Smart Safety Surveillance

A life-cycle approach to promoting safety of medical products

Pre-ICDRA

DAY 1 Monday 3rd September		
8:30am-9:00am	**Opening Session:** **Moderator:** Michael Ward, Coordinator of Regulatory Systems Strengthening Team, WHO **Opening Remarks** - Emer Cooke, Head of Regulation of Medicines and other Health Technologies, WHO - Lorraine Nolan, Chief Executive, Health Products Regulatory Authority	
9:00am-10:30am	**Plenary 1: Smart Safety Surveillance – a shared responsibility** Moderated panel Discussion **Session objectives:** To understand the Smart Safety Surveillance (3S), what this means and review challenges, opportunities and roles & responsibilities for advancing 3S **Moderator/co-moderator:** Sten Olsson, ISOP **Speakers and panellists:** June Raine, UK Peter Marks, USA Paul Dearden, Abbvie Derick Mitchell, IPPOSI Djamila Reis, Cape Verde Raj Long, BMGF Shanthi Pal, WHO	
10:30am-11:00am	**Coffee**	
11:00am-12:30pm	**Plenary 2: Regulatory collaboration, convergence and harmonization: "transfer" of regulatory information** Moderated panel discussion **Session objectives:** To promote awareness and advocate for use of facilitated registration pathways as part of regulatory strategies to accelerate access to medicines **Moderator/co-moderator:** Lorraine Nolan, Ireland **Speakers and panellists:** Luther Gwaza, WHO Tracey Brett, FHI 360 Charles Preston, PAHO Agnès Saint-Raymond, EMA Petra Dörr, Switzerland Regine Lehnert, Germany Stephen Cook, IFPMA Johannes Gaeseb, Namibia	
12:30pm-2:00pm	**Lunch**	
2:00pm-3:30pm	**Workshop 1: Regulatory preparedness for public health emergencies** Presentations followed by a moderated panel discussion **Session objectives:** Formulating recommendations for a clear repartition of roles for the different regulatory	**Workshop 2: Certification of Pharmaceutical Products: is it still "fit for purpose" in a modern environment?** Presentations followed by a moderated panel discussion **Sessions objectives:**

Pre-ICDRA

DAY 1 Monday 3rd September		
	partners and stakeholders for the regulatory management of Public Health Emergencies **Moderator/co-moderator:** Agnès Saint-Raymond, EMA François-Xavier Lery, WHO **Speakers and panellists:** Uwe Scherf, USA Delese Mimi Darko, Ghana Emer Cooke, WHO Bianca Zimon, Brazil Alain Alsalhani, MSF	Promoting awareness that the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce is being revised based on request of the Expert Committee (ECSPP), Member States and other stakeholders **Moderator/co-moderator:** Murray M. Lumpkin, BMGF **Speakers and panellists:** Julia Lidner, EMA Gugu Mahlangu, Zimbabwe Celeste Sanchez, Cuba Lawrence Liberti, CIRS Heather Hockenhull, IFPMA Nevena Miletic, IFPMA
3:30pm-4:00pm	**Coffee**	
4:00pm-5:30pm	**Workshop 3: Global Benchmarking of Regulatory Systems: from individual countries to networks.** Presentations followed by a moderated panel discussion **Session objective:** Promote awareness of global initiatives on regulatory system strengthening and their contribution to the performance and measurement of regulatory networks **Moderator/co-moderator:** Margareth Ndomondo-Sigonda, AU NEPAD Petra Dörr, Switzerland **Speakers and panellists:** Mike Ward, WHO Jane H. Mashingia, EAC David Jefferys, IFPMA Analia Porras, PAHO David Mukanga, BMGF	**Workshop 4: Risk-based inspections: potential for work-sharing** Presentations followed by a moderated panel discussion **Session objective:** Promote awareness and advocate for work-sharing in areas related to inspections using existing mechanisms and tools as part of regulatory strategies for decision making **Moderator/co-moderator:** Ann Hayes, Ireland Andrea Keyter Julsing, South Africa **Speakers and panellists:** Stephan Roenninger, EFPIA Andrei Catalin Spinei, EMA Naoyuki Yasuda, Japan Barbara Allen, IFPMA Susanne Keitel, EDQM
6:00pm-9:30pm	**Pre-ICDRA Welcome Reception** Clayton Hotel Burlington Road	

Pre-ICDRA

DAY 2 Tuesday 4th September		
9:00am-10:30am	**Workshop 5: Enabling access to innovative medical products in resource-limited settings** Presentations followed by a moderated panel discussion **Session objective:**	**Workshop 6: Changing procurement models: maintaining safety and quality of medical products** Presentations followed by a moderated panel discussion **Session objective:**

Pre-ICDRA

DAY 2 Tuesday 4th September		
	To raise the awareness of the importance of a holistic approach in addressing the issues of access to medical products, especially in the resource-limited settings and on promoting the collaboration and work sharing based on the principle of reliance **Moderator/co-moderator:** Dan Hartman, BMGF **Speakers and panellists:** Martin Harvey Allchurch, EMA Greg Perry, IFPMA Iin Susanti, BIOFARMA, Indonesia Lilit Ghazaryan, Armenia Naoyuki Yasuda, Japan	To discuss the spectrum of challenges and risks countries face in ensuring the continued supply of quality-assured medical products when transitioning from support provided by global health programmes, and possible strategies to address this growing concern **Moderator/co-moderator:** Pavle Zelić, Serbia **Speakers and panellists:** Akmaral Kabdenova, Kazakhstan Tetyana Dumenko, Ukraine Botswana (TBC) Hanne Bak Pedersen, WHO Saltanat Moldoisaeva, WHO Boniface Dongmo Nguimfack, WHO (remote) Jude Nwokike, USP
10:30am-11:00am	**Coffee**	
11:00am-12:30pm	**Workshop 7: Local production of medical products: regulators' role** Presentations followed by a moderated panel discussion **Session objective:** To discuss the challenges faced by regulators in low and middle-income countries in the face of burgeoning local production and how can they contribute to promoting confidence in the quality of locally produced medical products **Moderator/co-moderator:** Thomas Schreitmueller, IFPMA Michael Ward, WHO **Speakers and panellists:** Mustafizur Rahman, Bangladesh Samir Desai, Cadila Healthcare Ltd., India David Woo, WHO Paul Tanui, AU NEPAD Bianca Zimon, Brazil	**Workshop 8: Regulation of advanced therapies** Presentations followed by a moderated panel discussion **Session objective:** To provide an overview of advanced therapies, challenges regulators face, potential benefits of experience gained, opportunities for regulatory convergence, and the need for standards for evaluation **Moderator/co-moderator:** Peter Marks, USA Delese Mimi Darko, Ghana **Speakers and panellists:** Peter Marks, USA Delese Mimi Darko, Ghana Martina Schüßler-Lenz, EMA Emmanuelle Charton, EDQM João Batista da Silva Junior, Brazil
12:30pm-2:00pm	**Lunch**	
2:00pm-3:30pm	**Workshop 9: Progress in regulation of medical devices (including IVDs)** Presentations followed by a moderated panel discussion **Session objective:** This session will provide an update on progress in regulation of medical devices in various regions in the world **Moderator/co-moderator:** Agnes Kijo, Tanzania Irena Prat, WHO **Speakers and panellists:** Madoka Murakami, Japan Lupi Trilaksono, Indonesia Agnes Kijo, Tanzania Ainura Abalieva, Kyrgyzstan Sunday Kisoma, Tanzania	**Workshop 10: Regulation of biosimilars** Presentations followed by a moderated panel discussion **Session objective:** To promote implementation of WHO standards, facilitate regulatory convergence and collaboration among countries and help defining the role of regulators and other key players in the context of biotherapeutic regulation **Moderator/co-moderator:** Ines Fradi, Tunisia Agnès Saint-Raymond, EMA **Speakers and panellists:** Ivana Knezevic, WHO Ines Fradi, Tunisia Khamusi Mutoti, South Africa Maria Fernanda Reis e Silva Thees, Brazil

Pre-ICDRA

DAY 2 Tuesday 4th September	
	Susanne Keitel, EDQM
3:30pm-4:00pm	**Coffee**
4:00pm-5:30pm	**Plenary 3: Partnerships to enhance better regulatory outcome** Presentations followed by a moderated panel discussion **Session objective:** To promote awareness of existing and new regulatory partnerships and examine how regulators and other organizations can adopt a more strategic and effective approach to building regulatory capacity through partnerships **Moderator/co-moderator:** Ian Hudson, UK Michael Ward, WHO **Speakers and panellists:** David Mukanga, BMGF Margareth Ndomondo-Sigonda, AU NEPAD Anna Sieg, Switzerland Anna Laura Salvati, Italy Dorthe Poulsen, Denmark Dragana Šmidling Koruga, Serbia Jude Nwokike, USP Cherng Yeu Neo, CoRE

ICDRA

DAY 2 Tuesday 4th September			
6:30pm-9:30pm	**ICDRA Welcome Reception** National Gallery of Ireland		
DAY 3 Wednesday 5th September			
9:00am-10:30am	**Plenary 1: ICDRA Opening Ceremony** **Moderator:** Michael Ward, Coordinator of Regulatory Systems Strengthening Team, WHO **Key note speaker** – Simon Harris TD, Minister for Health **Opening Remarks** – Emer Cooke, Head of Regulation of Medicines and other Health Technologies, WHO – Lorraine Nolan, Chief Executive, HPRA – Guido Rasi, Executive Director, European Medicines Agency **Music to close opening session**		
10:30am-11:00am	**Coffee**		
11:00am-12:30pm	**Plenary 2: 17th ICDRA recommendations: how well are we doing?** **Moderator:** Michael Ward, WHO HQ **Highlights from the 18th ICDRA pre-meeting** Samvel Azatyan, WHO **Consolidated report from WHO Regions and the report from WHO Headquarters** Emer Cooke, WHO **Discussion including WHO Regional Advisers**		
12:30pm-1:15pm	**Lunch**		
1:15pm-2:45pm	**Plenary 3: Future direction of WHO Prequalification Programme** Presentation followed by a moderated panel discussion **Session objective:** The objective of the session is to promote awareness and solicit input from regulators on the future direction of the WHO Prequalification Programme and how the programme could facilitate innovation and access **Moderator/co-moderator:** Agnes Kijo, Tanzania **Speakers and panellists:** Deus Mubangizi, WHO Martin Harvey Allchurch, EMA Sinah Selelo, Botswana Sheikh A. Hussain, Pakistan Andrea Julsing Keyter, South Africa Adel Alharf, Saudi Arabia		
2:45pm-	**City tour** Historical walking tour of Dublin	**City tour** Powerscourt House and Gardens	**City tour** Guinness Storehouse

ICDRA

DAY 4 Thursday 6th September		
9:00am-10:30am	**Plenary 4: WHO strategic approaches to improving access to safe medical products** Presentations followed by a moderated panel discussion **Session objective:** To raise awareness of the WHO Regulation of Medicines and Health Technologies strategy to improve access to safe medical products and how this links with the 13th WHO General Programme Work strategic priorities of achieving universal health coverage, addressing health emergencies and promoting healthier populations **Moderator/co-moderator:** Jayne Crowe, Ireland Delese Mimi Darko, Ghana **Speakers and panellists:** Petra Dörr, Switzerland Adiela Saldaña, Chile Speaker from AFRO (TBC) Speaker from SEAR/WPRO (TBC) Hanne Bak Pedersen, WHO	
10:30am-11:00am	**Coffee**	
11:00am-12:30pm	**Workshop 1: Benchmarking of Regulatory Systems: towards mature regulatory systems** Presentations followed by a moderated panel discussion **Session objective:** Share country experiences on the impact of benchmarking on strengthening regulatory systems and discuss the impacts of RSS program as well as the new concept of WHO Listed Authorities (WLAs) on promoting reliance **Moderator/co-moderator:** Gopa Raychaudhuri, USA **Speakers and panellists:** Emer Cooke, WHO Noor Shah Kamawal, Afghanistan Penny Lukito, Indonesia Houda Langar, WHO Sebastian Duarte, Argentina Md. Mustafizur Rahman, Bangladesh Celeste Sanchez, Cuba S. Eswara Reddy, India Agnes Kijo, Tanzania Portia Nkambule, South Africa	**Workshop 2: Regulators role in containing antimicrobial resistance** Presentations followed by a moderated panel discussion **Session objective:** To galvanize support and commitment of all stakeholders at national level to address AMR through national action plans and ensure appropriate use of antimicrobials **Moderator/co-moderator:** Nobumasa Nakashima, Japan **Speakers and panellists:** Pavle Zelić, Serbia Fred Siyoi, Kenya Rocio Alatorre, Mexico Suchart Chongprasert, Thailand
12:30pm-2:00pm	**Lunch**	
2:00pm-3:30pm	**Workshop 3: Safety of blood and blood products** Presentations followed by a moderated panel discussion **Session objective:** Promote awareness of legal frameworks and practical aspects of effective hemovigilance systems **Moderator/co-moderator:** Jay Epstein, USA Khamusi Mutoti, South Africa **Speakers and panellists:** Anneliese Hilger, Germany	**Workshop 4: Regional regulatory networks: progress and challenges** Presentations followed by a moderated panel discussion **Session objective:** To promote awareness of existing and new regulatory networks, discuss the progress, benefits and challenges for regulators working together and how they can improve the collaboration and work sharing to accelerate access to essential medical products **Moderator/co-moderator:** Guido Rasi, EMA

ICDRA

DAY 4 Thursday 6th September		
	Jay Epstein, USA Washington Samukange, Germany Khamusi Mutoti, South Africa Isabelle Sainte-Marie, France Christian Schärer, Switzerland	**Speakers and panellists:** Aigul Shoranova, Kazakhstan Charles Preston, PAHO South East Asia Regulators Network (TBC) Maria Lourdes Santiago, Philippines
3:30pm-4:00pm	**Coffee**	
4:00pm-5:30pm	**Workshop 5: Regulation of clinical trials: focus on patient safety** Standard presentations session followed by questions and answers **Session objective:** To present and discuss ongoing efforts to improve collaboration between regulators, patients and industry in all stages of the medical product life cycle - from development to post-licensure use **Moderator/co-moderator:** Gopa Raychaudhuri, USA **Speakers and panellists:** Lembit Rägo, CIOMS Sejeng Dorah Diale, South Africa Massimiliano Sarra, Italy Gopa Raychaudhuri, USA	**Workshop 6: Does facilitated registration accelerate access?** Standard presentations session followed by questions and answers **Session objective:** To describe the elements of available facilitated registration mechanisms, and how the countries could optimise their regulatory systems to leverage on facilitated registrations to accelerate patient access to needed therapies **Moderator/co-moderator:** Portia Nkambule, South Africa **Speakers and panellists:** Deus Mubangizi, WHO Luther Gwaza, WHO Martin Harvey Allchurch, EMA Pia Angelique Priagola, Philippines Sunday Kisoma, Tanzania Tetyana Dumenko, Ukraine
6:30pm-9:30pm	**ICDRA Gala Dinner** Round Room at the Mansion House	

ICDRA

DAY 5 Friday 7th September		
9:00am-10:30am	**Plenary 5: Safety of medical products throughout the product life cycle: moderated panel discussion** Presentations followed by a moderated panel discussion **Session objective:** Several recommendations were made at the 17th ICDRA on the integration of pharmacovigilance within a regulatory framework to ensure accountability and best practices in the way medicinal products are handled throughout their life cycle. The panel will discuss some of these aspects from respective stakeholder perspectives for the end to end management of medicinal products **Moderator/co-moderator:** Bernice Mwale, Zambia Agnès Saint-Raymond, EMA **Speakers and panellists:** Tatsuya Kondo, Japan Agnès Saint-Raymond, EMA Almath Spooner, Ireland Lembit Rägo, CIOMS Françoise Renaud, WHO	
10:30am-11:00am	**Coffee**	
11:00am-12:30pm	**Workshop 7: Harmonization, work-sharing and reliance in pharmacovigilance** Presentations followed by a moderated panel discussion **Session objective:** To discuss harmonization efforts spearheaded by WHO and partners and illustrate progress with existing and new initiatives, such as the International Coalition of Medicines Regulatory Authorities (ICMRA) and other platforms in advancing the principles of work-sharing and reliance in pharmacovigilance **Moderator/co-moderator:** Rita Purcell, Ireland Hussain Al Ramimmy, Oman **Speakers and panellists:** Speaker on AVAREF (TBD) Mick Foy, UK Corinne De Vries, EMA Charles Preston, PAHO	**Workshop 8: Promoting medical products safety: supply chain integrity** Standard presentations session followed by the questions and answers **Session objective:** To examine the regulatory challenges faced by low, middle and high-income countries in the final part of the journey of a medical product to patients and consumers, a difficult 'last mile' to regulate and therefore vulnerable to the insertion of substandard and falsified medical products **Moderator/co-moderator:** Hugo Bonar, Ireland **Speakers and panellists:** Lahouari Belgharbi, Mexico Agnes Kijo, Tanzania Mr Andrei Spinei, EMA Pavle Zelić, Serbia
12:30pm-1:30pm	**Lunch**	
1:30pm-3:00pm	**Break-out session** Consolidation of Pre-ICDRA and ICDRA recommendations **Moderator/co-moderator:** Gugu Mahlangu, Zimbabwe Martin Harvey Allchurch, EMA	
3:00pm-4:30pm	**Plenary 6: 18th ICDRA recommendations (reporting back from the break-out session)** **Moderator:** Emer Cooke, Head of Regulation of Medicines and other Health Technologies, WHO **Recommendations and closing remarks** – Rita Purcell, Deputy Chief Executive, Health Products Regulatory Authority – Mariângela Simão, Assistant Director-General for Drug Access, Vaccines and Pharmaceuticals, WHO	