Medicines and Healthcare Products Regulatory Agency

PCWP plenary: COMP update June 2016

Daniel O'Connor (UK representative)
On behalf of the COMP

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The Committee for Orphan Medicinal Products (COMP) is the committee at the EMA responsible for reviewing 'orphan-medicinal-product designation'

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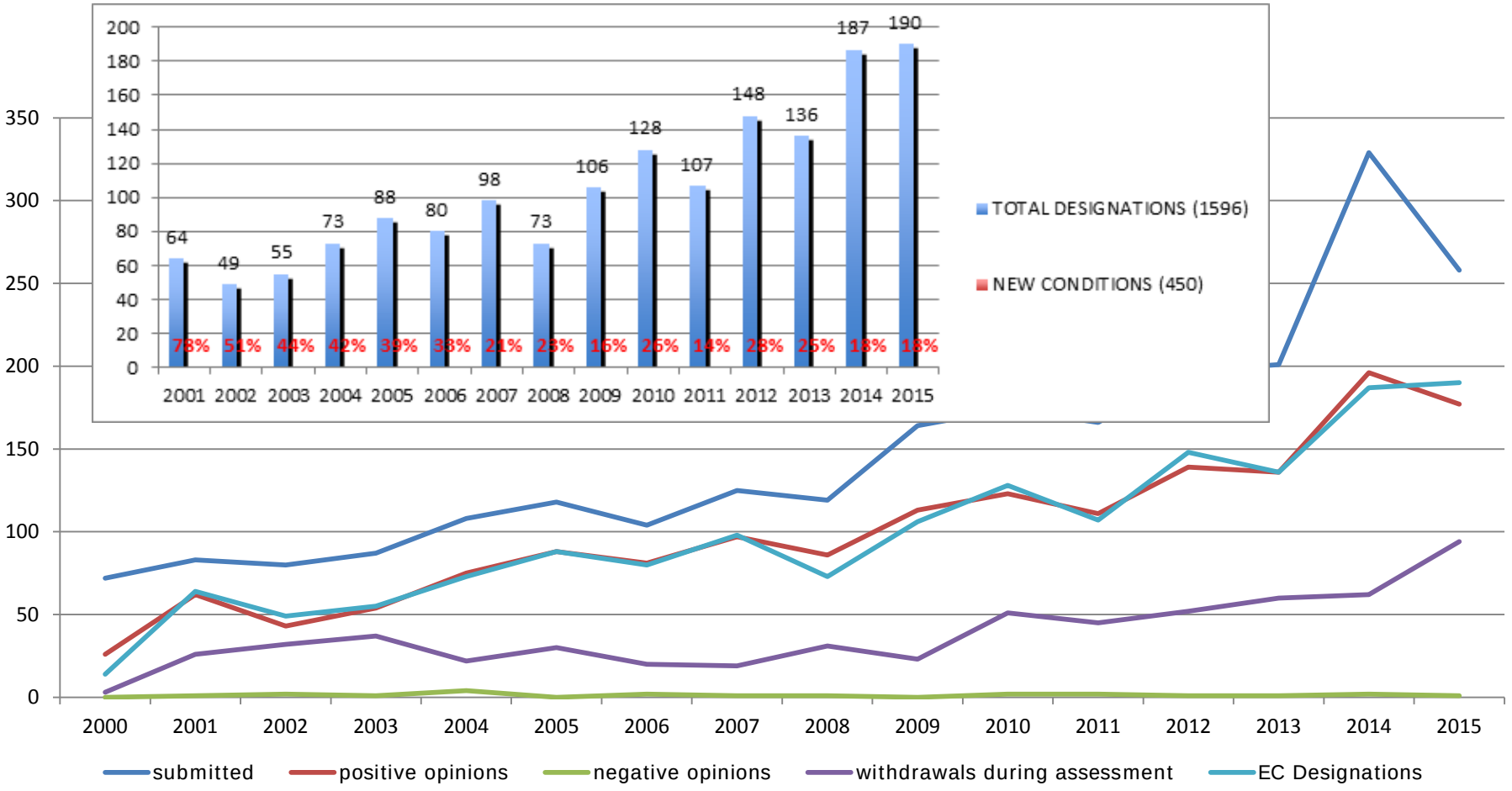

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More activity stimulated by Horizon 2020?

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- Topic: New therapies for rare diseases funding opportunities

- Dates: opening 29. July 2016, deadline 4. October 2016, 2nd stage 11. April 2017

*"Support will be provided to clinical trials on substances where **orphan designation has been given** by the European Commission, where the proposed clinical trial design **takes into account recommendations from protocol assistance** given by the European Medicines Agency, and where a clear patient recruitment strategy is presented."*

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COMP: CHMP presidency meeting

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- The presidency of the Council of the European Union rotates every six months
- During this six-month period, the presidency chairs meetings at every level in the Council,
  - Presidency meeting May 2016 Joint CHMP/COMP (Utrecht, The Netherlands)
- Joint CHMP/COMP sessions included cross talk and harmonization in scientific advices
- COMP topic: Significant benefit: challenges and opportunities
- COMP topic: How patients experience a difference & pros and cons about PROs
- COMP topic: Defining the orphan condition
  - Aim to hold a workshop towards the end of the year

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Commission guidance

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- 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 are now published

  http://ec.europa.eu/health/human-use/orphan-medicines/developments/2015_11_pc_orphans_en.htm

- *Satisfactory method authorised in the Union*:
  - Commonly used methods of diagnosis, prevention or treatment that are not subject to marketing authorisation (e.g. surgery, radiotherapy, medical devices, medicinal products prepared in a (hospital) pharmacy) may be considered satisfactory methods if there is scientific evidence as to the value of such method(s)

- Proposal for introduction of the reassessment of the orphan criteria for a new subset of the condition when a sponsor extends the use of its product after MA
  - COMP would consider whether new therapeutic indications have a significant benefit over existing treatments and that the applicant therefore merits its status of orphan for another sub-set of the same condition

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Thank You

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