

Improving the Response of Global Public Health in a Fast-changing World

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

2–5 December 2019, UN City, Copenhagen, Denmark

DAY 1	MONDAY, 2 DECEMBER
07:30-08:45	MEETING REGISTRATION: ENTRANCE TO UN CITY
PLENARY: IMI	PROVING THE RESPONSE OF GLOBAL PUBLIC HEALTH IN A FAST-CHANGING WORLD
08:45-08:50	Meeting opening and meeting overview Joel Schaefer, Communication Officer, Office of WHO Director-General
08:50-09:05	Welcome from meeting host agencies Hanne Bak Pedersen (Deputy Director, Programme Supply & Market Influencing, UNICEF Supply Division), Eric Dupont (Chief, Procurement Services Branch, UNFPA) & Dr Mariângela Simão (Assistant Director-General, Access to Medicines and Health Products, WHO Headquarters)
09:05-09:15	Administrative / security arrangements Jesper Palm Lundorf, UN Office of the Designated Official for Security
09:15-09:20	Overview of the day's themes and introduction to keynote address and response Joel Schaefer, Communication Officer, Office of WHO Director-General
09:20-09:40	Keynote address: "Fast Change, Slow Response" Dr Soumya Swaminathan, Chief Scientist, WHO Headquarters
09:40-10:00	Keynote address response: Using Al to Change the Game in Global Response Dr Padmanabhan Anandan, CEO, Wadhwani Institute for Artificial Intelligence
10:00-10:10	Quick questions Moderated by Joel Schaefer, Communication Officer, Office of WHO Director-General
10:10-10:40	Coffee / tea break
Theme 1	Emergency Preparedness: Progress Made but Not There Yet
10:40-10:45	Introduction to Theme 1 Joel Schaefer, Communication Officer, Office of WHO Director-General
10:45-11:05	Challenges in Emergency Preparedness Dr Hilde de Clerck, Emerging Infections Advisor, Médecins Sans Frontières – Operational Centre, Brussels, Belgium
11:05-11:25	Dx / Technology (title TBD) Catharina Boehme, CEO, Foundation for Innovative New Diagnostics
11:25-11:35	Quick questions Moderated by Joel Schaefer, Communication Officer, Office of WHO Director-General







Theme 2	Communication to Reduce Human "Resistance" to Care
11:35-11:40	Introduction to Theme 2
	Joel Schaefer, Communication Officer, Office of WHO Director-General
11:40-12:00	Communication for Emergencies / Resistance (title TBD)
11.40 12.00	Cristiana Salvi, Programme Area Manager, WHO Health Emergencies Programme, WHO Regional
	Office for Europe
12:00-12:20	Building resilient demand for vaccination
	Katrine Bach Haabersaat, Technical Officer, Vaccine-preventable Diseases and Immunization,
	WHO Regional Office for Europe
12:20-12:30	Quick questions
	Moderated by Cristiana Salvi, Programme Area Manager, WHO Health Emergencies Programme,
	WHO Regional Office for Europe
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12:30-13:45	Sandwich lunch
Theme 3	Progress and Outlook for Global Health Initiatives
13:45-13:50	Introduction to Theme 3
13.13 13.30	Joel Schaefer, Communication Officer, Office of WHO Director-General
13:50-14:10	Access to Treatment for Childhood Cancer
20.00 220	Dr Scott Howard, WHO Consultant, Cancer Control, Department of Noncommunicable Diseases,
	WHO Headquarters, Professor, University of Health Science Center, Memphis, USA and Secretary
	General, International Pediatric Oncology Society
14:10-14:30	Access to Diagnosis and Treatment for Hepatitis
	Dr Nicole Seguy, Joint Tuberculosis, HIV/AIDS & Hepatitis Programme, WHO Regional Office for
	Europe
14:30-14:50	Diagnosis and Treatment of Diabetes
	Dr Hans Hogerzeil, Emeritus Professor, Groningen University
14:50-15:10	Antimicrobial Resistance: towards Viable Markets for Diagnostics and Antibiotics
	Daniel Berman, Lead, Global Health Team, Nesta Foundation
15:10-15:20	Quick questions
	Moderated by Joel Schaefer, Communication Officer, Office of WHO Director-General
15:20-16:00	Coffee / tea break
15.20-16.00	Conee / tea break
Theme 4	Global Health Landscapes
16:00-16:05	Introduction to Theme 4
	Joel Schaefer, Communication Officer, Office of WHO Director-General
16:05-16:25	WHO prequalification: "Preserve the Core, Stimulate Progress"
	Deus Mubangizi, Coordinator, WHO Prequalification Team
16:25-16:45	Regulation of Vector Control Products: What's New?
	Dr Angus Spiers, Director, Innovation to Impact
16:45-17:05	Pharma Landscape: Challenges & Opportunities
	Dr Julie Gerberding, Executive Vice President and Chief Patient Officer, Strategic Communications,
	Global Public Policy, and Population Health, Merck & Co., Inc.
17:05-17:15	Quick questions
	Moderated by Joel Schaefer, Communication Officer, Office of WHO Director-General
17:15-17:30	Wrap-up
17.15 17.50	By Joel Schaefer, Communication Officer, Office of WHO Director-General
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17:30-19:00	Reception for all participants
17.50 15.00	neception for all participants







DAY 2	TUESDAY, 3 DECEMBER
07:30-08:45	MEETING REGISTRATION: ENTRANCE TO UN CITY
on "Local prod procurement t	sist of a procurement track and five prequalification tracks, held in parallel. In addition, a session luction and technical assistance" will be held from 15:30, i.e. in parallel with the latter part of the track. Peaks: 11:00–11:30 & 15:30–16:00 & Lunch break: 13:00–14:00
PROCUREMENT: UPDATES & CHALLENGES	
08:45-09:00	Introduction to procurement updates Given by Francisco Blanco, Chief of Quality Assurance Centre, UNICEF Supply Division
09:00-09:20	UNICEF procurement process, volume/price updates Cynthia Kamtengeni, Contracts Manager, Medicines and Nutrition Centre, UNICEF Supply Division & Robert Matthews, Contracts Manager, Health Technology Centre, UNICEF Supply Division
09:20–09:30	Q&A Chaired by Francisco Blanco, Chief of Quality Assurance Centre, UNICEF Supply Division
09:30–09:50	UNFPA procurement process, volume/price updates Roberto Mena, Procurement Specialist, Strategic Procurement, UNFPA
09:50–10:00	Q&A Chaired by Francisco Blanco, Chief of Quality Assurance Centre, UNICEF Supply Division
10:00–10:20	Global Fund's approach to procurement Azizkhon Jafarov, Manager, Global Sourcing Health Technologies
10:20–10:30	Q&A Chaired by Francisco Blanco, Chief of Quality Assurance Centre, UNICEF Supply Division
10:30–10:50	PAHO Procurement & Health in the Americas Daniel Rodriguez, Director, Procurement and Supply Management, Pan American Health Organization
10:50–11:00	Q&A Chaired by Francisco Blanco, Chief of Quality Assurance Centre, UNICEF Supply Division
11:00–11.30	Coffee/ tea break
11:30–11:40	Introduction to procurement challenges Given by Lisa Hedman, Technical Officer, Innovation, Access and Use, WHO Headquarters
11:40–12:00	Forecasting for decision-making Vineet Prabhu, Associate Director, Market Intelligence, Clinton Health Access Initiative
12:00–12:10	Q&A Chaired by Lisa Hedman, Technical Officer, Innovation, Access and Use, WHO Headquarters
12:10–12:30	Procurement for progressing global health initiatives: PAHO and HEARTS Jordi Balleste, Jordi Balleste, Strategic Fund Unit Chief, Procurement and Supply Management, Pa American Health Organization
12:30–12:50	Biotherapeutics for cancer: ensuring quality, safety and efficacy Dr Guido Pante, Expert, Biotherapeutic Products, Medicines Assessment, WHO Prequalification Team
12:50–13:00	Combined Q&A for above two topics Chaired by Daniel Rodriguez, Director, Procurement and Supply Management, Pan American Health Organization
13:00–14.00	Lunch







14:00–14:05	Introduction Lisa Hedman, Technical Officer, Innovation, Access and Use, WHO Headquarters
14:05-14:30	Implications for manufacturers of updated WHO guidelines
14.05-14.50	Dr Sabine Kopp, Scientist, Technologies Standards and Norms, WHO Headquarters
14:30–14:55	Country perspective on procurement of medicines: Iraq case study Dr Fadia Hanna, Senior Chief Manager & Dr Ahmed Jabbar, Chief Pharmacist-Import Manager, Ministry of Health, Iraq and Amgad Gholam Abbas Gaafar, Logistician, WHO Country Office, Iraq
14:55–15:20	Challenges of TB medicines market and sustainable pricing: getting the balance right Dr Kaspars Lunte, Global Sourcing Officer, Stop TB & Dr Magali Babaley, Strategic Procurement and Business Intelligence Manager
15:20–15:30	Combined Q&A for above three topics Chaired by Lisa Hedman, Technical Officer, Innovation, Access and Use, WHO Headquarters
15:30–16.00	Coffee/tea break
16:00 16:25	LINDS are a second and a second a second and
16:00–16:25	UNDP procurement processes, needs and challenges Dr Cécile Macé, Senior Health Procurement and Supply Management Adviser, UNDP
16:25–16:45	Procurement for treatment of neglected tropical diseases: what's new? Hye Lynn Choi, Technical Officer, Prequalification Team/Department of Neglected Tropical Diseases, WHO Headquarters
16:45-17:00	Combined Q&A for above two topics Chaired by Lisa Hedman, Technical Officer, Innovation, Access and Use, WHO Headquarters
WHO IN VITRO	D DIAGNOSTICS (IVDS) PREQUALIFICATION TRACK
WHO IN VITRO 08:45-09:00	IVD prequalification for new applicants: an overview
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14:00-14:45	IVD inspection update and Q&A Stephanie Croft, Inspector, Inspection Services, WHO Prequalification Team
14:45-15:15	Expert Review Panel for Diagnostics: update
	Dr René Becker-Burgos, Quality Assurance Specialist for Diagnostics Products, Global Fund.
WHO MEDICIN	NES PREQUALIFICATION TRACK
08:45-09:00	Introduction to medicines assessment update
	Dr Matthias Stahl, Group Lead, Medicines Assessment, WHO Prequalification Team
09:00-10.30	Quality Dr Lynda Paleshnuik, Lead Quality Assessor, Medicines Assessment Bioequivalence
	Dr John Gordon, Lead Bioequivalence Assessor, Medicines Assessment, , WHO Prequalification Team, WHO Prequalification Team
	Active pharmaceutical ingredients Dr Antony Fake, API Assessment Focal Point, Medicines Assessment; WHO Prequalification Team Update on WHO Public Assessment Reports
	Dr Regine Lehnert, Clinical Assessor, Medicines Assessment, WHO Prequalification Team Biosimilar products pilot
	Dr Guido Pante, Expert, Biotherapeutic Products, Medicines Assessment, WHO Prequalification Team
10:30-11.00	Q&A Chaired by Dr Matthias Stahl, Group Lead, Medicines Assessment, WHO Prequalification Team
11:00-11.30	Coffee/ tea break
11:30–12.30	Medicines inspection update and Q&A Vimal Sachdeva, Inspector, Inspection Services, WHO Prequalification Team
WHO VACCINI	ES & IMMUNIZATION DEVICES PREQUALIFICATION TRACK
08:45-09:20	WHO vaccines prequalification overview
	Carmen Rodriguez-Hernandez, Group Lead, Vaccines Assessment, WHO Prequalification Team
09:20–09:40	Vx inspection update Mustapha Chafai, Inspector, Inspection Services, WHO Prequalification Team
09:40–10.00	Q&A Chaired by Carmen Rodriguez-Hernandez, Group Lead, Vaccines Assessment, WHO Prequalification Team
10:00-10.45	Vaccine assessment: CMC (chemistry, manufacturing and control) and quality and clinical data Oliver Lapujade, Scientist, Vaccines Assessment, WHO Prequalification Team
10:45–11:00	Q&A Chaired by Carmen Rodriguez-Hernandez, Group Lead, Vaccines Assessment, WHO Prequalification Team
11:00-11.30	Coffee/ tea break
11:30–12.00	Vaccines testing: initial evaluation and post-prequalification monitoring Dr Ute Rosskopf, Scientist, Regulatory Systems Strengthening Team
12:00–12.15	Q&A Chaired by Rolando Dominguez Morales, Scientist, Vaccines Assessment, WHO Prequalification Team







12:15-12.45	Post-prequalification Rolando Dominguez Morales, Scientist, Vaccines Assessment, WHO Prequalification Team
12:45-13.00	Q&A
12.45-15.00	Chaired by Oliver Lapujade, Scientist, Vaccines Assessment, WHO Prequalification Team
	Chanea by Onver Euphjade, Scientist, Vaccines Assessment, WHO Frequalification realif
13:00-14.00	Lunch
14:00-14:30	Regulatory challenges of prequalified vaccines supplied through the UN system
	Olivier Lapujade, Scientist, Vaccines Assessment, WHO Prequalification Team
14:30-14:45	Q&A
	Chaired by Carmen Rodriguez-Hernandez, Group Lead, Vaccines Assessment, WHO Prequalification Team
14:45-15.15	Prequalification of immunization equipment: implications for vaccines
	Dr Isaac Gobina, Technical Officer, Immunization Devices Prequalification
15:15-15.30	Q&A
	Chaired by Carmen Rodriguez-Hernandez, Group Lead, Vaccines Assessment, WHO Prequalification
	Team
WHO VECTOR	R CONTROL PRODUCT PREQUALIFICATION TRACK
WHO VECTOR 08:45-09:00	
	Introduction to vector control assessment update & developments
08:45-09:00	Introduction to vector control assessment update & developments Marion Law, Group, Vector Control, Vaccines Assessment, WHO Prequalification Team
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UNFPA PREQ	UALIFICATION OF CONTRACEPTIVE DEVICES & MARKETS TRACK
08:50–09:05	UNFPA prequalification programme update Ashley Moyo, Technical Analyst, UNFPA Procurement Services Branch
09:05–09:40	Reporting changes to the prequalified product/site Dr Siva Kumar, Technical Expert Consultant, UNFPA
09:40–10:00	Quality complaints Dr William Potter, Technical Expert Consultant, UNFPA
10:00-10:30	Post-market surveillance David Hill, Technical Expert Consultant, UNFPA
10:30–11.00	Condom storage conditions and conducting stability studies Dr Siva Kumar, Technical Expert Consultant, UNFP
11:00-11.30	Coffee/ tea break
11:30–11.45	Condom storage conditions and conducting stability studies (continued) Dr Siva Kumar, Technical Expert Consultant, UNFPA
11:45–12.30	Quality monitoring strategies Dr William Potter, Technical Expert Consultant, UNFPA
12:30–13.00	Fee structure Ashley Moyo, Technical Analyst, UNFPA Procurement Services Branch
13:00–14.00	Lunch
15:30–16.00	Breakout session: Viable commercial markets for reproductive health products markets: are the possible without donors? Led by Ben Light, Senior Policy Adviser, Family Planning & Reproductive Health Supplies Coalition, UNFPA
LOCAL PRODI	JCTION & TECHNICAL ASSISTANCE
15:30–15:40	Introduction TBD
15:40–16.00	Leveraging and cultivating enabling factors for local production Dr Ji Cui Dong, Programme Manager, Local Production, Regulatory Systems & Strengthening Tean WHO Headquarters
16:00–16.15	Q&A Chaired by TBD
16:15–17:05	Technical assistance for IVD manufacturers Dr Gaby Vercauteren, Senior Advisor, Regulatory Systems Strengthening, WHO Headquarters
17:05–17:25	Technical assistance for medicines manufacturers
17.05-17.25	Rutendo Kuwana, Technical Officer, Regulatory Systems Strengthening, WHO Headquarters







DAY 3	WEDNESDAY, 4 DECEMBER
07:30-08:30	MEETING REGISTRATION: ENTRANCE TO UN CITY
Day 3 will be h	neld in plenary, with the exception of two lunchtime breakout sessions.
WHO POLICY,	DIAGNOSIS AND TREATMENT GUIDELINES UPDATES, AND WHO AND MODEL LIST UPDATES
08:30-08:35	Introduction Given by Deus Mubanqizi, Coordinator, WHO Prequalification Team
08:35-08:55	TB diagnostic policies and treatment guidelines updates Dr Kerri Viney, Scientist, Laboratories, Diagnostics and Drug-Resistance, WHO Global TB Programme
08:55-09:15	HIV and STI treatment guidelines updates Dr Marco Vitoria, Medical Officer, Treatment and Care, Department of HIV/AIDS, WHO Headquarters
09:15-09:35	Hepatitis B and C treatment guidelines updates Dr Antons Mozalevskis, Medical Officer, HIV/AIDS & Hepatitis Programme, WHO Regional Office for Europe
09:35-09:55	Malaria treatment guidelines update Dr Peter Olumese, Medical Officer, Prevention, Diagnosis & Treatment, WHO Global Malaria Programme Q&A
09:55-10:15	Chaired by Deus Mubangizi, Coordinator, WHO Prequalification Team Q&A Chaired by Deus Mubangizi, Coordinator, WHO Prequalification Team
WHO MODEL	LIST UPDATES
10:15-10:20	Introduction Given by Deus Mubangizi, Coordinator, WHO Prequalification Team
10:20-10:40	The 2 nd WHO Model List of Essential In Vitro Diagnostics Adriana Velazquez Berumen, Senior Advisor, Innovation, Access and Rational Use Team, WHO
10:40-11:00	Headquarters The 21st WHO Model List of Essential Medicines
10:40-11:00	Bernadette Cappello, Technical Officer, Secretariat, Essential Medicines List, WHO Headquarters Q&A Chaired by Deus Mubangizi, Coordinator, WHO Prequalification Team
11:00-11:30	Coffee/tea break







11:30-11:35	Introduction
	Given by Emer Cooke, Director, Director, Department of Regulation of Medicines and other Healt.
	Technologies, WHO Headquarters
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	latory Concepts
11:35-11:55	Good regulatory and good reliance practices Dr Samvel Azatyan, Group Lead, Regulatory Networks and Harmonization, Regulatory Systems
	Strengthening, WHO Headquarters
11:55-12:15	The WHO Global Benchmarking Tool (GBT)
	Dr Ali Khadem Broojerdi, Scientist, Regulatory Systems Strengthening, WHO Headquarters
12:15-12:35	WHO Listed Authorities: from concept to practice
12:35-13:00	Mr Hiiti Sillo, Scientist, Regulatory Systems Strengthening, WHO Headquarters Q&A
	Chaired by Dr Ali Khadem Broojerdi, Scientist, Regulatory Systems Strengthening, WHO
	Headquarters
13:00-14:00	Lunch
LUNCHTIME B	REAKOUT SESSIONS
	Breakout session: Safe abortion
	Led by Sophia Ahsan, Market Development Officer, Deputy Director, Reproductive Health Supplie
12:45-14:15	Coalition, with the participation of TBD UNFPA and WHO Headquarters
	Lunch will be available outside the meeting room for those participating
	Breakout session: The benefits of The International Pharmacopoeia for manufacturers
	Led by Dr Herbert Schmidt, Technical Officer, Technical Standards and Norms Team, WHO
12:45-14:15	Headquarters, with the participation of TBD
	Lunch will be available outside the meeting room for those participating
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Registration a	nd Marketing Authorization
14:00-14:15	Collaborative procedures: A brief introduction
	Dr Samvel Azatyan, Group Lead, Regulatory Networks and Harmonization, Regulatory Systems
	Strengthening, WHO Headquarters
14:15-15:00	Collaborative procedures: Best practices and remaining hurdles
	Moderated panel discussion (including Q&A)
	Regulators from Thailand, Zambia and Ukraine, and representatives of the European Medicines
	Agency (EMA) (Dr Agnès Saint-Raymond), the International Federation of Pharmaceutical
	Manufacturers and Associations (IFPMA) (Stephanie McGauley, Pfizer Global Brands (UK),
	International Generic and Biosimilar medicines Association (Imtiyaz Basade, Mylan Laboratories,
	India) and WHO (Dr Samvel Azatyan)
	Moderated by: Dr Petra Doerr, Petra Doerr Consulting Ltd.
15:00-15:30	Coffee/tea break







Market Survei	Market Surveillance	
15:30-15:35	Introduction	
	TBD, Uppsala Monitoring Centre	
15:35-16:00	Pharmacovigilance systems and procedures: the manufacturer's role and responsibilities	
	Dr Shanthi Pal, Group Lead: Medicines Safety and Vigilance, WHO Headquarters	
16:00-16:20	Where are we in the fight against substandard and falsified medical products?	
	Pernette Bourdillon Esteve, Analyst, Safety and Vigilance Team, WHO Headquarters	
16:20-16:30	Q&A	
	Chaired by TBD , Uppsala Monitoring Centre	
16:30-17:30	The "sartan case": lessons learnt for regulators and manufacturers	
	Brief introduction (what has happened and why)	
	Dr Susanne Keitel, Director, European Directorate for the Quality of Medicines (EDQM)	
	Moderated panel discussion	
	With the participation of: EDQM (Dr Susanne Keitel); the European Heart Network (Marilena	
	Vrana), EMA (Dr Agnès Saint-Raymond); IFPMA (Sylvia Meillerais, MSD Europe); Medicines for	
	Europe (TBD , TEVA Europe) and WHO (Dr Sabine Kopp).	
	Moderated by: Dr Petra Doerr, Petra Doerr Consulting Ltd.	
OFFICIAL MEE	TING CLOSURE	
17:30-17:45	Meeting highlights and recommendations	
17.50 17.15	TBD	
DAY 4	THURSDAY, 5 DECEMBER	
1-TO-1 MEETII	NGS WITH HOST AND 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 Pan American Health Organization contact Martha Suazo (suazomar@paho.org)
- for Global Drug Facility contact Kaspars Lunte (kasparsl@stoptb.org)
- for Global Fund contact Amelie Darmon (amelie.darmon@theglobalfund.org) for pharmaceuticals and René Becker-Burgos (rene.becker-burgos@theglobalfund.org) for diagnostic products
- for **UNDP** contact Zafar Yuldashev (zafar.yuldashev@undp.org)
- for UNFPA contact both Minna Soikkeli (soikkeli@unfpa.org) and Ashley Moyo (asmoyo@unfpa.org)
- for UNICEF contact Charlotte Armand Nielsen (canielsen@unicef.org)
- for WHO procurement contact Sophie Laroche (laroches@who.int) or, for medicines for neglected tropical diseases specifically, Hye Lynn Choi (hchoi@who.int).
- Charles Chiku for in vitro diagnostics assessment/inspection/performance evaluation for WHO prequalification — chikuc@who.int
- Matthias Stahl stahlm@who.int for medicines assessment for WHO prequalification
- Vimal Sachdeva <u>sachdevav@who.int</u> for **medicines inspection** for WHO prequalification
- Carmen Rodriguez-Hernandez rodriguezhernandezc@who.int for vaccines assessment or inspection for WHO prequalification
- Seloi Mogatle mogatle@unfpa.org for assessment or inspection of contraceptive devices for WHO/UNFPA prequalification
- Dominic Schuler schulerd@who.int for vector control product assessment or inspection for WHO prequalification
- Gaby Vercauteren <u>vercautereng@who.int</u> for technical assistance for IVD manufacturers







- ${\sf Rutendo\ Kuwana} \underline{{\sf kuwanaru@who.int}} {\sf for\ technical\ assistance\ for\ medicines\ manufacturers}$
- $\bullet \quad \text{Luther Gwaza} \underline{\text{gwazal@who.int}} \text{for collaborative registration}.$