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Press release

EMA and EUnetHTA step up interaction to align data requirements

A new joint platform for parallel consultation will provide advice to medicine developers and facilitate access to medicines for patients

The European Medicines Agency (EMA) and the European Network for Health Technology Assessment (EUnetHTA) are stepping up their efforts to provide developers of medicines with simultaneous, coordinated advice on their development plans and facilitate alignment of data requirements.

This initiative provides a single gateway for requests for parallel consultations with EMA and HTA bodies in the Member States on evidence-generation plans to support decision-making on marketing authorisation and health technology assessment. Not only will these consultations be possible for initial evidence generation but also for post-authorisation data collection. The objective is to help generate optimal and robust evidence in an efficient development plan that satisfies the needs of both regulators and HTA bodies.

"Enabling patients' access to medicines is no longer a job for regulators alone. Today, we need to work with all decision-makers in healthcare to make sure that medicines that can make a real difference to people's lives can actually reach them," said EMA Executive Director Guido Rasi. "Our work with EUnetHTA aims to align our respective requirements as much as possible so that developers can generate one set of data that allows the assessment of both the benefits and risks of a medicine and its added value."

This new initiative replaces the existing tool for parallel scientific advice by EMA and HTA bodies which required medicine developers to contact Member States' HTA bodies individually. It also builds on previous initiatives and pilots on HTA-regulatory collaboration led by EMA, EUnetHTA and the European Commission (see notes).

Medicines developers will need to notify simultaneously EMA and EUnetHTA of their intention to request parallel advice. EUnetHTA's Early Dialogue Secretariat, recently created to facilitate such consultations, will then coordinate the involvement of the HTA bodies that will take part in the parallel advice, taking into account the preferences of the requester.

EUnetHTA created the Early Dialogues Working Party (EDWP), composed of HTA bodies with demonstrated experience in Early Dialogues/Scientific Advice, to ensure high-quality advice and consistency over time.

The main benefits of this new platform will be:

- increased mutual understanding and problem solving ability through a more structured interaction between EMA and HTA bodies;
- improved coordination with, and greater participation of HTA bodies, as a result of the creation of an Early Dialogue Working party and an Early Dialogue Secretariat at EUnetHTA;
- streamlined logistics for the requesters.

These advantages are expected to lead to more robust outcomes resulting from the parallel consultation on evidence-generation plans for pharmaceuticals.

"Balancing access to new and innovative medicines with the sustainability of healthcare resources requires an assessment of the added value of new treatments. HTA bodies strive to evaluate, based on the available data, the added benefit that a new medicine brings to patients over existing treatments. As clinical studies form the evidence basis for both regulators and HTA bodies, our strengthened involvement in early dialogues and our collaboration with EMA will support the generation of evidence that better meets the needs of HTA bodies and will support informed decisions at national level," said EUnetHTA Joint Action 3 Director Wim Goettsch.

As patients are at the heart of both EMA and EUnetHTA's missions, patient representatives will be involved in parallel consultations on a routine basis so that their views and experiences can be incorporated into the discussions.

EMA and EUnetHTA have released joint guidance as well as joint templates that can be used by requesters of parallel consultations as of today; the first requests will be processed in September. In the interim, sponsors with pre-notified submissions will be informed about the transitional arrangements.

How stronger interaction between regulators and HTA bodies will benefit patients

Patients have access to medicines through a two-step process. First, a medicine requires a marketing authorisation from a medicine regulatory agency, which is based on the assessment of the balance of the benefits versus the risks of the medicine. Following regulatory approval, HTA bodies assess the value of the medicine versus other treatments available and, based on this assessment, provide recommendations to payers and other decision-makers. While there is some overlap between evidence requirements of regulators and HTA bodies, each may have specific requirements that need to be accounted for in the development plan.

Closer interaction between regulators and HTA bodies during the development of medicines is therefore expected to close these gaps and allow the development plan to address the needs of all parties. This early dialogue can also facilitate discussion on evidence generation required after the launch of a medicine to allow the continuous assessment of the benefit-risk balance and long-term effectiveness of the medicine.

EMA with its scientific committees, EUnetHTA, HTA bodies and the European Commission have been working closely in the past few years on various levels to reinforce HTA-regulatory collaboration and achieve timely patient access and sustainability of health care while providing incentives for innovation.

Notes

1. This press release, together with all related documents, is available on EMA's and EUnetHTA's websites.
2. EUnetHTA was established to create an effective and sustainable network for HTA across Europe – working together to develop reliable, timely, transparent and transferable information to contribute to HTA in European countries, creating a sustainable system of HTA knowledge sharing, and promoting good practice in HTA methods and processes. More information on the work of the EUnetHTA can be found on its website: www.eunethta.eu
3. Initiatives and pilots on HTA-regulator collaboration include: EMA's pilot on parallel advice; EUnetHTA Early Dialogues initiative and Shaping European Early Dialogues project financed by the European Commission.
4. EUnetHTA's Early Dialogue Working Party (EDWP) includes HTA bodies from France, Germany, the United Kingdom, Italy, Hungary, and the shared seat of the Netherlands and Belgium. See EUnetHTA website for more details.
5. The secretariat for Early Dialogues at EUnetHTA is operated by Haute Autorité de Santé (HAS), France. Scientific coordination is performed by HAS and Gemeinsamer Bundesausschuss (G-BA), Germany.
6. Regulatory only scientific advice and multi-HTA advice are still available.
7. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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