DRAFT AGENDA

JOINT UNICEF, UNFPA & WHO MEETING WITH MANUFACTURERS AND SUPPLIERS OF CONTRACEPTIVE DEVICES, IN VITRO DIAGNOSTIC PRODUCTS, VACCINES, FINISHED PHARMACEUTICAL PRODUCTS, ACTIVE PHARMACEUTICAL INGREDIENTS AND VECTOR CONTROL PRODUCTS

18–21 SEPTEMBER 2017, UN City Copenhagen, Marmorvej 51, 2100 Copenhagen, Denmark

Manufacturers who have requested an individual meeting with UNICEF (WHO), UNFPA or the Global Drug Facility should have been informed of the date and location of their meeting by the relevant contact persons indicated below. Manufacturers and suppliers are encouraged to attend the WHO prequalification update sessions ahead of individual meetings with UNICEF, UNFPA (WHO) or Global Drug Facility staff since these will provide information on meeting quality assurance requirements, as well as on the requirements themselves.

A welcome breakfast will be offered on Monday, 18 September, and lunch on Monday, Tuesday, and Wednesday, 18, 19 and 20 September. On Thursday, 21 September lunch can be purchased at the UN City cafeteria.

MONDAY, 18 SEPTEMBER	**Day 1**
07:30 – 09:00	**MEETING REGISTRATION: ENTRANCE TO UN CITY**
SESSION 1 IN AUDITORIUM I, II & III merged: OPENING OF MEETING	
08:45 – 09:00	**Welcome address —** Given by: Emer Cooke, Head, Regulation of Medicines and other Health Technologies (WHO), Suvi Rautio, Deputy Director, Supply Programme **(UNICEF)**;Eric Dupont, Chief, Procurement Services Branch (UNFPA)
09:00 – 09:10	**Administrative/security arrangements —** Given by: Jesper Palm Lundorf **(UN Office of the Designated Official for Security)**
09:10 – 09:20	**Introduction to meeting app —** Mercedes Pérez González **(WHO)**
SESSION 2 IN AUDITORIUM I, II & III merged: A REVIEW OF THE MARKETS FOR QUALITY-ASSURED PRODUCTS	
09:30 – 09:40	**Session introduction —** Given by: Raffaella Ravinetto **(Institute of Tropical Medicine Antwerp)**
09:40 – 10:40	**Markets for quality-assured products** **Given by:** Sarah Garner **(WHO)**
10:40 – 11:10	**Panel discussion:** Sarah Garner **(WHO),** Brian Kaiser **(Global Drug Facility)**, Sophie Logez **(Global Fund)**, Roberto Mena **(UNFPA)**, Vincent Bretin **(UNITAID)** **Chaired by:** Raffaella Ravinetto
11:10 – 11:40	**Coffee/tea break: Lounge area 9**
11:40 – 12:30	**Managing vaccines supplies and eliminating shortages** Review of supply and price issues **Given by:** Oleg Benes **(WHO)** and Tania Cernuschi **(WHO)**
12:30 – 13:00	**Panel discussion:** Oleg Benes **(WHO)**, Tania Cernuschi **(WHO),** Fumie Griego **(IFPMA),** Philipp Kalpaxis **(UNICEF),** Carmen Rodriguez-Hernandez **(WHO)** **Chaired by:** Raffaella Ravinetto
13:00 – 14:00	**Lunch: Lounge area 9**
SESSION 3 IN AUDITORIUM I, II & III merged: HOW MANUFACTURERS CAN ASSESS THE VALUE OF QUALITY-ASSURED PRODUCTS	
14:00 – 14:10	**Session introduction — Given by:** Jude Nwokike **(United States Pharmacopeia)**
14:10 – 15:00	**Going beyond price: impact and value analysis of quality-assured generic medicines** **Given by:** Deus Mubangizi **(WHO)**
15:00 – 15:30	**Panel discussion:** Deus Mubangizi **(WHO),** Harald Rinde **(BioBridge Strategies)**, Kaspars Lunte **(Global Drug Facility)**, Sophie Logez **(Global Fund)**, Roberto Mena **(UNFPA)**, Atieno Ojoo **(UNICEF)** **Chaired by:** Jude Nwokike **(Unites States Pharmacopeia)**
15:30 – 16:00	**Coffee/tea break: Lounge area 9**
16:00 – 16:45	**Stimulating introduction of new, innovative in vitro diagnostics** **Given by:** Theodor Visser **(Clinton Health Access Initiative)** & Gonzalo Domingo **(PATH)**
16:45 – 17:15	**Panel discussion:** Walter Zhang **(Shanghai ZJ Bio-Tech Co., Ltd.)**, Nagwa Hasanin **(UNICEF)**, Robyn Meurant **(WHO)**, Melanie Taylor **(WHO),** Harald Rinde **(BioBridge Strategies)** **Chaired by:** Jessica Jones **(Bill & Melinda Gates Foundation)**
17:15 – 18:30	**RECEPTION FOR ALL PARTICIPANTS: Lounge area 9**

TUESDAY, 19 SEPTEMBER — **Day 2**

SESSION 4: PROCUREMENT UPDATES ■ IVD PREQUALIFICATION FOR NEW APPLICANTS ■ INTRODUCTION TO VECTOR CONTROL PREQUALIFICATION

	Procurement updates AUDITORIUM III	WHO in vitro diagnostic prequalification for new applicants and post-marketing surveillance AUDITORIUM II	Introducing WHO vector control prequalification AUDITORIUM I	UNFPA / WHO contraceptive devices prequalification PRESS ROOM
08:30–08:45	**Introduction** **Given by:** Akthem Fourati (UNICEF)			
08:45–09:00				
09:00–09:15	**Pan American Health Organization (PAHO) update** **Given by:** Gabriel Rangel	**Introduced by:** Robyn Meurant (WHO)	**Introduced by:** Deus Mubangizi (WHO)	**Introduction to contraceptive devices technical updates** **Given by:** Munish Meherotra (Population Services International)
09:15 – 09:45	**UNICEF update** **Given by:** Akthem Fourati	**Given by:** Helena Ardura, Mercedes Peréz González & Anita Sands (WHO)	**Given by:** Marion Law (WHO)	**Contraceptive devices prequalification technical updates** **Given by:** John Gerofi, David Hill, Seloi Mogatle, William Potter & Thinlay Nono Wangchuk (UNFPA)
09:45 – 10:15	**The Global Fund update** **Given by:** Sophie Logez	**Q&A** **Chaired by:** Robyn Meurant (WHO)	**Q&A** **Chaired by:** Dominic Schuler (WHO)	
10:15 – 10:30	**Q&A** **Chaired by:** TBD			**Q&A** **Chaired by:** Munish Meherotra (Population Services International)
10:30 – 11:00	**Coffee/tea break: Lounge area 9**			

SESSION 5: PROCUREMENT UPDATES ■ INTRODUCTION TO VACCINES PREQUALIFICATION FOR NEW APPLICANTS ■ WHO/UNFPA PREQUALIFICATION TECHNICAL UPDATES BY PRODUCT TRACK ■ INTRODUCTION TO WHO PILOT PREQUALIFICATION OF BIOSIMILARS FOR CANCER TREATMENT

	Procurement updates continued AUDITORIUM III	In vitro diagnostics assessment for WHO prequalification AUDITORIUM I	Medicines assessment for WHO prequalification AUDITORIUM II	WHO vaccines prequalification for new & existing applicants & a technical update PRESS ROOM	Pilot project for WHO prequalification of biosimilars for cancer treatment ROOM 0.1.11
11:00 – 11:15	**Introduction to WHO procurement** **Given by:** Sophie Laroche	**Update on dossier assessments and performance evaluations** **Given by:** Robyn Meurant & Mercedes Peréz González(WHO)	**Introduction** **Given by:** Matthias Stahl (WHO)	**Vaccines assessment overview** **Given by:** Carmen Rodriguez-Hernandez (WHO)	**Introduction by:** Jayasree Iyer (Access to Medicines Foundation) **Quality assurance for biosimilars: regulatory, manufacturer & procurement perspectives** **With the participation of:** Janis Bernat (IFPMA), Anna Laura Salvati (Italian Medicines Agency), Suzette Kox (Medicines for Europe), Charles Preston (PAHO), Guido Pantè (for WHO), Emer Cooke (WHO) & Deus Mubangizi (WHO) **Q&A:** Jayasree Iyer (Access to Medicines Foundation)
11:15 – 11:30	**Q&A** **Chaired by:** TBD		**Quality** **Given by:** Lynda Paleshnuik (WHO) **Bioequivalence** **Given by:** John Gordon (WHO) **Active pharmaceutical ingredients** **Given by:** Antony Fake (WHO) **Q&A** **Chaired by:** Matthias Stahl (WHO)		
11:30 – 11:45	**Global Drug Facility (GDF) update** **Given by (TBC):** Kaspars Lunte / Nigorsulton Muzafarova			**The process: assessment and programmatic suitability for prequalification** **Given by:** Drew Meek (WHO)	
11:45 – 12:00		**Q&A** **Chaired by:** Robyn Meurant (WHO)		**Q&A** **Chaired by**: Carmen Rodriguez-Hernandez (WHO)	
12:00 – 12:15	**UNFPA update** **Given by:** Roberto Mena	**New guidance documents and technical specifications** **Given by:** Robyn Meurant (WHO)		**Common technical document updates** **Given by:** Drew Meek (WHO)	
12:15 – 12:30					
12:30 – 12:45	**Q&A** **Chaired by:** TBD			**Q&A** **Chaired by:** Carmen Rodriguez-Hernandez (WHO)	
12:45 – 13:00		**Q&A** **Chaired by:** Mercedes Peréz González (WHO)			
13:00 – 14:00	**Lunch: Lounge area 9**				

	UNFPA–UNICEF joint session: cold chain pharma is heating up with innovation AUDITORIUM II	In vitro diagnostics inspections: current challenges and future solutions AUDITORIUM I	Medicines inspections: current challenges and future solutions AUDITORIUM III	Update for vaccines inspections & overview of prequalification and post-prequalification vaccines testing PRESS ROOM	Technical assistance for IVD and medicines manufacturers ROOM 0.1.11	
14:00 – 14:20	**Recent studies on quality of oxytocin** **Given by:** Seloi Mogatle (UNFPA)	**IVD inspection technical updates** **Given by:** Kim Richards (WHO)	**Medicines inspections technical updates** **Finished pharmaceutical product inspections** **Given by:** Vimal Sachdeva (WHO) **API inspections** **Given by:** Xingyu Chen (WHO) **Contract research organization inspections** **Given by:** Vimal Sachdeva (WHO)	**Vaccines inspection technical updates** **Given by:** Mustapha Chafai (WHO)	**Introduced by:** Luther Gwaza (WHO) **Technical assistance for IVD & medicines manufacturers** **Given by:** Rutendo Kuwana & Gaby Vercauteren (WHO)	
14:20 – 14:30	**Discussion** **Chaired by:** Atieno Ojoo (UNICEF)					
14:30 – 14:45				**Prequalification and post-prequalification vaccines testing** **Introduction by:** Olexandr Polishchuk (WHO) **Given by:** Ute Rosskopf (WHO)		
14:45 – 15:00	**UNFPA innovation session: improving traceability (starting at 15:00)** **AUDITORIUM II**					
15:00 – 15:15	**Given by:** Jesper Kervin Franke (GS1) & Thinlay Nono Wangchuk (UNFPA)	**Q&A** **Chaired by:** Deus Mubangizi (WHO)	**Q&A** **Chaired by:** Ian Thrussell (for WHO)			
15:15 – 15:30				**Q&A** **Chaired by:** Olexandr Polishchuk & Carmen Rodriguez-Hernandez (WHO)	**Q&A** **Chaired by:** Luther Gwaza (WHO)	
15:30 – 15:45	**Q&A** **Chaired by:** Seloi Mogatle (UNFPA)					
15:45 – 16:15	**Coffee/tea break: Lounge area 9**					
1-TO-1 MEETINGS						
From 16:15	**1-to-1 MEETINGS WITH PROCUREMENT AGENCIES** **Global Drug Facility** **Room 0.1.19** **Contact:** Nigorsulton Muzafarova **PAHO procurement** **Room TBD** **Contact:** Gabriel Rangel **UNFPA** **Room 0.8.05** **Contact:** Seloi Mogatle **UNICEF** **Room 0.8.07** **Contact:** Charlotte Armand Nielsen **WHO procurement** **Room 0.2.12** **Contact:** Sophie Laroche	**1-to-1 MEETINGS WITH WHO PREQUALIFICATION TEAM** **IVD assessment/inspection/ performance evaluation** **Room 0.9.24** **Contact:** Mercedes Peréz González **Medicines assessment** **Rooms 0.9.30 and 0.9.32** **Contact:** Matthias Stahl **Medicines inspection** **Room 0.9.26 and 0.9.28** **Contact**: Vimal Sachdeva **Vaccines assessment/inspection** **Room 0.2.11** **Contact:** Carmen Rodriguez-Hernandez **Vaccines testing** **Room 0.7.48** **Contact:** Ute Rosskopf **Biosimilars for cancer treatment** **Room 0.2.13** **Contact:** Jacqueline Sawyer **Vector control**	**1-to1 MEETINGS WITH UNFPA PREQUALIFICATION TEAM (CONTRACEPTIVE DEVICES)** **Room 0.8.03** **Contact:** Ashley Moyo	**1-to-1 MEETINGS ON TECHNICAL ASSISTANCE FOR MANUFACTURERS SEEKING PREQUALIFICATION** **For IVDs** **Room 0.2.09** **Contact:** Gaby Vercauteren **For medicines** **Room 0.2.10** **Contact:** Rutendo Kuwana	**1-to-1 MEETINGS ON WHO COLLABORATIVE REGISTRATION PROCEDURE** **Room 0.1.20** **Contact:** Luther Gwaza/ Gabriela Zenhausern	

WEDNESDAY, 20 SEPTEMBER						
SESSION 6 IN AUDITORIUM I, II & III merged: INVESTING IN WHO PREQUALIFICATION						
09:00 – 09:10	**Session introduction** **Given by:** Deus Mubangizi (WHO)					
09:10 – 09:50	**Reducing prequalification cost and maximizing opportunities** **Given by:** Ian Thrussell (former WHO Expert inspector)					
09:50 – 10:15	**Q&A** **Chaired by:** Deus Mubangizi (WHO)					
10:15 – 10:45	**Coffee/tea break: Lounge areas 1 and 9**					
SESSION 7 IN AUDITORIUM I, II & III merged: GETTING PRODUCTS TO MARKETS PROMPTLY — WHO COLLABORATIVE REGISTRATION & CARIBBEAN REGULATORY SYSTEM						
10:45 – 10:50	**Session introduction** **Given by:** Emer Cooke (WHO)					
10:50 – 11:10	**WHO collaborative registration update: from medicines & vaccines to IVDs and vector control products** **Given by:** Luther Gwaza (WHO)					
11:10 – 11:30	**WHO collaborative registration from a regulator's point of view** **Given by:** Sunday Kisoma (Tanzania Food and Drugs Authority)					
11:30 – 11:45	**Caribbean Regulatory System Initiative: fast-tracking assessments and approvals of generic medicines approved by designated reference bodies** **Given by:** Charles Preston (Pan American Health Organization)					
11:45 – 12:00	**Q&A** **Chaired by:** Emer Cooke (WHO)					
SESSION 8 IN AUDITORIUM I, II & III merged: PREQUALIFICATION FEEDBACK: OPEN FORUM						
12:10 – 13:15	**Session introduced by:** Emer Cooke (WHO) **Moderated by:** Mark Kays (Interclarity Research & Consulting, Inc.) **With the participation of:** Emer Cooke (WHO) and senior staff of the WHO Prequalification Team					
13:15 – 14:30	**Lunch: Lounge area 9**					
1-TO-1 MEETINGS						
From 14:30	**1-to-1 MEETINGS WITH PROCUREMENT AGENCIES** **Global Drug Facility** **Room 0.1.19** **Contact:** Nigorsulton Muzafarova **PAHO procurement** **Room TBD** **Contact:** Gabriel Rangel **UNFPA** **Room 0.8.05** **Contact:** Seloi Mogatle **UNICEF** **Room 0.8.07** **Contact:** Charlotte Armand Nielsen	**1-to-1 MEETINGS WITH WHO PREQUALIFICATION TEAM** **IVD assessment/inspection/ performance evaluation** **Room 0.9.24** **Contact:** Mercedes Peréz González **Medicines assessment** **Rooms 0.9.30 and 0.9.32** **Contact:** Matthias Stahl **Medicines inspection** **Room 0.9.26 and 0.9.28** **Contact:** Vimal Sachdeva **Vaccines assessment/inspection** **Room 0.2.11** **Contact:** Carmen Rodriguez-Hernandez **Vaccines testing** **Room 0.7.48** **Contact:** Ute Rosskopf **Biosimilars for cancer treatment** **Room 0.2.13** **Contact:** Jacqueline Sawyer **Vector control**	**1-to1 MEETINGS WITH UNFPA PREQUALIFICATION TEAM (CONTRACEPTIVE DEVICES)** **Room 0.8.03** **Contact:** Ashley Moyo	**1-to-1 MEETINGS ON TECHNICAL ASSISTANCE FOR MANUFACTURERS SEEKING PREQUALIFICATION** **For IVDs** **Room 0.2.09** **Contact:** Gaby Vercauteren **For medicines** **Room 0.2.10** **Contact:** Rutendo Kuwana	**1-to-1 MEETINGS ON WHO COLLABORATIVE REGISTRATION PROCEDURE** **Room 0.1.20** **Contact:** Luther Gwaza/ Gabriela Zenhausern	**1-to-1 MEETINGS ON CARIBBEAN REGULATORY SYSTEM** **Room 0.1.01** **Contact:** Charles Preston

THURSDAY, 21 SEPTEMBER						Day 4
1-TO-1 MEETINGS						
09:00 – 12:00 14:00 – 17:00	**1-to-1 MEETINGS WITH PROCUREMENT AGENCIES** **Global Drug Facility** **Room 0.1.19** **Contact:** Nigorsulton Muzafarova **PAHO procurement** **Room TBD** **Contact:** Gabriel Rangel **UNFPA** **Room 0.8.05** **Contact:** Seloi Mogatle **UNICEF** **Room 0.8.07** **Contact:** Charlotte Armand Nielsen	**1-to-1 MEETINGS WITH WHO PREQUALIFICATION TEAM** **IVD assessment/inspection/ performance evaluation** **Room 0.9.24** **Contact:** Mercedes Peréz González **Medicines assessment** **Rooms 0.9.30 and 0.9.32** **Contact:** Matthias Stahl **Medicines inspection** **Room 0.9.26 and 0.9.28** **Contact:** Vimal Sachdeva **Vaccines assessment/inspection** **Room 0.2.11** **Contact:** Carmen Rodriguez-Hernandez **Vaccines testing** **Room 0.7.48** **Contact:** Ute Rosskopf **Biosimilars for cancer treatment** **Room 0.2.13** **Contact:** Jacqueline Sawyer **Vector control**	**1-to1 MEETINGS WITH UNFPA PREQUALIFICATION TEAM (CONTRACEPTIVE DEVICES)** **Room 0.8.03** **Contact:** Ashley Moyo	**1-to-1 MEETINGS ON TECHNICAL ASSISTANCE FOR MANUFACTURERS SEEKING PREQUALIFICATION** **For IVDs** **Room 0.2.09** **Contact:** Gaby Vercauteren **For medicines** **Room 0.2.10** **Contact:** Rutendo Kuwana	**1-to-1 MEETINGS ON WHO COLLABORATIVE REGISTRATION PROCEDURE** **Room 0.1.20** **Contact:** Luther Gwaza/ Gabriela Zenhausern	**1-to-1 MEETINGS ON CARIBBEAN REGULATORY SYSTEM** **Room 0.1.01** **Contact:** Charles Preston