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: IMPROVING THE RESPONSE OF GLOBAL PUBLIC HEALTH IN A FAST-CHANGING WORLD	
08:45–08:55	**Meeting opening and meeting overview** *Dr Hans Kluge, Nominee Regional Director of the WHO European Region* *Joel Schaefer, Communication Officer, Office of WHO Director-General*
08:55–09:10	**Welcome from meeting host agencies** *Hanne Bak Pedersen (Deputy Director, Programme Supply & Market Influencing, UNICEF Supply Division), Eric Dupont (Chief, Procurement Services Branch, UNFPA) & Emer Cooke (Director, Regulation of Medicines and other Health Technologies, WHO Headquarters)*
09:10–09:20	**Administrative / security arrangements** Jesper Palm Lundorf, UN Office of the Designated Official for Security
09:20–09:25	**Overview of the day's themes and introduction to keynote address and response** *Joel Schaefer, Communication Officer, Office of WHO Director-General*
09:25–09:40	**Keynote address: "Fast Change, Slow Response"** *Dr Soumya Swaminathan, Chief Scientist, WHO Headquarters*
09:40–10:00	**Keynote address response: Using AI to Change the Game in Global Response** *Dr Padmanabhan Anandan, CEO, Wadhwani Institute for Artificial Intelligence, India*
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	**Surviving Ebola: One Man, Three Experiences** *Mambu Momoh, Medical Laboratory Associate Instructor, Eastern Polytechnic College Kenema Sierra Leone*
11:05–11:25	**Diagnostics for Epidemic Preparedness: Disruption to Deliver** *Dr Cassandra Kelly, Director of Emerging Threats, Foundation for Innovative New Diagnostics, Switzerland*
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** *Samantha Bolton, WHO Consultant, Risk Communications and Campaigns*
12:00–12:20	**Building resilient demand for vaccination** *Katrine Bach Habersaat, Technical Officer, Vaccine-preventable Diseases and Immunization, WHO Regional Office for Europe*
12:20–12:30	**Quick questions** *Moderated by Samantha Bolton, WHO Consultant, Risk Communications and Campaigns*
12:30–13:45	**Sandwich lunch**
Theme 3	**Progress and Outlook for Global Health Initiatives**
13:45–13:50	**Introduction to Theme 3** *Joel Schaefer, Communication Officer, Office of WHO Director-General*
13:50–14:10	**Access to Treatment for Childhood Cancer** *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, Unit Leader, 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, Netherlands*
14:50–15:10	**Antimicrobial Resistance: towards Viable Markets for Diagnostics and Antibiotics** *Daniel Berman, Lead, Global Health Team, Nesta Foundation, UK*
15:10–15:20	**Quick questions** *Moderated by Joel Schaefer, Communication Officer, Office of WHO Director-General*
15:20–16:00	**Coffee / 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, WHO Headquarters*
16:25–16:45	**Regulation of Vector Control Products: What's New?** *Dr Angus Spiers, Director, Innovation to Impact, UK*
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., USA*
17:05–17:15	**Quick questions** *Moderated by Joel Schaefer, Communication Officer, Office of WHO Director-General*
17:15–17:30	**Wrap-up** *By Joel Schaefer, Communication Officer, Office of WHO Director-General*
17:30–19:00	**Reception for all participants**

DAY 2	TUESDAY, 3 DECEMBER
07:30–08:45	**MEETING REGISTRATION: ENTRANCE TO UN CITY**
Day 2 will consist of a procurement track and five prequalification tracks, held in parallel. In addition, a session on "Local production and technical assistance" will be held from 15:30, i.e. in parallel with the latter part of the procurement, WHO vector control prequalification and UNFPA prequalification tracks. **Coffee/tea breaks: 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 09:20–09:30	**UNICEF procurement** *Cynthia Kamtengeni, Contracts Manager, Medicines and Nutrition Centre, UNICEF Supply Division & Robert Matthews, Contracts Manager, Health Technology Centre, UNICEF Supply Division* **Q&A** *Chaired by Francisco Blanco, Chief of Quality Assurance Centre, UNICEF Supply Division*
09:30–09:50 09:50–10:00	**UNFPA procurement** *Roberto Mena, Procurement Specialist, Strategic Procurement, UNFPA Procurement Services Branch* **Q&A** *Chaired by Francisco Blanco, Chief of Quality Assurance Centre, UNICEF Supply Division*
10:00–10:20 10:20–10:30	**Global Fund's approach to procurement** *Azizkhon Jafarov, Manager, Supply Operation Department, Global Fund to Fight AIDS, Tuberculosis and Malaria* **Q&A** *Chaired by Francisco Blanco, Chief of Quality Assurance Centre, UNICEF Supply Division*
10:30–10:50 10:50–11:00	**PAHO Procurement & Health in the Americas** *Daniel Rodriguez, Director, Procurement and Supply Management, Pan American Health Organization* **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 part I** *Given by Lisa Hedman, Technical Officer, Innovation, Access and Use Team, WHO Headquarters*
11:40–12:00 12:00–12:10	**Forecasting for decision-making** *Dr Vineet Prabhu, Associate Director, Market Intelligence, Clinton Health Access Initiative* **Q&A** *Chaired by Lisa Hedman, Technical Officer, Innovation, Access and Use Team, WHO Headquarters*
12:10–12:30	**Procurement for progressing global health initiatives: PAHO and HEARTS** *Jordi Balleste, Strategic Fund Unit Chief, Procurement and Supply Management, Pan American Health Organization*
12:30–12:50	**Biotherapeutics for cancer: ensuring quality, safety and efficacy** *Dr Guido Pantè, Expert, Biotherapeutic Products, Medicines Assessment Group, WHO Prequalification Team, WHO Headquarters*
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 to procurement challenges part II** *Lisa Hedman, Technical Officer, Innovation, Access and Use Team, WHO Headquarters*
14:05–14:30	**Implications for manufacturers and procurers of updated WHO guidelines** *Dr Sabine Kopp, Scientist, Technologies Standards and Norms Team, WHO Headquarters*
14:30–14:55	**Country perspective on procurement of medicines: Iraq case study** *Zinah Nooruldeen, Pharmaceutical Coordinator, Universal Health Coverage/Life Course and Amgad 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 & Dr Magali Babaley, Strategic Procurement and Business Intelligence Manager, Global Drug Facility, Stop TB Partnership*
15:20–15:30	**Combined Q&A for above three topics** *Chaired by Lisa Hedman, Technical Officer, Innovation, Access and Use Team, WHO Headquarters*
15:30–16.00	**Coffee/tea break**
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, WHO 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 Team, WHO Headquarters*
WHO IN VITRO DIAGNOSTICS (IVDS) PREQUALIFICATION TRACK	
08:45–09:00	**IVD prequalification for new applicants: an overview** *Irena Prat, Group Lead, IVD Assessment Group, WHO Prequalification Team, WHO Headquarters*
09:00–10.20	**Introduction to IVD assessment** *Helena Ardura-Garcia, Technical Officer & Charles Chiku, Technical Officer, IVD Assessment Group, WHO Prequalification Team*
10:20–10:40	**Introduction to IVD inspection** *Dr Philippe Boeuf, Inspector, Inspection Services Group, WHO Prequalification Team*
10:40–11.00	**Q&A** *Chaired by Irena Prat, Group Lead, IVD Assessment Group, WHO Prequalification Team*
11:00–11.30	**Coffee/ tea break**
11:30–11:40	**Introduction to IVD update** *Irena Prat, Group Lead, IVD Assessment Group, WHO Prequalification Team*
11:40–12:40	**Dossier Assessment** *Dr Mark Lanigan, Technical Officer, IVD Assessment Group, WHO Prequalification Team* **Performance Evaluation** *Dr Anne-Laure Page, Scientist, IVD Assessment Group, WHO Prequalification Team* **Technical guidance and specifications** *Dr Ute Ströher, Technical Officer, IVD Assessment Group, WHO Prequalification Team* **Changes** *Helena Ardura-Garcia, Technical Officer, IVD Assessment Group, WHO Prequalification Team*
12:40–13.00	**Q&A** *Chaired by Irena Prat, Group Lead, IVD Assessment Group, WHO Prequalification Team*

13:00–14.00	**Lunch**
14:00–14:45	**IVD inspection update and Q&A** *Stephanie Croft, Inspector, Inspection Services Group, 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 MEDICINES PREQUALIFICATION TRACK	
08:45–09:00	**Introduction to medicines assessment update** *Dr Matthias Stahl, Group Lead, Medicines Assessment Group, WHO Prequalification Team, WHO Headquarters*
09:00–10.30	**Quality** *Dr Lynda Paleshnuik, Lead Quality Assessor, Medicines Assessment Group, WHO Prequalification Team* **Bioequivalence** *Dr John Gordon, Lead Bioequivalence Assessor, Medicines Assessment Group, WHO Prequalification Team* **Active pharmaceutical ingredients** *Dr Antony Fake, API Assessment Focal Point, Medicines Assessment Group, WHO Prequalification Team* **Update on WHO Public Assessment Reports** *Dr Regine Lehnert, Clinical Assessor, Medicines Assessment Group, WHO Prequalification Team* **Biosimilar products pilot** *Dr Guido Pantè, Expert, Biotherapeutic Products, Medicines Assessment Group, WHO Prequalification Team*
10:30–11.00	**Q&A** *Chaired by Dr Matthias Stahl, Group Lead, Medicines Assessment Group, 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 Group, WHO Prequalification Team*
WHO VACCINES & IMMUNIZATION DEVICES PREQUALIFICATION TRACK	
08:45–09:20	**WHO vaccines prequalification overview** *Olivier Lapujade, Scientist, Vaccines Assessment Group, WHO Prequalification Team, WHO Headquarters*
09:20–09:45	**Vaccines inspection update** *Mustapha Chafai, Inspector, Inspection Services Group, WHO Prequalification Team*
09:45–10.30	**Vaccine assessment: CMC (chemistry, manufacturing and control) and quality and clinical data** *Dr Godwin Enwere, Scientist, Vaccines Assessment Group, WHO Prequalification Team*
10:30–11:00	**Q&A** *Chaired by Mustapha Chafai, Inspector, Inspection Services Group, WHO Prequalification Team*
11:00–11.30	**Coffee/ tea break**
11:30–12.00	**Vaccines testing: initial evaluation for prequalification and post-prequalification monitoring** *Dr Ute Rosskopf, Scientist, Technical Assistance and Laboratories Group, Regulatory Systems Strengthening Team, WHO Headquarters*

12:00–12.15	**Q&A** *Chaired by Rolando Dominguez Morales, Scientist, Vaccines Assessment Group, WHO Prequalification Team*
12:15–12.45	**Post-prequalification** *Rolando Dominguez Morales, Scientist, Vaccines Assessment Group, WHO Prequalification Team*
12:45–13.00	**Q&A** *Chaired by Oliver Lapujade, Scientist, Vaccines Assessment Group, WHO Prequalification Team*
13:00–14.00	**Lunch**
14:00–14:30	**Regulatory challenges of prequalified vaccines supplied through the UN system** *Olivier Lapujade, Scientist, Vaccines Assessment Group, WHO Prequalification Team*
14:30–14:45	**Q&A** *Chaired by Dr Godwin Enwere, Scientist, Vaccines Assessment Group, WHO Prequalification Team*
14:45–15.15	**Prequalification of immunization equipment: implications for vaccines** *Dr Isaac Gobina, Technical Officer, Immunization Devices Assessment Group, WHO Prequalification Team*
15:15–15.30	**Q&A** *Dr Isaac Gobina, Technical Officer, Immunization Devices Assessment Group, WHO Prequalification Team*
WHO VECTOR CONTROL PRODUCT PREQUALIFICATION TRACK	
08:45–09:00	**Vector control assessment: updates & priorities** *Marion Law, Group Lead, Vector Control Assessment Group, WHO Prequalification Team, WHO Headquarters*
09:00–11:00	**Submission application process – making the process clearer and more efficient for manufacturers and PQT-VC** *Dominic Schuler, Technical Officer, Vector Control Assessment Group, WHO Prequalification Team* **Information on the project to review data requirements to support the prequalification of vector control products** *Marion Law, Group Lead & Dr Jeannette Martinez, Technical Officer, Vector Control Assessment Group, WHO Prequalification Team* **Report on Joint Meeting on Pesticide Specifications** *Marion Law, Group Lead & Dr Luis Pérez Albela, Scientist, Vector Control Assessment Group, WHO Prequalification Team*
11:00–11.30	**Coffee/ tea break**
11:30–12.00	**Vector control inspection update** *Dr Joey Gouws, Group Lead, Inspection Services, WHO Prequalification Team*
12:00–13.00	**Q&A** *Chaired by Marion Law, Group Lead, Vector Control Assessment Group, WHO Prequalification Team*
13:00–14.00	**Lunch**

14:00–15.30	**Product review of non-pyrethroid-only insecticide-treated nets** **Introduction** *Chaired by Marion Law, Group Lead, Vector Control Assessment Group, WHO Prequalification Team* **Data and process for product review** *Dominic Schuler, Technical Officer, Vector Control Assessment Group, WHO Prequalification Team* **Q&A** *Chaired by Marion Law, Group Lead, Vector Control Assessment Group, WHO Prequalification Team*
15:30–16.00	**Coffee/tea break**
16:00–17.00	**Product review of non-pyrethroid-only insecticide-treated nets** **Q&A (continued)** *Chaired by Marion Law, Group Lead, Vector Control Assessment Group, WHO Prequalification Team*
UNFPA PREQUALIFICATION 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 K. Sivakumar, 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 K. Sivakumar, Technical Expert Consultant, UNFPA*
11:00–11.30	**Coffee/ tea break**
11:30–11.45	**Condom storage conditions and conducting stability studies (continued)** *Dr K. Sivakumar, 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**
14:00–15.00	**Male condom packaging designs?** *Dr William Potter, Technical Expert Consultant, UNFPA*
15:30–16.00	**Coffee/tea break**

16:00–17:00	**Breakout session: Viable commercial markets for reproductive health products: are they possible without donors?** *Led by Ben Light, Senior Policy Adviser, Family Planning & Reproductive Health Commodity Security, UNFPA*
LOCAL PRODUCTION & TECHNICAL ASSISTANCE	
15:30–15:40	**Introduction** *Azizkhon Jafarov, Manager, Supply Operation Department, Global Fund to Fight AIDS, Tuberculosis and Malaria*
15:40–16.00	**Leveraging and cultivating enabling factors for local production** *Dr Jicui Dong, Programme Manager, Local Production, Regulatory Systems & Strengthening Team, WHO Headquarters*
16:00–16.15	**Q&A** *Chaired by Azizkhon Jafarov, Manager, Supply Operation Department, Global Fund to Fight AIDS, Tuberculosis and Malaria*
16:15–17:05	**Technical assistance for IVD manufacturers** *Dr Gaby Vercauteren, Senior Advisor, Technical Assistance and Laboratories Group, Regulatory Systems Strengthening Team, WHO Headquarters*
17:05–17:25	**Technical assistance for medicines manufacturers** *Rutendo Kuwana, Technical Officer, Technical Assistance and Laboratories Group, Regulatory Systems Strengthening Team, WHO Headquarters*
17:25–17:45	**Q&A** *Chaired by Azizkhon Jafarov, Manager, Supply Operation Department, Global Fund to Fight AIDS, Tuberculosis and Malaria*
DAY 3	**WEDNESDAY, 4 DECEMBER**
07:30–08:30	**MEETING REGISTRATION: ENTRANCE TO UN CITY**
Day 3 will be held in plenary, with the exception of two lunchtime breakout sessions.	
WHO POLICY, DIAGNOSIS AND TREATMENT GUIDELINES UPDATES, AND WHO AND MODEL LIST UPDATES	
WHO POLICY, DIAGNOSIS AND TREATMENT GUIDELINES UPDATES	
08:30-08:35	**Introduction** *Given by Deus Mubangizi, Coordinator, WHO Prequalification Team, WHO Headquarters*
08:35-08:55	**TB diagnostic policies and treatment guidelines updates** *Dr Kerri Viney, Scientist, Laboratories, Diagnostics and Drug-Resistance, WHO Global TB Programme, WHO Headquarters*
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 testing, diagnosis and 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, WHO Headquarters
09:55-10:15	**Q&A** *Chaired by Deus Mubangizi, Coordinator, WHO Prequalification Team*
WHO MODEL LIST UPDATES	
10:15–10:20 10:20–10:40 10:40–11:00 10:40–11:00	**Introduction** *Given by Deus Mubangizi, Coordinator, WHO Prequalification Team, WHO Headquarters* **The 2nd WHO Model List of Essential In Vitro Diagnostics** *Adriana Velazquez Berumen, Senior Advisor, Innovation, Access and Rational Use Team, WHO Headquarters* **The 21st WHO Model List of Essential Medicines** *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**
REGULATORY OVERSIGHT IN THE LIFECYCLE OF A MEDICAL PRODUCT	
11:30–11:35	**Introduction** *Given by Emer Cooke, Director, Director, Department of Regulation of Medicines and other Health Technologies, WHO Headquarters*
Evolving Regulatory Concepts	
11:35–11:55 11:55–12:15 12:15–12:35 12:35–13:00	**Good Regulatory and Good Reliance Practices** *Dr Samvel Azatyan, Group Lead, Regulatory Networks and Harmonization, Regulatory Systems Strengthening Team, WHO Headquarters* **The WHO Global Benchmarking Tool (GBT)** *Dr Alireza Khadem Broojerdi, Scientist, Country Regulatory Strengthening, Regulatory Systems Strengthening Team, WHO Headquarters* **WHO Listed Authorities: from concept to practice** *Hiiti Sillo, Group Lead, Country Regulatory Strengthening, Regulatory Systems Strengthening Team, WHO Headquarters* **Q&A** *Chaired by Dr Alireza Khadem Broojerdi, Scientist, Regulatory Systems Strengthening Team*
13:00–14:00	**Lunch**
LUNCHTIME BREAKOUT SESSIONS	
12:45–14:15	**Breakout session: Safe abortion** *Led by Safia Ahsan, Market Development Officer, Deputy Director, Reproductive Health Supplies Coalition, with the participation of UNFPA and WHO Headquarters* Lunch will be available outside the meeting room for those participating
12:45–13:45	**Breakout session: The benefits of The International Pharmacopoeia for manufacturers** *Led by Dr Herbert Schmidt, Technical Officer, Technical Standards and Norms Team, WHO Headquarters, moderated by Mark Kays, Interclarity Research & Consulting, Inc.* Lunch will be available outside the meeting room for those participating

Registration and Marketing Authorization	
14:00–14:15	**Collaborative procedures: A brief introduction** *Dr Samvel Azatyan, Group Lead, Regulatory Networks and Harmonization, Regulatory Systems Strengthening Team, WHO Headquarters*
14:15–15:00	**Collaborative procedures: Best practices and remaining hurdles** **Moderated panel discussion (including Q&A)** *Regulators from Thailand (Kulwadee Sawaspaiboontawee, Food and Drug Administration), Ukraine (Dr Tetyana Dumenko & Peter Golodiuk, State Expert Center of the Ministry of Health) and Zambia (Makomani Siyanga, Zambia Medicines Regulatory Authority), 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 Surveillance	
15:30–15:45	**Pharmacovigilance (PV) systems and procedures: the manufacturer's role and responsibilities** *Dr Shanthi Pal, Group Lead, Medicines Safety, Safety and Vigilance Team, WHO Headquarters*
15:45–16:00	**PV systems and procedures that support the manufacturer's PV roles and responsibilities** *Monica Plöen, Head of Pharmacovigilance Collaboration, Uppsala Monitoring Centre*
16:00–16:20	**Where are we in the fight against substandard and falsified medical products?** *Pernette Bourdillon Esteve, Acting Group Lead, Substandard and Falsified Medical Products, Safety and Vigilance Team, WHO Headquarters*
16:20–16:30	**Q&A** *Chaired by Dr Shanthi Pal, Group Lead, Medicines, Safety and Vigilance Team*
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 (Sylvie Meillerais, MSD Europe); International Generic and Biosimilar Medicines Association (Suzette Kox) and WHO (Dr Sabine Kopp).* *Moderated by: Dr Petra Doerr, Petra Doerr Consulting Ltd.*
OFFICIAL MEETING CLOSURE	
17:30–17:45	**Meeting highlights and recommendations** *Hanne Bak Pedersen, Deputy Director, Programme Supply & Market Influencing, UNICEF Supply Division*

DAY 4	THURSDAY, 5 DECEMBER
1-TO-1 MEETINGS 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 • Ute Rosskopf — rosskopfu@who.int — for **vaccines testing** for WHO prequalification • Matthias Stahl — stahlm@who.int — for **medicines assessment** for WHO prequalification • Vimal Sachdeva — sachdevav@who.int — for **medicines inspection** for WHO prequalification • Olivier Lapujade — lapujadeo@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 — vercautereng@who.int — for **technical assistance for IVD manufacturers** • Rutendo Kuwana — kuwanaru@who.int — for **technical assistance for medicines manufacturers** and for **collaborative registration**.	