unicef | for every child

UNFPA

World Health Organization

JOINT UNICEF – UNFPA – WHO MEETING WITH MANUFACTURERS AND SUPPLIERS

"Working together to improve access to health products during pandemics, a case for COVID-19"

DAY 1	Monday, 30 November 2020	
Opening	**Meeting Opening**	
12:00 – 12:30	**Session chair: Deus Mubangizi (WHO)**	
	Welcome from meeting host agencies	**UNICEF**: Hanne Bak Pedersen (Deputy Director, Supply Programme, Supply Division) **UNFPA**: Eric Dupont (Chief, Procurement Services Branch) **WHO**: Mariângela Simão (Assistant Director-General, Access to Medicines and Health Products)
	Meeting overview	Deus Mubangizi (WHO)
	Keynote speech — *Partnership actions needed to bring tools against COVID-19 to those in need*	Sir Andrew Witty (ACT-accelerator ambassador, former GSK CEO)
Session 1	**Access to COVID-19 Health Products**	
12:30 – 14:15	**Session chair: Mariângela Simão (WHO)**	
	ACT-accelerator overview — *update on the three products pillars, including medical devices, oxygen and PPE*	Bruce Aylward (WHO)
	Prequalification (PQ) and Emergency Use Listing (EUL) of health products — *update on the PQ and EUL procedures and collaboration with National Regulatory Agencies (NRAs)*	Deus Mubangizi (WHO)
	Manufacturers perspectives	**IFPMA**: John Mwangi (Bayer) **IGBA**: Suzette Kox (Secretariat) **DCVMN**: Sonia Pagliusi (Secretariat) or Nora Dellepiane (Consultant) **AdvaMed/MedTech Europe**: TBC
	Procurers perspectives	**UNICEF**: TBC **WHO**: TBC
	Q&A	
Session 2	**WHO Policy, Diagnosis & Treatment Guidelines Updates**	
14:15 – 16:00	**Session chair: Clive Ondari (WHO)**	
	WHO diagnosis and treatment guidelines updates — *upcoming updates and guidance on access and substitution during COVID-19 related restrictions*	
	◆ TB diagnosis & treatment guidelines update	Matteo Zignol (WHO)
	◆ HIV and STI diagnosis & treatment guidelines update	Marco Vitoria (WHO)
	◆ Hepatitis B and C diagnosis & treatment guidelines update	Philippa Easterbook (WHO)
	◆ Malaria diagnosis & treatment guidelines update	Peter Olumese (WHO)
	◆ Non-communicable diseases diagnosis & treatment guideline update	Andre Ilbawi (WHO) & Gojka Roglic (WHO)
	— *Q&A*	
	WHO model list updates	
	◆ The 3rd WHO model list of essential in vitro diagnostics & priority medical devices and PPE for COVID-19	Adriana Velazquez Berumen (WHO)
	◆ The 21st WHO model list of essential medicines	Bernadette Cappello (WHO)
	— *Q&A*	

unicef | for every child

UNFPA

World Health Organization

JOINT UNICEF – UNFPA – WHO MEETING WITH MANUFACTURERS AND SUPPLIERS

"Working together to improve access to health products during pandemics, a case for COVID-19"

DAY 2	Tuesday, 1 December 2020	
Parallel Session 3.1	**WHO Prequalification Update – In Vitro Diagnostics**	
12:00 – 14:00	**Session chair: Irena Prat (WHO/PQT)**	
	Introduction to IVD update **Dossier assessment** **Performance evaluation** **Technical guidance and specifications** **Changes** **Q&A**	Helena Ardura, Susie Braniff, Charles Chiku, Mark Lanigan, Anne-Laure Page & Ute Ströher (WHO/PQT)
Parallel Session 3.2	**WHO Prequalification Update – Medicines**	
12:00 – 14:30	**Session chair: Matthias Stahl (WHO/PQT)**	
	Introduction to medicines assessment update	Matthias Stahl (WHO/PQT)
	Quality	Lynda Paleshnuik (WHO/PQT)
	Bioequivalence	John Gordon (WHO/PQT)
	Active pharmaceutical ingredients	Isabelle Ortega (WHO/PQT)
	Update on WHO public assessment reports	Regine Lehnert (WHO/PQT)
	Biosimilar products pilot	Guido Pantè (WHO/PQT)
	Q&A	
Parallel Session 3.3	**WHO Prequalification Update – Vaccines & Immunization Devices**	
12:00 – 14:00	**Session chair: Olivier Lapujade (WHO/PQT)**	
	WHO vaccines prequalification overview	Olivier Lapujade (WHO/PQT)
	Vaccine assessment *— CMC (chemistry, manufacturing and control) and quality and clinical data*	Rolando Dominguez Morales & Olivier Lapujade (WHO/PQT)
	Vaccines testing *— Initial evaluation for prequalification and post-prequalification monitoring*	TBC (WHO/PQT)
	Post-prequalification	Rolando Dominguez Morales (WHO/PQT)
	Prequalification of immunization equipment: implications for vaccines	Isaac Gobina (WHO/PQT)
	Q&A	
Parallel Session 3.4	**WHO Prequalification Update – Vector Control Products**	
12:00 – 14:00	**Session chair: Marion Law (WHO/PQT)**	
	Introduction *— Beyond 5 Years: establishing PQ-VCP and moving into future*	
	Transition & continuation of WHO mandate to evaluate vector control products **Building an appropriate infrastructure and stakeholder base to support the new evaluation process** **Establishing a programme for the future** **Q&A**	Marion Law & Dominic Schuler (WHO/PQT)

JOINT UNICEF – UNFPA – WHO MEETING WITH MANUFACTURERS AND SUPPLIERS

"Working together to improve access to health products during pandemics, a case for COVID-19"

Parallel Session 3.5	**WHO Prequalification Update – Inspections**	
12:00 – 14:00	**Session chair: Joey Gouws (WHO/PQT)**	
	Update on activities of inspections including quality guidelines expectation	Dimitrios Catsoulacos, Stephanie Croft, Joey Gouws & Vimal Sachdeva (WHO/PQT)
	Inspections: business continuity plan	
	Inspections in emergency situations – tools to use	
	GMP expectations at antimicrobial manufacturing sites	
	Closing remarks	
Parallel Session 3.6	**UNFPA Prequalification Update – Contraceptive Devices**	
12:00 – 14:30	**Session chair: Seloi Mogatle (UNFPA)**	
	UNFPA prequalification programme update	Ashley Moyo (UNFPA)
	Remote inspections	Bill Potter
	Partnerships - Eco-friendly condom packaging	Sivakumar Kamakshinatha
	Quality monitoring strategies	Bill Potter
	Manufacturers feedback	Manufacturer representative (TBC)
	Q&A	
Session 4	**WHO Collaborative Registration Procedure Update**	
15:00 – 16:00	**Session chair: Murray Lumpkin (BMGF)**	
	Introductory presentation	Samvel Azatyan (WHO/REG)
	Panel discussion	
	◆ Africa Medical Devices Forum	Paulyne Wairimu (AMDF)
	◆ CDSCO India	Representative TBC (CDSCO India)
	◆ International Federation of Pharmaceutical Manufacturers and Associations	Angelika Joos (Merck)
	◆ MedTech Europe	Jesus Rueda Rodriguez (MedTech Europe)
	◆ National Reguatory Agencies	NRA representatives TBC

JOINT UNICEF – UNFPA – WHO MEETING WITH MANUFACTURERS AND SUPPLIERS

"Working together to improve access to health products during pandemics, a case for COVID-19"

DAY 3	Wednesday, 2 December 2020	
Session 5	**WHO Local Production & Assistance**	
12:00 – 13:00	**Session chair: Jicui Dong (WHO/LPA)**	
	Introduction **Leveraging and cultivating enabling factors for local production** **Strategies toward WHO Prequalification** **Technical assistance for IVD manufacturers** **Technical assistance for medicines manufacturers** **Q&A**	Fasika Alemu, Egan Cobbold, Jicui Dong & David Woo (WHO/LPA)
Parallel Session 6.1	**WHO Regulatory Updates**	
13:00 – 15:00	**Session chair: Petra Doerr (WHO/REG)**	
	Welcome & introduction	Petra Doerr (WHO/REG)
	Promoting and enhancing the use of reliance	
	◆ Good Regulatory Practices and regulatory flexibilities/agility	Petra Doerr (WHO/REG)
	◆ Good Reliance Practices and examples in	Samvel Azatyan (WHO/REG)
	◆ The WHO Listed Authorities: framework and ongoing work	Hiiti Sillo (WHO/REG)
	Hot topics	
	◆ Reporting of adverse events and incidents for products purchased by UN organizations through tenders	Anita Sands & Hiiti Sillo (WHO/REG)
	◆ Post-market and market surveillance of medical devices,	Anita Sands (WHO/REG)
	Q&A	
Parallel Session 6.2	**Procurement Overview**	
13:00 – 15:00	**Session chair: Francisco Blanco (UNICEF)**	
	Overview on procurement and market strategies for key products, forecasting/quantified need, tenders, available funding 2021-2022 and beyond	
	◆ Intro to session	Francisco Blanco (UNICEF)
	◆ UNFPA — Procurement at UNFPA: contraceptives, priority maternal health products and other RH medical products	Roberto Mena (UNFPA)
	◆ UNDP Procurement update	Zafar Yuldashev (UNDP)
	◆ WHO Procurement update	Sophie Laroche (WHO Procurement)
	◆ UNICEF — Market overview for key essential medicines for children, Bed nets, In Vitro Diagnostics and vaccines	Joyce Bakka (UNICEF)
	◆ Global Drug Facility 2020 update	Magali Babaley (GDF)
	◆ Global Fund Procurement update	TBC (Global Fund)
	◆ PAHO — Sustaining Health Access in the Americas during	Jordi Balleste Orpinell (PAHO)
	Plenary discussions & closing remarks	Fransisco Blanco (UNICEF)