WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR EUROPE

WELTGESUNDHEITSORGANISATION
REGIONALBÜRO FÜR EUROPA

ORGANISATION MONDIALE DE LA SANTÉ
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ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ
ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО

First PQTm workshop for Russian - speaking participants
UN City, Marmorvej 51, 2100 Copenhagen, Denmark
19-20 May 2017

2 February 2017

Original: English with Russian translation

Scope and purpose

Title of the seminar
First PQTm workshop for Russian-speaking participants
Organized/sponsored by
WHO PQTm/WHO Regional Office for Europe

Background
WHO PQTm has held annual assessment workshops in Copenhagen beginning in 2009. These workshops provide a high level of training in the practical aspects of quality and bioequivalence assessment - an area in which structured and practical training is lacking or generally unavailable. The workshops have been well attended by an international audience of regulators and been very well received, however in the past they have been limited to English-speaking participants. Interest has been expressed in a dedicated workshop for Russian-speaking attendees.

Objectives of the meeting:

- To provide the opportunity for Russian speaking participants to attend a WHO PQTm assessment workshop.
- To provide an overview of Prequalification of Medicines: who we are, what we do, and the guidelines and practices we apply.
- To deliver presentations covering the fundamental areas of quality and bioequivalence assessment by the senior experts in these areas;
- To provide an opportunity to increase knowledge in the important aspects of assessment of both the API (Active Pharmaceutical Ingredient) and FPP (Finished Pharmaceutical Product).
- To provide practical approaches and tips for assessment practices.
- To provide a forum with experts for questions and answers related to the presentation topics and beyond, i.e. open to all questions related to the assessment process;
- To gain an understanding of the needs and desires of the participants for possible future workshops.

Who should attend

The participants should be regulators who are involved in the **practical assessment of the quality (or BE) part of the dossier**, AND who have the capacity/interest and authority to communicate further in their respective organization what they learn.
It is advisable to engage management of the NRAs to participate in the course to better understand the role of assessment and its place in the regulatory settings.

Venue and date

UN City, Copenhagen, Denmark – 19-20 May 2017, 8:30 am to 5:30 pm

Communication for the nominations

All information about the nominations as well as Q&A with regards to the training details should go to DSP/HTP Olexandr Polishchuk at polishchuko@who.int with copy to Lisbeth Lindhardt at lindhardtl@who.int.