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Press release

EMA and EUnetHTA finalise joint work plan for 2017-2020

Medicines regulator and network of Health Technology Assessment (HTA) bodies continue to strengthen their collaboration

The European Medicines Agency (EMA) and the European Network for Health Technology Assessment (EUnetHTA) have published a joint work plan outlining key areas of collaboration for the next three years.

The EMA-EUnetHTA collaboration, which began in 2010, aims to harness synergies between regulatory evaluation and health technology assessment (HTA) along the lifecycle of a medicine whilst respecting their different remits. The overall goal is to improve the efficiency and quality of processes and ensure mutual understanding and dialogue on evidence needs. This facilitates improved access to medicines for patients in the European Union (EU).

“Regulators and HTA bodies have different responsibilities with regards to medicines. What unites us is a common goal of getting to the market more high-quality medicines that address unmet needs of millions of patients in the EU,” said EMA’s Executive Director, Professor Guido Rasi. “By working together, EMA and EUnetHTA help medicine developers to improve clinical research and become more efficient in generating the evidence each of us needs for good decision-making.”

“This work plan shows a broad commitment from the regulatory as well the HTA side to find clear synergy in our activities,” said EUnetHTA’s Director Wim Goettsch. “I believe that there is a common sentiment that these activities are essential to make our processes more transparent, efficient and timely for patients, producers and other key stakeholders.”

Some objectives of the new work plan include areas in which major progress has already been made, most notably:

- **Early dialogue / scientific advice**: a new joint platform for parallel consultation was created in July 2017 to provide developers of medicines with simultaneous, coordinated regulatory and HTA advice on their development plans and facilitate alignment of data requirements.
- **Information exchange at market entry**: the exchange of information on the outcome of the regulatory assessment at the time of marketing authorisation as part of EUnetHTA’s new

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framework for production of Relative Effectiveness Assessments (REAs).

- **Post-authorisation data generation**: post-licensing evidence generation tools, such as patient registries, are being optimised to serve data needs for various decision-makers.

In addition, EMA and EUnetHTA will further collaborate in a number of areas including:

- exploring how HTA bodies and regulators apply the concepts of unmet medical need and therapeutic innovation in view of possible synergies.
- understanding the conceptual similarities and differences between the significant benefit of orphan medicines versus their added therapeutic value.

These activities are directly related to the core activities of both organisations.

The three-year work plan is complementary to actions foreseen in EUnetHTA Joint Action 3, which runs until 2020.

Furthermore, the activities in this work plan will feed into the implementation of the areas for collaboration identified in the reflection paper from the HTA network on Synergies between regulatory and HTA issues on pharmaceuticals and will be developed in close cooperation with the European Commission.

More on EMA-EUnetHTA collaboration

The collaboration between EMA and EUnetHTA started in 2010. This collaboration began initially 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. Furthermore, topics of mutual interest were identified and included in the work plan for 2012-2015, for which a report is available.

EMA and EUnetHTA hold regular bilateral meetings to progress the various actions. Their meeting reports are published on their respective websites.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. 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 health technology assessment 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.
3. HTA bodies provide recommendations on the medicines that can be paid for or reimbursed by the healthcare system in a particular Member State.
4. You can read more on EMA's work with HTA bodies here.
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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