



PHARM 697

PHARMACEUTICAL COMMITTEE
21 October 2015

Subject: WHO Biological Qualifier

Agenda item 6b

Since the last update to the Pharmaceutical Committee at the occasion of its 73rd meeting in October 2014, the following developments have taken place concerning the WHO Biological Qualifier:

- The Biological Qualifier was discussed at the INN Expert Group meeting 14-16 October 2014; the executive summary can be found here: http://www.who.int/medicines/services/inn/59th_Executive_Summary.pdf?ua=1.
- A Biological Qualifier Regulatory Forum took place on 30th March 2015. The purpose of the meeting was to survey, review and discuss the Biological Qualifier proposal with National Drug Regulatory Agencies; no publicly available meeting report is available.
- The Biological Qualifier was discussed at the INN Expert Group meeting 13-15 April 2015; the executive summary can be found here: http://www.who.int/medicines/services/inn/60th_Executive_Summary.pdf?ua=1.
- A revised proposal for the Biological Qualifier was published in June 2015; the revised proposal can be found here: http://www.who.int/medicines/services/inn/bq_innproposal201506.pdf.pdf?ua=1.
- On 16 June 2015 a Front Page meeting with INN stakeholders took place to review comment in the proposal on the Biological Qualifier; the meeting report can be found here: http://www.who.int/medicines/services/inn/BQ_FP_meeting_final.pdf.
- At INN Expert Group meeting 13-16 October 2015 where Biological Qualifier is to be further discussed and may be adopted. Neither EMA, nor the European Commission is a member of the INN Expert Group and hence, has received no revised or final proposal for the Biological Qualifier.

Only oral information on discussion at the WHO INN Expert Group will be given at the 75th meeting of the Pharmaceutical Committee due to the proximity of the two meetings.

The current EU thinking remains that biosimilars should be closely aligned with their reference medicinal products and identification by INN together with a qualifier or code for each biosimilar would be contrary to such alignment.

However, industry stakeholders have informed the DG SANTE that national industry stakeholders are lobbying the national competent authorities for the introduction of the Biological Qualifier.

Action to be taken:

For information