





Global Health Supplies:

Paradigm Shifts in Market Authorization, Procurement and Supply **Chains Approaches**

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 28 November-01 December 2022 Joint Meeting will be a face-to-face meeting taking place at UN City, Marmorvej 51, 2100 Copenhagen, Denmark

DRAFT AGENDA

DAY 1	MONDAY, 28 NOVEMBER 2022
07:00-08:30	MEETING REGISTRATION: ENTRANCE TO UN CITY
SESSION 1 - PLENARY: 08:45-10:30 AUDITORIUM I, II & III	IMPROVING THE RESPONSE OF GLOBAL PUBLIC HEALTH IN A FAST-CHANGING WORLD
Live Streaming Link: https://s	streaming.uncity.dk/uncity/
08:45-09:00	Administrative / Security arrangements Henrik Pantmann, Head of Security – UN City Marta Seaone Aguilo – Facilitator
09:00-09:30	Welcome from meeting host agencies WHO - UNICEF – UNFPA Rogerio Pinto de Sa Gaspar, Director, RPQ, WHO Karen Hong, Chief Supply Chain Management Unit, UNFPA Etleva Kadilli, Director, UNICEF Supply Division
09:30-09:35	Outline of the meeting and Themes Marta Seaone Aguilo – Facilitator Deus Mubangizi, Unit Head, PQT, WHO
09:35-09:45	Remarks and introduction of Keynote speaker Mariangela Simão, Assistant Director-General, MHP, WHO
09:45-10:30	Keynote address
03.73 10.30	Dr Tedros Adhanom Ghebreyesus Director-General, World Health Organization
10:30-11:00	Coffee /Tea break







SESSION 2 - PLENARY:	Theme 1: NEW & COMPLEX PRODUCTS, COMPLEX PROCESSES - RACE TO
11:00-13:00	SUPPLY QUALITY PRODUCTS TO POPULATIONS IN NEED
AUDITORIUM I, II & III	Session Chair: Rogerio Pinto de Sa Gaspar, Director RPQ, WHO
Live Streaming Link: https://s	streaming.uncity.dk/uncity/
11:00-11:05	Introduction
11:05-11:50	 Product Evaluation perspective – Speaker: Guido Pante - focus on Biotherapeutics, e.g., mAbs or Insulin (Human/Analogues) Procurement & Supply Chain perspective – Hanne Bak Pedersen, UNICEF Industry Representative perspective – Speaker: Jing Zong, Gan & Lee Pharmaceuticals, focus on Biotherapeutics, e.g., mAbs or biologics like Insulin (Human/Analogues)) Innovator Industry Perspective – Speaker: Jules Millogo, Merck & Co., Inc (Online) Generic Industry perspective – Speaker: Dr Jaideep Gogtay, Cipla Ltd (Online)
11:50-12:20	Roundtable discussion - presenters and representatives from Procurement Agencies, WHO and Industry (IGBA/IFPMA) Facilitated by Session Chair - Rogerio Pinto de Sa Gaspar, Director, RPQ, WHO
12:20-13:00	Q&A
12.20 13.00	- Amu
13:00-14:00	Lunch
SESSION 3 - PLENARY 14:00-15:30 AUDITORIUM I, II & III	Theme 2: STRATEGIC SOURCING OF RAW MATERIALS TO ENSURE PRODUCTION CONTINUITY AND SUSTAINABILITY Session Chair: Antony Fake, PQT/MED, WHO
Live Streaming Link: https://s	
14:00-14:05	Introduction
14.00-14.03	Introduction
14:05-14:45	Presentations with perspectives from representatives of manufacturers • Vector Control Products – Speaker: Melinda Hadi, Vestergaard • In vitro diagnostics – Speaker: Mahendra Singh, Meril Diagnostics • Vaccines – Speaker: Stefan Paschen, Roche • Medicines – Speaker: Kamal Vashi, Mangalam Drugs & Organics Ltd
14:45-15:30	Panel discussion/Q&A
15:30-16:00	Coffee /Tea break
SESSION 4 - PLENARY 16:00- 17:00 AUDITORIUM I, II & III	Theme 3: REGIONAL PROCUREMENT & ENABLING REGULATORY ARRANGEMENTS Session Chair: Deus Mubangizi, Unit Head, Prequalification Unit (PQT), WHO
Live Streaming Link: https://s	streaming.uncity.dk/uncity/
16:00-17:00	Perspectives from Procurers and Regulatory: UNICEF - Francisco Blanco, Chief Quality Assurance Center WHO Procurement - Shipra Sharma, Procurement Officer PAHO Regulatory - Alexandra Mata (online) AMRH/AMA - Margareth Ndomondo Sigonda (online) UNITAID - Kehinde Onasanya
17:00-17:30	Panel Discussion/Questions & Comments
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17:30-18:00 AUDITORIUM I, II & III	WRAP-UP OF DAY 1 AND PLANS FOR DAY 2 Marta Seoane Aguilo, Facilitator Deus Mubangizi, Unit Head, PQT, WHO







DAY 2	TUESDAY, 29 NOVEMBER 2022
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 08:45-13:00 AUDITORIUM I & II	WHO IN VITRO DIAGNOSTICS (IVDs) PREQUALIFICATION TRACK
Zoom Registration Link: https://who.	zoom.us/webinar/register/WN_oHLRdgdxSqClkxDht9JQqw
Session 1: Moderator - Charles Chik	u
08:45-09:00	Introduction & Welcome Speaker: Susie Braniff, PQT/IVD, WHO
	PQT-IVD Updates 2022: achievements and plans
09:00-09:45	Speaker: PQT/IVD Team
09:45-10:00	Slido questionnaire Speaker: Jennifer Kealy, PQT/IVD, WHO
10:00-10:30	NATs to Detect Mycobacterium Tuberculosis DNA (TSS-17): Dossier Review & Performance Evaluation
10.00 10.00	Speaker: Marc Lanigan & Anne-Laure Page, PQT/IVD, WHO
	Website walk-through
10:30-10:45	Speaker: Miguel De Mestral, PQT/IVD, WHO
10:45-11:00	Q&A
10.43 11.00	ξωι
11:00-11:30	Coffee/Tea break
Carrier 2: Madameter, Aura Laure	Daniel Control of the
Session 2: Moderator – Anne-Laure 11:30-11:50	Development of new Technical Specifications for PQ (TSS):
1100 1100	Blood glucose monitoring devices and HbA1c POC devices
	Speaker: Deirdre Healy, PQT/IVD, WHO
11:50-12.10	ToC dossier submission
11.50-12.10	Speaker: Marc Lanigan, PQT/IVD, WHO
	7 7 7 7 7 7 7
12:10-12:40	Emergency Use Listing (EUL): progress, challenges and plans Speaker: Ute Ströher, PQT/IVD, WHO
12:40-12:55	Q&A
12:55-13:00	Wrap-up and close
	Speaker: Susie Braniff, PQT/IVD, WHO
12:00 14:00	Lunch
13:00-14:00	Lunch







SESSION 5.2 – PARALLEL TRACK	WHO MEDICINES PREQUALIFICATION TRACK
08:45-13:00 AUDITORIUM III	Session Chair: Matthias Stahl, Team Lead, PQT/MED, WHO
08:45-09:00	Introduction
00.43 03.00	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
00.50 10.15	Discoving Large
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)
10.40-11.05	Speaker: Regine Lehnert, PQT/MED, WHO
	Speaker. Regine Lenners, 1 Q1/MLD, WITO
11:05-11:35	Q&A
13:00-14:00	Lunch
SESSION 5.3 – PARALLEL TRACK 08:45–13:00 LOUNGE INDIAN OCEAN	WHO VACCINES & IMMUNIZATION DEVICES PREQUALIFICATION TRACK Session Chair: Carmen Rodriguez Hernandez, Team Lead, PQT/VAX, WHO
08:45-09:00	WHO vaccines prequalification overview
09:00-10:20	Vaccine assessment:
	CMC (chemistry, manufacturing and control), quality and post PQ activities and clinical data
	Speakers: Charity Ilonze & Olivier Lapujade, PQT/VAX, WHO
	Speakers, charty house & onvice Eapagade, 1 & 17 7777, WHO
10:20-10:40	Facilitated discussions
10:40-11:00	Programmatic suitability for PQ
	Speaker: Charity Ilonze, PQT/VAX, WHO
11:00-11:30	Coffee/Tea break
11:30-11:40	Immunization equipment
	Speaker: Carmen Rodriguez Hernandez, Team Lead, PQT/VAX, WHO
11:40-12:40	Risk benefit assessment procedures. Updates on EUL
11.10 12.10	Speaker: Olivier Lapujade, PQT/VAX, WHO
12:40-13:00	Facilitated discussions
13:00-14:00	Lunch







SESSION 5.4 - PARALLEL TRACK 08:45 - 13:00 LOUNGE PACIFIC OCEAN	WHO VECTOR CONTROL PRODUCT PREQUALIFICATION TRACK Session Chair: Marion Law, Team Lead, PQT/VCP, WHO
Zoom Registration Link: https://who.z	oom.us/webinar/register/WN_jFjz2hvHQjeHUuefJTWWEQ
08:45-09:00	Introduction to PQT/VCP programme of activities for Day 2 Session Speaker: Marion Law, Team Lead VCP
09:00-11:00	Consultation on comparative studies of insecticide treated nets for determination of non-inferiority Speaker: Jan Kolaczinski, Unit Head Global Malaria Programme
11:00-11:30	Coffee/Tea break
11:30–12:00	Consultation on comparative studies of insecticide treated nets for determination of non-inferiority Speaker: Jan Kolaczinski, Unit Head Global Malaria Programme
12:00-13:00	Comments and Questions
13:00-14:00	Lunch
SESSION 5.5 – PARALLEL TRACK 08:45 – 15:00 LOUNGE ATLTANTIC OCEAN	UNFPA PREQUALIFICATION OF CONTRACEPTIVE DEVICES & MARKETS TRACK Session Chair: Linda Serwaa, Head, Quality Assurance, Technical and WHO/UNFPA Prequalification, UNFPA
Zoom Registration Link: https://unfpa.	zoom.us/webinar/register/WN_qLgtbNacQCeX2mQ4a39MCg
08:45-09:05	General Prequalification Updates Speaker: Ashley Moyo
09:05-09:40	Quality monitoring for prequalified manufacturers Summary of analysis of 2021 annual report of quality complaints Speaker: Sivakumar Kamakshinatha
09:40-10:00	Maintenance of prequalification status Summary of analysis of 2021 annual report of significant changes Speaker: William Potter
10:00-10:30	Process Capability Indices and Control Charts <i>A practical overview of their application</i> Speaker: William Potter
10:30-11:00	Feedback from Manufacturers on Prequalification Webinars
11:00-11:30	Coffee/Tea break
11:30–12:00	Guidance development: Referee testing procedures <i>An overview</i> Speaker: Sivakumar Kamakshinatha
12:00–12:45	Feedback from manufacturers Webinars on improving prequalification technical documentation and how they have impacted their operations
12:45-13:00	Q&A
13:00-14:00	Lunch
14:00 -15:00	Alternate sources of raw materials A follow-up discussion and update from manufacturers - Speaker: Sivakumar Kamakshinatha







SESSION 6 – PLENARY	WHO INSPECTION SERVICES
14:00 - 17:00 AUDITORIUM I, II & III	Session Chair: Philippe Boeuf, PQT/INS, WHO
14:00–14:05	Introduction to PQT/INS programme of activities Speaker: Johanna Gouws, Team Lead, PQT/INS, WHO
14:05–14:30	PQT/INS Programme updates and future initiatives Speaker: Johanna Gouws, Team Lead, PQT/INS, WHO
14:30-14:45	GMP approach to Management of Antimicrobial Waste Speaker: Stephanie Croft, PQT/INS, WHO
14:45–15:00	UN sustainable goals and application to PQT Inspections Speaker: Dimitrios Catsoulacos, PQT/INS, WHO
15:00-15:30	Panel discussion: Inspection activities and initiatives that have an impact on sustainability Speaker: Solomon Onen & Dimitrios Dimas
15:30-16:00	Coffee/Tea break
16:00-16:15	Inspection & Review of CROs computerized systems validation Speaker: Elham Kossary, PQT/INS, WO
16:15–17:00	Annexure 1 update: Implications for Manufacturers Speaker: Chris Stubbs
SESSION 7 – PARALLEL TRACK 14:00- 17:00 LOUNGE PACIFIC OCEAN	LOCAL PRODUCTION & TECHNICAL ASSISTANCE Session Chair: Jicui Dong, Unit Head, LPA, WHO
Zoom Registration Link: https://wh	o.zoom.us/webinar/register/WN_Jsz2narQTdG9N3Np8jJJ_Q
14:00-14:15	Opening session Updates on WHO Local Production and Technical Assistance activities Speaker: Jicui Dong, Unit Head, LPA, WHO
14:15-14:30	Case Studies: Local production of medicines for domestic market and export Speaker: Perviz Dhanani, Universal Corporation Ltd, Kenya
14:30-14:45	Case Studies: Production of IVDs - the Institut Pasteur de Dakar's experience Speaker: Cheikh Tidiane Diagne, DIATROPIX, Senegal
14:45-15:00	Case Studies: Local production of vector control products Speaker: Dominic Schuler, PQT/VCP, WHO
15:00-15:15	Local procurement as a logical continuation of local production Speaker: Alekaw Tegegne, UNICEF
15:15-15:30	Case Studies: AVAREF joint review of the Oxford R21 malaria vaccine Speaker: Diadié Maiga, WHO/AVAREF







15:30-16:00	Coffee/Tea break
16:00-16:30	WHO PQ/EUL specialised TA
	Speakers: David Woo & Alain Fauconnier, LPA, WHO
16:30-16:55	Panel Discussion; Challenges and Benefits of Local Production
16:55-17:00	Closing remarks
18:00-20:00	
20.00	RECEPTION FOR ALL PARTICIPANTS
UN CITY CAFETERIA	11-0-11-11-11-11-11-11-11-11-11-11-11-11









DAY 3	WEDNESDAY, 30 NOVEMBER
07:00-08:30	ENTRANCE TO UN CITY
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SESSION 8-PLENARY 08:30-11:00	PROCUREMENT AND SUPPLY CHAIN: UPDATES, CHALLENGES & SOLUTIONS
AUDITORIUM I, II & III	
AUDITORIUM I, II & III	Session Chair: Francisco Blanco, Chief, Quality Assurance Center, UNICEF SD
Zoom Registration Link: https://	/who.zoom.us/webinar/register/WN_pdhZBN8cQVqZIZDhzp-qtg
08:30-08:45	Introduction to procurement updates
	Speaker: Francisco Blanco, Chief, Quality Assurance Center, UNICEF SD
00:45 00:00	LINEDA
08:45-09:00	UNFPA procurement Speaker: Roberto Mena, Head of Strategic Sourcing Team
	Speaker. Roberto Meria, freda di Strategic Sourcing Feam
09:00-09:15	UNDP Global Health Procurement and Supply chain architecture 2022
	Speaker: Zafar Yuldashev
09:15-09:30	WHO Procurement
	Speaker: Shipra Sharma, Procurement Officer, Supply Catalogues & LTAs, WHO
09:30-09:45	UNICEF Procurement: Comprehensive supply for impactful and cost-efficient health
	programmes.
	Speakers: Cynthia Kamtengeni, Michaela Beidova, Valeria Markova, Contracts
	managers
09:45–10:00	Global Fund Procurement & Supply Updates
	Speaker: Clarisse Morris, Specialist, Global Sourcing Health Technologies
10:00-10:15	Promoting access to TB products; GDF's end to end approach
20103 20120	Speaker: Brenda Waning
10:15-10:30	UNHCR Procurement
	Speaker: Federico Pasqualini
10:20 10:45	DALIO Progurament
10:30-10:45	PAHO Procurement Speaker: Jordi Balleste, Strategic Fund Procurement - Unit Chief, Procurement and
	Supply Management, PAHO
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10:45-11:00	Q&A Moderator Mary Atieno Ojoo, Technical Manager, UNICEF
11:00-11:30	Coffee/Tea break







SESSION 9 11:30-13:00	UPDATES ON POLICY, TREATMENT GUIDELINES, DIAGNOSTICS GUIDELINES & SUPPLY CHAIN POLICY
SESSION 9.1 - PARALLEL TRACK 11:30-13:00 AUDITORIUM III	VERIFICATION, VISIBILITY AND TRACEABILITY (The Basics and Beyond of Verification, Visibility and Track and Trace) Session Chair: Grant Courtney, Traceability Lead, UNICEF
Zoom Registration Link: https://unfpa.zo	oom.us/j/81538218144
11:30-11:55	TRVST traceability and verification System implementation – Manufacturer/country engagement blueprint and collaboration with regulators. Speakers: Grant Courtney and Max Kabalisa UNICEF
11:55-12:20	WHO reflections on verification and traceability Speakers: Anita Sands and Lisa Hedman, WHO
12:20-12:45	GS1 project – status of implementation Speaker: Rajesh Chigullapalli, UNFPA
12:45-13:00	Q&A Moderator: Patrick Gaparayi, Supply Chain manager UNICEF
13:00-14:00	Lunch
SESSION 9.2 - PARALLEL TRACK 11:30-13:00 AUDITORIUM I & II	OPPORTUNITIES, CHALLENGES AND SOLUTIONS TOWARDS ACHIEVING SUSTAINABLE TRANPORT WORLDWIDE Session Chair: Jean-Cedric Meeus, Chief, Global Transport and Logistics Center, UNICEF
Zoom Registration Link: https://unfpa.zo	oom.us/j/81538218144
11:30-13:00	Global Market Updates UN Transport Strategy: end to end solutions Sustainable transport and logistics; UN Greening, temperature-controlled transport, reefer containers Humanitarian Transport and Logistics Alliance Q&A: Challenges, opportunities, and solutions Speakers Jean-Cedric Meeus, UNICEF Daniele Andries, UNFPA Julian Robertson, WHO







SESSION 9.3 – PARALLEL TRACK 11:30–13:00 LOUNGE PACIFIC OCEAN	UPDATES ON TREATMENT GUIDELINES & DIAGNOSTICS GUIDELINES, ESSENTIAL MEDICINES LIST & ESSENTIAL DIAGNOSTICS LIST Session Chair: Clive Ondari, Director, HPS, WHO
Zoom Registration Link: https://who.zoc	om.us/webinar/register/WN_E-XiRvaKQie7ZrSO6JwzJA
11:35-11:45	Accelerating Innovation and Access to Paediatric Medicines Speaker: Martina Penazzato & Anjali Srivastava, GAP-f Secretariat, WHO
11:45-11:55	COVID-19 Living Guidelines Speaker: Jamie Rylance, Case Management Expert, HCR, WHO
11:55-12:05	Updates to Viral Hepatitis Speaker: Philippa Easterbrook, Scientist, TAC, WHO
12:05-12:15	HIV-STI Speaker: Cheryl Johnson, Technical Officer, TPP, WHO
12:15-12:30	TB Guidelines Speaker: Matteo Zignol, Unit Head, GTB, WHO
12:30-12:40	Sexual and Reproductive Health Guidelines
	Speaker: Laurence Läser, Technical Officer, PUA, WHO
12:40-12:50	WHO AWaKe Antibiotic Book Speaker: Benedikt Huttner, Team Lead, Essential Medicines, WHO
12:50-13:00	Q&A
13:00-14:00	Lunch







SESSION 10 - PLENARY	REGULATORY UPDATES
14:00-16:00	Session Chair: Samvel Azatyan, Regulatory Convergence & Networks, WHO
AUDITORIUM I, II & III	
Zoom Registration Link: https	://who.zoom.us/webinar/register/WN_aYYdiwO5TE2arD1fFTqoCw
14:00-16:00	WLA and Reliance
	Speaker: Alireza Khadem, Team Lead a.i., REG/RSS
	Facilitated Regulatory Pathways including CRP
	Speaker: Mariana Roldao Santos, Technical Officer, REG/FPI
	Safety Monitoring
	Speaker: Shanthi Pal, Team Lead, REG/PVG
	Complet Chain Intermity (Colector days and Falsifical)
	Supply Chain Integrity (Substandard and Falsified) Speakers: Anita Sands, Technical Officer, REG/ISF and Rutendo Kuwana, Team Lead,
	REG/ISF
	Norms and Standards for Product Regulation
	Speaker: Luther Gwaza, Team Lead, HPS/NSP
16:00-16:30	Coffee/Tea break
10.00	Tonico, rea sireat
16:30 - 17:00	PLENARY DISCUSSION & OFFICIAL MEETING CLOSURE
AUDITORIUM I, II & III	Key observations and thanks
Zoom Registration Link: https	://who.zoom.us/webinar/register/WN_aYYdiwO5TE2arD1fFTqoCw







DAY 4 THURSDAY, 1 DECEMBER 2022

1-TO-1 MEETINGS - WITH PARTICIPATING AGENCIES

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: Johanna Gouws gouwsi@who.int
- For WHO Prequalification of In Vitro Diagnostics: Irena Prat prati@who.int
- For WHO Prequalification of Medicines: Matthias Stahl <u>stahlm@who.int</u>
- For WHO Prequalification of **Vaccines & Immunization Devices**: Carmen Rodriguez Hernandez rodriguezhernandezc@who.int
- For WHO Prequalification of Vector Control Products: Marion Law <u>mlaw@who.int</u>
- For WHO Local Production: Jicui Dong dongj@who.int
- For WHO **Regulatory Updates**: Samvel Azatyan <u>azatyans@who.int</u>
- For UNICEF Inspection Services; Francisco Blanco fblanco@unicef.org
- For UNICEF Medicines Mary Atieno Ojoo mojoo@unicef.org
- For UNICEF Vaccines; Ann Ottosen; aottosen@unicef.org,
- For UNICEF In Vitro Diagnostics, Vector control products Wandani Sebonego wsebonego@unicef.org;
- For UNICEF Medical devices and consumables; Hani El-Jadaa heljadaa@unicef.org;
- For UNICEF Cold Chain and Immunization devices; Thomas Sorensen tsorensen@unicef.org;
- For UNFPA: Linda Serwaa <u>serwaa@unfpa.org</u>; Lorraine Molepo <u>molepo@unfpa.org</u>;
 Ashley Moyo <u>asmoyo@unfpa.org</u>