ICDRA (REGULATORS ONLY)

PATIENTS ARE WAITING: HOW REGULATORS COLLECTIVELY MAKE A DIFFERENCE

PRESENT CHALLENGES AND OPPORTUNITIES – ROADMAP FOR THE FUTURE

<table>
<tr><td colspan="3">DAY 4, 2 DECEMBER 2016, FRIDAY</td></tr>
<tr><td>09:00-10:30</td><td colspan="2">Plenary 7: Global scenery of regulatory convergence initiatives: linking opportunities - Panel discussion
Moderators:
Enrica Alteri, EMA and He Li, China
Participants:
− ICH - Martin Harvey-Allchurch, EMA
− ICMRA and APEC - Toshiyoshi Tominaga, Japan
− IPRF - Joan Blair, USA
− IGDRP - Silverani Padayachee, South Africa
− AMRH - Hiiti Sillo, Tanzania
− ASEAN - Salmah Bahri, Malaysia
− PANDRH - Charles Preston, AMRO PAHO
− SEARO Regulators' Network - S. Eswara Reddy, India
− PAHO/NRAs of reference - Mario Alanis, Mexico
− PIC/s - Joey Gouws, South Africa
− Regional activities: Eurasian Economic Union – Liudmila Reutskaya, Belarus</td></tr>
<tr><td>10:30-11:00</td><td colspan="2">Coffee</td></tr>
<tr><td>11:00-12:30</td><td>Workshop I: Regulators response to shortages of supplies
Moderators:
Andy Gray, South Africa and Gerald Heddell, United Kingdom
Speakers:
− API shortages and the process of approving importation of unregistered alternatives in the event of shortages - Henry Leng, South Africa
− Mandatory Drug Shortage Reporting Implementation – Kim Dayman-Rutkus, Canada
− Role of the Medicine Patent Pool in RSA – Anban Pillay, South Africa
− Approvals of donations – Maura Linda Sitanggang, Indonesia</td><td>Workshop J: Regulators role in addressing anti-microbial resistance
Moderator:
Rita Purcell, Ireland
Speakers:
− Regulators' role in containing the AMR: experience from Armenia – Lilit Ghazaryan, Armenia
− Regulators' role in addressing antimicrobial resistance. Main areas of work of COFEPRIS – Mario Alanis, Mexico
− Progress of AMR-related activities in Japan and collaboration of regulatory authorities - Nobumasa Nakashima, Japan</td></tr>
<tr><td>12:30-13:30</td><td colspan="2">Lunch</td></tr>
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13:30-15:00	**Plenary 8: Recommendations and closing remarks** **Moderator:** Suzanne Hill, WHO **Speakers:** − Session moderators reporting session outcomes/recommendations − Discussion − Remarks from the host of 18th ICDRA − Closing remarks – Emer Cooke, WHO