19 November 2013
EMA/669498/2013
Directorate

European Medicines Agency and EUnetHTA agree joint work plan

Focus on data generation that supports decision making by both regulators and health-technology assessment bodies

The European Medicines Agency (EMA) and EUnetHTA, the European network for Health Technology Assessment, today published a joint three-year work plan outlining key areas of collaboration. The publication of the work plan follows a commitment made at their May 2013 meeting, which reviewed the progress of their cooperation.

Building on collaboration since 2010, key areas for the next three years include:

- scientific advice/early dialogue with sponsors, involving medicines regulators and health-technology assessment (HTA) bodies;
- exchange on the development of scientific and methodological guidelines to facilitate clinical-trial design that can generate data relevant for both benefit-risk and relative effectiveness assessments;
- developing approaches for collection of post-authorisation data to support activities of both medicines regulatory authorities and HTA bodies;
- orphan medicinal products, exploring ways of sharing information for the common benefit of patients affected by rare diseases and the financial sustainability of the healthcare systems.

The EMA and EUnetHTA will review and update the work plan as necessary, and at least once annually.

More on EMA-EUnetHTA collaboration

The collaboration between the EMA and EUnetHTA started in 2010 to address recommendations by the Pharmaceutical Forum, a high-level group of European policy makers, to improve the way data published by EU regulators as part of their benefit-risk assessment contribute to relative effectiveness assessments by HTA organisations. The EMA and EUnetHTA started a project in the same year that looked specifically into how the information on the benefits and risks of a medicine contained in European public assessment reports (EPARs) could better address the needs of HTA organisations. The project has resulted in a series of improvements to the EPAR template. The EMA and EUnetHTA are in the process of publishing the outcome of this project in more detail.

See websites for contact details

European Medicines Agency www.ema.europa.eu
EUnetHTA www.eunethta.eu

The next meeting between the EMA and EUnetHTA will be held in December 2013. Minutes of the meeting will be published on the EMA and EUnetHTA websites following the meeting.

Notes

1. This press release, together with all related documents, is available on the European Medicines Agency's website and on EUnetHTA's website.
2. A link to the EMA-EUnetHTA three-year work plan 2013-2015 is available here http://www.eunethta.eu/outputs/ema-eunethta-3-year-work-plan
3. EUnetHTA is a network of organisations (from EU Member States, EEA and accession countries) and a large number of relevant regional agencies and not-for-profit organisations that produce or contribute to HTA in Europe. EUnetHTA enables scientific cooperation between HTA bodies in Europe. It is co-funded by the Public Health Progamme of the European Commission, DG Health and Consumers.
4. HTA bodies provide recommendations on the medicines that can be paid for or reimbursed by the healthcare system in a particular Member State.
5. European Medicines Agency and EUnetHTA review progress of their cooperation (Press release, 07/06/2013): http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/06/news_detail_001807.jsp&mid=WC0b01ac058004d5c1
6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu.
7. More information on the work of the European network for Health Technology Assessment can be found on its website: www.eunethta.eu.

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