Medicines and Healthcare Products Regulatory Agency

COMP update June 2015

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

MHRA

COMP update

Medicines and Healthcare Products Regulatory Agency

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

- Our agendas and minutes are published on the EMA webpage

- COMP’s agenda looks like this:
- Introduction to the meeting
- Applications for orphan designation
  - For first discussion/ opinion
  - For second discussion/ opinion
  - Appeals
  - Evaluation and validation on-going
- Requests for protocol assistance
- Overview of applications
- Review of OD for OMP at the time of marketing authorisation
- Procedural aspects

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  - COMP's significant benefit working group
- A new treatment would generally be of "significant benefit" if it provides a clinically relevant advantage or a major contribution to patient care
  - E.g. greater efficacy, an improved safety profile, and/or more favourable pharmacokinetic properties

- Work on-going to assist in:
  - Revision of the European Commission's 2003 Communication on Orphan Medicinal Products
  - Reviewing previous decisions with the goal of amending guidance documents where appropriate
  - Proposal for a workshop on significant benefit to be held on 7th December at EMA

- In terms of improving work processes, the EMA made a NCA/COMP Consultation on proposed process improvements for Orphan procedures
  - Outcomes to be implemented

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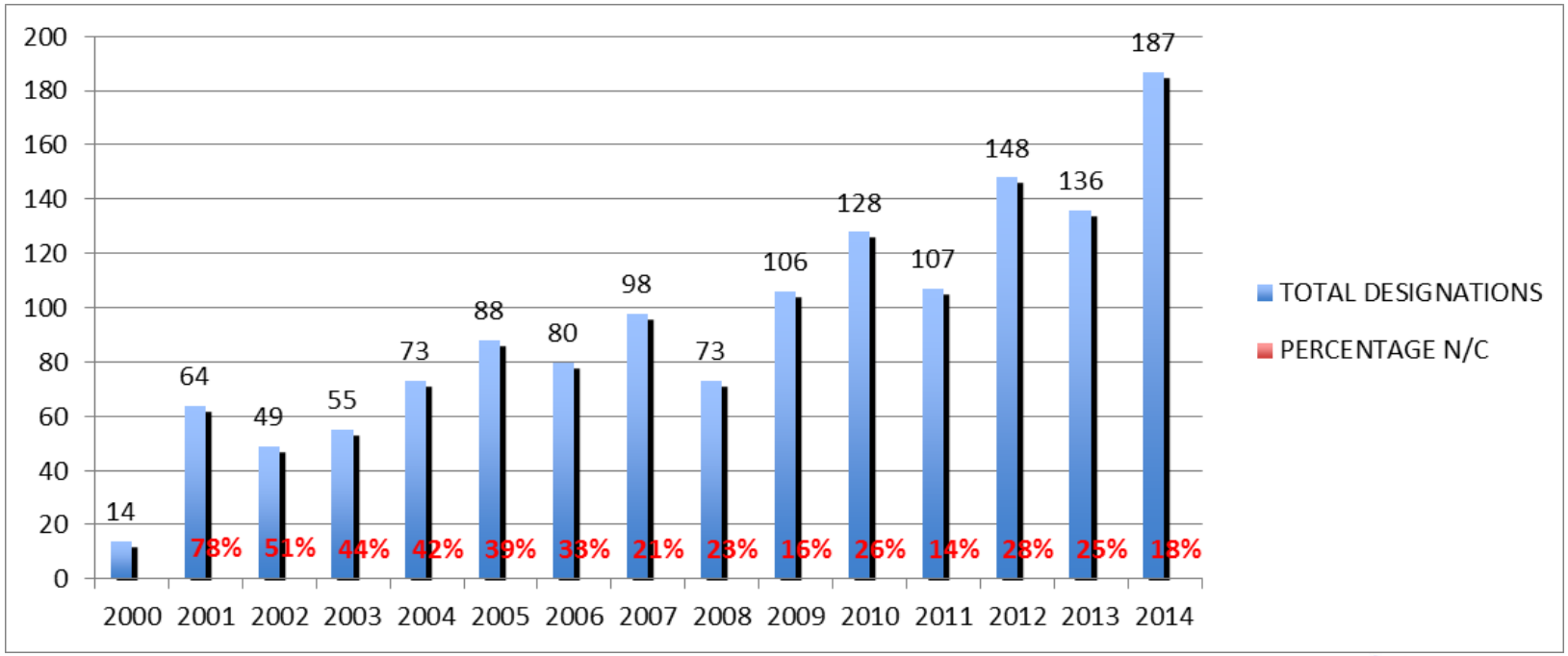
– Condition: any deviation(s) from the normal structure or function of the body, as manifested by a characteristic set of signs and symptoms (typically a recognised distinct disease or a syndrome)

– New statistics on the proportion of designations that relate to ‘new conditions’ - number of new conditions as a percentage of total number of designations



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Thank You

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