Medicines & Healthcare products Regulatory Agency

PCWP plenary: COMP update September 2016

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On behalf of the COMP

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COMP

- The Committee for Orphan Medicinal Products (COMP) is the committee at the EMA responsible for reviewing 'orphan-medicinal-product designation
  - Up to August 2016: 1735 orphan designations

- Following the Dutch presidency meeting in May, and building on the 2016 work plan, COMP will hold a closed workshop in December on defining the orphan condition

- Aim to cover:
  - What is a COMP condition
  - Merit and acceptability of different and evolving classification systems
  - Impact and interaction with other EMA committee's mandates
  - Recent challenges in defining a condition
  - Consider whether revision /additional guidance is required

  http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2010/07/WC500095341.pdf

Updated guidance / information

- December workshop report on demonstrating significant benefit of orphan medicines: concepts, methodology and impact on access (published July 2016)

http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/07/WC500210934.pdf

- Revision of the EC's 2003 Communication on Orphan Medicinal Products - to be replaced by a Notice from the Commission:
  - Responses to the public consultation published
  - Still awaiting the final publication in order to consider the impact

- EC is proposing to review the concept of 'similar medicinal products' in the context of the orphan legislation - important component of the principle of market exclusivity:
  - Aim to improve the implementation of the regulatory framework and to adapt the text to technical progress
  - Public consultation from 29 July 2016 to 04 November 2016

  http://ec.europa.eu/health/files/orphanmp/2016_07_pc_orphan/2016_07_consultation_paper.pdf

Thank You

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