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Press Office

Press release

EMA Management Board: highlights of October 2014 meeting

Focus on publication of clinical reports, medicines for rare diseases and patient involvement

EMA's policy on publication of clinical reports adopted

The European Medicines Agency's (EMA) Management Board unanimously adopted a new policy on the publication of clinical reports that underpin the decision-making on medicines. The policy will enter into force on 1 January 2015 and will apply to clinical reports supporting all applications for centralised marketing authorisations submitted after that date. Please see separate press release for further information.

Mid-year report: supporting the development of innovative medicines

The Management Board discussed the Agency's mid-year report for 2014.

Innovative medicines hold the potential to bring significant benefits to patients. Supporting the development of such medicines is a priority for the Agency. In the first half of 2014, interaction and dialogue with medicines developers increased. The number of requests for scientific advice and protocol assistance increased by 16% compared to the same period last year. This is in line with the continuous increase in requests seen in the past four years. When followed by applicants, scientific advice has been proven to increase the success rate of marketing authorisation applications.

The Board was updated on the progress of two ongoing pilot projects which aim to facilitate timely access to medicines for patients.

The number of requests for joint scientific advice with health technology assessment (HTA) bodies has considerably increased (six in the first half of 2014 compared with one in the first half of 2013). HTA bodies provide recommendations on medicines that can be paid for or reimbursed by the healthcare system in a particular Member State. Joint early dialogue between EMA, HTA bodies and medicines developers aims to facilitate agreement on a development plan and enable new medicines to reach patients in a timely manner.

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The Board also heard that the EMA has selected eight development programmes for in-depth discussion with the applicant as part of its adaptive licensing pilot project, which was launched in March 2014. The project is intended to explore the progressive licensing of medicines, a prospectively planned process, which starts with an early authorisation in a restricted patient population, followed by iterative phases of evidence gathering and adaptations of the marketing authorisation to expand access to the medicine for increasingly broader patient populations.

In the first half of 2014, the overall number of applications for marketing authorisation remained stable.

Steady increase in medicines for rare diseases

Bruno Sepodes, the Chair of the EMA's Committee for Orphan Medicinal Products (COMP), highlighted the steady increase in the number of medicines authorised for the treatment of rare diseases. So far, 93 medicines are available for patients.

The number of requests for the orphan designation of medicines for rare diseases, a status which offers a range of incentives to companies developing these medicines, is also increasing. In 2014, the COMP expects more than 300 requests for orphan medicines designations, a 50% increase compared to 2013 and the highest figure since the creation of the Committee.

The Chair stressed the importance of supporting companies during the early stages of development of their medicines. With more and more applications for orphan designation expected, scientific advice is essential to increase the chances for these developments to lead to new medicines for patients.

Involving patients and healthcare professionals in EMA activities

The Board received the 2013 annual report on the Agency's interaction with patients, consumers and healthcare professionals.

The overall number of patients and consumers involved in EMA activities has increased significantly since 2007. In 2013 more than 550 patients contributed to the work of the EMA. Patients and healthcare professionals now provide their views during the development, evaluation and safety monitoring of medicines. In addition, there has been growing collaboration on topics of common interest such as shortages of medicines, medication errors, and antimicrobial resistance.

In September 2014, the EMA started a pilot project to involve patients in the assessment of the benefits and risks of medicines in the EMA's Committee for Medicinal Products for Human Use (CHMP).

Since 2013, a formal Healthcare Professionals' Working Party (HCPWP) has supported the participation of doctors, pharmacists and other healthcare professionals in the work of the EMA.

Continued focus on replacement, reduction and refinement of animal testing

The Management Board renewed for the second time the mandate of the joint ad hoc expert group on the application of the so-called 3Rs principles. This group aims to promote best practice in relation to the replacement, reduction and refinement of the use of animals in the tests required by regulatory authorities. The group comprises experts from working parties of both the Committee for Medicinal Products for Veterinary Use (CVMP) and the CHMP.

Among other activities, the group has worked on opening up a route for the approval of alternative testing methods by the EMA. A guideline describing this route and the key principles underlying regulatory acceptance was adopted by the CHMP and the CVMP in September 2014 and is available on the EMA website.

Notes

1. All relevant documents adopted at the Management Board meeting will be available on the Agency's website in due course. This press release 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

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