## 19th International Conference of Drug Regulatory Authorities (ICDRA): Programme Overview

## "Smart Regulation: Delivering Quality Assured Medical Products for All"

## 14 - 18 October 2024, New Delhi, India

# Pre-ICDRA

| DAY 1 Monday 14 October | | |
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| **09:00-10:30** | **Plenary 1: ICDRA Opening Ceremony**<br>**Moderator:**<br>– Rogério Gaspar, Director, Regulation and Prequalification Department, WHO, Switzerland<br>**Welcome remarks**<br>– Rajeev Singh Raghuvanshi, Drugs Controller General of India (CDSCO), India<br>**Keynote speaker**<br>– Malebona Precious Matsoso, Co-chair, WHO Intergovernmental Negotiating Body, South Africa<br>**Welcome address**<br>– Punya Salila Srivastava, Secretary, Ministry of Health and Family Welfare, India<br>**Opening Remarks**<br>– Saima Wazed, WHO Regional Director for South-East Asia, India (video message)<br>– Jagat Prakash Nadda, Union Health Minister, Government of India<br>– Tedros Adhanom Ghebreyesus, WHO Director-General (video message)<br>– Narendra Modi, Honourable Prime Minister of India (video message)<br>**Cultural programme**<br>**Vote of thanks**<br>– Rajeev Wadhawan, Joint Secretary, Ministry of Health and Family Welfare, India | |
| **10:30-11:00** | **Coffee** | |
| **11:00-12:30** | **Plenary 2: Smart Regulation: The New Era of WLA and Increased Reliance**<br>Presentations followed by moderated panel discussion<br>**Session objectives:**<br>– Inform participants of the progress of the WLA framework, recent developments and prospects;<br>– Discuss and hear from the different groups of stakeholders what opportunities and potential benefits the new WLA framework bring for them/their area of work (i.e., regulators/WHO PQ using the output of other regulators), procurers and industry representatives and patients;<br>– Exchange on ideas and areas for increased reliance for all regulatory functions in the new era of WLA.<br>**Co-moderators:**<br>– Emer Cooke, Executive Director, European Medicines Agency, Netherlands<br>– Rajeev Singh Raghuvanshi, Drugs Controller General of India (CDSCO), India<br>**Speakers and panellists:**<br>– Alireza Khadem, Team Lead, RSS, WHO, Switzerland<br>– Hui C. Yang, Head of Supply Operations, The Global Fund, Switzerland<br>– Kimberlee Trzeciak, Deputy Commissioner, US Food and Drug Administration, USA<br>– Richard Rukwata, Director General, Medicines Control Authority of Zimbabwe, Zimbabwe<br>– Manish Paliwal, IFPMA, Regulatory Affairs South Asia Cluster Lead, Pfizer, India<br>– JS Arora, World Patients Alliance (WPA), India<br>– Lawrence Nzumbu, Technical Officer, PQT, WHO, Switzerland | |
| **12:30-13:30** | **Lunch** | |
| **13:30-15:00** | **Workshop 1: Sustainable Local Production of Quality Assured Medical Products** | **Workshop 2: Strengthening Regulatory Systems Through Partnerships: CIP** |

Presentations followed by a moderated panel discussion

**Session objectives:**

- Promoting awareness regarding support to local production offered by WHO

**Co-moderators:**

- Peter Twomey, Head of Inspections, European Medicines Agency, Netherlands
- Lawrence Evans, US Pharmacopeia, USA

**Speakers and panellists:**

- Jicui Dong, Unit Head, Local Production and Assistance, WHO, Switzerland
- Tanvir Ahmed, DGDA, Bangladesh
- Sai Prasad, Executive Director, Bharat Biotech, India
- Priti Shah, AstraZeneca, United Kingdom
- Gabriela Zenhäusern, Deputy Head Stakeholder Engagement, Swissmedic, Switzerland
- Yonah H Malwisi, Director, Medicines Control, Medicines and Medical Devices Authority, Tanzania
- Mohammed Shafiqur Rahman, Panacea Biotec, India

Presentations followed by a moderated panel discussion

**Session objectives:**

- Provide participants with updates on the progress of the CIP Network, recent developments and future prospects at global, regional and national level
- Exchange on recommendations for areas for improvements, expansion of the scope of CIP Network activities and enhancement of coordination and information sharing

**Co-moderators:**

- Jude Nwokike, Vice President, US Pharmacopeia, USA
- Martine Umuhoza, Deputy Director-General, Rwanda Food and Drugs Authority, Rwanda

**Speakers and panellists:**

- Hiiti Sillo, Unit Head, Regulation and Safety, WHO, Switzerland
- Rita Endang, Deputy Chairperson, BPOM, Indonesia
- Martine Umuhoza, Deputy Director-General, Rwanda Food and Drugs Authority, Rwanda
- Jude Nwokike, Vice President, US Pharmacopeia, USA
- Martin Harvey, Head of International Affairs, European Medicines Agency, Netherlands
- Vijay Paul, US Agency for International Development (USAID), India
- David Mukanga, Deputy Director, Africa Regulatory Systems, Bill and Melinda Gates Foundation, Uganda
- Kate Kikule, MTaPs/MSH, USA

**15:00-15:30** **Coffee**

**15:30-17:00**

**Workshop 3: Building Bridges for Effective Pharmacovigilance Systems**

Presentations followed by a moderated panel discussion

**Session objective:**

- Highlight the importance of collaboration between pharmacovigilance (PV) stakeholders.
- Review real-world cases, with examples of successful collaboration between PV stakeholders.
- Propose recommendations for strengthening collaborations between all concerned stakeholders

**Co-moderators:**

- Mulugeta Russom, Head, Eritrean Pharmacovigilance Centre, Eritrea
- Pawan Kumar, Additional Commissioner, Ministry of Health and Family Welfare, India

**Speakers and panellists:**

- Immaculate Ampeire, Senior Medical Officer, Ministry of Health, Uganda
- Manal Younus, Director, Iraqi Pharmacovigilance Center, Ministry of Health, Iraq

**Workshop 4: SF Medical Products: Need and Viability for Global Track and Trace Technologies**

Presentations followed by a moderated panel discussion

**Session objective:**

- Understand the importance of traceability systems in ensuring the safety and quality of medical products.
- Identify challenges and opportunities related to implementation of traceability systems
- Learn about best practices and global standards.
- Explore common technical denominators for interoperability in traceability systems

**Co-moderators:**

- Tara Gooen, Director, Manufacturing, Guidance and Policy Staff for Pharma Compliance, US Food and Drug Administration, USA
- Heran Gerba, Director General, Ethiopian Food and Drug Authority, Ethiopia

**Speakers and panellists:**

- Edouard Munyangaju, Rwanda Food and Drugs Authority, Rwanda
- Max Kabalisa, UNICEF Supply Division, Denmark

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| | – Norleen Binti Mohamed Ali, Head of Pharmacovigilance Section, National Pharmaceutical Regulatory Agency, Malaysia<br>– Priya Bahri, Senior Lead, European Medicines Agency<br>– Vivekanandan Kalaiselvan, Senior Principal Scientific Officer, Indian Pharmacopoeia Commission, India | – John Kayode, National Agency for Food and Drug Administration, Nigeria<br>– Shekhar Nambi, IFPMA (Johnson & Johnson), Singapore<br>– Seth Seaneke, Deputy Chief Executive Officer, Food and Drugs Authority of Ghana, Ghana<br>– S. Swaminathan, CEO, GS1, India |
| **19:00-21:00** | **Pre-ICDRA Welcome Reception** | |
| **DAY 2 Tuesday 15 October** | | |
| **09:00-10:30** | **Workshop 5: Access to Medical Products: CRP, FRP, Joint Assessment Procedures**<br>Presentations followed by a moderated panel discussion<br>**Session objective:**<br>– Objective of the workshop is to discuss on the impact of facilitated product introduction pathways on increasing access to medical products.<br>**Co-moderators:**<br>– Sannie Chong, IFMPA, Singapore<br>– Gabriela Zenhäusern, Deputy Head Stakeholder Engagement, Swissmedic, Switzerland<br>**Speakers and panellists:**<br>– Marie Valentin, Team Lead, FPI, WHO, Switzerland<br>– Cynthia Ban, IFPMA (Sanofi), Canada<br>– Makomani Siyanga, Director-General Zambia Medicines Regulatory Authority (ZAMRA), Zambia<br>– Sakhile Dube Mwedzi, SADC Secretariat, Zimbabwe<br>– Tharnkamol Chanprapaph, Senior Expert on Drug Standards, Food and Drug Administration, Thailand<br>– Fanny Carrillo, Medical Supervisor of Pharmaceutical Products, Superintendency of Sanitary Regulation, El Salvador | **Workshop 6: Quality of Pharmaceutical Starting Materials**<br>Presentations followed by a moderated panel discussion<br>**Session objective:**<br>– Promote awareness on the dimension and impact of problems with the quality of pharmaceutical starting materials.<br>– Regulator and other stakeholder experiences, approaches and interventions.<br>– Discuss global solutions with focus on high risk starting materials<br>**Co-moderators:**<br>– Lorraine Danks, Senior Programme Officer, Bill and Melinda Gates Foundation, South Africa<br>– Patricia Serpa, Coordinator of Quality Management System, Brazilian Health Regulatory Agency (ANVISA), Brazil<br>**Speakers and panellists:**<br>– Timothy Bamgbose, National Agency for Food and Drug Administration, Nigeria<br>– Tara Gooen, Director, Manufacturing, Guidance and Policy Staff for Pharma Compliance, US Food and Drug Administration, USA<br>– Priscilla Zawislak, International Pharmaceutical Excipients Council (IPEC), USA<br>– Satyanarayana KJ, Director, GTE Small Molecule Technology (Pfizer), IFPMA, India<br>– Vishakha Metkar, Regional Regulatory Director, Colorcon South Asia, India |
| **10:30-11:00** | **Coffee** | |
| **11:00-12:30** | **Workshop 7: Regulation of Advanced Therapy Medicinal Products**<br>Presentations followed by a moderated panel discussion<br>**Session objective:**<br>– Promoting the establishment of robust regulatory frameworks and the implementation of WHO standards;<br>– Facilitating regulatory convergence and collaboration among countries;<br>– Identifying the needs for WHO standards and technical assistance from the perspectives of regulators and manufacturers.<br>**Co-moderators:** | **Workshop 8: Replacing, Reducing and Refining dependence on animal studies**<br>Presentations followed by a moderated panel discussion<br>**Session objective:**<br>– Promoting awareness;<br>– Creating opportunities for collaboration;<br>– Formulating recommendations.<br>**Co-moderators:**<br>– Laura Viviani, SciEthiQ, Italy<br>– Paul Stickings, Head of Vaccine Reference Materials, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom<br>**Speakers and panellists:** |

- Gopa Raychaudhuri, Associate Director for Special Programs, US Food and Drug Administration, USA
- Wittawat Viriyabancha, Pharmacist, Food and Drug Administration, Thailand

**Speakers and panellists:**

- Fabricio Carneiro de Oliveira, Brazilian Health Regulatory Agency (ANVISA), Brazil
- Seth Seaneke, Deputy Chief Executive Officer, Food and Drugs Authority of Ghana, Ghana
- Annam Visala, CDSCO, India
- Srinivasan N Kellathur (IFPMA), Singapore
- Paul Stickings, Head of Vaccine Reference Materials, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom
- Sunil Goel, DCVMN, India
- Rita Purcell, Deputy Chief Executive, HPRA, Ireland
- Muthusamy Kalaivani, India Pharmacopoeia, India
- Quinton Meyer, Director, South African National Control Laboratory, South Africa

**12:30-13:00** **Lunch**

**13:30-15:00**

**Workshop 9: African Medicines Agency – from Concept to Reality**

Presentations followed by a moderated panel discussion

**Session objective:**

- Provide an update on the operationalisation of the AMA
- To solicit further information on AMA's position within the existing African Regulatory Network and the expectations/role of NRAs/RECs as well as the African pharmaceutical industry;
- To learn from an existing regulatory network and formulate recommendations on the way forward.

**Co-moderators:**

- David Mukanga, Deputy Director, Africa Regulatory Systems, Bill and Melinda Gates Foundation, Uganda
- Adam Fimbo, Director General, Medicines and Medical Devices Authority, Tanzania

**Speakers and panellists:**

- Nkaelang Modutlwa, AUC, Ethiopia
- Chimwemwe Chamdimba, Head, African Medicines Regulatory Harmonisation, AUDA-NEPAD, South Africa
- Hiiti Sillo, Unit Head, Regulation and Safety, WHO, Switzerland
- Nevena Miletic, Regulatory Policy Lead, F.Hoffmann-La Roche (IFPMA)
- Richard Rukwata, Director General, Medicines Control Authority of Zimbabwe, Zimbabwe
- Martin Harvey, Head of International Affairs, European Medicines Agency, Netherlands

**Workshop 10: Improving Access to Medical Devices (including IVDs) Through Prequalification and Reliance**

Presentations followed by a moderated panel discussion

**Session objective:**

- Provide information on the WHO prequalification of IVDs
- Explaining the process of reliance and recognitions: principles, applicability, and process through prequalification and CRP
- Addressing conditions for applying reliance
- Understanding successes and challenges for implementation of reliance for IVDs pre-market approval
- Making explicit the link between applying reliance and improving access to IVDs

**Co-moderators:**

- Irena Prat, Team Lead, PQT, WHO, Switzerland

**Speakers and panellists:**

- Augusto Geyer, Regulatory Specialist, Brazilian Health Regulatory Agency (ANVISA), Brazil
- Christian Kapinga, Medicines and Medical Devices Authority, Tanzania
- Paulyne Wairimu, PPB Kenya and AMDF Chair, Kenya
- Dallas Batlegang, BOMRA, Botswana
- Agnes Kijo, Technical Officer, FPI, WHO, Switzerland

**15:00-15:30** **Coffee**

**15:30-17:00** **Plenary 3: Prequalification of Medical Products**

Presentations followed by a moderated panel discussion

**Session objective:**

- To promote PQT's contribution to public health
- Introduce and solicit input on new initiatives such as expanded PQ pathways, parallel guideline development and PQ processes and WHO's Coordinated Scientific Advice (CSA)

**Co-moderators:**

- Jackson Hungu, Programme Manager, Unitaid, Switzerland
- Emer Cooke, Executive Director, European Medicines Agency, Netherlands

**Speakers and panellists:**

- Lawrence Nzumbu, Technical Officer, PQT, WHO, Switzerland
  - Elisabeth Pluut, Scientist, PQT, WHO, Switzerland (remote participation for Q&A)
- Francisco Blanco, UNICEF, Denmark
- Felchism Apolnary, Manager, Medicines Registration, Medicines and Medical Devices Authority, Tanzania
- Gabriela Zenhäusern, Deputy Head Stakeholder Engagement, Swissmedic, Switzerland
- Janis Bernat, Director, Scientific & Regulatory Affairs, IFPMA, Switzerland

**19:00-21:00** **ICDRA Welcome Reception**

# ICDRA

## DAY 3 Wednesday 16 October

**09:00-10:30** **Plenary 1: ICDRA Opening Ceremony**

**Recommendations from 18th ICDRA: How Well We Are Doing?**

**Moderator:**
- Rogério Gaspar, Director, Regulation and Prequalification Department, WHO, Switzerland

**Keynote speaker**
- Kimberlee Trzeciak, Deputy Commissioner, US Food and Drug Administration, USA

**Opening Remarks**
- Rajeev Singh Raghuvanshi, Drugs Controller General of India (CDSCO), India
- Yukiko Nakatani, Assistant Director-General, Access to Medicines and Health Products, WHO, Switzerland
- Atul Goel, Director General of Health Services, Ministry of Health and Family Welfare, Govt. of India
- Anupriya Patel, Minister of State, Ministry of Health and Family Welfare, Govt. of India

**Highlights from 18th ICDRA and passing the ICDRA flag to CDSCO**
- Rita Purcell, Deputy Chief Executive, HPRA, Ireland

**Consolidated report from WHO Regions and the report from WHO Headquarters**
- Hiiti Sillo, Unit Head, Regulation and Safety, WHO, Switzerland

**Panel discussion involving WHO Regional Advisers**

**10:30-11:00** **Coffee**

**11:00-12:30** **Plenary 2: Effective Regulatory Harmonization and Convergence Through Regional/ Continental Networks**

Presentations followed by a moderated panel discussion

**Session objective:**

This plenary session will address key aspects of effective cooperation among regulators, including:
- The need for harmonization in regulatory science in 2024
- Reliance as a facilitator of effective collaboration among regulators
- The role of regulatory networks in supporting convergence efforts and joint activities, such as assessment and inspection

The plenary will seek input on best practices, lessons learned, existing challenges, and potential ways forward.

**Co-moderators:**
- David Mukanga, Deputy Director, Africa Regulatory Systems, Bill and Melinda Gates Foundation, Uganda
- Lenita Lindström, Senior Expert, European Commission, Belgium

**Speakers and panellists:**
- Rita Purcell, Deputy Chief Executive, HPRA, Ireland
- Chandrashekhar Ranga, Joint Drugs Controller, CDSCO, India
- Naoyuki Yasuda, Associate Executive Director, Pharmaceuticals and Medical Device Agency (PMDA), Japan
- Chimwemwe Chamdimba, Head, African Medicines Regulatory Harmonisation, AUDA-NEPAD, South Africa
- Edgard Robin Rojas-Cortes, Technical Officer, Pan American Health Organization, USA

**12:30-13:30** **Lunch**

**13:30-15:00** **Plenary 3: Good Regulatory Practices: a Journey from GBT to WLAs**

Presentations followed by a moderated panel discussion

**Session objective:**

- Recommendation on updating GBT revision VI based on its application in different country settings and different product streams, as well as on recommendations from stakeholders
- Promoting awareness about WLA framework, by discussing lessons learnt on implementation, challenges and expected impact on access to medicines in agreement with GRP

**Co-moderators:**

- Gopa Raychaudhuri, Associate Director for Special Programs, US Food and Drug Administration, USA
- Richard Rukwata, Director General, Medicines Control Authority of Zimbabwe, Zimbabwe

**Speakers and panellists:**

- Alireza Khadem, Team Lead, RSS, WHO, Switzerland
- Gabriela Zenhäusern, Deputy Head Stakeholder Engagement, Swissmedic, Switzerland
- Cheng Leng Chan, Group Director, Health Sciences Authority, Singapore
- Martin Harvey, Head of International Affairs, European Medicines Agency, Netherlands
- Norleen Mohamed Ali, Head of Pharmacovigilance Section, National Pharmaceutical Regulatory Agency, Malaysia
- Antonio Barra Torres, President-Director, Brazilian Health Regulatory Agency (ANVISA), Brazil

**15:00 -** **City tours**

## DAY 4 Thursday 17 October

**09:00-10:30** **Plenary 4: Regulation of Medical Devices (including IVDs): Global, Regional and Country Trends**

Presentations followed by a moderated panel discussion

**Session objective:**

- Promoting the importance for developing global, regional and country strategies to strengthening regulation of medical devices including IVDs.
- Share evolving global, regional and country regulatory trends for medical devices
- Addressing the impact of variability in regulatory requirements
- Soliciting recommendations for future actions and follow up for the member states and the WHO

**Co-moderators:**

- Antonio Barra Torres, President-Director, Brazilian Health Regulatory Agency (ANVISA), Brazil
- Rajeev Singh Raghuvanshi, Drugs Controller General of India (CDSCO), India

**Speakers and panellists:**

- Agnes Kijo, Technical Officer, Facilitated Product Introduction Team, WHO, Switzerland
- Lenita Lindström, Senior Expert, European Commission, Belgium
- Paulyne Wairimu, Chair of the African Medical Devices Forum (AMDF), Kenya
- Augusto Geyer, Regulatory Specialist, Brazilian Health Regulatory Agency (ANVISA), Brazil
- Woei Jiuang Wong, Assistant Group Director, Health Sciences Authority, Singapore
- Razan J Asally, Head of Medical Evaluation Section, Saudi Food and Drugs Authority (SFDA), Saudi Arabia

**10:30-11:00** **Coffee**

**11:00-12:30**

**Workshop 1: Strengthening and Promoting Networking of NCLs**

Presentations followed by a moderated panel discussion

**Session objective:**

- Promoting awareness about the work developed by laboratory networks and the impact on supporting and strengthening the pharmaceutical regulatory system;
- Share learned lessons and current good practices within the laboratory networks and the work developed by National Quality Control Laboratories, supporting National Regulatory Authorities;
- Formulating recommendations

**Co-moderators:**

- Bonaventure Chilinde, Director, Laboratory Services, National Drugs Quality Control

**Workshop 2: Clinical trials: from WHA Recommendations to Action**

Presentations followed by a moderated panel discussion

**Session objective:**

- Promoting awareness of participants on WHA Recommendations, ICH guidance, WHO normative guidance and key ongoing updates including about the World Medical Association Declaration of Helsinki
- Promote regulatory best practices and harmonization in the regulation of Clinical Trials
- Formulating recommendations

**Co-moderators:**

- Lembit Rago, Secretary-General, CIOMS, Switzerland

**Speakers and panellists:**

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| | Laboratory, Zambia Medicines Regulatory Authority (ZAMRA), Zambia<br>- Arvind Kukrety, Deputy Drugs Controller, CDSCO, India<br>**Speakers and panellists:**<br>- Annette Burchardt, InphA, Germany<br>- Susan Gracia Arpan, Head of NQCLDF, BPOM, Indonesia<br>- Quinton Meyer, Director, South African National Control Laboratory, South Africa<br>- Tran Thi Thanh Hue, Quality Secretary of Quality Management Unit, National Institute of Drug Quality Control, Vietnam<br>- Sumir Rai Bhalla, CDL Kasauli, India | - Vasee Moorthy, Senior Advisor, Science Division, WHO, Switzerland<br>- Heran Gerba, Director General, Ethiopian Food and Drug Authority, Ethiopia<br>- Peter Twomey, Head of Inspections, European Medicines Agency, Netherlands<br>- Olga Rassokhina, Project Lead, Paul-Ehrlich-Institut, Germany |
| **12:30-13:30** | **Lunch** | |
| **13:30-15:00** | **Workshop 3: Advancements in Regulation of Traditional Medicines: Challenges and Opportunities**<br>Presentations followed by a moderated panel discussion<br>**Session objective:**<br>- Sharing information regarding evolving regulation of herbal medicines: a global landscape<br>- Sharing unique challenges in standardization, quality control, clinical trials, and pharmacovigilance of herbal medicines.<br>- Proposing opportunities for integration and the way forward<br>**Co-moderators:**<br>- Goh Cheng Soon, Director, Ministry of Health, Malaysia<br>- Dammika Abeygunawardena, Commissioner, Department of Ayurveda, Sri Lanka<br>**Speakers and panellists:**<br>- Neil Gower, Chairperson, Complementary Medicines Committee, South African Health Products Regulatory Authority (SAHPRA), South Africa<br>- Ana Cecilia Carvalho, Specialist in Helth Regulation, Brazilian Health Regulatory Agency (ANVISA), Brazil<br>- Arackal Raghu, Deputy Director General, Ministry of Ayush, India<br>- Yonah H Malwisi, Director Medicines Control, Medicines and Medical Devices Authority, Tanzania<br>- Koustubha Upadhyaya, Adviser, Ministry of Ayush, Government of India, India | **Workshop 4: QMS for Regulators and Inspectorates**<br>Presentations followed by a moderated panel discussion<br>**Session objective:**<br>- Promoting awareness about different approaches for QMS establishment and maintenance<br>- Identifying challenges and recommendations for implementation of QMS at regulatory authorities with different regulatory settings<br>**Co-moderators:**<br>- Petra Doerr, Director, European Directorate for the Quality of Medicines & HealthCare (EDQM), France<br>- Heran Gerba, Director General, Ethiopian Food and Drug Authority, Ethiopia<br>**Speakers and panellists:**<br>- Duduzile Ntoko, QMS Manager, South African Health Products Regulatory Authority (SAHPRA), South Africa<br>- Patricia Serpa, Coordinator of Quality Management System, Brazilian Health Regulatory Agency (ANVISA), Brazil<br>- Dwi Damayanti, Head of Food and Drug Investigation Laboratory, BPOM, Indonesia<br>- Manabu Miyake, Depty Director, Pharmaceuticals and Medical Device Agency (PMDA), Japan<br>- Dragana Smidling Koruga, Coordinator for regulatory system strengthening, Medicines and Medical Devices Agency of Serbia (ALIMS), Serbia |
| **15:00-15:30** | **Coffee** | |
| **15:30-17:00** | **Workshop 5: Norms and Standards for Medical Products: Efficient management of post-approval changes**<br>Presentations followed by a moderated panel discussion<br>**Session objective:** | **Workshop 6: SF Medical Products: Artificial Intelligence, Machine Learning and Barcodes: The Time for Global Use?**<br>Presentations followed by a moderated panel discussion<br>**Session objective:**<br>- Explore the potential of artificial intelligence (AI) and machine learning (ML) in enhancing |

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| | – Identify the current practices and norms governing post-approval changes for medical products.<br>– Analyze potential future practices and standards in a globalized context, drawing on lessons learnt from marketing authorizations.<br>– Develop strategies for streamlining both global and national regulatory requirements and practices for handling post-approval changes<br>**Co-moderators:**<br>– Mphatso Kawaye, Director General, Pharmacy and Medicines Regulatory Authority, Malawi<br>– Rubina Bose, Deputy Drugs Controller (I), CDSCO, India<br>**Speakers and panellists:**<br>– Richard Siggers, Senior Scientific Evaluator, Vaccine Quality Division, Health Canada, Canada (remote participation)<br>– Fabricio Carneiro de Oliveira, General Manager (Office Head), Brazilian Health Regulatory Agency (ANVISA), Brazil<br>– Azuana Ramli, Deputy Director, Centre of Product and Cosmetic Evaluation, Ministry of Health, Malaysia | the detection and prevention of SF medical products on a global scale<br>– Share insights and best practices from regulators and industry stakeholders on leveraging AI, ML to detect SF medical products and improve patient safety<br>– Discuss the feasibility and challenges of implementing AI, ML for widespread use in detecting and preventing SF medical products across various international regulatory landscapes<br>– Initiate discussions on a potential roadmap for the global implementation of AI, ML, and barcode technologies to combat the threat of SF medical products<br>**Co-moderators:**<br>– Pavle Zelić, Manager, International Cooperation Communications, Medicines and Medical Devices Agency of Serbia (ALIMS), Serbia<br>– Woei Jiuang Wong, Assistant Group Director, Health Sciences Authority, Singapore<br>**Speakers and panellists:**<br>– Ana Carolina Moreira Marino Araujo, Head of International Affairs, Brazilian Health Regulatory Agency (ANVISA), Brazil<br>– Nicolas Perez Gonzalez, Swissmedic, Switzerland (remote participation)<br>– Phil Tregunno, Deputy Director, Patient Safety Monitoring, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom<br>– Kuniki Imagawa, Deputy Division Director, Pharmaceuticals and Medical Device Agency (PMDA), Japan |
| **19:00-21:30** | **ICDRA Gala Dinner** | |
| **DAY 5 Friday 18 October** | | |
| **09:00-10:30** | **Workshop 7: How to best regulate medicines for children and pregnant & lactating individuals**<br>Presentations followed by a moderated panel discussion<br>**Session objective:**<br>– Inform the regulatory authorities of the ongoing and recent activities to improve development and registration of paediatric medicines<br>– Discuss dedicated aspects for regulation of medicines for pregnant, lactating individuals: labelling, inclusion in clinical trials.<br>– Foster discussion between regulatory authorities on how to work better together for addressing the needs of under-represented populations.<br>– Invite more NRAs to join the Paediatric Regulatory Network<br>**Co-moderators:**<br>– Petra Doerr, Director, European Directorate for the Quality of Medicines & HealthCare (EDQM), France | **Workshop 8: GxP Inspections**<br>Presentations followed by a moderated panel discussion<br>**Session objective:**<br>The workshop objective is to make participants aware of the use of smart regulation in GxP inspections. This includes the best practices adopted by some of the NMRAs, the use of various tools, including the risk-based approach in planning and scheduling of inspections, and the use of reliance and recognition. The expected outcome would be to promote reliance and recognition among the NMRAs and discuss the possibility of establishing a Network and/or developing a guideline or instructions on using smart regulation for GxP inspections.<br>**Co-moderators:**<br>– Wayne Muller, Auditor, South African Health Products Regulatory Authority (SAHPRA), South Africa |

- Mojisola Christianah Adeyeye, Director General, National Agency for Food and Drug Administration and Control, Nigeria

**Speakers and panellists:**

- Lynne Yao, Director, Division of Pediatric and Maternal Health, US Food and Drug Administration, USA (remote participation);
- Martin Harvey, Head of International Affairs, European Medicines Agency, Netherlands
- Naoyuki Yasuda, Associate Executive Director, Pharmaceuticals and Medical Device Agency (PMDA), Japan
- Patricia Serpa, Coordinator of Quality Management System, Brazilian Health Regulatory Agency (ANVISA), Brazil

**Speakers and panellists:**

- Rubina Bose, Deputy Drugs Controller (I), CDSCO, India
- Christian Schärer, Head of Inspectorate, Swissmedic, Switzerland
- Mimin Jiwo Winanti, Director of Drugs Distribution and Service Control, BPOM, Indonesia
- Makomani Siyanga, Director-General Zambia Medicines Regulatory Authority (ZAMRA), Zambia
- Peter Twomey, Head of Inspections, European Medicines Agency, Netherlands

**10:30-11:00** **Coffee**

**11:00-12:30**

**Workshop 9: IMS for Regulators (Including the Role of AI)**

Presentations followed by a moderated panel discussion

**Session objective:**

- To raise awareness of regulators and relevant stakeholders on the gaps in regulatory IMS and sources of misalignment between the needs of regulators and the existing systems within the NRAs
- To come-up with recommendations for harmonizing and accelerating the development and implementation of IMS in NRAs including the integration of AI into IMS and identification of support mechanisms by WHO and partners to establish sustainable and scalable regulatory IMS, especially for NRAs with limited resources

**Co-moderators:**

- Linsey Hollett, Assistant Deputy Minister, Health Canada, Canada
- Boitumelo B. Semete, Chief Executive Officer, South African Health Products Regulatory Authority (SAHPRA), South Africa

**Speakers and panellists:**

- Rajeev Singh Raghuvanshi, Drugs Controller General of India (CDSCO), India
- Adam Mitangu Fimbo, Director General. Medicines and Medical Devices Authority, Tanzania
- Olga Rassokhina, Project Lead, Paul-Ehrlich-Institut, Germany
- David Mukanga, Deputy Director, Africa Regulatory Systems, Bill and Melinda Gates Foundation, Uganda

**Workshop 10: Regulators' Role in Containing AMR**

Presentations followed by a moderated panel discussion

**Session objective:**

- Enhance participants' awareness of the alarming progression of antimicrobial resistance (AMR) and relevant national and international strategies
- Galvanize support and commitment from all stakeholders to implement national policies and strategies, and to strengthen international coalitions to prevent and control AMR

**Co-moderators:**

- Emer Cooke, Executive Director, European Medicines Agency, Netherlands
- Lata Kapoor, Joint Director, National Centre of Disease Control, MoHFW, India

**Speakers and panellists:**

- Åsa Kumlin Howell, Head of international Affairs, Swedish Medical Products Agency (MPA) on behalf of RAGNA, Sweden
- Carmen Bullon, FAO, Italy (remote participation)
- Jennifer Bonnah, Chief Regulatory Officer, Food and Drug Authority of Ghana, Ghana
- Taruna Ikrar, Chairperson BPOM, Indonesia (remote participation)
- Svenja E. Sander, Head of Unit, Drug Resistance, Department of Veterinary Medicinal Products at the Federal Office of Consumer Protection and Food Safety, Germany

**12:30-13:30** **Lunch**

**13:30-15:00** **Plenary 5: Regulatory Preparedness and Response: Lessons Learned From COVID-19 Pandemic**

Presentations followed by a moderated panel discussion

**Session objective:**

- Review best practices, lessons and challenges on regulatory preparedness and response

- Identify key recommendations for future preparing and responding to future public health emergencies

**Co-moderators:**

- Daniel Hartman, Director, Integrated Development, Bill and Melinda Gates Foundation, USA
- Rogerio Gaspar, Director, Department of Regulation and Prequalification, WHO, Switzerland

**Speakers and panellists:**

- Gopa Raychaudhuri, Associate Director for Special Programs, US Food and Drug Administration, USA
- Rita Endang, Deputy Chairperson, BPOM, Indonesia
- Mojisola Christianah Adeyeye, Director General, National Agency for Food and Drug Administration and Control, Nigeria
- Supriya Sharma, Chief Medical Officer, Health Canada, Canada
- Pavle Zelic, Manager, International Cooperation Communications Medicines and Medical Devices Agency of Serbia (ALIMS), Serbia

**15:00-15:30** **Coffee**

**15:30-17:00** **Plenary 6: 19th ICDRA Recommendations and Closing**

**Moderator:**

- Rogério Gaspar, Director, Regulation and Prequalification Department, WHO, Switzerland

**Recommendations of the Conference**

- Hiiti Sillo, Unit Head, Regulation and Safety, WHO, Switzerland

**Closing remarks**

- Yukiko Nakatani, Assistant Director-General, Access to Medicines and Health Products, WHO, Switzerland
- Rajeev Singh Raghuvanshi, Drugs Controller General of India (CDSCO), India

## 19th ICDRA: Programme Overview

**Theme: "Smart Regulation: Delivering Quality Assured Medical Products for All"**

**14 - 18 October 2024, New Delhi, India**

| Time | Pre-ICDRA | | | ICDRA | | | | |
|---|---|---|---|---|---|---|---|---|
| | **14 October 2024** | **15 October 2024** | | **16 October 2024** | **17 October 2024** | | **18 October 2024** | |
| 9.00-10.30 | Plenary 1<br>**Opening Ceremony**<br><br>**(Palash Hall, Grand Ball Room A, B and C, 6th Floor)** | WS 5<br>**Access to Medical Products: CRP, FRP, Joint Assessment Procedures**<br><br>**(Palash Hall, Grand Ball Room A and B, 6th Floor)** | WS 6<br>**Quality of Pharmaceutical Starting Materials**<br><br>**(Palash Hall, Grand Ball Room C, 6th Floor)** | Plenary 1<br>**Opening. Recommendations from 18th ICDRA: How Well We Are Doing?**<br><br>**(Palash Hall, Grand Ball Room A and B, 6th Floor)** | Plenary 4<br>**Regulation of Medical Devices (including IVDs): Global, Regional and Country Trends**<br><br>**(Palash Hall, Grand Ball Room A and B, 6th Floor)** | | WS 7<br>**Paediatric Medicines and Maternal Health**<br><br>**(Palash Hall, Grand Ball Room A and B, 6th Floor)** | WS 8<br>**GxP Inspections**<br><br>**(Palash Hall, Grand Ball Room C, 6th Floor)** |
| 10.30-11.00 | Coffee break<br><br>(Pre function area 6th Floor) | Coffee break<br><br>(Pre function area 6th Floor) | | Coffee break<br><br>(Pre function area 6th Floor) | Coffee break<br><br>(Pre function area 6th Floor) | | Coffee break<br><br>(Pre function area 6th Floor) | |
| 1100-12.30 | Plenary 2<br>**Smart Regulation: The New Era of WLA and Increased Reliance**<br><br>**(Palash Hall, Grand Ball Room C, 6th Floor)** | WS 7<br>**Regulation of Advanced Therapy Medicinal Products**<br><br>**(Palash Hall, Grand Ball Room A and B, 6th Floor)** | WS 8<br>**Replacing, Reducing and Refining dependence on animal studies**<br><br>**(Palash Hall, Grand Ball Room C, 6th Floor)** | Plenary 2<br>**Effective Regulatory Harmonization and Convergence Through Regional/ Continental Networks**<br><br>**(Palash Hall, Grand Ball Room A and B, 6th Floor)** | WS 1<br>**Strengthening and Promoting Networking of NCLs**<br><br>**(Palash Hall, Grand Ball Room A and B, 6th Floor)** | WS 2<br>**Clinical trials: from WHA Recommendations to Action**<br><br>**(Palash Hall, Grand Ball Room C, 6th Floor)** | WS 9<br>**IMS for Regulators (Including the Role of AI)**<br><br>**(Palash Hall, Grand Ball Room A and B, 6th Floor)** | WS 10<br>**Regulators' Role in Containing AMR**<br><br>**(Palash Hall, Grand Ball Room C, 6th Floor)** |
| 12.30-13.30 | Lunch break- 2nd,5th and 6th Floor. | Lunch break- 2nd,5th and 6th Floor. | | Lunch break- 2nd,5th and 6th Floor. | Lunch break- 2nd,5th and 6th Floor. | | Lunch break- 2nd,5th and 6th Floor. | |

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| 13.30-15.00 | WS 1<br>**Sustainable Local Production of Quality Assured Medical Products**<br><br>**(Palash Hall, Grand Ball Room A and B, 6th Floor)** | WS 2<br>**Strengthening Regulatory Systems Through Partnerships: CIP**<br><br>**(Palash Hall, Grand Ball Room C, 6th Floor)** | WS 9<br>**African Medicines Agency – from Concept to Reality**<br><br>**(Palash Hall, Grand Ball Room A and B, 6th Floor)** | WS 10<br>**Improving Access to Medical Devices (including IVDs) Through Prequalification and Reliance**<br><br>**(Palash Hall, Grand Ball Room C, 6th Floor)** | Plenary 3<br>**Good Regulatory Practices: a Journey from GBT to WLAs**<br><br>**(Palash Hall, Grand Ball Room A and B, 6th Floor)** | WS 3<br>**Advancements in Regulation of Traditional Medicines: Challenges and Opportunities**<br><br>**(Palash Hall, Grand Ball Room A and B, 6th Floor)** | WS 4<br>**QMS for Regulators and Inspectorates**<br><br>**(Palash Hall, Grand Ball Room C, 6th Floor)** | Plenary 5<br>**Regulatory Preparedness and Response: Lessons Learned From COVID-19 Pandemic**<br><br>**(Palash Hall, Grand Ball Room A and B, 6th Floor)** |
| 15.00-15.30 | Coffee break<br><br>(Pre function area 6th Floor) | | Coffee break<br><br>(Pre function area 6th Floor) | | Coffee break<br><br>(Pre function area 6th Floor) | Coffee break<br><br>(Pre function area 6th Floor) | | Coffee break<br><br>(Pre function area 6th Floor) |
| 15.30-17.00 | WS 3<br>**Building Bridges for Effective Pharmaco-vigilance Systems**<br><br>**(Palash Hall, Grand Ball Room A and B, 6th Floor)** | WS 4<br>**SF Medical Products: Need and Viability for Global Track and Trace Technologies**<br><br>**(Palash Hall, Grand Ball Room C, 6th Floor)** | Plenary 3<br>**Prequalification of Medical Products**<br><br>**(Palash Hall, Grand Ball Room A and B, 6th Floor)** | | Excursions/City tours | WS 5<br>**Norms and Standards for Medical Products**<br><br>**(Palash Hall, Grand Ball Room A and B, 6th Floor)** | WS 6<br>**SF Medical Products: Artificial Intelligence, Machine Learning and Barcodes: The Time for Global Use?**<br><br>**(Palash Hall, Grand Ball Room C, 6th Floor)** | Plenary 6<br>**Recommendations and Closing**<br><br>**(Palash Hall, Grand Ball Room A and B, 6th Floor)** |
| 19.00-21.00 | Pre-ICDRA Reception<br><br>(Amphitheatre) | | ICDRA Reception<br><br>(Amphitheatre) | | | ICDRA Gala Dinner<br><br>(Amphitheatre) | | |

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