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

18–21 September 2017

UN City, Marmorvej 51, 2100 Copenhagen, Denmark

Draft programme (of 21 June 2017)

This UN meeting will 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. The 2017 meeting will cover not only vitro diagnostic products (IVDs), vaccines, finished pharmaceutical products, active pharmaceutical ingredients, and contraceptive devices, but also vector control products.

Day 1

Plenary sessions will focus on:

- prices and markets for quality-assured IVDs, medicines and vaccines across different therapeutic areas
- managing vaccines supplies and prices to keep prices stable and eliminate shortages
- looking beyond price when valuing quality-assured medicines
- stimulating introduction of new, innovative IVDs.

Day 2

Procurement issues covered will include:

- **changes to TB treatment guidelines** and what this means for **Global Drug Facility** medicines procurement
- the **new approach to health procurement**, known as **wambo.org,** that is being pioneered by the **Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria**
- the **use of barcodes by UNFPA or USAID** for identifying and tracking procured hormonal contraceptives as they move through the supply chain
- **UNICEF procurement needs**
- the value of **WHO pharmaceuticals procurement** (currently around US$ 180 million per year), the products procured and needed, and how vendors are selected
- **temperature-controlled transport of pharmaceuticals** which is of great concern of to both **UNFPA** and **UNICEF** given a recent survey that showed that more than 60% of oxytocin samples did not comply with specifications.

Also on **Day 2**, participants can learn about IVD prequalification, vaccines prequalification, recently-introduced vector control prequalification or the upcoming pilot project for prequalification of biosimilars for cancer treatment.

The **introduction to IVD prequalification** and the **introduction to vaccines prequalification** are designed especially for new applicants, i.e. for manufacturers who are unfamiliar with prequalification and/or considering submission of an application for prequalification assessment. The introductions will provide an overview of what products would be eligible for assessment, the assessment process (including the

type and extent of information that must be submitted), the components of assessment and how these are carried out, as well as the technical areas of difficulty that WHO has observed that IVD manufacturers commonly face when seeking prequalification.

The **introduction to vector control prequalification** will explain the evolution of WHO's approach to supporting the development, evaluation and adoption of new vector control products and tools, and the division of responsibilities between the WHO Prequalification Team and the WHO Pesticide Evaluation Scheme. WHO prequalification of vector control products started in January 2017 and primarily benefits populations affected by major vector-borne diseases such as malaria, dengue fever and other arboviral diseases, Chagas disease, lymphatic filariasis, visceral leishmaniasis, and human African trypanosomiasis. Products evaluated are generally pesticidal active ingredients for use in formulated end-use vector control products, such as long-lasting insecticidal bed nets and insecticide for indoor residual sprays.

At the time of the meeting the **WHO pilot project for prequalification of biosimilars for cancer treatment** will have just been launched, with an invitation to manufacturers to submit applications for prequalification of biosimilar versions of rituximab (used principally to treat non-Hodgkin's lymphoma and chronic lymphocytic leukemia), and trastuzumab (used to treat breast cancer). The project is a first step towards making some of the most expensive treatments for cancer more widely available in low- and middle-income countries. The introduction to this project will include an overview of the procedure and processes for prequalifying medicines in this important therapeutic area.

Technical updates will be given for prequalification product streams: contraceptive devices, IVDs, medicines and vaccines. Assessment updates for IVDs, medicines and vaccines will cover any recent changes to prequalification requirements and outline new guidance. The inspections updates will summarize current inspection challenges relating to IVDs, medicines and vaccines. The contraceptive devices update will include a review of male condom specification and prequalification guidelines, risk management during production of condoms and IUDs, and also consider funding for prequalification of condoms and intrauterine devices (IUDs). The update on **technical assistance for IVDs and medicines** will describe WHO's new approach to provision of this type of support for manufacturers.

Day 3

The day's three session will have a common theme: making the most of WHO prequalification. The first session will provide an overview of **the investments that manufacturers may have to make when seeking prequalification, the range of likely costs involved, and how best to make use of prequalification guidance and resources to minimize that cost**. The second session will provide an update on **WHO's collaborative registration procedure (CRP)**: the achievements to date in using CRP to accelerate market access for prequalified medicines and vaccines, and plans for extending those achievements to IVDs and vector control products. It will also include a brief **introduction to the Caribbean Regulatory System**, which includes prompt granting of marketing authorization — following abbreviated review of product dossiers that conform to international standards — as one of its objectives. (The Caribbean Public Health Agency/Caribbean Regulatory System receives support from national regulatory authorities of regional reference designated by the Pan American Health Organization (PAHO).) The third session will be an open forum at which manufacturers will be invited **to present their suggestions for improving prequalification processes** and to pose questions regarding, for example, **WHO prequalification performance and how that is measured** and **fees for prequalification**.

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, wambo.org** and/or **the Global Drug Facility (GDF)** 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 **Global Drug Facility** contact Nigorsulton Muzafarova (muzafarovan@who.int)
- for **UNFPA** contact Seloi Mogatle (mogatle@unfpa.org)
- for **UNICEF** contact Charlotte Armand Nielsen (canielsen@unicef.org)
- for **wambo.org** contact TBD
- for **WHO procurement** contact Sophie Laroche (laroches@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 collaborative procedure for registration
- a PAHO staff member on the Caribbean Regulatory System.

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 Peréz 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
- TBD — but contact prequal@who.int — for **biosimilars for cancer treatment** 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 in vitro diagnostics manufacturers**
- Rutendo Kuwana — kuwanaru@who.int — for **technical assistance for medicines manufacturers**
- Luther Gwaza or Gabriela Zenhausern — gwazal@who.int /zenhauserng@who.int — for **collaborative registration**
- Charles Preston — prestoncha@paho.org — for the **Caribbean Regulatory System**.

Manufacturers and suppliers are encouraged to attend the procurement or WHO prequalification update ahead of individual meetings with UNICEF, UNFPA, WHO or GDF staff since these will provide the latest information on requirements and how to meet them. In requesting a 1-to-1 meeting participants should indicate the topic(s) for which they have questions or are seeking further information; this will assist staff in their preparation for the 1-to-1 meetings.

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

Poster presentations

Participants will have the opportunity to make a **poster presentation**. Interested participants are invited to submit a brief outline of their planned presentation to: prequal@who.int. Outlines will be reviewed and a small number selected for display in the foyer of UN City.