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Press Office

Press release

Outcome report on first European collaboration between regulators and HTA organisations: improving the contribution of regulatory assessment reports to health technology assessment

The report of an initiative undertaken jointly by the European Medicines Agency (EMA) and the European network for Health Technology Assessment (EUnetHTA) to make regulators' reports about scientific assessments of medicines better usable by health technology assessment (HTA) bodies, has been published in Value in Health, the Journal of The International Society For Pharmacoeconomics And Outcomes Research.

The article, entitled "Improving the contribution of regulatory assessment reports to health technology assessments – a collaboration between the European Medicines Agency and the European network for Health Technology Assessment", is authored by staff members of the EMA and representatives of EUnetHTA. This work was the first joint project between regulators and HTA bodies on a European level and is part of their ongoing dialogue to support policy-maker decisions in the future.

Clinical data generated by pharmaceutical companies during the development process of a medicine is the basis for the evaluation of the benefit/risk balance of a medicine for the purpose of marketing authorisation. The same data informs the assessment of the effectiveness of the new medicines compared to existing therapies, as part of the HTA process to support decision making on appropriate utilisation, price and reimbursement in EU Member States.

The joint EMA-EUnetHTA project responded to a political recommendation to consider how the assessment of the favourable and unfavourable effects of a medicine as contained in the EMA's European Public Assessment Reports (EPARs) can best be used to inform the assessment of the relative effectiveness of new medicines for HTA purposes in EU Member States. As part of this project, the EMA and EUnetHTA developed an improved structure and presentation of key information with the view to increase clarity and transparency of the outcome of the scientific-review process as reflected in the EPARs.

"With the improved presentation of data and information in the EPAR it is envisaged that this regulatory document through harmonised efficacy data presentation will be more useful in the context of rapid relative effectiveness assessments by HTA bodies when they inform policy makers and healthcare decision makers in the future," explain the authors.

Beyond the EPARs project, the EMA and EUnetHTA are continuing to explore other areas of collaboration or exchange of information. These include ways for sponsors to obtain scientific advice or early dialogues with regulators and HTA or payer bodies, discussions and exchange on scientific and methodological guidelines, exploring opportunities of exchange on regulatory assessments in view of subsequent health technology assessments, post-licensing data generation and the specificities of orphan medicinal products. Regular meetings are held between EMA and EUnetHTA, most recently on 15 May 2014. Minutes from these meetings are made available on the websites of both the EMA and EUnetHTA, as is the joint three-year work plan.

The value of cooperation between regulators and HTA bodies has a real potential to reduce the time for a medicinal product to reach patients. It also has potential to reduce development costs for sponsors, by shaping medicines development programmes so that they generate data relevant for the needs of both regulatory authorities and HTA bodies.

Notes

1. This press release, together with all related documents, is available on the EMA and EUnetHTA's websites.
2. Berntgen M, Gourvil A, Pavlovic M, Goettsch W, Eichler H-G, Kristensen FB; Improving the contribution of regulatory assessment reports to health technology assessments – a collaboration between the European Medicines Agency and the European Network for Health Technology Assessment, Value in Health.
3. 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.
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 EUnetHTA can be found on its website: www.eunethta.eu

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