

**JOINT UNICEF PHARMACEUTICAL SUPPLIER MEETING &
WHO PREQUALIFICATION OF MEDICINES PROGRAMME
3rd MEETING WITH MANUFACTURERS OF FINISHED PHARMACEUTICAL PRODUCTS AND
ACTIVE PHARMACEUTICAL INGREDIENTS
24–26 September 2012
UNICEF Supply Division, Oceanvej 10–12, 2100 Copenhagen, Denmark**

08:30–09:15	MEETING REGISTRATION		
SESSION 1: MONDAY 24 SEPTEMBER, INNOVATION ROOM, OPENING OF MEETING			
09:15–09:30	Welcome address: Shanelle Hall, Director, UNICEF Supply Division		
09:30–09:45	Administrative arrangements: Charlotte Thaarup, Administrative Assistant, UNICEF Supply Division		
SESSION 2: MONDAY 24 SEPTEMBER, UNICEF & PQP SESSIONS			
INNOVATION ROOM: Access to essential medicines for women and children — UNICEF priorities		Chair: Shanelle Hall	
		RED ROOM, BLUE ROOM & ORANGE ROOM: PQP meetings with individual manufacturers on inspection issues	
09:45–10:15	Review of UNICEF work in procurement and supply of medicines: Francisco Blanco, UNICEF Supply Division	09:45–13:00	Manufacturers who have requested a meeting have been sent details of meeting time and location by Stephanie Croft (crofts@who.int/+41 79 213 4305) of the PQP inspection team.
10:15–11:00	Priority actions for increasing availability, affordability, accessibility and rational use of essential commodities for women's and children's health: UN Commission on Life-saving Commodities for Women and Children: Hanne Bak Pedersen, UNICEF Supply Division		
11:00–11:30	Coffee/tea break		
11:30–12:00	Strategies to control pneumonia, diarrhoea and malaria: Mark Young, UNICEF Programme Division		
12:00–13:00	Innovation for elimination of mother-to-child transmission of HIV: Chewe Luo, UNICEF Programme Division		
13:00–14:00	Lunch: UNICEF cafeteria		

SESSION 3: MONDAY 24 SEPTEMBER, INNOVATION ROOM: UNICEF & PQP JOINT SESSION			
Demand and markets for quality medicines		Chair: Lembit Rägo, WHO/EMP	
14:00–14.15	Opening remarks: Kees de Joncheere, Director, WHO Department of Essential Medicines and Pharmaceutical Policies (WHO/EMP)		
14:15–14:35	How prequalification makes a difference and why it is still needed: Ellen 't Hoen (IS Academy HIV/AIDS, School for Social Science Research, University of Amsterdam)		
14:35–16:15	Pharmaceutical procurement: covering Global Fund to Fight AIDS, Tuberculosis and Malaria (Joelle Daviaud); UNICEF (Francisco Blanco); UNFPA (Eric Dupont); Global Drug Facility (Paloma Marroquin Lerga); USAID (Mike Hope); UNDP (Jacqueline Pontre); AIDS Medicines & Diagnostics Service (Boniface Dongmo Nguimfack); UNITAID (TBC)		
16:15–16:45	Coffee/tea break		
16:45–17:15	WHO Expert Review Panel: bringing needed products to market: Matthias Stahl, Head of Assessment, PQP		
17:15–17:45	Discussion and questions		
SESSION 4: TUESDAY 25 SEPTEMBER: UNICEF SESSION (WITH PARTICIPATION OF SOME PQP TECHNICAL STAFF)			
INNOVATION ROOM: UNICEF review of operations including quality assurance issues		GREY ROOM & ORANGE ROOM: PQP meetings with individual manufacturers on assessment and inspection issues	
09:00–10:30	Review of operations related to medicines: procurement process, projects, tenders, efficiency: David Muhia/Gitanjali Sakhuja/Karin Thomsen, UNICEF	08:00–12:45	Manufacturers who have requested a meeting with PQP assessors or inspectors have been sent details of meeting time and location by Matthias Stahl of the PQP assessment team (stahlm@who.int /+41 79 249 539) or Stephanie Croft (crofts@who.int/+41 79 213 4305) of the PQP inspection team.
10:30–11:00	Overview of UNICEF's quality assurance system for procurement of medicines: Peter Svarrer Jakobsen, UNICEF		
11:00–11:30	Coffee/tea break		
11:30–12:00	Technical requirements for medicines: Henrik Nielsen, UNICEF		
12:00–12:30	Requirements for warehouse orders: planning, packing and shipping: Susanne Fraise, UNICEF		
12:30–12:45	Closing remarks: Hanne Bak Pedersen, UNICEF		

12:45–14:00	Lunch		
SESSION 5: TUESDAY 25 SEPTEMBER: UNICEF & PQP PARALLEL SESSIONS			
Blue Room, Purple Room, Green Room: UNICEF meetings with individual manufacturers	INNOVATION ROOM: Prequalification assessment procedures & guidelines Chair: Matthias Stahl, PQP		
14:00 onwards	Manufacturers who have requested a meeting have been sent details of meeting time and location by Charlotte Thaarup.	14:00–14:30 Quality assessment update: Lynda Paleshnuik, Health Canada & external assessor	
		14:30–14:50 BE assessment update: John Gordon, Health Canada & external assessor	
		14:50–15:10 API assessment update: Antony Fake, PQP	
		15:40–16:00 Coffee/tea break	
		INNOVATION ROOM: From the manufacturers' point of view Chair: Valérie Faillat-Proux, Sanofi	
		16:00–17:00 Short presentations by manufacturer representatives: Venkatesh Katgeri (Cipla Ltd); Kavita Sehwan (Ipca Laboratories Ltd); Alex Zheng (Beijing Holley-Cotec Pharmaceuticals Co., Ltd); Kunle Okelola (Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria)	
		17:00–17:30 Discussion and questions	
		ADINA HOTEL: PQP meetings with individual manufacturers on assessment issues	
		18:00–23:00 Manufacturers who have requested a meeting have been sent details of meeting time and location by Matthias Stahl of the PQP assessment team (stahlm@who.int /+41 79 249 539).	

SESSION 6: WEDNESDAY 26 SEPTEMBER: UNICEF & PQP PARALLEL SESSIONS					
Blue Room, Purple Room, Green Room: UNICEF meetings with individual manufacturers		PURPLE ROOM & ADINA HOTEL: PQP meetings with individual manufacturers on assessment issues		INNOVATION ROOM: Inspections: Chair: Ian Thrusell, PQP problem areas for manufacturers	
09:00 onwards	Manufacturers who have requested a meeting have been sent details of meeting time and location by Charlotte Thaarup	08:00–23:00	Manufacturers who have requested a meeting have been sent details of meeting time and location by Matthias Stahl of the PQP assessment team (stahlm@who.int / +41 79 249 539).	Achieving good manufacturing practice	
				09:00–09:45	Examples of critical and major observations from GMP inspections of manufacturing sites, quality control laboratories and contract research organizations: Ian Thrusell, PQP
				09:45–10:10	Discussion
				10:10–10:30	Coffee/tea break
				Optimizing prequalification impact for patients, manufacturers & national medicines regulatory authorities	
				10:30–11:00	Accelerated procedure for registration of WHO-prequalified medicines: Milan Smid, PQP
				11:00–11:30	Discussion
				11:30–12:00	Coffee/tea break
				GREEN ROOM: PQP meetings with individual manufacturers on inspection issues	
				14:00–19:00	Manufacturers who have requested a meeting have been sent details of meeting time and location by Stephanie Croft (crofts@who.int /+41 79 213 4305) of the PQP inspection team.