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Press Office

Press release

Early dialogue between regulators and health technology assessment bodies key to medicines development

EMA and multiple stakeholders to develop tools for industry

"A strong interaction between regulators and health technology assessment bodies (HTAs) is critical to enable innovation to reach patients, and ultimately for the benefit of public health," said Guido Rasi, Executive Director of the European Medicines Agency (EMA) at the EMA-HTA workshop on parallel scientific advice which took place on Tuesday, 26 November. "This is the first workshop where we have tried to bridge these two worlds together to share views," Rasi added.

Some new medicines authorised by the European Commission based on the EMA's scientific opinions fail to be reimbursed and/or used as expected because they fail to match the requirements of HTA bodies. There is a clear need to initiate early dialogue between medicines developers, the EMA and HTA bodies to discuss and agree on a development plan that generates data that both parties can use to determine a medicine's benefit-risk balance and value.

Since 2010, the EMA has put in place a pilot project of parallel scientific advice with HTA bodies that allows developers to receive simultaneous feedback from both regulators and HTA bodies on their development plans for new medicines. The EMA, with the support of the European medicines regulatory network, has so far conducted 25 parallel scientific advice procedures with several HTA bodies taking part in this pilot project. Currently, a further six procedures are expected to start in 2014.

Following the workshop, and based on the experience gained by all stakeholders, guidance for EMA-HTA parallel scientific advice will be developed and published for public consultation in early 2014. The guidance will detail the timelines and actions whereby applicants can seek simultaneous feedback from regulators and HTA bodies on their development plans. The final guidance will take into account feedback from all stakeholders.

"I believe that this guidance can be a major tool for medicines development, which will help new medicines with a positive benefit-risk balance and expected added value to reach patients in a faster and more transparent way. This simultaneous feedback will ultimately lead to better advice for companies, to help them meet the requirements of all stakeholders and consequently increase predictability," said Tomas Salmonson, Chair of the Agency's Committee for Medicinal Products for

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Human Use (CHMP). This was also discussed by health ministries involved in the HTA Network established under Directive 2011/24/EU.

In addition, HTA bodies have initiated the Shaping European Early Dialogues for health technologies (SEED) consortium, financed by the European Commission, to explore a number of scenarios for conducting early dialogues. The EMA is associated with the consortium and will take part in the dialogues.

The workshop brought together over 280 representatives from the European Commission, European regulators, HTA bodies from 12 European Union countries, EUnetHTA, the pharmaceutical industry, payers, patients, healthcare professionals and academics, as well as representatives from the CHMP, the Pharmacovigilance Risk Assessment Committee, the Paediatric Committee, the Committee for Advanced Therapies, the Committee for Orphan Medicinal Products and the Agency's Scientific Advice Working Party.

A report and video from the workshop will be published in early 2014.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the EMA-HTA workshop, including all presentations, is available here: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2013/06/event_detail_000721.jsp&mid=WC0b01ac058004d5c3
3. HTA bodies provide recommendations on the medicines that can be paid for or reimbursed by the health care system in a particular Member State.
4. SEED is a consortium led by the Haute Autorité de Santé (HAS) in France consisting of 14 national and regional HTA bodies: AETSA (Spain), AIFA (Italy), ASSR (Italy), AVALIA-T (Spain), CVZ (Netherlands), G-BA (Germany), GYEMSZI (Hungary), HAS (France), HIQA (Ireland), HVB (Austria), IQWIG (Germany), ISCIII (Spain), KCE (Belgium) and NICE (UK).
5. More information on the work of the European Commission in this area is available here:

   http://ec.europa.eu/health/technology_assessment/policy/network/index_en.htm
6. More information on the work of EUnetHTA can be found on its website: http://www.eunethta.eu
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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