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Press Office

Press release

European Medicines Agency and EUnetHTA review progress of their cooperation

Focus on facilitation of development plans through advice procedures

The European Medicines Agency (EMA) and EUnetHTA, the European network for Health Technology Assessment (HTA), met to review the progress of their cooperation in London on 14 May 2013. This was the sixth meeting since the start of their collaboration in 2010.

The focus of this meeting was on how regulators and HTA bodies can work together to facilitate drug development by cooperating in giving advice to pharmaceutical companies. EUnetHTA is piloting joint early dialogue with technology sponsors by a number of national HTA agencies and the EMA has a scientific advice programme in place to guide companies in the design of trials that will generate appropriate evidence to enable better decision-making by all players in the healthcare systems of EU Member States.

The value of cooperation between medicines regulators and HTA organisations is significant for patients, since it has a real potential to improve conditions for patients' timely access to an effective medicine. It should also reduce the development costs for sponsors, since the product development programme will be aimed at generating data relevant for both regulatory and HTA needs.

The collaboration between the EMA and EUnetHTA started in 2010 to address recommendations by 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 was looking specifically into how the information on the benefits and risks of a medicine contained in its European public assessment reports (EPAR) 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.

In addition, the EMA and EUnetHTA are working together on a number of other topics, such as providing mutual input on methodological and disease-specific guidelines, evidence requirements and publication of data relevant for orphan designated medicines, and collaboration on study registries.

At their London meeting EMA and EUnetHTA agreed the development of a joint 3-year work programme. It is expected that the programme will be finalised and published in September 2013.

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Both EMA and EUnetHTA have now also agreed on a common approach to transparency of their joint meetings. From now on, all meeting minutes will be published systematically. In addition, the minutes of all previous meetings will also be made available on the websites of both EMA and EUnetHTA.

Notes

1. This press release, together with all related documents, is available on the EMA website the EUnetHTA website.
2. HTA bodies provide recommendations on the medicines that can be paid for or reimbursed by the healthcare system in a particular Member State.
3. The minutes of all six meetings are available here: http://www.eunethta.eu/news/all-minutes-eunethtaema-meetings-are-now-available
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu
5. More information on the work of the European network for Health Technology Assessment can be found at its website: www.eunethta.eu

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