiences/best practices are shared.

**Recommendations for industry:**
- Further work on broader implementation of WHO’s guidance (standardized categorization and processes) and other International guidelines on PACs (e.g., ICHQ12);
- Support the discussions between NRAs on PACs to contribute for a greater implementation of harmonization systems and reliance mechanisms. Further work can be developed to enhance exchange of information with NRAs (e.g., by reducing confidentiality barriers);
- Facilitate/ensure sameness of product and dossier when applying reliance mechanisms and ensure that information is shared in a timely manner. Industry to share their robust QA systems, including QMS, with NRAs to build trust and facilitate PAC management overall.
Workshop 3: Preventing, detecting and responding to substandard/falsified medical products

Member States:
- Support national focal point for substandard/falsified medical products to ensure timely reporting of incidents to the Global Surveillance Monitoring System;
- Harmonize national requirements for product labelling and information to minimize safety risks.

WHO:
- Develop guidance on how to select technologies/methodologies to detect substandard and falsified medical products;
- Support Member States to implement track and trace requirements for medical products, including supporting adoption of global trust repository for traceability of COVAX supplied commodities;
- Support Member States and NRAs in harmonization of product labelling and information requirements through networks and development of normative guidance;
- Scale up the development and deployment of tools and a database to automate the conduct of medical products quality surveys.
Workshop 4: Pharmacovigilance of medicinal products related to COVID-19: illustrating the value of regulatory reliance, work sharing and timely exchange of safety information

Member States:

- Reliance can be practiced by all NRAs regardless of the availability of resources. Member States should rely on work of others where possible and focus limited resources on what needs to be done at the country level;
- Promote collection of good quality data for adverse event reporting using standardized methods and tools;
- Enhance collaboration between immunization programmes and the NRA and encourage submission of adverse event reports to the WHO global database, Vigibase.

WHO:

- Continue to support regional and global collaboration and cooperation in pharmacovigilance including platforms that promote reliance;
- Sustain best practices and new platforms for collaboration to maintain the momentum gained in pharmacovigilance in the global response to the COVID-19 pandemic.
WHO and Member States

• Strengthening regulatory systems should go hand-in-hand with strengthening local production;

• Continue to foster collaboration between regulators, industry and other stakeholders in promoting local production to improve timely access to safe and quality assured medical products.
Workshop 6: Blood and blood products

**Member States:**

- The Ministries of Health should provide effective leadership and governance for the development of national blood regulation system (including inspection and haemovigilance measures) which are key to the safety of donation, blood products and transfusion;

- Use the Global Benchmarking Tool+Blood for self-assessment, identify gaps and needs in the field of blood regulation;

- Put in place and implement appropriate governance to support collaboration of regulators, blood establishments and hospitals to develop and improve a well functioning blood system.

**WHO:**

- Support the development and strengthening of national blood regulatory systems as priority of WHO Action Framework to advance universal access to safe, effective and quality assured blood products 2020-2023, including through continuously providing technical support to the regional networks/fora of blood regulators;

- Provide periodical report, including through ICDRA, about the progress achieved in implementing the Action Framework;

- Support implementation of WHO guidances and blood policies at country level - particularly in low- and middle-income countries (LMICs).
Workshop 7: Good Regulatory Practices and Good Reliance Practices

Member States:
- MS invited to integrate the principles of the GRP and GRelP in their regulatory systems and consider establishing a national roadmap in consultation with stakeholders to monitor progress in implementation;
- Support WHO activities in the implementation of these good practices in order to improve the efficiency of the global regulatory oversight.

WHO:
- Involve all relevant stakeholders (NRA, industry, donors, other interested parties) in planning and facilitating GRP and GRelP implementation and conveying relevant global consultations;
- To help MS implementing GRP and GRelP by providing additional practical guidance and advocating for NRA good collaboration practices.
Workshop 8: Medical devices including in vitro diagnostics:
Impact of reliance approaches in accelerating product introduction during the COVID-19 global pandemic

Member States:
- MS NRAs to consider introducing legal provisions that allow fast track regulatory pathway in emergency and specified non-emergency situations to enhance decision making, accelerate review and approval of needed medical devices including IVDs;
- MS NRAs to strengthen capacity building elements, through joint assessment which will provide regulators with technical expertise, strengthen NRAs capacity to assess products and contribute in building confidence and trust between NRAs.

WHO:
- Continue to promote regulatory reliance and facilitated product introduction approaches, and further refine by evaluating their impact during global pandemic;
- Finalize and roll-out the draft GBT+ for medical devices for systematic assessment of regulatory systems for medical devices including IVDs;
- Advocate for the use of the Global Model Regulatory Framework (GMRF) to widely reach out to countries that are at the early stages of establishing regulatory systems for medical devices and IVDs.
Thank you for your attention!

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