



COMP update to the PCWP

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On behalf of the COMP



COMP update

- The Committee for Orphan Medicinal Products (COMP) is the committee at the EMA that is responsible for reviewing 'orphan-medicinal-product designation'
- Agendas and minutes are published on the EMA webpage;
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000201.jsp&mid=WC0b01ac0580028e78
- We continue to see increasing numbers of applications;
 - 45 new applications in the November COMP, including a number of new conditions
 - Approximately 300 applications in 2014
- The work plan of the PCWP and HCWP were presented to the COMP in November
- COMP is currently finalizing the work plan for 2015-18, drawing on discussions from the Rome presidency meeting

Joint CHMP, CAT, COMP meeting

- Joint CHMP, CAT, COMP Meeting for the Italian Presidency was held in Rome in October
- The Presidency meetings provide an important opportunity for the committees to interaction and discuss both regulatory and scientific issues/ challenges
- One focus of the COMP's was on setting up of working group to develop a guideline/ scientific paper on the issues related to significant benefit

Ebola

- Cases of ebola have been reported in the EU and the EMA is encouraging developers of treatments or vaccines against ebola to apply for orphan designation
- Applications for orphan designation of Ebola medicines will be treated as a priority and EMA has committed to fast-tracking their evaluation