

PRE-ICDRA MEETING (OPEN)

PATIENTS ARE WAITING: HOW REGULATORS COLLECTIVELY MAKE A DIFFERENCE

STRENGTHENING REGULATORY SYSTEMS THROUGH CONVERGENCE, RELIANCE AND NETWORKS

DAY 1, 27 NOVEMBER 2016, SUNDAY	
07:30 – 08:30	Registration:
08:30 – 09:00	Opening Session: <ul style="list-style-type: none"> – Welcome address – Emer Cooke, Head RHT, WHO – Keynote address – Malebona Precious Matsoso, Director General of Health, South Africa
09:00-10:30	Plenary 1: African Medicines Regulatory Harmonization Initiative: accomplishments, challenges and path forward. Moderated panel discussion Moderators: Hudu Mogtari, Ghana and Fred Siyoi, Kenya Participants: <ul style="list-style-type: none"> – David Mukanga, Bill and Melinda Gates Foundation – Alexander Schulze, Swiss Agency for Development and Cooperation – Margareth Ndomondo-Sigonda, AU NEPAD Agency – REC Secretariats <ul style="list-style-type: none"> ○ EAC – Jane Mashingia ○ SADC - Fortunate Bhembe – Samvel Azatyan, WHO HQ – Representatives of NMRAs <ul style="list-style-type: none"> ○ Gugu Mahlangu, Zimbabwe ○ Markieu Janneh Kaira, Gambia ○ Gopa Raychaudhuri, USA ○ Petra Dörr, Switzerland ○ Christoph Conrad, Germany – Sharon Olmstead, IFPMA
10:30-11:00	Coffee
11:00-12:30	Plenary 2: Collaboration and harmonization in the field of medical devices (including IVDs). Moderators: Joey Gouws, South Africa and Carlo Pettinelli, EC Speakers:

	<ul style="list-style-type: none"> - International Medical Device Regulators Forum - Madoka Murakami, Japan - Pan African Harmonization Working Party - Hiiti Sillo, Tanzania - Eastern-Mediterranean regional harmonization - NazeehAlothmany, Saudi Arabia <ul style="list-style-type: none"> - EU model of medical devices legislation harmonization - Carlo Pettinelli, European Commission <p>Panel discussion on regulatory convergence and vision on future collaboration</p> <ul style="list-style-type: none"> - Madoka Murakami, Japan - Hiiti Sillo, Tanzania - Mikhail Murashko, Russian Federation - Carlo Pettinelli, European Commission - NazeehAlothmany, Saudi Arabia - Joey Gouws, South Africa
12:30-14:00	Lunch
14:00-15:30	<p>Workshop 1: East African Community Medicines Regulatory Harmonization Project – what has been achieved so far?</p> <p>Moderators: David Mukanga, BMGF and Margareth Ndomondo-Sigonda, NEPAD</p> <p>Speakers:</p> <ul style="list-style-type: none"> - Hiiti Sillo, Tanzania; - Apollo Muhairwe, World Bank - The EAC MRH: Swissmedic perspective on achievements and lessons learned - Anna Sieg, Switzerland - EAC Industry Experience: Opportunities and Challenges - John Mwangi, Kenyan Pharmaceutical Association
	<p>Workshop 2: Regulating medical devices: the involvement of stakeholders</p> <p>Moderator: Monica Eimunjeze, NAFDAC, Nigeria</p> <p>Speakers:</p> <ul style="list-style-type: none"> - Regulating medical devices: a stepwise approach involving stakeholders - Abdullah ALDobaib, Saudi Arabia - Industries view on regulating medical devices - Tanya Vogt, SAMED South Africa - What does the patient expect form regulators and industry in regulating medical devices? - KawaldipSehmi IAPO (International Alliance of Patients Organizations), United Kingdom - View from a regulator with a well-established regulatory system - Madoka Murakami, Japan
15:30-16:00	Coffee

<p>16:00-17:30</p>	<p>Workshop 3: The GMP/GDP Inspection landscape and opportunities for better use of resources Co-moderators: Joey Gouws, South Africa and Naoyuki Yasuda, Japan Speakers:</p> <ul style="list-style-type: none"> - The GMP/GDP Inspection landscape and opportunities for better use of resources in Africa region - Kate Kikule, Uganda - The GMP/GDP Inspection landscape and opportunities for better use of resources in EU and PIC/S countries - Gerald Heddell, United Kingdom - The GMP/GDP Inspection landscape and opportunities for better use of resources: Industry view - Stephan Rönninger, EFPIA
<p>Requests sent</p>	<p>Workshop 4: Enablers for regulatory cooperation and sustainability Moderator: Markieu Janneh Kaira, Gambia Speakers:</p> <ul style="list-style-type: none"> - Cooperation in Regulation: a strategic imperative for sustainability - Patrick Lukulay, USP - Common rules and principles on the circulation of medical products in EAEU - Liudmila Reutskaya, Belarus - Considerations in sustaining regulatory cooperation – Paul Tanui, NEPAD - Cooperation in the European regulatory system - Karl Broich, Germany
<p>18:00-19:00</p>	<p>Pre-ICDRA Welcome Reception</p>