PRE-ICDRA MEETING (OPEN)

PATIENTS ARE WAITING: HOW REGULATORS COLLECTIVELY MAKE A DIFFERENCE

STRENGTHENING REGULATORY SYSTEMS THROUGH CONVERGENCE, RELIANCE AND NETWORKS

DAY 2, 28 NOVEMBER 2016, MONDAY		
09:00-10:30	**Workshop 5: Stakeholders collaboration in emergency situations: learning from Ebola, Zika and the R&D Blueprint** **Moderator:** Helen Rees, South Africa **Speakers:** − What pathogens should we prepare for and what products do we need? - Lucille Blumberg, South Africa − Regulation of products for emergency use – progress and challenges (AVAREF) - Mimi Darko, Ghana − A new product development coalition - Karianne Johansen, Coalition for Epidemic Product Innovation (CEPI) **Discussion: Are platform technologies the answer?** − All speakers − Melanie Saville (Janssen) - IFPMA − Morena Makhoana (BioVac) – DCVMN	**Workshop 6: Shortages of medicines: what regulators can do to help?** **Moderators:** Greg Perry, Medicines Patent Pool and Anban Pillay, South Africa **Speakers:** − The link between post approval change complexity and drug shortage: it is time for solutions! – Anders Vinther (Sanofi Pasteur) on behalf of IFPMA − Shortages: An EU perspective – Gerald Heddell, United Kingdom − Potential strategies to improve Yellow Fever Virus vaccine supply – Ivana Knezevic – WHO HQ
10:30-11:00	**Coffee**	
11:00-12:30	**Workshop 7: Regulatory cooperation for new treatments: stakeholders' views** **Moderators:** Paul Dearden, United Kingdom and Wiltshire Johnson, Sierra Leone **Speakers:** − Regulatory Cooperation for new treatments – Vincent Ahonkhai, BMGF − Ensuring the Quality of New MDR-TB Medicines Through Public Quality Control Standards – Daniel Bempong, USP − PDP needs from clinical research to registration: an update on challenges and progress made - Nathalie Strub Wourgaft, DNDi	**Workshop 8: Promise of more effective regulatory system through cooperation, reality or myth: what has been achieved today?** **Moderator:** Mimi Choong, Singapore **Speakers:** − Increasing Performance of Regulatory Authorities - Example of MHLW/PMDA - Nobumasa Nakashima, Japan − Achievements of cooperation in the European regulatory system - Tomas Salmonson, EMA − Nobody can do everything alone: Swissmedic approach to increasing effectiveness through cooperation - Cordula Landgraf, Switzerland

12:30-14:00	**Lunch**	
14:00-15:30	**Workshop 9: Work sharing** **Moderator:** Salmah Bahri, Malaysia **Speakers:** − ZaZiBoNA – Sinah Selelo, Botswana − IGDRP - Silverani Padayachee, South Africa − Experience of work-sharing in the European regulatory system - Christer Backman, Sweden − Benefits of mutual collaboration including a historical perspective - David Jefferys, IFPMA	**Workshop 10: Good reliance practices** **Moderator:** Donna Kusemererwa, Uganda **Speakers:** − Global network of national vaccine control laboratories - Derek Litthauer, South Africa − Caribbean Regulatory System - Maryam Karga-Hinds, Barbados − Experience of reliance in the European regulatory system - Martin Harvey-Allchurch, EMA − Experiences of reliance/recognition on WHO PQ (API) - Mabatane Davis Mahlatji, South Africa
15:30-16:00	**Coffee**	
16:00-17:30	**Plenary 3: Maximizing regulatory strengthening outcomes: a global coalition approach.** **Moderated panel discussion** **Moderators:** Christoph Conrad, Germany and Raj Long, BMGF **Participants:** − Petra Dörr, Swissmedic − Margareth Ndomondo-Sigonda, NEPAD − Alexander Schulze, Swiss Development Cooperation − Apollo Muhairwe, World Bank − Jude Nwokike, USP-PQM − Melissa Thumm, MSH-SIAPS − Mustafizur Rahman, Bangladesh − Kate Hencher, UNITAID − Mike Ward, WHO HQ	