World Health Organization

11th Annual Meeting on Collaborative Registration Procedure

Regulatory Reliance through Facilitated Product Introduction: *CRP impact and future prospects for countries and patients.*

Doha, Qatar – Hotel Hilton
11 to 13 of December 2023
Agenda

Sunday 10 Dec	**Preparatory meeting (only WHO staff)**	
Mon 11 Dec	**Collaborative Registration Procedure Annual Meeting (Day 1)** **Open sessions to WHO, NRAs, SRAs, Industry and Partners** **Rapporteurs: Nyasha Maregere,** *WHO Facilitated Product Introduction* **Ana Rita Nogueira,** *WHO Facilitated Product Introduction* **Moderator: Hiiti Sillo, WHO Regulation and Safety**	
08:00-09:00	**Arrival of participants and Registration to CRP Annual Meeting**	All
09:00– 09:20	**Opening session – keynote address** *(10 minutes for each intervention)*	Hiiti Sillo, *Unit Head Regulation and Safety WHO* Dr Rayana Ahmad BOU HAKA, *WHO Representative of Qatar*
09:20 - 09:30	Introduction of participants	Marie Valentin*, Team Lead Facilitated Product Introduction WHO*
09:30 – 09:40	Overview of the objectives, agenda and logistics/housekeeping	Marie Valentin*, Team Lead Facilitated Product Introduction WHO*
09:40– 11:00	**Plenary 1: High level panel on Facilitated Regulatory Pathways** - Principles of facilitated regulatory pathways - Existing facilitated regulatory pathways: characteristics and documented efficiencies - Role of WHO and regional economic communities (RECs) - Good Reliance Practices: main principles and linkages to facilitated regulatory pathways - Regulatory reliance and Global Benchmarking Tool (GBT) - Risk based approach to regulatory systems	**Speakers:** - Deusdedit Mubangizi*, Unit Head Prequalification WHO* - Jackson Hungu, UNITAID - Marie Valentin*, WHO Facilitated Product Introduction* - Murray Lumpkin*, Bill and Melinda Gates Foundation* - Alireza Khadem Brooderji, *WHO, Regulatory Systems Strengthening,* - Ann Ottosen*, United Nations Children`s Fund*

		Moderator: Hiiti B. Sillo*, WHO Regulation and Safety*
11:00 – 11:30	**Group photo and coffee break**	**All**
11:30- 13:00	**Plenary 2: Facilitating national medical products registration through Collaborative registration procedure (CRP**) - Principles and methodology of CRP - CRP statistics: by countries and regions and by CRP stream - SRA CRP and PQ CRP (medicines, vaccines, IVDs) - National regulatory authorities' experiences: numbers and types of products, timelines, experiences, recommendations *Short presentations/interventions from each of the speaker (5 minutes max) followed by Q&A and discussion*	**Speakers:** - Mariana Roldao Santos, *WHO Facilitated Product Introduction* - Rutendo Kadzunge, *Medicines Control Authority of Zimbabwe.* - Naira Romanova, *Scientific Centre of Drug and Medical Technology, Armenia* - Laurant Tshimpaka Kalala, *Pharmaceuticals Regulatory Authority, Democratic Republic of Congo* - Tanapon Wongkaew, *Thailand Food and Drugs Administration* **Moderator:** Victoria Palmi, *European Medicines Agency, EMA*
13:00 – 14:00	**Lunch**	**All**
14:00 – 15:30	**Plenary 3: Perspectives from the Partners, RECs and SRA** - Reflections on regulatory reliance and position of CRP in facilitating access to quality assured medical products - What works best and what could be improved? - Available and foreseen commitments to WHO and Member States *Short presentations/interventions from each of the speaker (5 minutes max) followed by Q&A and discussions*	**Speakers:** - Charles Preston, *Bill and Melinda Gates Foundation* - Cherise Scott, *UNITAID* - Kerrine Ottley, *CARPHA CRS* - Ann Ottosen*, United Nations Children`s Fund* - Azri Nasruddin ASEAN - Alex Juma, *AUDA- NEPAD* - Karen Loft, *Therapeutic Goods Administration* - Sandra Ligia González, *Advanced Medical Technology Association, ADVAMED* **Moderator:** Hiiti B. Sillo*, WHO Regulation and Safety*
15:30- 16:00	**Coffee break**	

16:00 – 17:30	**Workshop 1: Experience sharing from Industry and recommendations** - Reflections on experience of CRP implementation and added value to regulatory processes - Regulatory convergence and harmonization as experienced in CRP implementation - What works best and areas that require improvements to the procedure - Commitment towards sustained use of CRP across the regions - Proposals for expansion of scope of products and functions - Industry proposal on effective management of post approval changes under reliance mechanisms *Presentations (5 min each) and Q&A (15min)*	**Speakers** - Viviane Robbrecht, *Janssen Pharmaceuticals* - Janis Bernat, I*nternational Federation of Pharma Manufacturers & Asso.* - Sebastian Comellas, *Developing Countries Vaccines Manufacturing Network.* - Sandhya Jadhav, *Macleods Pharmaceutical Limited* - Giulia Di Persio, *ViiV Healthcare* - Suzette Kox, *International Generic and Biosimilar Medicines Association (IGBA)* - Laurence Descourvieres, *Abbott Diagnostics Medical Co.* - Sandra Ligia González, *Advanced Medical Technology Association, ADVAMED* **Moderator:** Murray Lumpkin, *Bill and Melinda Gates Foundation* (virtually)
17:30 – 18:30	**Free Time**	
18:30 – 21:30	**Reception**	All participants
	End of day one	
Tue 12 Dec	**Collaborative Registration Procedure Annual Meeting (Day 2)** **Open sessions to WHO, NRAs, SRAs and Industry (before 15:00)** **Closed Session to NRAs only (after 15:00)** **Moderator: Marie Valentin*, WHO Facilitated Product Introduction***	
09:00 – 10:30 For face-to-face participants Participants online can join from 10 am	**Workshop 2: Interactive sessions in groups** - Case Study 1: Facilitated registration pathways - Case Study 2: National registration system - Case Study 3: Applying facilitated pathways in public health emergencies - Case Study 4: CRP Tools *Group discussion (4 groups) 45 minutes, presentations from the 4 groups 10 minutes each including Q&A (45 minutes)*	**Facilitator:** Sunday Kisoma, *WHO Facilitated Product Introduction Team* **Moderator:** Amélie Darmon, PhD, *Global Fund*

10:30-11:00	**Coffee break**	
11:00 – 13:00	**Workshop 3: WHO Prequalification** - How PQ assessment is performed (product assessment, Site inspections and product testing) - Format and content of shared assessment reports - Guidelines/standards used for product assessment - Post prequalification activities and implications on CRP products *Presentations (25 minutes each) followed by Q&A (20 minutes)*	**Speakers:** - Lawrence Nzumbu, *WHO Prequalification, medicines* - *Olivier Lapujade, WHO Prequalification vaccines* - Susie Branif, *WHO Prequalification, In vitro diagnostics* - Stephanie Croft, *WHO Prequalification, Inspections* **Moderator:** Jackson Hungu, *UNITAID*
13:00 – 14:00	**Lunch**	
14:00 – 15:00	**Workshop 4: Overview of SRA approaches and pathways in the assessments of medical products** - SRA processes, guidelines and standards - Assessment pathways, practices and timelines implemented by SRAs - Format and content of assessment and inspection reports generated as part of marketing authorization process - Post approval activities and implications on CRP products *Presentation (25 minutes TGA) and practical illustration (20 minutes for EMA) followed by Q&A (15 minutes)*	**Speakers:** - Victoria Palmi, *European Medicines Agency, EMA* - Karen Loft, *Therapeutic Goods Administration* **Moderator:** Sergio Cavalheiro Filho, *International Federation of Pharma Manufacturers & Asso.*
15:00 – 15:45 Closed Session	**Plenary 4: Practical examples of NRA's good practices for implementation of CRP and recommendations** - Agreement of the national regulatory authority to participate in the CRP, including focal point - Quality management and information management systems - Adopted registration pathways - Organization of assessment activities - Effectiveness of risk-based review strategies - Incorporating CRP into the steps of common regulatory pathways. *Presentation of max 5 minutes each NRA followed by 15 minutes for Q&A*	**Speakers:** - Ntsetselele Kago, *Botswana Medicines Regulatory Authority.* - Beatrice Ayim, *Ghana Food and Drugs Authority* - Sakeni Hadebe, *Zambia Medicines Regulatory Authority* - Jonathan Oghene Uviase, *Nigeria Food and Drugs Administration* - Dr. Ali Arale, *Pharmacy and Poison Board, Kenya* **Moderator:**

		Phillipe Doo-Kingue, WHO Regional Office for Africa, AFRO
15:45-16:15	**Free Timel**	
16:15 – 17:00 Closed Session	**Workshop 5: Application of reliance-based approaches in GMP Inspections and site Quality Audits** - Existing Reliance in site inspections and audits - GMP desk assessments: recommendations and methods - Quality Audits desk assessments: recommendations and methods *Presentation (15 minutes) followed by illustration of desk assessment templates and requirements (20), followed by Q&A (10 minutes)*	**Facilitator** Stephanie Croft, *WHO Prequalification, Inspections* **Moderator:** Joseph Kabatende, *WHO Regional Office for Africa, AFRO*
17:00	**Closing Session End of Day 2**	
Wed 13 Dec	**Collaborative Registration Procedure Annual Meeting (Day 3)** **Closed Session to NRAs only (From 8.30 am to 11pm)** **Open sessions to WHO, NRAs, SRAs and Industry (From 11:30am to 14:.30pm)** **Moderator:** Ann Ottosen*, United Nations Children`s Fund*	
08:30 – 9:00 Closed Session	The Collaborative Registration Procedure in practice – 2023 perspectives - Best practices - Specific national requirements - Communications - Risk based assessments and inspections *Presentation (15 minutes) followed by 15 minutes discussion*	**Facilitator:** Agnes Kijo, *WHO Facilitated Product Introduction Team*
9:00 – 11:00 Closed Session Agnes to introduce 10 minutes Parallel session 1h30 hour Agnes and Mariana to report back for each session 5 minutes each, 10 minutes for questions	**Workshop 6**: **Parallel Sessions: Road trip to a successful assessment and regulatory decisions - *essential tips*** **Parallel Session 1: Product dossier verification and Abridged assessments** - Medicines and Vaccines (PQ and SRA) **Parallel Session 2: Product dossier verification and Abridged assessments –** In Vitro diagnostics *Mix of presentations, activities (demo tools), experiences sharing, Q&A and breaks*	**Facilitator:** Rutendo Kadzunge, *Medicines Control Authority of Zimbabwe* **Moderators:** Dorina Pilgari, *WHO Regional Office for Europe, EURO* Co Moderator: Mariana Roldao Santos, *WHO Facilitated Product Introduction* **Facilitator:** Gudula Mpanda, *Tanzania Medicines and Medical Devices Authority*

	Close of session: 5 minutes for moderators to close the session. Feedback and discussion in Plenary	**Moderator:** Agnes Kijo, *WHO Facilitated Product Introduction Team*
11:00 – 11:30	**Coffee Break**	
11:30 – 12:30	**Tools to support implementation of CRP including the Electronic Prequalification System** - CRP guidelines - Templates for screening, verification, abridged assessment - Electronic Prequalification System *Presentation of 45 minutes, 15 minutes for all interventions*	**Facilitators:** Nyasha Maregere, *WHO Facilitated Product Introduction Team* *Sunday Kisoma, WHO Facilitated Product Introduction Team* Ana Rita Nogueira**,** *WHO Facilitated Product Introduction Team*
12:30 – 13:30	**Lunch**	
13:30 – 14:15 14:15 – 14:30	**Closing plenary** Meeting summary, recommendations, and way forward **Closing remarks**	Marie Valentin, Team *Lead, WHO Facilitated Product Introduction*
14:30	**End of Day 3**	