



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

BMWP-Interested Party Meeting 2017

Joint PCWP-HCPWP 15 March 2017

Presented by Camille Vleminckx - Oncology, Haematology and Diagnostics Office

An agency of the European Union



Biosimilar Medicinal product Working Party (BMWP)

- Working Party of the CHMP

- [Composition](#):

Quality, non-clinical and clinical expertise

1 Chair + 1 Vice Chair

Elena Wolff-Holz



Martina Weise



+ 8 members

+ observers, additional experts

Tasks include:

- Preparing, reviewing and updating guidelines
- Contribution to the Scientific advice working party activities
- Contribution to CHMP product assessment
- Contribution to international co-operation with other regulatory authorities
- Liaising with interested parties
- Contribution to comparability-related workshops and training



BMWP-Interested party meeting

- Planned during September BMWP meeting (21 September)
- Discuss with stakeholders topics of mutual interest with a view to share experience and identify areas for future collaboration and focus
- Proposal to organise a dedicated session with Patients and HCP representatives (esp. from therapeutic areas recently exposed/soon to be exposed to biosimilars)

15 December 2016
EMA/CHMP/BMWP/627014/2016 Rev 0

Work plan for the Biosimilar Medicinal Products Working Party (BMWP) for 2017

Chairperson: Elena Wolff-Holz

Status of the work plan: December 2016: Adopted

6. Contribution to dialogue and engagement with stakeholders and external parties

6.1. Workshops

None.

6.2. Other activities with stakeholders and external parties

Organise one meeting with interested parties (e.g., learned societies, patients' organisations, Academia networks, pharmaceutical industry representatives): Q2/Q3 2017.

In collaboration with other working parties, provide support to communication activities on biosimilars e.g. through workshops, medical conferences and publications.



Contribution from PCWP-HCPWP

- Questions to PCWP and HCPWP:
 - Would such an interaction be of interest to HCPWP and PCWP?
 - If yes, what topics PCWP/HCPWP would like to discuss with BMWP?



Thank you for your attention

Further information

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