ENSURING HEALTH EQUITY: PARTNERSHIPS FOR ACCESSIBLE QUALITY PRODUCTS

Joint UNICEF, UNFPA and WHO meeting with manufacturers and suppliers of
in vitro diagnostic products, vaccines & immunization devices, finished pharmaceutical products, active pharmaceutical ingredients, contraceptive devices and vector control products

The 2 - 6 December 2024, Joint Meeting will be a hybrid meeting with in-person attendance taking place at UN City, Marmorvej 51, 2100 Copenhagen, Denmark

DRAFT AGENDA

DAY 1	**MONDAY, 2 DECEMBER 2024**
07:00–08:30	**MEETING REGISTRATION: ENTRANCE TO UN CITY**
SESSION 1 - PLENARY: 08:45–10:30 AUDITORIUM I, II & III	**WELCOMING REMARKS AND OFFICIAL OPENING OF THE MEETING** *Facilitator: Marta Seoane, WHO* *Hybrid*
08:45–09:00	Administrative / Security arrangements *Henrik Pantmann, Head of Security – UN City*
09:00–09:30	Welcome from meeting host agencies: *WHO - UNICEF – UNFPA* • *Natasha Azzopardi Muscat, Director CPS /EURO* • *Yukiko Nakatani, ADG/MHP* • *Srinivas Rajan , Officer In Charge/QM Advisor Supply Chain Management Unit, UNFPA* • *Kennedy Ongwae, Deputy Director Supply Programme • Supply Division, UNICEF*
09:30–09:40	Outline of the meeting Objectives, Agenda, Themes, and expected outcomes *Rogerio Gaspar, Director, Regulation and Prequalification, WHO*
09:40–09:45	Remarks and introduction of Keynote speakers *Marta Seoane, WHO*
09:45–10:30	Keynote addresses 1. *H.E Dr Jean Kaseya, Director-General of the Africa Centres for Disease Control and Prevention (Africa-CDC)-15 min* 2. *Dr Matshidiso Moeti, WHO Regional Director for Africa-15 min* 3. *PAHO (Place holder)-15 min*
10:30–11:00	**Coffee /Tea break**

Version of : *Novermber 2024*

SESSION 2 - PLENARY: **11:00–13:00** **AUDITORIUM I, II & III**	**EXPANDING ACCESS FOR QUALITY HEALTH PRODUCTS THROUGH PARTNERSHIPS AND SYSTEMS STRENGTHENING** *Facilitator: Marta Seoane, WHO* *Hybrid*
11:00-11:05	Introduction- *Rogerio Gaspar, Director, Regulation and Prequalification, WHO*
11:05–12:30	Panel discussion: Sustainable ecosystem for manufacturing of health products • WHO-*Yukiko Nakatani, ADG/MHP, Mubashar SHEIKH, Director/QNS, Deus Mubangizi, Director/HPS, Tania Cernuschi, Unit Head/IVB* • Gavi- *Dominic Hein, Director of Market Shaping*, • The Global Fund- *Lin (Roger) Li, Senior Manager, Direct Sourcing* • NEPAD- African Medicines Regulatory Harmonization (AMRH)- *Chimwemwe Chamdimba, Principal Programme Officer - Policy Specialist* • International Coalition of Medicines Regulatory Authorities (ICMRA)-*Emer Cooke*, *Martin Harvey (EMA)* • The Bill & Melinda Gates Foundation (BMGF)- *Murray M. Lumpkin, Deputy Director, Regulatory Affairs* • International Federation of Pharmaceutical Manufacturers and Associations(IFPMA)- *Janis Bernat, Director, Scientific & Regulatory Affairs* • International Generic and Biosimilar Medicines Association (IGBA)- *Susana Almeida, Secretary General, IGBA* **Moderator**: *Rogerio Gaspar*
12:30-13:00	Q&A
13:00–14:00	**Lunch**
SESSION 3 - PLENARY **14:00–15:30** **AUDITORIUM I, II & III**	**ACCELERATING ACCESS TO QUALITY PRODUCTS THROUGH LOCAL MANUFACTURING** *Moderator: Jicui Dong Unit Head, Local Production & Assistance, WHO* *Hybrid*
14:00-14:05	Introduction *Rogerio Gaspar, Director, Regulation and Prequalification, WHO*
14:05 – 14:25	"Overcoming the challenges in local production to improve timely access" Presentations* (5 min each): • Ecosystem-wide approach for sustainability and quality of local production – Mr David Woo, Technical Officer, LPA/WHO • WHO Health Technology Access Program (HTAP) – A targeted approach to bridging the access gap -Mike Ward • Overcoming the challenges in local production to improve timely access of pharmaceuticals Mr Ajay Pal, CEO, Quality Chemical Industries Ltd, Uganda apal@qcil.com • Overcoming the challenges in local production to improve timely access of vaccines Mr Abdul Muktadir, Chairman & Managing Director, Incepta Pharmaceuticals Ltd, Bangladesh muk@inceptapharma.com • Overcoming the challenges in local production to improve timely access of diagnostics Mrs Wenjing Chen, General Manager, Shenzen Mindray Biomedical Electronics Co., Ltd., China lydia.chen@mindray.com
14:25 – 15:00	Panel discussion

	• UNICEF: Kristina - UNICEF • USP: Dr Jude Nwokike, Vice President, USP, Director of the PQM+ Program, jin@usp.org + 3 presenters above from the industry
15:00–15:30	Q&A
15:30–16:00	**Coffee /Tea break**
SESSION 4 – PLENARY **16:00– 17:00** **AUDITORIUM I, II & III**	**TECHNOLOGY AND COLLABORATION FOR GLOBAL HEALTH** *Facilitator: Marta Seoane, WHO* *Hybrid*
16:00–17:00	**Title: Innovation and collaboration towards access to medicines** • Panel discussion 1, Innovations: quantification approaches, key figures, advancements in traceability (bar codes) • Panel discussion 2, Collaborations: Quality assurance in supply chain, assessments outcomes of national procurement systems, understanding gaps and shortages of essential medicines **Facilitator:** Lisa Hedman **Panelists:** **Technology:** Anita Sands (WHO) Max Kabalisa (UNICEF) Karen Kreidi (WHO) **Collaborations:** David Jauch, IGBA (Fresenius) Mariana Widmer, WHO Richard Sambumba, UNFPA Lidia Porto, UNFPA
17:00–17:30	Q&A
17:30–18:00 **AUDITORIUM I, II & III**	**WRAP-UP OF DAY 1 AND PLANS FOR DAY 2** • *Facilitator: Marta Seoane, WHO* • *Rogerio Gaspar, Director, Regulation and Prequalification, WHO*

DAY 2	**TUESDAY, 3 DECEMBER 2024**
07:00–08:40	**ENTRANCE TO UN CITY**
SESSION 5 **08:45–13:00**	**WHO AND UNFPA PREQUALIFICATION UPDATES-PARALLEL SESSIONS**
SESSION 5.1 – PARALLEL TRACK (AUDITORIUM II) **08:45–13:00**	**WHO IN VITRO DIAGNOSTICS (IVDs) PREQUALIFICATION TRACK** *Session chair: Irena Prat, Team Lead, PQT/IVD, WHO* *Attendance mode: Hybrid*
Updates on Prequalification of in vitro diagnostics	
08:45–11:00	Welcome and overview of 2024 achievements *Speaker: Irena Prat, PQT/IVD, WHO*

	Product dossier *Speaker: Susie Braniff, PQT/IVD, WHO* Performance evaluations *Speaker: Anne-Laure Page, PQT/IVD, WHO* PQ Technical Specification Series and Technical Guidance Series *Speaker : Ute Ströher, PQT/IVD, WHO* Changes to prequalified IVDs *Speaker: Fatma Gruszka* Q&A *Irena Prat, PQT/IVD, WHO*
13:00–14:00	**Lunch**
SESSION 5.2 – PARALLEL TRACK (AUDITORIUM III) 08:45–13:00	**WHO MEDICINES PREQUALIFICATION TRACK** *Session Chair: Matthias Stahl, Team Lead, PQT/MED, WHO* *Attendance mode: In-person only*
08:45–09:00	Introduction *Speaker: Matthias Stahl, Team Lead, PQT/MED, WHO*
09:00–09:25	Quality (Finished Pharmaceutical Products) *Speaker: Wondiyfraw Worku, PQT/MED, WHO*
09:25–09:50	Quality (Active Pharmaceutical Ingredients) *Speaker: Antony Fake, PQT/MED, WHO*
09:50–10:15	Bioequivalence *Speaker: John Gordon, PQT/MED, WHO*
10:15–10:40	Biotherapeutics & Biosimilars *Speaker: Guido Pante, PQT/MED, WHO*
10:40–11:05	WHO Public Assessment Reports (WHOPARs) *Speaker: Regine Lehnert, PQT/MED, WHO*
11:05-11:35	Q&A
13:00–14:00	**Lunch**
SESSION 5.3 – PARALLEL TRACK (PRESS ROOM) 08:45–13:00	**WHO VACCINES & IMMUNIZATION DEVICES PREQUALIFICATION TRACK** *Session Chair: Marion Law RPQ-PQT/VAX, WHO* *Attendance mode: Hybrid*
08:45–08:50	Welcome and introduction- *Marion Law RPQ-PQT/VAX, WHO*
08:50–10:20	WHO vaccines prequalification overview- *Olivier Lapujade- PQT/VAX, WHO* Vaccine assessment:CMC (chemistry, manufacturing and control), clinical and post PQ activities. *Speakers: Olivier Lapujade, Rolando Dominguez PQT/VAX, WHO*
10:20–10:40	Programmatic suitability for PQ *Speaker: Elisabeth Pluut, PQT/VAX, WHO*

10:40–11:10	Facilitated discussions
11:10–11:30	**Coffee/Tea break**
11:30–12:00	Risk-benefit assessment procedures. Updates on EUL *Speaker: Marion Law, RPQ-PQT/VAX, Elisabeth PluutPQT/VAX, WHO*
12:00–12:20	ePQS and eCTD updates applicable for VAX *Speaker: Emma Hernandez, PQT/VAX, WHO (remotely)*
12:20–13:00	Facilitated discussions/Q&A
13:00–14:00	**Lunch**
SESSION 5.4 – PARALLEL TRACK (AMAZON) **08:45 – 13:00**	**WHO VECTOR CONTROL PRODUCT PREQUALIFICATION TRACK** *Session Chair: A.g Team Lead, Dominic Schuler PQT/VCP, WHO* *Attendance mode: Hybrid*
08:45–10:00	*General Updates, Workplan for 2025, Prioritization of guideline development-PQT/VCP*
10:00–11:00	Who does what!? - Mapping assessment and advisory groups in VC-*PQT/VCP*
11:00–11:30	**Coffee/Tea break**
11:30–12:30	PQ Dossiers - Partnerships, reliance, and recognition before and after assessment-PQT/VCP
12:30–13:00	ePQS Portal – Status of pilot and development of guidance-PQT/VCP
13:00–14:00	**Lunch**
SESSION 5.5 – PARALLEL TRACK (AUDITORIUM I) **08:45 – 15:00**	**UNFPA PREQUALIFICATION OF CONTRACEPTIVE DEVICES & MARKETS TRACK** *Session Chair:* ***Linda Serwaa, Head, Quality Assurance, Technical and WHO/UNFPA Prequalification, UNFPA*** *Attendance mode: Hybrid*
08:45-09:15	WHO/UNFPA Prequalification (PQ) program updates *Speaker: Ashley Moyo, Technical Analyst, UNFPA*
09:15–9:45	summary of analysis of quality complaints *Speaker: David Hill, technical Expert for the UNFPA PQ Programme*
9:45 –10:15	summary of analysis of reported significant changes *Speaker: David Hill , technical Expert for the UNFPA PQ Programme*
10:15 –10:45	Considerations for Prequalification of types of IUDs (e.g.Cu375, other innovations) *Speaker: Dr Sivakumar*
10:45 – 11:15	Sharing good practices or success stories by manufacturers : Innovative packaging to reduce carbon prints, ensure user friendliness without compromising quality Speaker : PJ Reddy (Indus Medicare); Karex ltd
11:15 – 11:30	**Coffee/Tea break**

11:30–12:00	*'Global procurement agency specifications - feedback and recommended improvements from procurers* *Dialogue: International Procurers and UNFPA*
12:00–12:45	Sharing good practices or success stories for ensuring product quality by manufacturers (condom package integrity, risk management etc.) *Speaker : manufacturers*
12:45–13:00	Q&A
13:00–14:00	**Lunch**
14:00 – 14:30	Manufacturing requirements for lubricants including HVAC recommendations *Speaker : Dr Bill Potter*
14:30 – 15:00	Update on the revision of ISO 4074:2015 *Speaker : Dr Bill Potter*
15:00 –16:00	Innovative projects on condom packaging presentations Dialogue: Dr Sivakumar, manufacturers, international procurers
SESSION 6 – PARALLEL TRACK (AUDITORIUM II) **14:00 – 17:00**	**WHO INSPECTION SERVICES** *Session Chair: Mustapha Chafai, Team Lead, PQT/INS, WHO* *Attendance mode: Hybrid*
14:00–14:15	Introduction to PQT/INS programme of activities, Mustapha Chafai, Team Lead, INS
14:15–14:30	Medicines Inspection Updates (APIs and FPPs), Dimitrios Catsoulacos, Technical officer
14:30–14:45	Bioequivalence Inspection Updates, Elham Kossary, Technical officer
14:45–15:00	Vaccines Inspection Updates, Andrea Geyer, Technical officer
15:00-15:30	Questions and Answers
15:30-15:45	**Coffee/Tea break**
15:45–16:00	In-vitro diagnostics Inspection Updates, Philippe Boeuf, Technical officer ,
16:00-16:15	Vector Control Inspection Updates, Mark Conrad, Technical officer
16:15-16:30	Desk assessment and reliance approaches, Mohamed Refaat, Technical officer
16:30 – 16:45	Update on new guidelines, DEG/EG contamination and the use of new technologies, Vimal Sachdeva, Technical officer
16:45 – 17:00	Questions and answers
SESSION 7 – PARALLEL TRACK (AUDITORIUM III) **14:00- 17:00**	**LOCAL PRODUCTION & TECHNICAL ASSISTANCE** *Session Chair: Jicui Dong, Unit Head, LPA, WHO* *Attendance mode: Hybrid*

14:00-14:15	Opening session Updates on WHO Local Production and Assistance activities *Speaker: Jicui Dong, Unit Head, LPA, WHO*
14:15-14:25	WHO PQ/EUL specialized technical assistance: overview *Speaker: David Woo, Technical Officer, LPA, WHO*
14:25-14:35	Specialized technical assistance for medicines *Speaker: Kim Notenboom, Technical Officer, LPA, WHO*
14:35-14:45	Specialized technical assistance for vaccines *Speaker: Alan Fauconnier, Technical Officer, LPA, WHO*
14:45-14:55	Specialized technical assistance for IVDs *Speaker: David Woo, Technical Officer, LPA, WHO*
14:55-15:00	Closing remark *Speaker: Jicui Dong, Unit Head, LPA, WHO*
18:00–20:00 **UN CITY CAFETERIA**	**RECEPTION FOR ALL PARTICIPANTS**

DAY 3	**WEDNESDAY, 4 DECEMBER 2024**
08:00–08:30	**ENTRANCE TO UN CITY**
SESSION 8 – PLENARY: 08:30–13:00 (AUDITORIUM I, II & III)	**WHAT'S NEW? UPDATES FROM UNICEF, UNFPA, WHO AND PARTNERS** *Session chair: Francisco Blanco, Chief, Medicines and Nutrition, UNICEF* *Attendance mode: Hybrid*
08:45–09:00	Introduction to Procurement Update Session *Francisco Blanco - Chief, Medicines and Nutrition Center (MNC,) UNICEF*
09:00–09:15	WHO Procurement-Shipra Sharm *Procurement Officer , WHO/HQ*
09:15-09:35	Global Fund Procurement & Supply Updates Speaker : Lin Li (Senior Manager, Direct Sourcing)
09:35-09:55	Promoting access to TB products: GDF's 2024 updates Speaker: Magali Babaley, Strategic Procurement and Business Intelligence Manager
09:55–10:15	UNFPA Procurement and Strategic Sourcing Speaker: Ksenia Jensen Development Supplies Procurement Specialist, Supply Chain Management Unit, UNFPA
10:15-10:40	**Coffee/Tea break**
10:40-11:00	UNICEF Supply 360°. *Alex Costa Chief, Health Technology Center, UNICEF Supply Division*
11:00-11:20	UNHCR Medical Supply Procurement Update Speaker Federico Pasqualini, Pharmacy Management Officer

11:20-11:40	UNDP Global Health Supply Center *Speaker: Mira Persson, Procurement Specialist*
11:40-12:00	PAHO Procurement Speaker: Jordi Balleste Procurement - Strategic Fund, Unit Chief
12:00-12:15	Gavi update on support to diagnostics procurement Speaker: Antara Sinha, Senior Programme Manager, Gavi
12:15-12:30	Plenary and Q&A
12:30-13:30	**Lunch Break**

SESSION 9 – PARALELL TRACK (AUDITORIUM III) 13:30–17:00	**DEEP DIVE INTO UNICEF SPECIFIC ISSUES. Medicines and health technologies** *Session Chair: Caroline Kiyiika, Contracts manager, UNICEF* *Attendance mode: Hybrid*
13:30-14:10	UNICEF Health programme and supply priorities 2023-2025 *Speaker: Francisco Blanco, Chief, Medicines and Nutrition Centre, UNICEF*
14:10-14:30	Becoming a supplier to UNICEF. Steps for successful engagement: Tendering, contracting *Speaker: Kanchana Perera,Contract Officer ,Medicines and Nutrition Centre, UNICEF*
14:30-15:00	Becoming a supplier to UNICEF. Steps for successful engagement: Technical requirements for Pharmaceutical Products *Speaker: Peter Mbwiiri Ikamati, Technical Specialist, Medicines and Nutrition Centre, UNICEF*
15:00-15:30	**Coffee/Tea break**
15:30-16:00	Becoming a supplier to UNICEF. Steps for successful engagement: Quality Assurance for Pharma *Speaker: Unine Felix , Quality Assurance Specialist, Quality Assurance Centre, UNICEF*
16.00-16.20	Traceability and Verification System & supplier onboarding *Speakers: Jean Pierre Amorij Technical Specialist, Vaccine Centre, UNICEF* *Max Kabalisa , Supply Chain Manager ,Supply Chain System Strengthening Centre, UNICEF*
16:20-16:40	Sustainable procurement in UNICEF. Supplier landscape and initiatives *Speaker: Tom I. Harrison-Prentice and Joao Ulisses Lopes Loli Junior, Sustainable Markets Centre, UNICEF*
16:40-17:00	Q&A
SESSION 10: PARALELL TRACK (AUDITORIUM I&II) 13:30–17:00	**UNFPA's SUPPLY CHAIN MANAGEMENT: Industry Consultation** *Session Chair: Linda Serwaa Product Quality Assurance Manager* *Attendance mode: Hybrid*
13:30-13:50	Overview of the new Supply Chain Management Unit's strategic objectives and priority initiatives Speaker : Srini Rajan, , Quality Management advisor, UNFPA

13:50-14:10	Market Shaping: Strategic Sourcing and expansion of Supplier base and product portfolio; Contract management; case studies from LTAs, Speaker : Cristina Palau, Category Specialist, UNFPA
14:10-14:30	Last Mile Assurance Process and its linkage to supply chain systems strengthening in Countries Speaker: Lidia Porto, Country Support Manager
14:30-15:00	Technical Services; Technical and Quality assurance requirements for qualification of RH products ; : Incentivising Local production and procurement of Reproductive Health commodities . Speakers: Farai Masekela (Technical Specialist)), Product Quality Assurance, UNFPA Olga Maria Pineda (Technical Analyst), Product Quality Assurance, UNFPA
15:00-15:30	**Coffee/Tea break**
15:30-16:00	Consultation : Manufacturer -Procurer Dialogue *Speaker : Safia Ahsan , Senior Technical Officer (RHSC) and Martyn Smith, Director (RHSC)*
16.00-16.30	Consultation : Procurers and manufacturers dialogue towards ensuring excellent supply of quality assured Reproductive Health commodities. *Speaker : Safia Ahsan , Senior Technical Officer (RHSC) and Martyn Smith, Director (RHSC)*
16:30-17:00	Q &A

DAY 4	**THURSDAY, 5 DECEMBER 2024**
07:00–08:40	**ENTRANCE TO UN CITY**
SESSION 11 – PLENARY SESSION (AUDITORIUM I, II & III) **08:45–13:00**	**REGULATORY UPDATES FROM WHO AND PARTNERS** *Session Chair: Hiiti Sillo, Unit Head, Regulation and Safety, WHO* *Attendance mode: Hybrid*
8:45-10:30	**WHO Listed Authority (WLA) and Coalition of Interested Parties (CIP)** Panel discussion **Chair:** - Anna Laura Salvati, WHO/RSS **Moderator:** - Murray Lumpkin, BMGF **Panelsist**: - Rogerio Gaspar, WHO/RPQ - Anna Laura Salvati, WHO/RSS - Engy ELHOSARY , WHO/RSS - Jude Nwokike, USP - Marie Valentine, WHO FPI

	- Angelika Joos, MSD (IFPMA) **Objectives**: - Promoting awareness about WLA initiative and updating participants on the recent progress - Provide participants with updates on the progress of the CIP Network, recent developments, and prospects **Layout and methods:** - Introduction to session, objectives, introduction of speakers/panelists – Murray Lumpkin, BMGF (5 minutes) - WLA update (15 min) - Anna Laura Salvati, RSS - WLA impact on prequalification of medical products (10 minutes) - Rogerio Gaspar, RPQ/PQT - Discussion with panelists – All (15 minutes) - CIP updates and way forward – Engy ElHosary - RSS (10 minutes) - Discussion with panelists – All (15 minutes) - Question & Answer (15 min) - Recommendations and Closing – Moderator (5 minutes) Additional topics to be expanded in the panel discussion (specific questions to be developed for panelists) and Q&A sessions: **WLA** - Promoting reliance through WLA initiative: impact on CRP - Manufacturers' perspective of the WLA initiative - Procurers' perspective of the WLA **CIP** - success stories and added values • NRA Perspectives on "WLA and" CIP
10:30-11:00	**Coffee/Tea break**
11:00-12:20	**WHO Collaborative Registration Procedure** Panel discussion **Moderator:** Marie Valentin, WHO FPI **Speakers**: - Sandhya Jadhav, MacLeods Pharmaceuticals, - Deon Poovan, SAHPRA (online) - Worasuda Yoogthong, Thai FDA (online) - Sunday Kisoma, WHO/FPI - Dominic Schuler, WHO/VCP **Objectives**: - To share experience on participation in WHO Collaborative Registration Procedure – Manufacturer. - To provide update on progress in implementation of CRP, including revised guidelines and new CRP procedure for

	facilitating access to prequalified vector control products – Sunday Kisoma, WHO/FPI. - NRA perspectives (SAHPRA and Thai FDA). - WHO PQT support to WHO CRP of vector control products, information to be shared and alignment of PQT requirements to national requirements. **Layout and methods**: - Introduction to session, objectives, and introduction of speakers – Moderator (3 minutes) - Experience and perspectives from manufacturers – MacLeods Pharmaceuticals (15 minutes) - CRP updates and outlook – Sunday Kisoma, WHO/FPI (15 minutes) - NRA experience and perspectives – Deon Poovan, SAHPRA (10 minutes) - NRA experience and perspectives – Worasuda Yoogthong, Thai FDA (10 minutes) - WHO PQT support and data sharing – Dominic Schuler, WHO/PQT (15 minutes) - Discussion, Question and Answers – All (15 minutes) Recommendations and Closing – Moderator (2 minutes)
12:20 – 13:00	Regulatory guidelines and standards – Updates - Luther Gwaza, WHO/NSP (15 minutes) - Tiequn Zhou, WHO/NSB (15 minutes) Questions and answers 10 minutes
13:00–14:00	**Lunch**
SESSION 12 – PARALLEL SESSION (AUDITORIUM III) 14:00–17:00	**TREATMENT AND DIAGNOSTIC GUIDELINES, ESSENTIAL MEDICINES LISTS (Inc for Children), ESSENTIAL IN VITRO DIAGNOSTICS LIST** *Moderator: Deus Mubangizi, Director, HPS, WHO* *Attendance mode: Hybrid*
14:00-14:05	Introductory remarks: *Deus Mubangizi, Director, Department of Health Product Policy and Standards, WHO*
14:05-14:15	Tuberculosis-Matteo Zignol (virtually)
14:15-14:35	HIV, Hepatitis and STIs-TBC (Marco to confirm)
14:35-14:45	NCDs-Bashier (tbc-Virtually)
14:45-15:00	SRH including MCA-Mariana Widmer
15:00-15:15	Q&A
15:15-15:30	**Coffee/Tea break**
15:30-15:50	WHO model list of essential in vitro diagnostics and MDv nomenc-Ana ACEVES
15:50-16:00	WHO Model List of Essential Medicines (+ children-EML)- Lorenzo MOJA

16:00-16:15	GMP - - (Tbc-by Andrea)
16:15-16:25	WHE and living guidelines-Janet Diaz
16:25-16:35	NTDs -Daniel Dagne
16:35-17:00	Q&A
SESSION 13: PARALLEL SESSION (AUDITORIUM I & II) 14:00 – 17:00	**REQUIREMENTS FOR STORAGE AND TRANSPORTATION OF TIME AND TEMPERATURE SENSITIVE HEALTH PRODUCTS (TEMPERATURE CONTROL AND MONITORING OF SHIPMENTS)** *Chair: TBD* *Attendance mode: Hybrid*
14:00 – 15:00	• How the UN 3PL intermodal freight forwarder strategy managed by UNICEF on behalf of the UN is aligned to a decentralization strategy – *Jean Cedric Meeus, Chief, Global Transport Center, UNICEF SD-15 min* • UNFPA presentation of the temperature monitoring program – *Johnson Moyo, Quality Assurance Analyst, UNPFA-15 min* **Q & A-30 min**
15:00-15:30	**Coffee/Tea break**
15:30 – 16:30	• GDF's experience for transport of medical products, challenges and opportunities – 15 min **Q & A-30 min**
NTD IVD WORKSHOP: DAY 1 (PACIFIC LOUNGE)	**A WORKSHOP WITH NEGLECTED TROPICAL DISEASES (NTD) DIAGNOSTICS MANUFACTURERS** **Moderator: *Patrick Lammie, WHO NTD***
14:00-14:10	Opening remarks- *Rogerio Gaspar, Director, WHO/RPQ*
14:10-14:20	Welcome and workshop objectives-*Daniel Argaw Dagne, Hye Lynn Choi, WHO NTD* • WHO code of conduct • Logistics (coffee break, badge, etc.)
14:20-14:40	WHO Diagnostic Technical Advisory Group for Neglected Tropical Diseases- *Daniel Argaw Dagne, WHO NTD*
14:40-15:00	Target Product Profiles (TPPs) for NTD diagnostics- *Patrick Lammie, WHO NTD*
15:00-15:30	**Coffee Break**
15:30-15:45	Access to NTD diagnostics and WHO response- *Afework Tekle, WHO NTD (virtual)* (Issues around supply, procurement, forecast, etc.)
15:45-16:00	WHO Expert Review Panel for NTD diagnostics (ERPD NTD) and lessons learned from the pilot-Hye Lynn Choi
16:00-16:30	Q&A

SESSION 14 – PLENARY (AUDITORIUM I, II & III) 17:00 – 17:30	**PAHO PRESENTATION-JUDIT (PAHO- 15 MIN)** **PLENARY DISCUSSION & OFFICIAL MEETING CLOSURE (15 MIN)** • **Key observations and thanks** • **Closing remarks by Dr Rogerio Gaspar, Director, RPQ, WHO**

DAY 5	**FRIDAY, 6 DECEMBER 2024**
NTD IVD WORKSHOP: DAY 2 (AUDITORIUM I & II)	**A WORKSHOP WITH NEGLECTED TROPICAL DISEASES (NTD) DIAGNOSTICS MANUFACTURERS** **Moderator: *Hye Lynn Choi, Daniel Argaw Dagne***
9:00-10:45	Prequalification of IVDs overview, PQ guidance documents and ERPD overview- *Irena Prat, Fatima Gruszka, Deirdre Healy, Ute Ströher (virtually)*
10:45-11:00	**Coffee Break**
11:00-11:45	Quality management system (QMS) - *Jadwiga Nitkiewicz, LPA (virtually)*
11:45-12:00	Q&A
12:00-14:00	**Lunch Break**
14:00-14:15	Post marketing surveillance (PMS)-*Anita Sands, ISF*
14:15-14:30	WHO Essential Diagnostics List-Virtual- *Ana Aceves Capri, EDL*
14:30-15:00	Local production and technical assistance- *Jicui Dong LPA*
15:00-15:30	WHO Collaborative Registration Procedure- *Agnes Kijo, FPI*
15:30-15:45	***Coffee Break***
15:45-16:00	H-TAP- *Cheleka Mpande*
16:00-17:00	Discussion and wrap-up- *Patirick Lammie*
1-TO-1 MEETINGS – WITH PARTICIPATING AGENCIES ***NOTE: 1-To-1 Meetings will not only be held on Day 5, but they can be scheduled on any day starting from Day 2 and except during plenary sessions. Participants are encouraged to contact the agency of interest below to be able to schedule a meeting between Day 2 and 5 as schedules allow***	
Entrance to UN City for a 1-to-1 meeting will be dependent on meeting confirmation (including meeting time and location) from the agency with whom the meeting has been requested.	
Meeting participants can request a meeting by contacting these agency staff:	

- For WHO Prequalification **Inspection Services**: Mustapha Chafai, chafaim@who.int, Vimal Sachdeva, sachdevav@who.int
- For WHO Prequalification of **In Vitro Diagnostics**: Irena Prat, prati@who.int
- For WHO Prequalification of **Medicines**: Matthias Stahl, stahlm@who.int
- For WHO Prequalification of **Vaccines & Immunization Devices**: Marion Law, mlaw@who.int
- For WHO Prequalification of **Vector Control Products**: Dominic Schuler, schulerd@who.int
- For WHO **Local Production**: Jicui Dong, dongj@who.int
- For WHO **Regulatory Updates**: Marie Valentin, valentinm@who.int
- For WHO **H-TAP**: Cheleka Mpande, , mpandec@who.int
- For UNICEF **Inspection Services;** Helene Moller; hmoller@unicef.org
- For UNICEF **Medicines Francisco Blanco** fb**lanco@unicef.org and Mar**y Atieno Ojoo, mojoo@unicef.org
- For UNICEF **Vaccines;** Ann Ottosen; aottosen@unicef.org**,**
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