EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Early dialogue with regulators and HTA bodies

Parallel scientific advice at EMA helps to reconcile different data requirements in one development plan to improve timely patient access to new medicines

The European Medicines Agency (EMA) has published today a report on its pilot on parallel scientific advice with health-technology-assessment (HTA) bodies that finished at the end of March 2016. This initiative that allows developers of new medicines to receive simultaneous feedback on their development plans from both regulators and HTA bodies is being continued.

Since its start in July 2010, a total of 63 parallel scientific advice procedures were completed by December 2015. 14 applications for the parallel scientific advice procedure are currently registered for 2016 (four are ongoing, two are completed and eight are due to start). Take up of parallel scientific advice increased significantly, as the number of procedures almost tripled in 2015 compared to the previous year.

The report also indicates that a high level of alignment between the requirements of regulators and HTA bodies was achieved with the parallel scientific advice procedure. An analysis of a subset of 31 parallel scientific advice procedures completed between the start of the pilot and May 2015 showed that in approximately 70% of cases, one clinical trial design or one development programme could satisfy the evidence needs of regulators and HTA bodies.

“Our parallel scientific advice fosters a different, more rational approach to the development of medicines, by bringing together requirements of regulators and HTA bodies in a single development programme,’’ said Professor Guido Rasi, EMA’s Executive Director. “This ensures that patients only participate in well-designed clinical trials that generate the evidence needed for both regulatory and health technology assessment. Ultimately, this will improve timely access by patients to meaningful new medicines across Europe for the benefit of public health.”

Following regulatory approval, a growing number of Member States have systems in place that provide for HTA bodies to give recommendations on whether a medicine can be paid for by the health care system, taking into account the best possible use of available resources and national legislation.

Parallel scientific advice is one of the Agency’s key initiatives to improve patient access to important new medicines because it ensures that the envisaged clinical trials generate appropriate data for

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regulators and HTA bodies and allow the assessment of both benefit-risk balance and added value. This can reduce delays between a medicine's marketing authorisation and decisions on reimbursement.

Following the completion of the pilot, parallel scientific advice with HTA bodies and other relevant stakeholders is now routinely offered as part of the Agency's scientific advice activities.

Best practice guide for developers

EMA has also published today a consolidated best practice guide which sets out the different phases of the process for regulatory-HTA parallel scientific advice and highlights ideal timelines and actions for all parties involved. This guide, together with a document that gives an overview of the HTA bodies that have participated in EMA's parallel scientific advice initiative so far, provides comprehensive information on the procedure.

EMA will continue to work closely with its stakeholders in the European Union (EU) to refine the model for greater and more robust interaction for parallel advice, and to progress a range of activities across the lifecycle of a medicine between developers of medicines, regulators, HTA bodies and payers, whilst respecting the remits of the different players.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. In addition to the parallel scientific advice pilot at EMA, they are a number of other initiatives ongoing. All of these pilots are in line with the joint efforts between EMA and the Joint Action European network for Health Technology Assessment (EUnetHTA) to foster cooperation between regulators and HTA bodies.
3. More information on the work of EUnetHTA can be found on its website www.eunethta.eu
4. More information on the work of the European Medicines Agency can be found on its website www.ema.europa.eu