WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR EUROPE

WELTGESUNDHEITSORGANISATION
REGIONALBÜRO FÜR EUROPA

ORGANISATION MONDIALE DE LA SANTÉ
BUREAU RÉGIONAL DE L'EUROPE

ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ
ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО

First BTP workshop for Russian -speaking participants
UN City, Marmorvej 51,
2100 Copenhagen, Denmark
05 – 07 July 2017

Version: 05 February 2017

Original: English with Russian translation

Scope and purpose

Title of the seminar
Implementation of WHO guidelines of biotherapeutics including biosimilars in Russian speaking countries

Organized/sponsored by
WHO HQ/WHO Regional Office for Europe

Background
WHO guidelines on evaluation of similar biotheraptic products (SBPs) were adopted by the WHO Expert Committee for Biological Standardization (ECBS) in 2009, and provided a set of globally acceptable principles regarding the regulatory evaluation of SBPs. However, it was recognized that they will not by themselves resolve all issues, so the International Conference of Drug Regulatory Authorities in 2010 recommended that WHO supplement its guidance on the evaluation of SBPs by providing up-to-date guidelines for the evaluation of biotherapeutic products in general. In response to this, the WHO guidelines on the quality, safety, and efficacy of biotherapeutic protein products prepared by recombinant DNA technology were developed and adopted by the ECBS in 2013. Furthermore, the 67th World Health Assembly (2014) adopted a resolution on the critical needs in the biotherapeutics area (including SBPs) in order to promote access to these products as well as to ensure their quality, safety and efficacy (WHA 67.21). It requests WHO to support national regulatory authorities to develop national regulatory frameworks to meet current/ international regulatory expectations.

The 1st implementation workshop for Russian speaking countries in EURO on WHO guidelines for biotherapeutics and SBPs has been planned in Copenhagen, Denmark as a step towards the implementation of principles in two WHO guidelines. Although they are separated documents, many principles in the documents are cross-linked. In addition, contrasting the evaluation principles of one to another would help regulators better understanding on their implication.

Objectives of the meeting:

- 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.

Who should attend

Member States will be invited to participate and discuss about the key principles in evaluating biotherapeutic products including SBPs. Before the workshop, a survey is going to be conducted for better understanding of the country situation in order to identify their regulatory issues and needs. We seek nomination from each country who has knowledge and experience in reviewing dossiers on quality, nonclinical or clinical evaluation of biotherapeutics including biosimilars for the licensure.
The participants should be regulators who are involved in the **practical assessment of the quality and clinical part of the dossier for biotherapeutics**, 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 – 05 – 07 July 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