Where the World is Going and What We Should do Next

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

24–27 September 2018, UN City, Copenhagen, Denmark

DAY 1	**24 September**
07:30–08:45	**MEETING REGISTRATION: ENTRANCE TO UN CITY**
08:45–09:00	**Meeting opening and overview** Etleva Kadilli (Director, UNICEF Supply Division), Eric Dupont (Chief, Procurement Services Branch, UNFPA) & Emer Cooke (Head, Regulation of Medicines and other Health Technologies, WHO)
09:00–09:05	**Administrative / security arrangements** Jesper Palm Lundorf, UN Office of the Designated Official for Security
09:05–09:20	**Keynote address: Where the world is going and what we should do next** *Dr Laurel Sprague, Chief, Community Mobilization, Community Support, Social Justice and Inclusion at UNAIDS*
09:20–09:30	**Overview of the day's themes and introduction to "New realities" theme** *Joel Schaefer, Communication Officer, Office of WHO Director-General*
Theme 1	**New realities**
09:30–09:55	Predictive modelling for new priorities (outbreaks/emergencies, vector control) and known priority disease states (HIV, malaria, TB) *Dr Jonna Mazet, Director of the One Health Institute in the University of California, Davis School of Veterinary Medicine & Principal Investigator and Global Director of the viral emergence early warning project (PREDICT), with USAID's Emerging Pandemic Threats Program*
09:55–10:15	The first WHO Essential Diagnostics List: what it means for manufacturers and procurers *Dr Sarah Garner, Coordinator, Innovation, Access and Use, Department of Essential Medicines and Health Products, WHO*
10:15–10:45	**Coffee / tea break**
Theme 1	**New realities (continued)**
10:45–10:50	Introduction to Theme 1, part 2 *Joel Schaefer, Communication Officer, Office of WHO Director-General*
10:50–11:05	The shifting reproductive health medicines landscape *John Skibiak, Director, Reproductive Health Supplies Coalition (RHSC)*
11:05–11:20	…the innovator view *Dr Klaus Brill, ex-Vice President of Global HealthCare Programs at Bayer AG in Berlin & manufacturers' representative on the RHSC Executive Committee*
11:20–11:35	…the generic view *Lester Chinery, Director of Programmes, Concept Foundation*

Theme 2	**Emergency preparedness**
11:35–11:40	Introduction to Theme 2 *Joel Schaefer, Communication Officer, Office of WHO Director-General*
11:40–11:55	Working with WHO to bring an Ebola vaccine where needed *Dr Jules Millogo, Director, Public Health Partnerships, Global Vaccines, Merck*
11:55–12:10	Working with countries to facilitate authorization of clinical trials in the African region *Delese Mimi Darko, Chair, Steering Committee, AVAREF (African Vaccine Regulatory Forum) and CEO of Food and Drugs Authority, Ghana*
12:10–12:30	WHO support for regulatory preparedness for public health emergencies *Carmen Rodriguez Hernandez, Group Lead, Vaccines Assessment, WHO Prequalification Team*
12:30–13:00	**Panel discussion around Themes 1 and 2** *Moderated by Joel Schaefer, Communication Officer, Office of WHO Director-General*
13:00–14:00	**Sandwich lunch**
Theme 3	**New market needs**
14:00–14:05	Introduction to Theme 3 *Joel Schaefer, Communication Officer, Office of WHO Director-General*
14:05–14:25	HPV vaccine supply *Tania Cernuschi, Manager, Expanded Programme on Immunization Plus, WHO*
14:25–14:45	Country perspectives: HPV diagnostics procurement *Dr Teymur Seyidov, Sexual and Reproductive Health Programme Specialist, UNFPA*
14:45–15:10	Critical success factors for diagnostics companies competing in low- and middle-income markets *Dr Mickey Urdea, Founding Partner, Halteres Associates*
15:10–15:30	Expanded mandate: Medicines Patent Pool for essential medicines *Esteban Burrone, Head of Policy, Medicines Patent Pool*
15:30–16:00	**Coffee / tea break**
16:00–16:30	Cutting premature mortality from cancer, cardiovascular diseases and diabetes *Dr Sarah Garner, Coordinator, Innovation, Access and Use, Department of Essential Medicines and Health Products, WHO*
16:30–17:00	Vector control: never has the pipeline been so rich, but…. *Dr Nick Hamon, CEO, Innovative Vector Control Consortium*
17:00–17:30	**Panel discussion** *Moderated by Joel Schaefer, Communication Officer, Office of WHO Director-General*
17:30–17:40	**Wrap-up** *By Joel Schaefer*
17:40–19:00	**Reception for all participants**

DAY 2	25 September
Coffee / tea breaks are scheduled for 11:00–11:30 and 15:30–16:00. A sandwich lunch is scheduled for 13:00–14:00.	
Procurement track	
08:30–08:45	Introduction to procurement updates *Abdallah Makhlof, Chief, Health Technnology Centre, UNICEF Supply Division*
08:45–09:15	UNICEF procurement update *Dr Atieno Ojoo, Team Lead, Technical Unit, Medicines and Nutrition Centre, UNICEF Supply Division*
09:15–09:30	Q&A
09:30–10:00	Global Fund's quality assurance policy *Dr Amélie Darmon, Quality Assurance Associate Specialist*
10:00–10:15	Q&A
10:15–10:45	Global Drug Facility procurement update *Dr Magali Babaley, Strategic Procurement and Business Intelligence Manager, Global Drug Facility*
10:45–11:00	Q&A
11:30–12:00	UNFPA procurement update *Roberto Mena, Procurement Specialist*
12:00–12:15	Q&A
12:15–12:45	WHO procurement update: quality assurance policy for procurement and selection of wholesale distributors *Sophie Laroche, Quality Officer, WHO Procurement*
12:45–13:00	Q&A
14:00–14:30	Pan American Health Organization procurement update *Adriana Oxman, Procurement Specialist (PAHO Revolving Fund) & Marcos Chaparro, Procurement Specialist (PAHO Strategic Fund)*
14:30–14:45	Q&A
14:45–15:15	UNDP Procurement update *Dr Cécile Macé, Senior Health PSM Advisor, UNDP*
15:15–15:30	Q&A
WHO treatment guidelines updates	
16:00–17:30	Upcoming changes to WHO TB Treatment Guidelines *Presented by Dr Dennis Falzon, WHO Global TB Programme and moderated by Dr Kaspars Lunte, Global Drug Facility*
16:00–17:30	Accelerated introduction of HPV screening and treatment for elimination of cervical cancer *Led by Dr Hugo de Vuyst, International Agency for Research on Cancer and WHO Department of Reproductive Health and Research, with the participation of Dr Ricky Lu, Director of Family Planning and Reproductive Health, and Cervical Cancer Prevention Programs, Jhpiego, Dr Mauricio Maza, Basic Health International and Kate Hencher, Programme Manager, Unitaid*

WHO prequalification: biosimilars track	
16:15–16:45	*Update on pilot prequalification of biosimilars for cancer treatment* *Guido Pantè, WHO consultant*
16:45–17:00	*Q&A* *Chaired by Deus Mubangizi, Coordinator, WHO Prequalification Team*
WHO prequalification: in vitro diagnostics (IVD) track	
08:45–09:00	Introduction to assessment update *Irena Prat, Group Lead, IVD Assessment*
09:00–09:45	Update on dossier assessments and performance evaluations *Dr Mark Lanigan, Technical Officer, IVD Assessment* *Dr Willy Urassa, Scientist, IVD Assessment* *Mercedes Pérez González, Technical Officer, IVD Assessment* *Helena Ardura, Technical Officer, IVD Assessment*
09:45–10:00	Q&A *Chaired by Irena Prat, Group Lead, IVD Assessment*
10:00–10:45	New guidance & technical specifications *Dr Ute Ströher, Technical Officer, IVD Assessment*
10:45–11:00	*Q&A* *Chaired by Irena Prat, Group Lead, IVD Assessment*
11:30–12:00	Alternative evaluation pathway *Dr Willy Urassa, Scientist, IVD Assessment* *Mercedes Pérez González, Technical Officer, IVD Assessment*
12:00–12:15	Q&A *Chaired by Irena Prat, Group Lead, IVD Assessment*
12:15–12:45	Stability studies for in vitro diagnostics *Dr Mark Lanigan, Technical Officer, IVD Assessment*
12:45–13:00	Q&A *Chaired by Irena Prat, Group Lead, IVD Assessment*
14:00–14:15	Introduction to IVD inspection update *Dr Joey Gouws, Group Lead, Inspection Services*
14:15–15:00	Inspection technical update *Dr Dragana Milic, Technical Officer, Inspection Services*
15:00–15:30	Q&A *Chaired by Dr Dragana Milic, Technical Officer, Inspection Services*
16:00–16:20	Inspection compliance criteria *Dr Dragana Milic, Technical Officer, Inspection Services*
16:20–16:30	Q&A *Chaired by Dr Joey Gouws, Group Lead, Inspection Services*

WHO prequalification: medicines track	
08:45–09:00	Introduction to medicines assessment update *Dr Matthias Stahl, Group Lead, Medicines Assessment*
09:00–10:20	Quality *Dr Lynda Paleshnuik, Lead Quality Assessor, Medicines Assessment* Bioequivalence *Dr John Gordon, Lead Bioequivalence Assessor, Medicines Assessment* Active pharmaceutical ingredients *Dr Antony Fake, API Assessment Focal Point, Medicines Assessment* Update on WHO Public Assessment Reports *Dr Regine Lehnert, Clinical Assessor, Medicines Assessment*
10:20–11:00	Q&A *Chaired by Dr Matthias Stahl, Group Lead, Medicines Assessment*
11:30–11:45	Introduction to medicines inspection update *Dr Joey Gouws, Head, Inspection Services*
11:45–12:30	Inspection technical update (covering finished pharmaceutical products, active pharmaceutical ingredients and contract research organizations) *Vimal Sachdeva, Technical Officer, Inspection Services*
12:30–13:00	Q&A *Chaired by Dr Joey Gouws, Head, Inspection Services*
14:00–14:30	Sponsors' responsibilities for clinical trials *Elham Kossary, Technical Officer, Inspection Services*
14:30–14:45	Q&A *Chaired by Vimal Sachdeva*
WHO prequalification: vaccines track	
08:30–08:45	Introduction to assessment update and vaccines assessment overview *Carmen Rodriguez-Hernandez, Group Lead, Vaccines Assessment*
08:45–09:15	Programmatic suitability *Dr Drew Meek, Technical Officer, Vaccines Assessment*
09:15–09:30	Q&A *Mustapha Chafai, Technical Officer, Inspection Services*
09:30–09:45	Introduction to vaccines inspection update *Dr Joey Gouws, Group Lead, Inspection Services*
09:45–10:15	Inspection technical update *Mustapha Chafai, Technical Officer, Inspection Services*
10:15–10:30	Q&A *Chaired by Carmen Rodriguez-Hernandez, Group Lead, Vaccines Assessment*
11:30–12:00	Common technical document survey results *Dr Alain Fauconnier, Scientist, Vaccines Assessment*
12:00–12:15	Q&A *Chaired by Carmen Rodriguez-Hernandez, Group Lead, Vaccines Assessment*
12:15–12:45	Controlled temperature chain *Dr Drew Meek, Scientist, Vaccines Assessment*
12:45–13:00	Q&A *Chaired by Carmen Rodriguez-Hernandez, Group Lead, Vaccines Assessment*

14:00–14:30	Post-prequalification *Carmen Rodriguez-Hernandez, Group Lead, Vaccines Assessment*
14:30–14:45	Q&A *Chaired by Mustapha Chafai, Technical Officer, Inspection Services*
WHO prequalification: vector control	
09:00–09:15	Introduction and overview *Mark Kays, Interclarity Research & Consulting, Inc.*
09:15–09:45	Overview and progress update *Marion Law, Vector Control Prequalification Group Lead*
09:45–10:15	A company perspective on working with WHO prequalification *Melinda Hadi, Trials Manager, Vestergaard*
10:15–10:45	Q&A *Chaired by Mark Kays, Interclarity Research & Consulting, Inc.*
11:30–11:45	Introduction to the quality "workshop *Dominic Schuler, Technical Officer, Vector Control Prequalification*
11:45–12:05	…chemistry *Dr Luis Pérez-Albela, Scientist, Vector Control Prequalification*
12:05–12:20	Q&A *Chaired by Mark Kays, Interclarity Research & Consulting, Inc.*
12:20–12:40	…safety *Dr Jess Rowland, Assessor, Vector Control Prequalification*
12:40–13:00	Q&A *Chaired by Mark Kays, Interclarity Research & Consulting, Inc.*
14:00–14:20	…efficacy *Dr Charles Wondji, Assessor, Vector Control Prequalification*
14:20–14:35	Q&A *Chaired by Mark Kays, Interclarity Research & Consulting, Inc.*
14:35–15:55	…inspection *Dr Joey Gouws, Group Lead, Inspection Services*
15:55–15:30	Q&A *Chaired by Mark Kays, Interclarity Research & Consulting, Inc.*
16:00–16:20	…documentation *Dominic Schuler, Technical Officer, Vector Control Prequalification*
16:20–16:40	Q&A *Chaired by Mark Kays, Interclarity Research & Consulting, Inc.*
16:40–17:00	…decision-making *Marion Law, Vector Control Prequalification Group Lead*
17:00–17:15	Q&A *Chaired by Mark Kays, Interclarity Research & Consulting, Inc.*
17:15–17:30	Wrap-up *Mark Kays, Interclarity Research & Consulting, Inc. & Marion Law, Marion Law, Vector Control Prequalification Group Lead*

Technical assistance for manufacturers track	
10:00–10:15	Introduction to technical assistance for IVD manufacturers *Dr Luther Gwaza, Technical Officer, WHO Regulatory Systems Strengthening*
10:15–10:45	Technical assistance for IVD manufacturers *Dr Gaby Vercauteren, Senior Adviser, WHO Regulatory Systems Strengthening*
10:45–11:00	Q&A *Chaired by Dr Luther Gwaza, Technical Officer, WHO Regulatory Systems Strengthening*
11:30–11:45	Introduction to technical assistance for medicines manufacturers *Dr Luther Gwaza, Technical Officer, WHO Regulatory Systems Strengthening*
11:45–12:15	Technical assistance for medicines manufacturers *Rutendo Kuwana, Regulatory Systems Strengthening*
12:15–12:45	Q&A *Chaired by Dr Luther Gwaza, Technical Officer, WHO Regulatory Systems Strengthening*
Break-out sessions	
14:45–15:30	Access to quality-assured medicines for maternal and child health: focus on uterotonics *Led by Deus Mubangizi, Coordinator, WHO Prequalification Team and with the participation of Lester Chinery, Director of Programmes, Concept Foundation and Seloi Mogatli, Technical Specialist, Procurement Services, UNFPA.*
15:30–16:15	Benzathine benzyl penicillin: securing continued supply to address essential needs for treatment of rheumatic heart disease and syphilis *Led by Dr Melanie Taylor, Medical Officer, WHO Department of Reproductive Health and Research, Sexually-transmitted Infections Programme* *Exceptionally, this session runs during the afternoon coffee/tea break but, for those attending, these will be available outside the room where the session is held.*
16:15–17:15	Open discussion on diagnostics company success criteria *Led by Dr Mickey Urdea, Founding Partner, Halteres Associates*
1-to-1 meetings	
Time permitting	UNDP, UNICEF, Global Fund, Global Drug Facility, UNFPA, Pan American Health Organization, WHO procurement, PQT assessment and inspection and vector control groups, and WHO technical assistance and collaborative procedure groups.

DAY 3	**26 September**
Regulatory forum for manufacturers	
08:30–08:45	Introduction *Dr Mariângela Simão, Assistant Director-General, Medicines, Vaccines and Pharmaceuticals, WHO*
08:45–09:05	WHO-listed Authorities: promoting timely access and reliance *Mike Ward, Coordinator, Regulatory Systems and Strengthening Team, Regulation of Medicines and other Health Technologies, WHO*
09:05–09:30	Q&A *Chaired by Emer Cooke, Head, Regulation of Medicines and other Health Technologies*
09:30–10:10	Why perform abridged assessment for prequalification? *Introduction: Dr Luther Gwaza* In vitro diagnostics (IVD) abridged assessment *Irena Prat, Group Lead, IVD Assessment* Medicines abridged assessment *Dr Theo Dekker, Senior Quality Assessor, Medicines Assessment* Vaccines abridged assessment *Carmen Rodriguez-Hernandez, Group Lead, Vaccines Assessment*
10:10–10:30	Q&A *Chaired by Deus Mubangizi, Coordinator, WHO Prequalification Team*
10:30–11:00	Collaborative Procedure for IVDs, medicines and vaccines: update *Dr Luther Gwaza, Technical Officer, Regulatory Systems and Strengthening Team, Regulation of Medicines and other Health Technologies, WHO*
11:00–11:15	Q&A *Chaired by Deus Mubangizi, Coordinator, WHO Prequalification Team*
11:15–11:45	**Coffee / tea break**
WHO prequalification feedback forum	
11:45–12:45	Introduced and moderated by Mark Kays, Interclarity Research & Consulting, Inc.
Official meeting closure	
12:45–13:00	Meeting highlights and recommendations *Dr Mariângela Simão, Assistant Director-General, Medicines, Vaccines and Pharmaceuticals, WHO*
Continuation of 1-to-1 meetings	
13:00 onwards	UNICEF, Global Fund, Global Drug Facility, UNFPA, Pan American Health Organization, PQT assessment and inspection and vector control groups, and WHO technical assistance and collaborative procedure groups according to time permitting.
DAY 4	**27 September**
Continuation of 1-to-1 meetings	
All day	UNDP, UNICEF, Global Fund, Global Drug Facility, UNFPA, Pan American Health Organization, PQT assessment and inspection and vector control groups, and WHO technical assistance and collaborative procedure groups according to time permitting.