

Where the World is Going and What We Should do Next

Joint UNICEF, UNFPA and WHO meeting with manufacturers and suppliers of in vitro diagnostic products, vaccines, finished pharmaceutical products, active pharmaceutical ingredients, contraceptive devices and vector control products

24–27 September 2018

UN City, Marmorvej 51, 2100 Copenhagen, Denmark

As in previous years, this UN meeting will welcome and bring together a wide range of stakeholders — manufacturers, quality, safety and efficacy experts, procurement agencies, and international donors — whose combined efforts bring needed health products to vulnerable populations. But this year’s agenda is a little different.

Day 1 will include a clear focus on tomorrow, asking the question, “What are some of the things we need to do or could do today to tackle some of tomorrow’s health challenges?”

Plenary sessions will cover:

- predictive modelling for new priorities (outbreaks/emergencies, vector control) and known priority disease states (HIV, malaria, TB)
- what the first WHO Essential Diagnostics List means for manufacturers and procurers
- the shifting reproductive health medicines landscape, including “innovator” and “generic” viewpoints
- issues relating to demand and supply of health products during emergencies
- new market needs (covering HPV, non-communicable diseases, IVDs for low- and middle-income countries, the Medicines Patent Pool’s expanded mandate and vector control).

Day 2 will focus more on today, covering the current procurement requirements and procedures of major international procurers. Day 2 will also cover prequalification requirements — particularly recent changes — for in vitro diagnostics (IVDs), active pharmaceutical ingredients, finished pharmaceutical products and vaccines.

Day 2 will include an all-day workshop for vector control, starting with an overview of current public health challenges in vector control and the need for innovation to tackle them. This will be followed by a step-by-step guide to development of a product dossier for evaluation WHO prequalification.

Participants will also be able to hear updates on treatment guidelines for TB and HPV, and attend break-out sessions on uterotonics, benzathine benzyl penicillin and success factors for in vitro diagnostic manufacturers.

Two sessions on **technical assistance** — for IVDs and medicines — will describe WHO’s approach to provision of this type of support for manufacturers.

Day 3 will largely take the form of a “regulatory forum for manufacturers”. Implications of the WHO-listed Authority concept for manufacturers will be explained, followed by a session on abridged assessment for prequalification. (Products registered by a WHO-listed Authority will be eligible for abridged assessment for prequalification.)

The latest developments relating to WHO’s collaborative procedure for registration will also be presented, including achievements to date in using the procedure to accelerate market access for prequalified



medicines and vaccines, and progress in extending those achievements to IVDs and vector control products.

Also on Day 3, a “prequalification feedback forum” will give meeting participants an opportunity to make their suggestions for improving prequalification processes or to pose questions regarding those processes.

1-to-1 meetings

During the **afternoons of Days 2 and 3, and during all of Day 4**, manufacturers will have an opportunity to meet 1-to-1 with UNFPA and/or UNICEF and/or Global Fund and/or the Global Drug Facility (GDF) and/or WHO procurement should they require detailed information regarding the procurement requirements and procedures of these agencies. Meeting participants can request a meeting by contacting these agency staff:

- for **Pan American Health Organization** contact Adriana Oxman (for Revolving Fund queries relating to vaccines) (oxmanadr@paho.org) or Marcos Chaparro (for queries relating to Strategic Fund) (chaparrm@paho.org)
- for **Global Drug Facility** contact Kaspars Lunte (kasparsl@stoptb.org)
- for **Global Fund** contact Amélie Darmon (amelie.darmon@theglobalfund.org) (available 25 and 26 September only)
- for **UNDP** contact Zafar Yuldashev (zafar.yuldashev@undp.org)
- for **UNFPA** contact Seloi Mogatle (mogatle@unfpa.org)
- for **UNICEF** contact Charlotte Armand Nielsen (carnielsen@unicef.org)
- for **WHO procurement** contact Sophie Laroche (laroches@who.int) (available 24 and 25 September only).

Manufacturers will also be able to meet 1-to-1 with:

- the WHO Prequalification Team
- WHO staff members working on technical assistance
- WHO staff members working on the WHO collaborative procedure for registration.

Manufacturers will be able to raise questions relating to current or proposed applications for WHO prequalification, and/or to seek further information regarding prequalification requirements, technical assistance or collaborative registration. Manufacturers can request a meeting by contacting:

- Mercedes Pérez González — for **in vitro diagnostics assessment/inspection/performance evaluation** for WHO prequalification — perezgonzalezm@who.int
- Matthias Stahl — stahlm@who.int — for **medicines assessment** for WHO prequalification
- Vimal Sachdeva — sachdevav@who.int — for **medicines inspection** for WHO prequalification
- Carmen Rodriguez-Hernandez — rodriguezhernandezc@who.int — for **vaccines assessment & 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 prequalification of **vector control products**
- Gaby Vercauteren — vercautereng@who.int — for **technical assistance for IVD manufacturers**
- Rutendo Kuwana — kuwanaru@who.int — for **technical assistance for medicines manufacturers**
- Luther Gwaza — gwazal@who.int — for **collaborative registration**.

Manufacturers and suppliers are encouraged to attend the relevant meeting sessions ahead of any individual meetings since the sessions will provide the latest information on requirements and how to meet them. When requesting a 1-to-1 meeting, and to assist agency staff, participants should indicate the topic(s) for which they have questions or are seeking further information.

Meetings may also be possible at times other than indicated on the agenda, depending on the availability of the staff members concerned.

