



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 January 2016
Human Medicines Development and Evaluation

BMWP Workshop on immunogenicity assessment of biotechnology derived therapeutic proteins with interested parties

The European Medicines Agency (EMA) will hold a workshop on immunogenicity assessment of biotechnology derived therapeutic proteins to discuss the [Draft CHMP/BMWP guideline on immunogenicity assessment of biotechnology-derived therapeutic proteins](#). The workshop will be held on **09 March 2016** at the EMA offices in London.

The draft revised guideline was released in October 2015 for a four month external consultation ending on 31 January 2016. This EMA workshop is intended to complement the external consultation with a discussion among experts on the key issues relevant to the assays and methods used to explore and assess the immunogenicity of therapeutic proteins. It will focus on the following aspects:

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

Participants will include experts from BMWP, BWP, other regulatory authorities as well as stakeholders who provided comments on the draft guideline and specifically invited interested parties.

To express your interest in attending the workshop, please use the attached [registration form](#) and send it back to EMA (BMWP.Secretariat@ema.europa.eu) before **15 February 2016**. After this date, registration will be closed and invitations will be sent on 17 February 2016. Seats will be allocated to ensure a fair representation across all stakeholder groups.

The workshop will also be broadcast live.

Further information can be obtained from BMWP secretariat (E-mail: BMWP.Secretariat@ema.europa.eu).

The EMA looks forward to welcoming you at the workshop.

