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International Nonproprietary Names for Pharmaceutical Substances

World Health Organization

WHO Drug Information

WHO Drug Information provides an overview of topics relating to medicines development, regulation, quality and safety. The journal also publishes and reports on guidance documents and includes lists of International Nonproprietary Names for Pharmaceutical Substances (INN), ATC/DDD classification and monographs for The International Pharmacopoeia. It presents and describes WHO policies and activities while reflecting on technical and pharmaceutical topics of international and regional interest.

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Abbreviations and websites

CHMP	Committee for Medicinal Products for Human Use (EMA)
EMA	European Medicines Agency (www.ema.europa.eu)
EU	European Union
FDA	U.S. Food and Drug Administration (www.fda.gov)
Health Canada	Federal department responsible for health product regulation in Canada (www.hc-sc.gc.ca)
HPRA	Health Products Regulatory Authority, Ireland(www.hpra.ie)
HSA	Health Sciences Authority, Singapore (www.hsa.gov.sg)
ICDRA	International Conference of Drug Regulatory Authorities
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (www.ich.org)
IGDRP	International Generic Drug Regulators Programme (https://www.igdrp.com)
INN	International Nonproprietary Names
MHLW	Ministry of Health, Labour and Welfare, Japan
MHRA	Medicines and Healthcare Products Regulatory Agency, United Kingdom (www.mhra.gov.uk)
Medsafe	New Zealand Medicines and Medical Devices Safety Authority (www.medsafe.govt.nz)
Ph. Int	*The International Pharmacopoeia* (http://apps.who.int/phint/)
PMDA	Pharmaceuticals and Medical Devices Agency, Japan (www.pmda.go.jp/english/index.htm)
Swissmedic	Swiss Agency for Therapeutic Products(www.swissmedic.ch)
TGA	Therapeutic Goods Administration, Australia(www.tga.gov.au)
WHO	World Health Organization (www.who.int)
WHO MHP	WHO Access to Medicines and Health Products Division (www.who.int/medicines/en/)
WHO RPQ	WHO Regulation and Prequalification Department
WHO PQT	WHO Prequalification Unit (https://www.who.int/topics/prequalification/en/)
WHO HPS	WHO Health Product Policy and Standards Department

Note: The online version of this issue is available at *https://www.who.int/our-work/access-to-medicines-and-health-products/who-drug-information*

EXTRAORDINARY (VIRTUAL) INTERNATIONAL CONFERENCE OF DRUG REGULATORY AUTHORITIES (ICDRA)

20 - 24 SEPTEMBER 2021

The World Health Organization (WHO) held an extraordinary International Conference of Drug Regulatory Authorities (ICDRA) on September 2021. This virtual conference gave the opportunity to the global regulatory community and other key stakeholders to exchange information, best practices and collaborative approaches related to regulation of medical products, especially important during the current challenging times of the COVID-19 pandemic.

The decision for the extraordinary ICDRA was taken as the planned 2020 ICDRA which should have taken place in India had to be cancelled due to COVID-19 pandemic. The conference is intended to bridge to the 19th ICDRA, which will be organized in India in 2022, when situation permits.

The theme of the Extraordinary (Virtual) Conference was "***Smart Regulation: Timely Delivery of Quality Assured Medical Products for All during the Global Pandemic***".

International Conference of Drug Regulatory Authorities (ICDRA) website:
https://www.who.int/teams/regulation-prequalification/regulation-and-safety/regulatory-convergence-networks/icdra

Extraordinary (Virtual) ICDRA 2021 - Presentations and Recommendations available at:
https://www.who.int/teams/regulation-prequalification/regulation-and-safety/regulatory-convergence-networks/icdra/extraordinary-(virtual)-icdra---presentations

ICDRA RECOMMENDATIONS

More than 300 delegates attended the Extraordinary (Virtual) International Conference of Drug Regulatory Authorities (ICDRA) Plenaries and Parallel Working Sessions from 20 to 24 September 2021.

The recommendations issued at the end of each Plenary and Parallel Working Sessions, were presented at the end of the conference and are set out on the following pages. They are reproduced here as provided by the moderators in the closing plenary session and finalized following the consultations with the participants during ICDRA.

Feedback, particularly from non-participating authorities, is welcome. For any feedback regarding the below recommendations, please contact ICDRA's Secretariat at icdra@who.int.

Plenary 2: Global Benchmarking Tool (GBT) and WHO-listed Authorities (WLA)

Recommendations to Member States:

- Regional approach to regulatory systems strengthening should be promoted through support of National Regulatory Authorities (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.

Recommendations to 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

Recommendations to WHO:

- 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

Recommendations to 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, electronic certificates for medicinal products (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 Information Management Systems (IMS), including the capacity to conduct virtual meetings, at the country, regional and continental level, aligned with international standards, is encouraged.

Recommendations to 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.

Workshop 1: Access to Medical Product: Regulatory flexibilities/agilities during Public Health Emergencies

Recommendations to Member States:

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

Recommendations to WHO:

- Identify regulatory flexibility/agility approaches adopted at the national, regional and global level during the COVID-19 pandemic or other Public Health Emergencies (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 National Regulatory Authorities (NRAs) to implement Good Regulatory Practices (GRP) and Good Reliance Practices principles (GRelP).

Workshop 2: Post-approval changes (PAC) in the overall products life cycle

Recommendations for 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 to 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 Quality Assurance (QA) systems, including Quality Management Systems (QMS), with NRAs to build trust and facilitate PAC management overall.

Workshop 3: Preventing, detecting and responding to substandard/falsified medical products

Recommendations to 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.

Recommendations to 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

Recommendations to 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