



WORLD HEALTH ORGANIZATION
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Date: 19 May 2017

Dr Nino Berdzuli
Deputy Minister
Ministry of Labour, Health and Social Affairs
144, Ak. Tsereteli Ave.
0119 Tbilisi
Georgia

Dear Dr Berdzuli,

**First Prequalification Team Medicines (PQTm) workshop for Russian-speaking regulators
Copenhagen, Denmark, 19-20 May 2017**

I have the honour to inform you that the World Health Organization Regional Office for Europe plans to hold the above-mentioned meeting.

The aim of the meeting is:

- 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.
- An outline of the scope and purpose of the meeting and a copy of the provisional agenda are enclosed.

I have pleasure in inviting you to nominate three participants from your organization. The participants should be regulators who are involved in the **practical assessment of the quality (or bioequivalence) part of the dossier**, and who have the capacity/interest and authority to communicate further in their respective organization what they learn.

The working language will be English and simultaneous interpretation into Russian will be provided.

Travel for participants will be arranged and paid for by this office, and they will also receive a daily subsistence allowance for the duration of the meeting in accordance with our travel regulations.

I look forward to receiving your nominations, giving the names, functional titles and addresses of the proposed participants at your early convenience. We shall then communicate with them directly and provide them with the necessary documentation and administrative information in good time.

Dr Olexandr Polishchuk is responsible for this activity and it would be appreciated if you would address your reply to him at polishchuko@who.int with copy to Mrs Lisbeth Lindhardt at lindhardtl@who.int.

Yours sincerely,



Dr Hans Kluge
Director, Division of Health Systems and Public Health

Enclosures:

Scope and purpose
Provisional agenda

Copy for information:

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