

COMP update

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On behalf of the COMP



COMP update

- The Committee for Orphan Medicinal Products (COMP) is the committee at the EMA 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
- The agendas of the PCWP HCPWP meetings are shared with the COMP
- 2014 was a busy year:
 - 329 applications (running total of 2127)
 - 196 designations (running total of 1430)
 - 25 new conditions were given orphan designation

- 82 medicines for human use recommended by the CHMP in 2014
 - 17 were for rare diseases (100 granted to date)
- COMP's has set up a significant benefit working group:
 - Consists of members of the COMP, EMA and EC representative
 - Objectives including reviewing experience of significant benefit to date, both for designation criteria and at time of marketing authorisation
 - Reviewing and amending relevant guidance documents where appropriate
- Cases of ebola have been reported in the EU and the EMA is encouraging developers of medicines to apply for orphan designation
 - A number of applications for treatment of Ebola virus disease have been received