



WORLD HEALTH ORGANIZATION
ORGANISATION MONDIALE DE LA SANTÉ
WELTGESUNDHEITSORGANISATION
ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ

REGIONAL OFFICE FOR EUROPE
BUREAU RÉGIONAL DE L'EUROPE
REGIONALBÜRO FÜR EUROPA
ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО

Head office:
UN City, Marmorvej 51,
DK-2100 Copenhagen Ø, Denmark
Tel.: +45 45 33 70 00; Fax: +45 45 33 70 01
Email: contact@euro.who.int
Website: <http://www.euro.who.int>

Date: 1 June 2017

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

Dear Dr Berdzuli,

Implementation of WHO guidelines of biotherapeutics (BTP) including biosimilars in Russian speaking countries

**First BTP workshop for Russian-speaking participants
Copenhagen, Denmark, 5 – 7 July 2017**

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

I seek your support to facilitate the nomination of three participants from your country. Participants should be regulators involved in the practical assessment of the quality and clinical area of the dossier for biotherapeutics and who have the ability and authority to encourage capacity building within their respective organizations regarding the outcome of this important event. It is our recommendation to engage management of the National Drug Agency to participate in the meeting in order to better understand the role of assessment and its place in regulatory settings.

The aim of the meeting is:

- to facilitate implementation of WHO guidelines for biotherapeutics into regulatory practices in the countries,
- to discuss key regulatory issues relevant to assurance of quality, safety, and efficacy of biotherapeutics with regulators,
- 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 guidelines implementation 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 programme are enclosed.

The working language will be English with simultaneous interpretation into Russian.

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, polishchuko@who.int with copy to Lisbeth Lindhardt, lindhardtl@who.int

Sincerely yours,



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

Enclosures:

Scope and purpose
Provisional programme

Copy for information to:

Dr Nana Kavtaradze, Head, Executive Office, Ministry of Labour, Health and Social Affairs, 144, Ak. Tsereteli Ave., 0119 Tbilisi, Georgia

Mr Shalva Tsiskarashvili, Permanent Representative, Permanent Mission of Georgia to the United Nations Office and other international organizations in Geneva, Rue Richard-Wagner 1, CH-1202 Genève, Switzerland

H.E. Mr Nikoloz Rtveliashvili, Ambassador Extraordinary and Plenipotentiary, Embassy of Georgia, Nybrogade 10, 1st. Floor, 1203 Copenhagen K, Denmark

Mr Niels Scott, United Nations Resident Coordinator, UNDP Resident Representative, United Nations Development Programme, UN House, 9 Eristavi St., 0179 Tbilisi, Georgia

Dr Marijan Ivanusa, Head of WHO Office, WHO Country Office, Georgia, UN House, 9 Eristavi St., 0179 Tbilisi, Georgia