



Medicines & Healthcare products
Regulatory Agency

PCWP – all eligible meeting: COMP update November 2017

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On behalf of the COMP



Some COMP activities

- COMP workshop on Prevalence
 - Key to the orphan designation is confirming the rarity of the condition
 - Workshop in December to discuss best practice and methodological challenges
- Strategic review and learning president meeting in Portugal in September (on behalf of Estonia)
 - Considering further the impact of the Commission's new Notice
 - Discussion on prevalence criteria
 - How close is significant benefit to HTA decisions
- COMP 'conditions' working group
 - Working group considering some of the challenges in defining a condition
 - Work on a paper for publication considering conditions based on adverse events and treatment modalities, use of mechanism of action to justify breadth of a condition
 - Histology agnostic workshop in December

Publication of Orphan Maintenance Assessment Report (OMAR)

- Currently the EMA publish the public summary of opinion, recommendation for maintenance of OD at the time of MA and COMP minutes
- Considered that there is an important information gap between the marketing authorisation and the review of the maintenance of the orphan status
- Patients' organisations, national competent authorities, HTA bodies and payers have requested more information on the grounds for maintenance
- OMAR is not expected to be longer than 20 pages, with the aim to publish the OMAR at the same time as the CHMP EPAR
- Start using October CHMP opinions with first publication December 2017 / January 2018

Similarity assessment – new guidance expected

- A public consultation took place from 29 July 2016 to 04 November 2016 on the concept of "similar medicinal product" in the context of the orphan legislation
- Member States shall not, for a period of 10 years, accept another application for the same therapeutic indication, in respect of a similar medicinal product
- 'Similar' means an identical active substance with the same principal molecular structural features (but not necessarily all of the same molecular features) and which acts via the same mechanism
- Responses to the public consultation published in March

https://ec.europa.eu/health/human-use/orphan-medicines/2016_07_pc_orphan_en

Thank You

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