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

Workshop on implementation of WHO guidelines of biotherapeutics including biosimilars in Russian speaking countries

31 May 2017

Copenhagen, Denmark
05 – 07 July 2017

Original: English

Provisional programme

Wednesday, 5 July 2017

Session 1	**Welcome and Introduction**
08:30 - 09:00	Registration – Participants
09:00 - 09:15	Opening remarks
09:15 - 09:35	Self-introduction
09:35 - 09:50	Announce the results of assessing DOI; Housekeeping announcement – WHO EURO
Session 2	**Background and Objectives**
09:50 - 10:15	WHO activities/updates in the area of biotherapeutics – Dr H. Kang (WHO HQ)
10:15 - 10:30	Background, objectives and expected outcomes of the meeting – WHO EURO
10:30 - 11:00	***Coffee break***
Session 3	**Regulatory expectations for biotherapeutics including biosimilars**
11:00 - 11:30	Quality aspect - TBD
11:30 - 12:00	Clinical aspect – TBD
12:00 - 12:30	Immunogenicity assessment – Dr R. Thorpe (WHO consultant)
12:30 - 13:00	Discussion
13:00 - 14:00	**Lunch break**
Session 4	**Specific considerations and challenges in development of biosimilars**
14:00 - 14:30	Issues related to reference products – Industry representative
14:30 - 15:00	Extrapolation of indication – Industry representative
15:00 - 15:30	Discussion
15:30 – 16:00	***Coffee break***

Session 5	**Guiding principles for regulatory assessment of biotherapeutics**
16:00 - 17:00	Key principles in WHO guidelines & Review examples – Dr E. Griffiths (WHO consultant)
17:00 - 17:30	Discussion

Thursday, 6 July 2017

Session 6	**Analytical comparability assessment of biosimilars**
09:00 - 09:30	Introduction and summary of IPRF material for regulatory reviewers – Dr H. Kang (WHO HQ)
09:30 - 10:30	Experience sharing from pre-workshop self-study – Representatives (4 countries)
10:30 - 11:00	***Coffee break***
11:00 - 11:30	Evaluation and interpretation of quality comparability exercise results (EPO case) – Industry representative
11:30 - 12:00	Discussion
12:00 - 13:00	***Lunch break***
Session 7	**Case study**
13:00 - 13:30	The role and influence of the quality assessment (EPO) – TBD
13:30 - 15:30	Work in groups
15:30 - 16:00	***Coffee break***
16:00 - 17:00	Feedback from groups – Leader of each group
17:00 - 18:00	Overall discussion & Conclusion
18:00	Close of open meeting

Friday, 7 July 2017 Closed sessions (regulators and participants without conflict of interest)

Session 8	**Report from countries**
09:00 - 10:30	Country situation (regulatory framework, approval process, recent updates and challenges), Implementation of WHO guidelines (practical uses or plan for implementation), and Proposal to WHO – A representative from each country
10:30 - 11:00	***Coffee break***

Session 9	**Conclusions and next steps**
11:00 - 12:00	Discussion & Lessons learnt
12:00 – 13:00	Summary of the workshop: Conclusions and next steps
13:00	Close of meeting