ICDRA

29 NOVEMBER – 2 DECEMBER 2016 (REGULATORS ONLY)

«PATIENTS ARE WAITING: HOW REGULATORS COLLECTIVELY MAKE A DIFFERENCE»

"PRESENT CHALLENGES AND OPPORTUNITIES – ROADMAP FOR THE FUTURE"

	Tuesday, 29 November, 2016
07:30-18:00	**Registration** Strelitzia Conservatory, Ground Floor, CTICC
09:00-10:30	**Plenary 1: (Auditorium 2, Level 1, CTICC)** **Opening Session** Welcome Remarks - Helen Rees, Chair of Medicines Control Council, South Africa Opening Remarks - WHO AFRO Reflections on the 16th ICDRA - Patricia Pereira Tagliari, Brazil **Cultural presentation** Keynote Address – Malebona Precious Matsoso, Director General of Health, South Africa
10:30 – 11:00	**Tea and Coffee Break** **(Restaurants Area, Ground Floor, CTICC)**
11:00-12:30	**Plenary 2 (Auditorium 2, Level 1, CTICC):** **Update on 16th ICDRA recommendations: Global context, local actions** **Moderator:** Suzanne Hill, WHO **Discussion including WHO Regional Advisers:** WHO AFRO WHO AMRO/PAHO WHO EMRO WHO EURO WHO SEARO WHO WPRO
12:30 – 14:00	**Lunch** **(Restaurants Area, Ground Floor, CTICC)**
14:00-15:30	**Plenary 3 (Auditorium 2, Level 1, CTICC):** **Strengthening of Regulatory Systems: Follow-up on WHA Resolution 67.20** **Moderators:** Gopa Raychaudhuri, USA and TogiJunice Hutadjulu, Indonesia **Speakers:** – The Global Benchmarking Tool - Alireza Khadem, WHO – Capacity building – a more sustainable approach to training - Julio Sánchez Y Tépoz, Mexico – Human Resource development: the importance of a competent workforce - Luther Gwaza, Zimbabwe – The role of regulatory networks – AVAREF: an African success story - Hudu Mogtari, Ghana

15:30 – 16:00	**Tea and Coffee Break** **(Restaurants Area, Ground Floor, CTICC)**
16:00-17:30	**Plenary 4 (Auditorium 2):** **Regulatory preparedness for public health emergencies** **Moderator:** Helen Rees, South Africa **Speakers:** – Update on Zika: regulatory responses and challenges on diagnostics, vector control, vaccines and therapeutics - David Wood, WHO – Strengthening national regulatory and ethics bodies to address the challenges of public health emergencies - Mimi Darko, Ghana FDA – Anticipating evidence needs to inform research and regulatory review for public health emergencies - Guido Rasi, EMA **Discussion: Pros and cons of emergency listing, conditional approvals, and adaptive regulatory pathways for products for public health emergencies** **Participants:** – Wiltshire Johnson, Sierra Leone – Gopa Raychaudhuri, USA – All speakers
19:00 – 23:00	**ICDRA Welcome Reception** **The Lookout, V&A Waterfront**

	Wednesday, 30 November 2016	
08:00-14:00	**Registration / Help Desk Open** **Jasminium Conservatory, Ground Level, CTICC**	
09:00-10:30	**Workshop A** **(Meeting Room 2.4, Level 2, CTICC):** **Similar biotherapeutic products** **Moderators:** Enrica Alteri, EMA and Monica Eimunjeze, Nigeria **Speakers:** – Biosimilars: how the EU experience can benefit regulators in other regions - John Borg, Malta – Role of regulators in technology transfer of similar biotherapeutic products – Togi Hutadjulu Indonesia – Biosimilars in African countries: challenges and opportunities - Hudu Mogtari, Ghana – How to get healthcare professionals and patients to accept biosimilars? – Parichard Chirachanakul, Thailand – Public standards for biosimilars - Susanne Keitel, EDQM	**Workshop B** **(Meeting Room 2.6, Level 2, CTICC):** **Regulating medical devices: how to take steps for successful implementation** **Moderator:** Ms Gugu Mahlangu, Zimbabwe **Speakers:** – WHO Global Model Regulatory framework for medical devices including IVDs - Agnes Kijo, Tanzania – The AHWP Playbook - Maura Linda Sitanggang, Indonesia – The new EU regulation for medical devices - Carlo Pettinelli, European Commission

	Discussion Participants: – NMRA of Mexico (COFEPRIS) – All speakers	
10:30 – 11:00	**Tea and Coffee Break** **(Restaurants Area, Ground Floor, CTICC)**	
11:00-12:30	**Workshop C** **(Meeting Room 2.4, Level 2, CTICC):** **Harmonization and work-sharing in Pharmacovigilance: what does this mean in practice** **Moderators:** TBC **Speakers:** – Managing risks: think globally, act locally- EnricaAlteri, EMA – Fred Siyoi, Kenya – Adopt or adapt - What is the better solution for a LMIC? - Djamila Reis, Cape Verde, – Raj Long, BMGF, BMGF	**Workshop D** **(Meeting Room 2.6, Ground Level, CTICC):** **Blood products – old and new challenges** **Moderator:** Jay Epstein, USA **Speakers:** – Regulation of blood and blood components as essential medicines - Christian Schärer, Switzerland – Implementation of new blood regulation in Ghana - Edwin Nkansah, Ghana – Regulation of antivenoms - James Southern, South Africa
12:30 – 18:00	**Afternoon Tours departure, Ground Level, CTICC – Walter Sisulu Avenue** **Lunch will be served on the buses**	

	Thursday, 1 December 2016
08:00-18:00	**Registration and Help Desk Open** **Jasminium Conservatory, Ground Floor, CTICC**
09:00-10:30	**Plenary 5 (Auditorium 2, Level 1, CTICC):** **Good Regulatory Practices: Why are they important?** **Moderators:** Vincent Ahonkhai, BMGF and Toshiyoshi Tominaga, Japan **Speakers:** – WHO Good Regulatory Practices – a country perspective - Gugu Mahlangu, Zimbabwe – Good Regulatory Practices: Brazil's experience - Patricia Pereira Tagliari, Brazil. – Good Reliance Practices: a growing necessity - Guido Rasi, EMA
10:30 – 11:00	**Tea and Coffee Break** **Restaurants Area, Ground Floor, CTICC**
11:00-12:30	**Plenary 6 (Auditorium 2, Level 1, CTICC):** **SSFFC medical products and supply chain integrity** **Moderator:** Mrs Yetunde Oni, Nigeria **Speakers:** – Member State Mechanism - Hashim Yusufu, Nigeria, – Supply Chain Integrity - Akbar Abdollah-Asl, Iran – Developing National Strategies - Hiiti Sillo, Tanzania – Global Surveillance and focal point network - Michael Deats, WHO

12:30 – 14:00	**Lunch** **Restaurants Area, Ground Floor, CTICC**	
14:00-15:30	**Workshop E** **(Meeting Room 2.4, Level 2, CTICC):** **Regulatory challenges of medical products for maternal & child health** **Moderators: TBC** **Speakers:** – Mechanisms to improve maternal health - Helen Rees, South Africa – Medicines use in pregnancy – Evaluation of vaccines for maternal immunization - regulatory issues - James Southern, South Africa – Paediatric medicines – Medicines for use in pregnancy and podiatric medicines – Enrica Alteri, EMA	**Workshop F** **(Meeting Room 2.6, Level 2, CTICC):** **Effective communications for preventing, detecting and responding to SSFFC medical products?** **Moderator:** United Kingdom **Speakers:** – Updates from the Member State Mechanism – Post-market surveillance/Monitoring o Tanzania o Serbia o United Kingdom o Indonesia
15:30 – 16:00	**Tea and Coffee Break** **Restaurants Area, Ground Floor, CTICC**	
16:00-17:30	**Workshop G** **(Meeting Room 2.4, Level 2, CTICC):** **Updates on vaccines regulation** **Moderators:** Gopa Raychaudhuri, USA and Hiiti Silo, Tanzania **Speakers:** – A country perspective of regulation of vaccines and how it can be improved - William Wekwete, Zimbabwe – Tools to support evaluation of candidate vaccines of global public health importance - James Southern, South Africa – Synergies and convergence in quality control testing of vaccines - Heidi Meyer, Germany **Discussion Participants:** – Ali Hosseini, Iran – Lucky Slamet, Indonesia – All speakers	**Workshop H** **(Meeting Room 2.6, Level 2, CTICC):** **Safety of herbal medicines: present challenges and opportunities** **Moderators:** Werner Knöss, Germany and Narayan Prasad Dhakal, Nepal **Speakers:** – Challenges and opportunities in ensuring the safety of herbal medicines (Outcome from IRCH's workshop on safety of herbal medicines) - Ibrahim Aljuffali, Saudi Arabia – National experience in ensuring the safety of herbal medicines - Neil Gower, South Africa – National priorities, challenges and opportunities in ensuring the safety of herbal medicines - Mario Alanis, Mexico – National Priorities: Challenges & Opportunities in ensuring the Safety of Herbal Medicines in Japan - Dr Naoyuki Yasuda, Japan **Discussion**
19:00-23:00	**Gala Dinner** **Two Oceans Aquarium, V&A Waterfront**	

	Friday, 2 December 2016	
08:00-15:00	**Registration and Help Desk Open** **Jasminium Conservatory, Ground Floor, CTICC**	
09:00-10:30	**Plenary 7 (Auditorium 2, Level 1, CTICC):** **Global scenery of regulatory convergence initiatives: linking opportunities - Panel discussion** **Moderators:** Enrica Alteri, EMA and China **Participants:** – ICH - Martin Harvey-Allchurch, EMA – ICMRA - Toshiyoshi Tominaga, Japan – IPRF - Joan Blaire, USA – IGDRP - Health Canada – AMRH - Hiiti Sillo, Tanzania – ASEAN - Salmahbahri, Malaysia – APEC - TBDC – PANDRH - Ana-Paula Juca, AMRO/PAHO – PAHO/NRAs of reference - Julio Sánchez Y Tépoz, Mexico – PIC/s - Joey Gouws, South Africa – Regional activities - Eurasian Customs Union (Belarus, TBC)	
10:30 – 11:00	**Tea and Coffee Break** **Restaurants Area, Ground Floor, CTICC**	
11:00-12:30	**Workshop I** **(Meeting Room 2.4, Level 2, CTICC):** **Regulators response to shortages of supplies** **Moderators:** TBC **Speakers:** – APIs - China – Gaps in Implementation - Canada – Requirements - TBC – Approvals of donations – Indonesia	**Workshop J:** **(Meeting Room 2.6, Level 2, CTICC)** **Regulators role in addressing anti-microbial resistance** **Moderator:** Rita Purcell, Ireland **Speakers:** – Lilit Ghazaryan, Armenia – Mario Alanis, Mexico – Progress of AMR-related activities in Japan and collaboration of regulatory authorities - Nobumasa Nakashima, Japan
12:30 – 14:00	**Lunch Break** **Restaurants Area, Ground Floor, CTICC**	
14:00-15:30	**Plenary 8 (Auditorium 2, Level 1, CTICC):** **Recommendations and closing remarks** **Moderator:** Suzanne Hill, WHO **Speakers:** – Session moderators reporting session outcomes/recommendations – Discussion – Closing remarks - Suzanne Hill, WHO	