

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, finished pharmaceutical products, active
pharmaceutical ingredients, contraceptive devices and vector control products**

**2–5 December 2019
UN City, Marmorvej 51, 2100 Copenhagen, Denmark**

Each year, the World Health Organization (WHO), together with the United Nations Children's Fund (UNICEF) and the United Nations Population Fund (UNFPA), holds a four-day meeting for manufacturers of medicines, vaccines, in vitro diagnostics (IVDs), reproductive health and vector control products to discuss issues around the production and supply of quality products needed for vulnerable populations.

The theme of the 2019 joint meeting is: "Improving the Response of Global Public Health in a Fast-Changing World", recognizing that while much has been achieved, much remains to be achieved, and needs to be achieved with greater speed and efficiency. The meeting will provide manufacturers with information, discussion and insights to address long-term planning needs – discoveries, trends and developments shaping the global healthcare landscape – as well as technical updates relating, for example, to international procurement or prequalification, and an opportunity to meet with UN agency hosts on specific topics.

Day 1 will be held in plenary, focus on tomorrow and open with a keynote address and response on the meeting theme. These will be followed by presentations delivered by a group of global health thought-leaders on topics related to high-impact areas:

- emergency preparedness
- communication to reduce human resistance to care
- progress and outlook for global health initiatives
- global health landscapes.

Day 2 will cover:

- the current procurement requirements, procedures and challenges of international procurers
- an overview of IVD prequalification for new applicants
- WHO prequalification updates — for IVDs, active pharmaceutical ingredients, finished pharmaceutical products, vaccines and vector control products
- UNFPA prequalification requirements for contraceptive devices.

Of especial note, the update for WHO medicines assessment for prequalification will include an update on the biosimilar products prequalification pilot.



A session covering **local production**, and **technical assistance** for IVDs and medicines, will provide an update on the work of WHO and other UN agencies to promote local production, and information on WHO's approach to provision of technical assistance for IVD and medicines manufacturers.

Day 3

The first part of day 3 will be dedicated to:

- WHO policy, diagnosis and treatment guidelines updates (for tuberculosis, HIV and sexually-transmitted infections, hepatitis B and C, and malaria)
- WHO Model List updates for IVDs and for essential medicines.

The theme of the regulatory session is regulatory oversight in the lifecycle of a medical product, covering:

- evolving regulatory concepts (specifically, good regulatory and good reliance practices, the WHO Global Benchmarking Tool and WHO Listed Authorities)
- WHO Collaborative Procedure best practices and remaining hurdles
- market surveillance (including pharmacovigilance and an overview of WHO's work to tackle substandard and falsified medical products).

The regulatory session will also include a closer look at the “sartan case”. Angiotensin-II-receptor agonists (sartans) are a group of antihypertensives. Sartan medicines that contain nitrosamine-impurities were first detected in July 2018. Since then, many more have been detected around the globe, resulting in the recall of numerous batches and, ultimately, shortages of these medicines that are used by millions of patients. A brief introduction to the case will be followed by a moderated panel discussion focusing on the lessons that can be learnt by both regulators and manufacturers — not just with respect to this case, but all medical products.

During the lunch break participants will be able to attend a breakout session on safe abortion or The International Pharmacopoeia.

1-to-1 meetings

During the **afternoons of Days 2 and 3, and during all of Day 4**, manufacturers will be able 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 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).



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:

- Charles Chiku — for **in vitro diagnostics assessment/inspection/performance evaluation** for WHO prequalification — chikuc@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 — rodriguezhernandezcc@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**
- 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.

