

ICDRA (REGULATORS ONLY)

PATIENTS ARE WAITING: HOW REGULATORS COLLECTIVELY MAKE A DIFFERENCE

PRESENT CHALLENGES AND OPPORTUNITIES – ROADMAP FOR THE FUTURE

DAY 3, 1 DECEMBER 2016, THURSDAY		
09:00-10:30	Plenary 5: Good Regulatory Practices: Why are they important? Moderators: Vincent Ahonkhai, BMGF and Toshiyoshi Tominaga, Japan Speakers: <ul style="list-style-type: none"> – 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 – Enrica Alteri, EMA – Good Regulatory Practices: India’s experience – S. Eswara Reddy, India 	
10:30-11:00	Coffee	
11:00-12:30	Plenary 6: SSFFC medical products and supply chain integrity Moderator: Yetunde Oni, Nigeria Speakers: <ul style="list-style-type: none"> – WHO Member State Mechanism on Substandard and Falsified Medical Products – Yetunde Oni, Nigeria – A case study: Falsified Vaccines and Regulatory Challenges – Penny K Lukito, Indonesia – Pharmaceutical supply chain integrity - Akbar Abdollah-Asl, Islamic Republic of Iran – WHO Global Surveillance and Monitoring System – Hiiti Sillo, United Republic of Tanzania – Global Surveillance and focal point network – Michael Deats, WHO HQ 	
12:30-14:00	Lunch	
14:00-15:30	Workshop E: Regulatory challenges of medical products for maternal & child health Moderators: Helen Rees, South Africa and Mimi Darko, Ghana Speakers: <ul style="list-style-type: none"> – Evaluation of vaccines for maternal immunization: regulatory issues – James Southern, South Africa – Successes and challenges in the field of paediatric medicines – Enrica Alteri, EMA – Meeting children needs: new TB formulations – Suzanne Hill, 	Workshop F: Effective Communication for preventing, detecting and responding to SSFFC medical products Moderator: Paul Brewer, United Kingdom Speakers: <ul style="list-style-type: none"> – Effective Communication for preventing, detecting and responding to SSFFC medical products – Paul Brewer, United Kingdom – Risk Communication and the Member State Mechanism - Paul Brewer, United Kingdom – Drawing attention – new strategies

	<p>WHO HQ</p> <ul style="list-style-type: none"> – Paediatric medicines: recent legislative changes in Switzerland – Petra Dörr, Switzerland 	<p>in raising awareness on Substandard and Falsified Medical products – Pavle Zelic, Serbia</p> <ul style="list-style-type: none"> – Effective Communications on Substandard and Falsified Medical Products, The Tanzania Experience - Adonis Bitegeko, United Republic of Tanzania – NAFDAC Communication Strategies on Substandard and Falsified medical products - Yetunde O. Oni, Nigeria
15:30-16:00	Coffee	
16:00-17:30	<p>Workshop G: Updates on vaccines regulation</p> <p>Moderators: Gopa Raychaudhuri, USA and Hiiti Silo, United Republic of Tanzania</p> <p>Speakers:</p> <ul style="list-style-type: none"> – 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 <p>Discussion</p> <p>Participants:</p> <ul style="list-style-type: none"> – Ali Hosseini, Iran – Lucky Slamet, Indonesia – All speakers 	<p>Workshop H: Safety of herbal medicines: present challenges and opportunities</p> <p>Moderators: Werner Knöss, Germany and Narayan Prasad Dhakal, Nepal</p> <p>Speakers:</p> <ul style="list-style-type: none"> – 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 - Naoyuki Yasuda, Japan <p>Discussion</p>
19:00-23:00	Gala Dinner	