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Press release

Exploring opportunities for collaboration between regulators and healthcare payers

European Medicines Agency and healthcare payer organisations held joint meeting on 19 September

The European Medicines Agency (EMA) and European Union (EU) healthcare payers met for the first time on 19 September 2017 at EMA's offices in London to explore synergies and foster mutual understanding and cooperation to help improve timely and affordable access of patients to new medicinal products. The meeting aimed to be complementary to EMA's existing cooperation with Health Technology Assessment (HTA) bodies and especially with EUnetHTA.

EMA and representatives from the Association Internationale de la Mutualité (AIM), an association of mutuals and other non-profit healthcare payers, the European Social Insurance Platform (ESIP), the Medicine Evaluation Committee (MEDEV) and the multi-stakeholder platform Mechanism of Coordinated Access to Orphan Medicinal Products (MoCA) discussed how their cooperation can contribute to boosting sustainable access to medicines for EU citizens.

"Regulators, HTA bodies and payers – we all perform an important task in one way or the other as gatekeepers for medicines to the healthcare systems in the EU," said EMA's Executive Director, Professor Guido Rasi, during his opening statement. "But we also have an increasingly important role as enablers of medicine development. Our cooperation can help medicine developers to address some of the inefficiencies of the current system of clinical research so that they become better at generating the evidence each of us needs for good decision-making."

Patients' access to new medicines in the EU today is determined by sequential processes. The first step is the marketing authorisation, which is granted following the assessment of the benefits and risks of a medicine by a regulatory authority such as EMA. Before the medicine reaches the patient, pricing and reimbursement decisions are adopted by healthcare payers at the national and regional level. These decisions are often prepared and supported by (cost-)effectiveness and relative effectiveness assessments of the medicine, an activity performed by HTA bodies. The decisions by payers take into account the medicine's added therapeutic value, its impact on healthcare budgets, the seriousness of the disease in view of treatment alternatives and other factors.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 8427 **Facsimile** +44 (0)20 3660 5555
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

Experience over the last decades has shown that delays in pricing and reimbursement negotiations at national and regional level can sometimes occur, because drug developers are primarily focused on demonstrating the safety, efficacy and quality of a medicine for regulatory assessment but often do not generate sufficient evidence for cost-effectiveness assessments and pricing and reimbursement decisions. As a consequence, more research is required post-authorisation. Timely, adequate information could streamline decision-making and facilitate faster access to appropriate care.

Collaboration between regulators and healthcare payers is an important approach to tackle these challenges because it creates synergies that help to improve and speed up patients' real access to new treatments across the EU. The special challenges in the field of medicines for rare diseases ('orphan medicines') are addressed in the exchanges within MoCA, where patient involvement is key to the multi-stakeholder process. The meeting might foster future cooperation and will complement the already existing collaboration with HTA bodies, represented by EUnetHTA, with a focus on synergies in activities of mutual interest.

EMA and EU payers will consider organising follow-up meetings to explore the above and other areas of collaboration, and discuss how to create a more effective partnership in order to improve the exchange of knowledge and information between regulators and payers.

A report on the meeting will be published in due course.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu
3. EUnetHTA
4. Association Internationale de la Mutualité (AIM)
5. European Social Insurance Platform (ESIP)
6. Medicine Evaluation Committee (MEDEV)
7. Mechanism of Coordinated Access to orphan medicinal products (MoCA)

Contact our press officers

Tel. +44 (0)20 3660 8427
E-mail: press@ema.europa.eu
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