CAT feedback

PCWP/HCPWP joint meeting 20 September 2017, London

Presented by: Bernd Gänsbacher
CAT representative

Advanced Therapy Medicinal Products (ATMP)
Regulation (EC) No 1394/2007

Gene therapy medicinal product GTMP

Somatic cell therapy

Tissue engineered product

Genetically modified cells

http://www.mta-dialog.de

➔ **Recombinant nucleic acid**

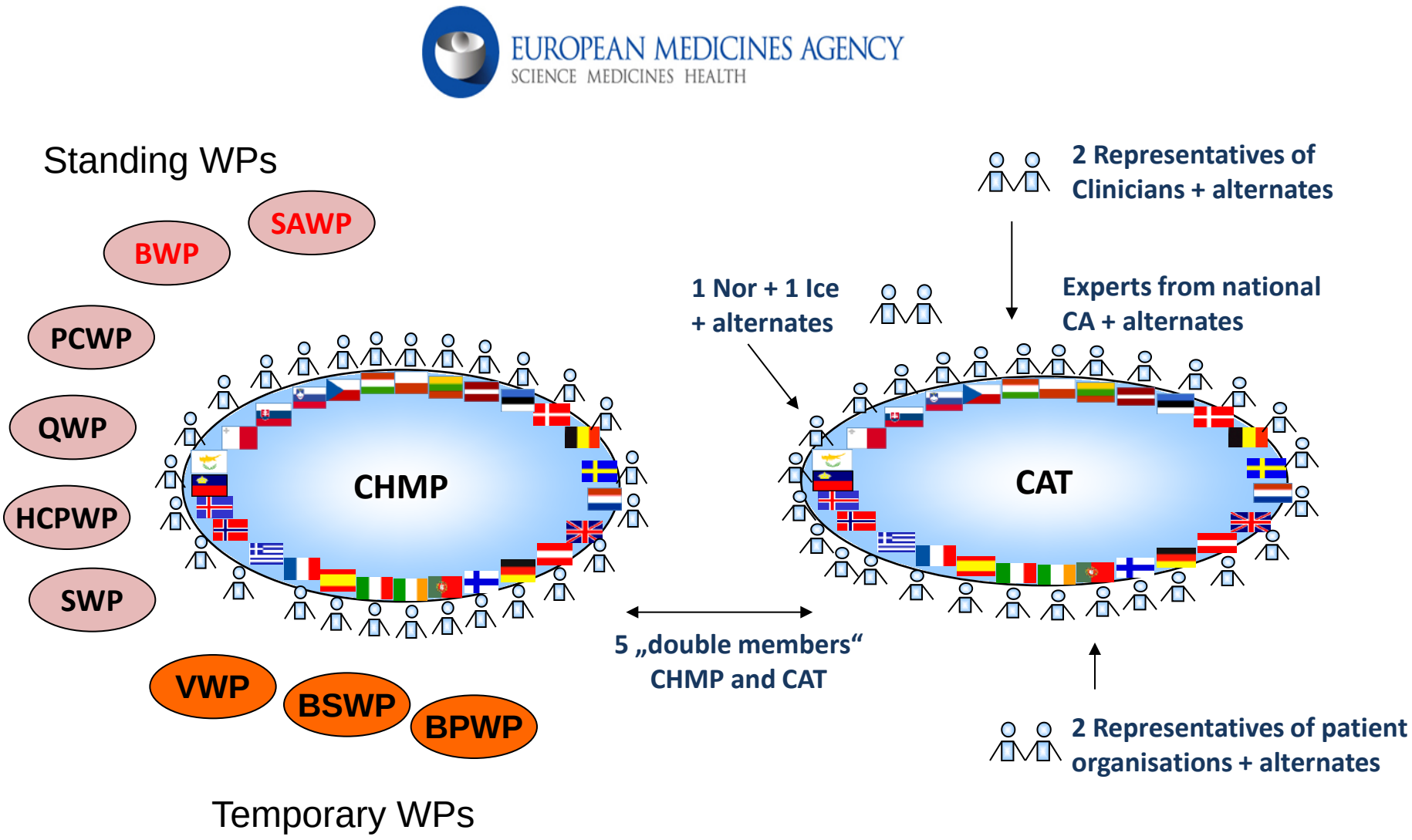
http://www.biotechnologie.de

➔ **Pharmaco-immunological…**

http://www.authormapper.com

➔ **Regeneration, repair….**

Committee for Advanced Therapies (CAT)



CAT statistics 2009-July 2017

Role of the CAT

1**. ATMP Classification**: EMA procedural advice on provision of scientific recommendation on advanced therapy medicinal products classification in accordance with Article 17 of Regulation (EC) No 1394/2007".

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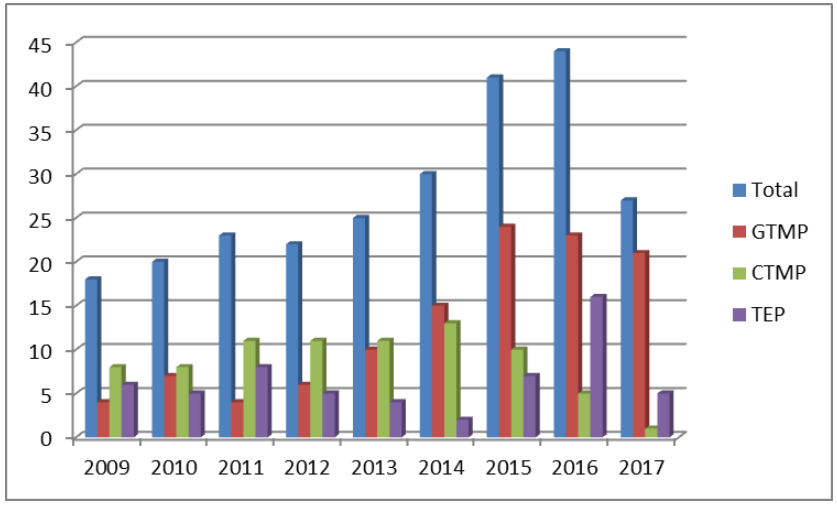
2**. ATMP Certification**: EMA procedural advice on certification of quality and non -clinical data for small and medium enterprises developing advanced therapy medicinal products"

3**. ATMP Scientific Advice**: EMA procedural advice on provision of scientific recommendation on advanced therapy medicinal products classification in accordance with Article 17 of Regulation (EC) No 1394/2007"

4. **ATMP MAA:** The CAT is responsible for preparing a draft opinion on the quality, safety and efficacy of each ATMP for final approval by the CHMP.

Scientific Advice for ATMPs

- 250 SA procedures started – CAT involved (routinely) in all SA for ATMPs
- Increase in SA's for ATMPs over period 2012 - 2016 (especially for GTMP)



SA requests until July 2017

Marketing authorisation procedure (until July 2017)

- 16 MAA for ATMPs submitted
- 9 ATMPs authorised (3 GTMP, 2 CTMP, 4 TEP) , 2 under review.
  - Chondrocelect – TEP – Comm Dec 5/10/09 / MA withdrawn July 2016
  - Glybera – GTMP – Comm Dec 25/10/12 / MA will stop Oct 2017
  - MACI – TEP, combined ATMP – Comm Dec 27/6/13 / MA suspended Sept. 2014
  - Provenge – sCTMP - Comm Dec 6/9/13 / MA withdrawn May 2015
  - Holoclar – TEP – Comm Dec 17/2/15
  - Imlygic – GTMP – Comm Dec 16/12/15
  - Strimvelis – GTMP – Comm Dec 26/5/16
  - Zalmoxis – CTMP - Comm Dec 18/8/16
  - Chondrosphere – TEP – Comm Dec 10/7/17
- 5 MAA announced start in 2017