

## PROVISIONAL AGENDA

JOINT UNICEF, UNFPA & WHO MEETING WITH MANUFACTURERS AND SUPPLIERS OF DIAGNOSTIC PRODUCTS, VACCINES, FINISHED PHARMACEUTICAL PRODUCTS AND ACTIVE PHARMACEUTICAL INGREDIENTS 22 –25 September 2014

UN City Copenhagen, Marmørvej 51, 2100 Copenhagen, Denmark

The plenary sessions to be held on Monday 22 September will take place in Auditorium II. The rooms where individual meetings between manufacturers and UNFPA, UNICEF or WHO will be held are indicated below. The manufacturers who have requested such a meeting will have been informed of the time of their meeting. UNFPA, UNICEF and WHO contact names and details for these meetings are also given below and on the last page of this agenda.

### MONDAY, 22 SEPTEMBER

08:00	09:00	MEETING REGISTRATION: ENTRANCE TO UN CITY
09:00	09:20	Welcome address
09:20	09:30	Administrative/security arrangements
<b>Session 1 in Auditorium II: Product priorities for development and procurement</b>		
09:30	09:40	Session introduction
09:40	10:45	<b>Product priorities: part 1</b> - HIV/AIDS - TB - Malaria
10:45	11:00	Q&A
11:00	11:30	Coffee/tea break
11:30	12:15	<b>Product priorities: part 2</b> - Reproductive health - Maternal/neonatal/child health
12:15	12:30	Q&A
12:30	12:50	Medicines procurement policies and requirements: UNICEF, UNFPA, Global Fund to Fight AIDS, Tuberculosis and Malaria, Global Drug Facility, Médecins Sans Frontières, International Committee of the Red Cross
12:50	13:00	Q&A
13:00	14:00	Lunch
<b>Session 2 in Auditorium II: Getting medicines to markets: funds and mechanisms</b>		
14:00	14:15	Session introduction
14:15	15:00	<b>Market perspective:</b> - Global Fund - UN Commission on Lifesaving commodities for Women and Children - UNITAID
15:00	15:15	<b>Tentative:</b> Focus on procurement potential in Africa
15:15	15:30	Q&A
15:30	16:00	Coffee/tea break
16:00	16:15	Regulatory impediments to accessing markets
16:15	16:30	Collaboration to accelerate registration of medicines and vaccines: combined procedure
16:30	16:50	Regulators' experience with collaborative process to accelerate medicines registration
16:50	17:10	Manufacturers' experience with collaborative process to accelerate medicines registration
17:10	17:40	Procuring diagnostics in the absence of stringent regulatory approval or prequalification: Expert Review Panel update
17:40	18:00	Sustainable Procurement in Health Sector Initiative
18:00	18:15	Q&A
18:00	20:00	RECEPTION FOR ALL PARTICIPANTS IN ????

PARALLEL SESSIONS	UNICEF	FOCUS ON WHO DIAGNOSTICS PREQUALIFICATION	FOCUS ON WHO MEDICINES PREQUALIFICATION	UNFPA & FOCUS ON DIAGNOSTICS AND MEDICINES FOR REPRODUCTIVE HEALTH	FOCUS ON WHO VACCINES PREQUALIFICATION
09:00 – 09:15		Technical updates session introduction Given by: Irena Prat	Technical updates session introduction Given by: Matthias Stahl		Session introduction Given by: Carmen Rodriguez-Hernandez
09:15 – 09:30		Technical updates diagnostics abbreviated assessment Given by: Anita Sands	Technical updates medicines assessment Quality: given by Lynda Paleshnuik Bioequivalence: given by John Gordon Active pharmaceutical ingredients: given by Isabel Ortega		Vaccines assessment overview Given by: Carmen Rodriguez-Hernandez
09:30 – 09:45		Technical updates diagnostics assessment Given by: Robyn Meurant			
09:45 – 10:00					
10:00 – 10:30		Technical updates diagnostics inspections Given by: Sabine Ohse	Q&A Chaired by: Matthias Stahl		Q&A Chaired by: Drew Meek & Olivier Lapujade
10:30 – 11:00	Coffee/tea break	Coffee/tea break	Coffee/tea break	Coffee/tea break	Coffee/tea break
11:00 – 11:30	Unicef engagement with medicines suppliers: needs and operations	Technical updates laboratory evaluations Given by: Willy Urassa and Jane Cunningham	Introduction to medicines inspections technical updates Given by: Deus Mubangizi		The WHO vaccines prequalification process: quality assessment Given by: Drew Meek
11:30 – 12:00		Q&A Chaired by: Irena Prat	Technical updates medicines inspections: finished pharmaceutical products Given by: Vimal Sachdeva		The WHO vaccines prequalification process: clinical assessment Given by: Olivier Lapujade
12:00 – 12:30		Technical assistance diagnostics Given by: Gaby Vercauteren	Technical updates medicines inspections: active pharmaceutical ingredients Given by: Xingyu Chen Technical updates medicines inspections: bioequivalence studies		Post-prequalification activities Given by: Drew Meek & Olivier Lapujade
12:30 – 13:00		Q&A Chaired by: Irena Prat	Q&A Chaired by: Ian Thrussell		Q&A Chaired by: Carmen Rodriguez-Hernandez
13:00 – 14:30	Lunch	Lunch	Lunch	Lunch	Lunch
14:30 – 14:45	Unicef engagement with diagnostics suppliers: needs and operations	WHO diagnostics prequalification meetings with manufacturers Contact for assessment team: Anita Sands Contact for inspection team: Sabine Ohse Contract for technical assistance team: Gaby Vercauteren	WHO medicines prequalification meetings with manufacturers	UNFPA meetings with manufacturers Contact: Isabel Manzano	Programmatic suitability Given by: Drew Meek
14:45 – 15:00			Contact for assessment team: Matthias Stahl Contact for inspection team: Vimal Sachdeva		Q&A Chaired by: Carmen Rodriguez-Hernandez & Oliver Lapujade
15:00 – 15:30			Contact for technical assistance team: Milan Smid		Procedure for accelerated registration of vaccines including Q&A Given by: Carmen Rodriguez-Hernandez
15:30 – 16:00	Coffee/tea break	Coffee/tea break	Coffee/tea break	Coffee/tea break	Coffee/tea break
16:00 – 18:00	Unicef engagement with diagnostics suppliers: needs and operations	WHO diagnostics prequalification meetings with manufacturers  Contact for assessment team: Anita Sands Contact for inspection team: Sabine Ohse Contract for technical assistance team: Gaby Vercauteren	WHO medicines prequalification meetings with manufacturers  Contact for assessment team: Matthias Stahl Contact for inspection team: Vimal Sachdeva Contact for technical assistance team: Milan Smid	UNFPA meetings with manufacturers Contact: Isabel Manzano	WHO vaccines prequalification meetings with manufacturers Contact: Camen Rodriguez-Hernandez

PARALLEL SESSIONS	UNICEF	FOCUS ON WHO DIAGNOSTICS PREQUALIFICATION	FOCUS ON WHO MEDICINES PREQUALIFICATION	FOCUS ON DIAGNOSTICS AND MEDICINES FOR REPRODUCTIVE HEALTH	FOCUS ON WHO VACCINES PREQUALIFICATION
09:00 – 10:45		<b>WHO diagnostics prequalification side event:</b>  Introduction for manufacturers who are new to diagnostics prequalification	<b>WHO medicines prequalification meetings with manufacturers</b>  <b>Contact for assessment team:</b> Matthias Stahl <b>Contact for inspection team:</b> Vimal Sachdeva <b>Contact for technical assistance team:</b> Milan Smid	<b>UNFPA meetings with manufacturers</b> <b>Contact:</b> Isabel Manzano	<b>WHO vaccines prequalification meetings with manufacturers</b>  <b>Contact:</b> Camen Rodriguez-Hernandez
10:45 – 11:15	Coffee/tea break	Coffee/tea break	Coffee/tea break	Coffee/tea break	Coffee/tea break
11:15 – 11:35		<b>Tentative:</b> <b>Harmonization of malaria rapid diagnostic tests</b> Given by: Clinton Health Access Initiative			
11:35 – 13:00		<b>WHO diagnostics prequalification meetings with manufacturers</b>  <b>Contact for assessment team:</b> Anita Sands <b>Contact for inspection team:</b> Sabine Ohse <b>Contact for technical assistance team:</b> Gaby Vercauteren	<b>WHO medicines prequalification meetings with manufacturers</b>  <b>Contact for assessment team:</b> Matthias Stahl <b>Contact for inspection team:</b> Vimal Sachdeva <b>Contact for technical assistance team:</b> Milan Smid	<b>What comes once quality is met? UNFPA procurement</b> <b>Given by:</b> Lilia Velinova, Miranda Wu Hansen	<b>WHO vaccines prequalification meetings with manufacturers</b>  <b>Contact:</b> Camen Rodriguez-Hernandez
13:00 – 14:30	Lunch	Lunch	Lunch	Lunch	Lunch
14:30 – 15:30		<b>WHO diagnostics prequalification meetings with manufacturers</b>  <b>Contact for assessment team:</b> Anita Sands <b>Contact for inspection team:</b> Sabine Ohse <b>Contact for technical assistance team:</b> Gaby Vercauteren	<b>WHO medicines prequalification meetings with manufacturers</b>  <b>Contact for assessment team:</b> Matthias Stahl <b>Contact for inspection team:</b> Vimal Sachdeva <b>Contact for technical assistance team:</b> Milan Smid	<b>Green procurement and supplier engagement</b> <b>Given by:</b> Katarina Veem, Pauline Gothberg, Christoph Hammelmann	<b>WHO vaccines prequalification meetings with manufacturers</b>  <b>Contact:</b> Camen Rodriguez-Hernandez
15:30 – 16:00	Coffee/tea break	Coffee/tea break	Coffee/tea break	Coffee/tea break	Coffee/tea break
16:00 – 18:00		<b>WHO diagnostics prequalification meetings with manufacturers</b>  <b>Contact for assessment team:</b> Anita Sands <b>Contact for inspection team:</b> Sabine Ohse <b>Contact for technical assistance team:</b> Gaby Vercauteren	<b>WHO medicines prequalification meetings with manufacturers</b>  <b>Contact for assessment team:</b> Matthias Stahl <b>Contact for inspection team:</b> Vimal Sachdeva <b>Contact for technical assistance team:</b> Milan Smid	<b>Green procurement and supplier engagement (cont.)</b> <b>Moderated discussion</b>	<b>WHO vaccines prequalification meetings with manufacturers</b>  <b>Contact:</b> Camen Rodriguez-Hernandez

THURSDAY, 24 SEPTEMBER						Page 4
PARALLEL SESSIONS	UNICEF	FOCUS ON WHO DIAGNOSTICS PREQUALIFICATION	FOCUS ON WHO MEDICINES PREQUALIFICATION	FOCUS ON DIAGNOSTICS AND MEDICINES FOR REPRODUCTIVE HEALTH	FOCUS ON WHO VACCINES PREQUALIFICATION	
09:00 – 10:00		<b>WHO diagnostics prequalification meetings with manufacturers</b>  <b>Contact for assessment team:</b> Anita Sands <b>Contact for inspection team:</b> Sabine Ohse <b>Contract for technical assistance team:</b> Gaby Vercauteren	<b>WHO medicines prequalification meetings with manufacturers</b>  <b>Contact for assessment team:</b> Matthias Stahl <b>Contact for inspection team:</b> Vimal Sachdeva <b>Contact for technical assistance team:</b> Milan Smid			
10:45 – 11:15	Coffee/tea break	Coffee/tea break	Coffee/tea break	Coffee/tea break	Coffee/tea break	
11:15 – 13:00		<b>WHO diagnostics prequalification meetings with manufacturers</b>  <b>Contact for assessment team:</b> Anita Sands <b>Contact for inspection team:</b> Sabine Ohse <b>Contract for technical assistance team:</b> Gaby Vercauteren	<b>WHO medicines prequalification meetings with manufacturers</b>  <b>Contact for assessment team:</b> Matthias Stahl <b>Contact for inspection team:</b> Vimal Sachdeva <b>Contact for technical assistance team:</b> Milan Smid			

**CONTACT DETAILS FOR REQUESTING MEETING WITH ASSESSMENT OR INSPECTION TEAMS:**

**For meetings with UNFPA**

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**For meetings with UNICEF procurement**

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**For meetings with WHO prequalification of diagnostics assessors**

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**For meetings with WHO prequalification of diagnostics inspectors**

**Sabine Ohse:** ohses@who.int; tel: +41 22 791 2988; mobile: **TBC**

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**For meetings with WHO prequalification of medicines inspectors**

**Vimal Sachdeva:** sachdevav@who.int; tel: +41 22 791 3615; mobile: +41 79 500 6533

**For meetings with WHO prequalification of vaccines team**

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**For meetings with WHO prequalification technical assistance team**

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