

## ICDRA (REGULATORS ONLY)

### PATIENTS ARE WAITING: HOW REGULATORS COLLECTIVELY MAKE A DIFFERENCE PRESENT CHALLENGES AND OPPORTUNITIES – ROADMAP FOR THE FUTURE

DAY 1, 29 NOVEMBER 2016, TUESDAY	
08:00-09:00	Registration
09:00-10:30	<b>Plenary 1: Welcome Remarks</b> <b>Moderator:</b> Michael Ward, WHO HQ <b>Opening Remarks</b> <ul style="list-style-type: none"><li>– Helen Rees, Chair of Medicines Control Council, South Africa</li><li>– Rufaro Chatora, WHO Representative, South Africa</li><li>– Reflections on the 16<sup>th</sup> ICDRA - Patricia Pereira Tagliari, Brazil</li></ul> <b>Cultural presentation</b> <b>Keynote Address:</b> Malebona Precious Matsoso, Director General of Health, South Africa
10:30-11:00	Coffee
11:00-12:30	<b>Plenary 2: Update on 16<sup>th</sup> ICDRA recommendations: Global context, local actions</b> <b>Moderators:</b> Michael Ward, WHO HQ <b>Speakers:</b> <ul style="list-style-type: none"><li>– Highlights from the 17<sup>th</sup> ICDRA pre-meeting – Samvel Azatyan, WHO HQ</li><li>– Consolidated report from WHO Regions – Suzanne Hill, WHO HQ</li><li>– Report from WHO Headquarters – Emer Cooke, WHO HQ</li></ul> <b>Discussion including WHO Regional Advisers:</b>
12:30-14:00	Lunch
14:00-15:30	<b>Plenary 3: Strengthening of Regulatory Systems: Follow-up on WHA Resolution 67.20</b> <b>Moderators:</b> Gopa Raychaudhuri, USA and Togi Junice Hutadjulu, Indonesia <b>Speakers:</b> <ul style="list-style-type: none"><li>– The Global Benchmarking Tool - Alireza Khadem, WHO HQ</li><li>– Capacity building – a more sustainable approach to training – Mario Alanis, Mexico</li><li>– Human Resource development: the importance of a competent workforce - Luther Gwaza, Zimbabwe</li><li>– The role of regulatory networks – AVAREF: an African success story – Hudu Mogtari, Ghana</li></ul>
15:30-16:00	Coffee

<p><b>16:00-17:30</b></p>	<p><b>Plenary 4: Regulatory preparedness for public health emergencies</b></p> <p><b>Moderator:</b> Helen Rees, South Africa</p> <p><b>Speakers:</b></p> <ul style="list-style-type: none"> <li>- Update on Zika: regulatory responses and challenges on diagnostics, vector control, vaccines and therapeutics - David Wood, WHO HQ</li> <li>- Strengthening national regulatory and ethics bodies to address the challenges of public health emergencies - Mimi Darko, Ghana FDA</li> <li>- Anticipating evidence needs to inform research and regulatory review for public health emergencies – Enrica Alteri, EMA</li> </ul> <p><b>Discussion: Pros and cons of emergency listing, conditional approvals, and adaptive regulatory pathways for products for public health emergencies</b></p> <p><b>Participants:</b></p> <ul style="list-style-type: none"> <li>- Wiltshire Johnson, Sierra Leone</li> <li>- Gopa Raychaudhuri, USA</li> <li>- All speakers</li> </ul>
<p><b>19:00-23:00</b></p>	<p><b>ICDRA Welcome Reception</b></p>