**JOINT UNICEF, UNFPA & WHO MEETING WITH MANUFACTURERS AND SUPPLIERS OF DIAGNOSTIC PRODUCTS, FINISHED PHARMACEUTICAL PRODUCTS AND ACTIVE PHARMACEUTICAL INGREDIENTS**

23–25 September 2013  
UN City Copenhagen, Marmorvej 51, 2100 Copenhagen, Denmark

The open meeting sessions will be held 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 for these meetings are also given below.

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<tr>
<th>08:00–09:00</th>
<th>MEETING REGISTRATION</th>
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**SESSION 1: MONDAY 23 SEPTEMBER: UNICEF, UNFPA, WHO OPENING SESSION**

| 09:00–09:20 | Welcome address  
**Eric Dupont, Chief, Procurement Services Branch, UNFPA**  
**Shanelle Hall, Director, UNICEF Supply Division**  
**Lembit Rägo, Head, Regulation of Medicines and Health Technologies, WHO Department of Essential Medicines and Health Products** |
|-------------|------------------|
| 09:20–09:30 | Administrative/security arrangements  
**Søren Thomas Fugleberg, UN City Security** |

**SESSION 2: MONDAY 23 SEPTEMBER: MARKET DEMAND, (NEW) PRODUCT PRIORITIES & GETTING PRODUCTS TO MARKET QUICKLY**

| 09:30–09:40 | Session introduction  
**Hanne Bak Pedersen, Programme Manager, Health Technologies and Pharmaceuticals, WHO European Regional Office** |
|-------------|-----------------|
| 09:40–10:10 | Maternal, newborn and child health: product priorities and market prospects  
**Mark Young, Senior Health Specialist, UNICEF Programme Division, New York** |
| 10:10–10:45 | UN Commission on Lifesaving Commodities for Women and Children: product priorities and market prospects  
**Blerta Maliqi, RMNCH (Reproductive, maternal, newborn and child health) Strategy and Coordination Team, Senior Programme Specialist** |
| 10:45–11:15 | Coffee/tea break |
### 11:15–12:15
**HIV/AIDS, malaria, TB and neglected tropical diseases: product priorities and market prospects**

*Martin Auton, Senior Specialist, HIV Product Portfolio, The Global Fund to Fight AIDS, Tuberculosis and Malaria*

*John Loeber, Diagnostics Procurement Team Manager/Principal Officer, Contracts and Commercial Affairs, Global Drug Facility/Stop TB Partnership Secretariat*

*Lembit Rägo, Head, Regulation of Medicines and Health Technologies, WHO Department of Essential Medicines and Health Products*

*Robert Staley, Procurement Strategic and Technical Manager, Supply Chain Management System, Voluntary Pooled Procurement Program Partnership for Supply Chain Management*

### 12:15–12:45
**Speeding up access to markets: WHO Expert Review Panel & WHO accelerated registration procedure**

*How manufacturers, procurers and patients benefit*

*Joelle Daviaud, Health Products Quality Assurance Specialist, The Global Fund to Fight AIDS, Tuberculosis and Malaria*

*Namrata Vyas, Assistant Manager, International Marketing, Hetero Labs Limited*

### 12:45–13:00
**Q&A**

*Chairied by: Hanne Bak Pedersen, Programme Manager, Health Technologies and Pharmaceuticals, WHO European Regional Office*

### 13:00–14:00
**Lunch**

### SESSION 3: MONDAY 23 SEPTEMBER: NEW PRODUCT DEVELOPMENT & (IN PARALLEL) UNFPA PROCUREMENT Q&A, & UNICEF & WHO INDIVIDUAL MEETINGS WITH MANUFACTURERS

#### 14:00–14:15
**Session introduction**

*Jean-René Kiechel Senior Pharma Advisor & Product Manager, DNDi*

**UNFPA Q&A on procurement open to all manufacturers**

*Auditorium II*

*15:15–16:30*

*Contact: Isabel Lucas Manzano: manzano@unfpa.org; +45 2320 8325*

#### 14:15–14:45
**Diagnostics new product development: WHO's scientific and regulatory role, regulatory pathways and demand creation**

*Irena Prat, Technical Officer, WHO Prequalification of Diagnostics Programme*

#### 14:45–15:15
**Diagnostics product development projects**

*Smiljka de Lussigny, Technical Officer, HIV, UNITAID*

#### 15:15–15:30
**Q&A**

*Chairied by: Elliot Cowan, Principal, Partners in Diagnostics*

#### 15:30–16:00
**Coffee/tea break**

#### 16:00–16:30
**Medicines Patent Pool product development projects, including links with WHO medicines prequalification**

*Sandeep Juneja, Business Development Director, Medicines Patent Pool*

#### 16:30–17:00
**WHO’s scientific and regulatory contribution to product development**
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</table>
| 17:00–17:15  | **Q&A**  
Chaired by: Elliot Cowan, Principal, Partners in Diagnostics                                                                                                                                 |WHO diagnostics prequalification meetings with manufacturers                              |
|              | Room 0.3.25, 0.3.26  
Contact: Gaby Vercauteren: g.who.int  
+41 79 467 32 59  
Contact: Irena Prat  
p.who.int: +41 79 596 56 92                                                                 |WHO medicines prequalification meetings with manufacturers                             |
|              | Rooms 0.2.9, 0.2.10, 0.2.11, 0.2.17 VIP, 1.2.1  
Contact for assessment team: Matthias Stahl  
stahlm@WHO.int: +41 79 249 3539  
Contact for inspection team:  
Xingyu Chen: chenxi@who.int: +41 79 728 6972  
Contact for accelerated registration:  
Monika Zweygarth: zweygarthm@who.int: +41 76 530 4306                                                                 |                                                                                      |
| 18:00–20:00  | **RECEPTION FOR ALL PARTICIPANTS, IN RECEPTION AREA OF UN CITY**                                                                                                                                       |                                                                                      |

**SESSION 4: TUESDAY 24 SEPTEMBER: WHO PREQUALIFICATION TECHNICAL UPDATE SESSION & (IN PARALLEL) UNICEF INDIVIDUAL MEETINGS WITH MANUFACTURERS**

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<tr>
<th>Time</th>
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</table>
| 08:30–08:45  | **Session introduction**  
Lembit Rägo, Head, Regulation of Medicines and Health Technologies  
WHO Department of Essential Medicines and Health Products                                                                 |UNICEF diagnostics meetings with individual manufacturers                              |
|              | Room 0.2.15  
Contact: Charlotte Thaarup  
cthaarup@UNICEF.org: +45 3527 3083                                                                 |UNICEF medicines meetings with individual manufacturers                             |
| 08:45–09:05  | **Technical updates: diagnostics assessment**  
Irena Prat, Technical Officer, WHO Prequalification of Diagnostics Programme                                                                 |                                                                                      |
| 09:05–09:25  | **Technical updates: diagnostics inspection**  
Jeanette Twell, AAQ Consulting                                                                 |                                                                                      |
| 09:25–09:45  | **Technical updates: diagnostics laboratory evaluation**  
Gaby Vercauteren, Coordinator, WHO Prequalification of Diagnostics Programme                                                                 |                                                                                      |
| 09:45–10:15  | **Q&A**  
Chaired by: Elliot Cowan, Principal, Partners in Diagnostics                                                                                                                                 |                                                                                      |
<p>| 10:15–10:45  | <strong>Coffee/tea break</strong>                                                                                                                                                                                   |                                                                                      |</p>
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| 10:45‒11:40 | Technical updates: medicines assessment issues & new guidance (regarding quality, bioequivalence and active pharmaceutical ingredients)  
*Antony Fake, API Lead Assessor, WHO Prequalification of Medicines Programme*  
*John Gordon, Lead Bioequivalence Assessor, WHO Prequalification of Medicines Programme*  
*Lynda Paleshnuik, Lead Quality Assessor, WHO Prequalification of Medicines Programme* |                                                                                                     |
| 11:40‒12:35 | Technical updates: deficiencies observed during inspections & new guidance (focusing on inspection procedures and new guidelines, top 10 deficiencies found during inspections of contract research organizations, active pharmaceutical ingredient manufacturing sites and finished pharmaceutical product manufacturing sites)  
*Stephanie Croft, Inspector, WHO Prequalification of Medicines Programme*  
*Deus Mubangizi, Acting Head of Inspections, WHO Prequalification of Medicines Programme*  
*Vimal Sachdeva, Inspector, WHO Prequalification of Medicines Programme*  
*Ian Thrussell, Expert Inspector, WHO Prequalification of Medicines Programme* |                                                                                                     |
| 12:35‒13:00 | Q&A                                                                                               | *Chaired by: Ian Thrussell, Expert Inspector, WHO Prequalification of Medicines Programme*            |
| 13:00‒14:15 | Lunch                                                                                             |                                                                                                     |

**SESSION 5: TUESDAY 24 SEPTEMBER: PROCUREMENT POLICIES AND REQUIREMENTS & (IN PARALLEL) WHO INDIVIDUAL MEETINGS WITH MANUFACTURERS**

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| 14:15‒14:30 | Session introduction  
*Francisco Blanco, Chief of Medicines & Nutrition, UNICEF Supply Division* | WHO diagnostics prequalification meetings with manufacturers  
Rooms 0.3.25, 0.3.26  
Contact: Gaby Vercauteren: vercautereng@who.int  
+41 79 467 32 59  
Contact: Irena Prat  
prati@who.int; +41 79 596 56 92  
WHO medicines prequalification meetings with manufacturers  
Rooms 0.2.9, 0.2.10, 0.2.11, 0.2.17 VIP, 1.2.1  
Contact for assessment team: Matthias Stahl  
stahlm@who.int; +41 79 249 3539  
Contact for inspection team: Xingyu Chen  
chenxi@who.int; +41 79 728 6972  
Contact for accelerated registration:  
Monika Zweygarth: zweygarthm@who.int; +41 76 530 4306 |                                                                                                     |
| 14:30‒15:15 | Diagnostics and medicines procurement policies and requirements of UNICEF, UNFPA, Global Fund to Fights AIDS, Tuberculosis and Malaria and other funders/donors, including UN Initiative on Green Procurement in the Health Sector  
*Yasna Singh, Communication Associate, UNDP*  
*Morten Sørensen, Deputy Chief, Procurement Services Branch, UNFPA*  
*Monika Zweygarth, on behalf of Interagency Pharmacists’ Group* |                                                                                                     |
<p>| 15:15‒15:30 | Q&amp;A                                                                                               | <em>Chaired by: Francisco Blanco, Chief of Medicines &amp; Nutrition, UNICEF Supply Division</em>           |
| 15:30‒16:00 | Coffee/tea break                                                                                  |                                                                                                     |</p>
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<th>Room/Contact</th>
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<tr>
<td>16:00‒16:30</td>
<td>Quality of procured medicines: what may go wrong</td>
<td>Deus Mubangizi, Acting Head of Inspections, WHO Prequalification of Medicines Programme</td>
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<tr>
<td>16:30‒17:00</td>
<td>Model Quality Assurance System for assessing procurement agencies and what it means for manufacturers</td>
<td>Joelle Daviaud, Health Products Quality Assurance Specialist, The Global Fund to Fight AIDS, Tuberculosis and Malaria</td>
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<tr>
<td>17:00‒17:15</td>
<td>Q&amp;A</td>
<td>Chaired by: Deus Mubangizi, Acting Head of Inspections, WHO Prequalification of Medicines Programme</td>
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**SESSION 6: WEDNESDAY 25 SEPTEMBER: MARKETS AND PRODUCT DEVELOPMENTS FOR REPRODUCTIVE HEALTH DIAGNOSTICS & MEDICINES & (IN PARALLEL) WHO INDIVIDUAL MEETINGS WITH MANUFACTURERS**

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<tr>
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<tbody>
<tr>
<td>09:00‒09:15</td>
<td>Session introduction</td>
<td>John Skibiak, Director, Reproductive Health Supplies Coalition</td>
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<tr>
<td>09:15‒09:45</td>
<td>Quality, assured reproductive health medicines: the business case</td>
<td>Louis Riceberg, Principal, BioBridge Strategies</td>
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<tr>
<td>09:45‒10:00</td>
<td>Q&amp;A</td>
<td>Chaired by: John Skibiak, Director, Reproductive Health Supplies Coalition</td>
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<tr>
<td>10:00‒10:30</td>
<td>Overview of new developments in diagnostics: multi, analyte tests for hepatitis B, hepatitis C and syphilis</td>
<td>Gaby Vercauteren, Coordinator, WHO Prequalification of Diagnostics Programme</td>
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<tr>
<td>10:30‒10:45</td>
<td>Q&amp;A</td>
<td>Chaired by: Elliot Cowan, Principal, Partners in Diagnostics</td>
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<tr>
<td>10:45‒11:15</td>
<td>Coffee/tea break</td>
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**SESSION 7: WEDNESDAY 25 SEPTEMBER: IMPROVING ACCESS TO QUALITY, ASSURED REPRODUCTIVE HEALTH MEDICINES AND DIAGNOSTICS & (IN PARALLEL) UNFPA/UNICEF/WHO INDIVIDUAL MEETINGS WITH MANUFACTURERS**

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<tr>
<td>11:15‒11:30</td>
<td>Session introduction</td>
<td>Morten Sørensen, Deputy Chief, Procurement Services Branch, UNFPA</td>
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<td>11:30‒12:15</td>
<td>How Concept Foundation supports medicines manufacturers to achieve WHO prequalification</td>
<td>Lester Chinery, Director of Operations, Concept Foundation</td>
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</tbody>
</table>

WHO diagnostics prequalification meetings with manufacturers
Room 0.3.25, 0.3.26
Contact: Gaby Vercauteren: vercautereng@who.int
+41 79 467 32 59
Contact: Irena Prat
prati@who.int; +41 79 596 56 92

WHO medicines prequalification meetings with manufacturers
Room 0.2.9, 0.2.10, 0.2.11, 0.2.17 VIP, 1.2.1
Contact for assessment team: Matthias Stahl
stahlm@who.int; +41 79 249 3539
Contact for inspection team: Xingyu Chen
chenxi@who.int; +41 79 728 6972
Contact for technical assistance: Milan Smid
smidm@who.int; +41 79 530 4306

UNFPA meetings with individual manufacturers
Room 1.102
Contact: Seloi Mogatle
mogatle@unfpa.org; +45 8192 7816
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<th>Time</th>
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| 12:15–12:30  | Q&A                                                                     Chairled by: Ian Thrussell, Expert Inspector, WHO Prequalification of Medicines Programme | UNICEF diagnostics meetings with individual manufacturers  
Room 0.2.15  
Contact: Charlotte Thaarup  
cthaarup@unicef.org: +45 3527 3083  
UNICEF medicines meetings with individual manufacturers  
Room 0.2.13  
Contact: Charlotte Thaarup  
cthaarup@unicef.org: +45 3527 3083  
WHO diagnostics prequalification meetings with manufacturers  
Rooms 0.3.25, 0.3.26  
Contact: Charlotte Thaarup  
cthaarup@unicef.org: +45 3527 3083 |
| 12:30–13:30  | Lunch                                                                   |                                                                                                           |
| 13:30–14:30  | Manufacturer feedback and discussion on challenges and opportunities for entering the global reproductive health medicines market  
Chen Ying, Deputy Director, Foreign Trade Department, China Resources Zizhu Pharmaceutical Co., Ltd  
Sweety Thoppil, Cipla Institutional Business Development  
TBC, Famy Care Ltd  
Chairled by: Ian Thrussell, Expert Inspector, WHO Prequalification of Medicines Programme | WHO diagnostics prequalification meetings with manufacturers  
Rooms 0.3.25, 0.3.26  
Contact: Charlotte Thaarup  
cthaarup@unicef.org: +45 3527 3083 |
| 14:30–15:00  | Overview of Marie Stopes International procurement policies and requirements  
Tracey Brett, Associate Director Procurement & Logistics, Marie Stopes International | WHO medicines prequalification meetings with manufacturers  
Rooms 0.2.9, 0.2.10, 0.2.11, 0.2.17 VIP, 1.2.1  
Contact for assessment team: Matthias Stahl: stahlm@who.int: +41 79 249 3539  
Contact for inspection team: Xingyu Chen: chenxi@who.int: +41 79 728 6972  
Contact for technical assistance: Milan Smid: smidm@who.int: +41 79 530 4306 |
| 15:00–15:30  | Overview of USAID procurement policies and requirements  
Erin Seaver, Programme Adviser, Commodities Security & Logistics Division, Office of Population and Reproductive Health, USAID |                                                                                                           |
| 15:30–16:00  | Coffee/tea break                                                        |                                                                                                           |
| 16:00–16:30  | Overview of UNFPA procurement policies and requirements  
Morten Sørensen, Deputy Chief, Procurement Services Branch, UNFPA |                                                                                                           |
| 16:30–16:45  | Q&A                                                                     Chairled by: Francisco Blanco, Chief of Medicines & Nutrition, UNICEF Supply Division |                                                                                                           |
| 16:45–17:00  | Wrap up & closing remarks  
Morten Sørensen, Deputy Chief, Procurement Services Branch, UNFPA |                                                                                                           |