EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CHMP Reflections on the experience with Conditional Marketing Authorisation

Summary for EC Expert Group STAMP meeting on 6 May 2015

Presented by Sonia Ribeiro
Head of Regulatory Affairs Office
Human Medicines Development and Research Support Division

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- Revision of CHMP Guideline
- Recommendations for topics to be discussed at STAMP

Main conclusions of CHMP Reflection

- The CHMP has actively used the provision of a CMA
- CMA indicates highly promising products
- Some difficulties and limitations exist in the use of this provision, including a possible negative perception of CMA by some stakeholders
- Further guidance could be provided to the applicants based on the experience gained so far
- Importance of early dialogue with the applicant, involving also other stakeholders
- Reflection process ongoing – further discussions planned

Update proposal for CHMP Guideline

- Section on the requirement of 'positive benefit-risk balance':
  - Clarification on benefit-risk balance in case of non-comprehensive data;
  - Include examples and further guidance on the level of evidence required at the time of authorisation (e.g. use of surrogate endpoints that are reasonably likely to translate into clinical benefit) and the data that can be provided post-authorisation through specific obligations (SOs);
- Consider also improvements in patient care as a possible major therapeutic advantage, in addition to better safety and/or efficacy;
- Serious debilitation and life-threatening effects only in the long-term;
- Extent and type of data required to be included in annual renewal submissions.

Recommendations for consideration by STAMP

- CMA in fact indicates promising products and there would be advantages from changing any negative perception of CMA over standard MA
- Encouraging early dialogue (involving also other stakeholders) and prospective planning of CMA is crucial, e.g. to ensure feasibility of SOs
- Issues with obtaining reimbursement when comprehensive data are not available remain very important from a practical perspective, need to involve HTA bodies to ensure that CMA translates into early access to medicines
- It would be beneficial to introduce conditional approval of new indications

Thank you for your attention

Further information

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact