



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Evaluation Division

Workshop on immunogenicity assessment of biotechnology-derived therapeutic proteins

Workshop Summary

9th March at the European Medicines Agency, 30 Churchill Place, Canary Wharf, London, UK, meeting room 3A

The CHMP Biosimilar Medicinal Products Working Party (BMWP) is revising the 'Guideline on Immunogenicity Assessment of biotechnology-derived therapeutic proteins' (CHMP/BMWP/14327/06). The draft revised guideline was released in October 2015 for a four month public consultation ending on 31 January 2016.

This EMA Workshop was intended to complement the public consultation to allow for additional discussion on issues relevant to the assays and methods used to explore and assess the immunogenicity of therapeutic proteins. It focused on the following aspects:

- The development of adequate assays for detecting and measuring immune response in humans including challenges in assessing relative immunogenicity;
- Innovative non-clinical models that could better predict immunogenicity of biotechnology-derived therapeutic proteins in humans;
- Immunogenicity and risks associated with the use of products containing therapeutic proteins including pharmacovigilance aspects.

The workshop was announced on the EMA website and participants included representatives of BMWP, the Biologics Working Party, other regulatory authorities, patient and healthcare professionals and industry stakeholders.

The workshop was broadcast live and a recording is published on the EMA website together with all the presentations from the workshop. All relevant documents can be found under the following link:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2016/01/event_detail_001257.jsp&mid=WC0b01ac058004d5c3



The Guideline is being revised in light of the comments provided during the public consultation. The overview of comments will be published once all the comments have been reviewed and it has been approved by CHMP.

It is expected that the final version of the guideline will be published during the fourth quarter of 2016.