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Cooperation between regulators and HTA bodies creates synergies

EMA and EUnetHTA publish outcome of joint 2012-2015 work plan

The European Medicines Agency (EMA) and the European network for Health Technology Assessment (EUnetHTA) published today a report on their joint work plan covering the period between November 2012 and December 2015.

The EMA-EUnetHTA collaboration aims to create synergies between regulatory evaluation and health technology assessment (HTA) along the lifecycle of a medicine. The overall goal is to improve efficiency and quality of processes for the benefit of public health in the European Union (EU).

The report highlights the value of EMA and EUnetHTA collaboration that fosters an approach to the generation of data on medicines, pre- and post-authorisation, that reconciles regulatory and HTA requirements into one clinical development programme. This is expected to improve the usefulness of the regulatory evaluation and the information derived from it for subsequent HTA. This will also enhance sharing experience and knowledge along the life span of medicines.

Key achievements since 2012 include:

- **Joint regulatory / HTA scientific advice / early dialogue for medicine developers to reduce duplication and to streamline and optimise the whole medicine development process for the benefit of patients:** EMA and EUnetHTA participated in each other's pilot projects to explore efficient processes by which regulators and HTA bodies can give medicine developers simultaneous feedback on their development plans. The goal is to bring together data requirements for both benefit-risk (regulatory) and value assessments (HTA) in a single development plan, which generates data that satisfy the needs of regulators and HTA bodies.
- **Improved EMA assessment reports to address the needs of HTA bodies:** EMA and EUnetHTA have worked together to change the way information on the benefits and risks of a medicine in the European public assessment report (EPAR) is presented. This has resulted in improvements to the report structure. EMA and EUnetHTA also discussed options to display key effects observed for a medicine in a structured manner, making value judgment in scientific decision-making more transparent.
- **Approaches for collection of robust data post-authorisation:** A number of initiatives explored methods to generate and collect high-quality data that fulfil the information needs of regulators

and HTAs once a medicine is authorised and used by doctors and patients. EMA and EUnetHTA collaborated to foster development and use of patient registries that can collect data relevant for both organisations. A patient registry collects information about patients who are affected by a particular condition.

- **Facilitating EUnetHTA's pilot projects on rapid relative effectiveness assessment of pharmaceuticals:** EMA and EUnetHTA worked to facilitate a framework to allow timely provision of information from the regulatory benefit-risk assessment reports in the rapid relative effectiveness assessments of medicines.
- **Discussion on the therapeutic indication for medicines:** The recognition of the importance of the wording of the indication as approved by regulators for subsequent HTA, led to the discussions which will contribute to the future development of principles for optimisation, as well as an exchange of views on how to document the scientific reasoning behind it.

EMA and EUnetHTA will continue their collaboration. Further areas for cooperation have been identified in the report. These include more structured interactions in the context of marketing authorisation applications, such as pre-submission dialogue and exchange at the time of concluding the regulatory assessment; further improvement of regulatory reports to support later HTA (e.g., inclusion of patient reported outcomes); and collaboration on the development of scientific guidelines on the design of clinical development programmes in specific conditions. This work will be defined in the context of a multi-year programme led by EUnetHTA and co- funded by the European Commission to strengthen scientific and technical activities on HTA in Europe (Joint Action 3).

Notes

1. This press release, together with all related documents, is available on EMA's website and on EUnetHTA's website.
2. In addition to these initiatives a parallel scientific advice process at EMA is currently ongoing. This is in line with the joint efforts between EMA and the Joint Action EUnetHTA to foster cooperation between regulators and HTA bodies.
3. EPARs reflect the scientific conclusions reached by the Agency's Committee for Medicinal Products for Human Use (CHMP) at the end of the evaluation process, after deletion of commercially confidential information. An EPAR is published for every medicine authorised through the centralised procedure in the European Union.
4. 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 Programme of the European Commission, DG Health and Consumers and performs the function of the scientific and technical cooperation of the HTA Network established as per the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. More information on the work of EUnetHTA can be found on its website: www.eunethta.eu
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu
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