10 January 2012
EMA/MB/975513/2011 Corr*
Press Office

Press release

European Medicines Agency's Management Board endorses work programme 2012

In 2012 the Agency will focus on implementing new pharmacovigilance legislation

The European Medicines Agency's Management Board, at its meeting on 15 December 2011, adopted the Agency's work programme and budget for 2012 which are driven by the implementation of the pharmacovigilance legislation.

The work programme forecasts a stable number of applications for marketing authorisation for human and veterinary medicines in 2012. The Agency expects some 112 applications in total (2011: 111), with 52 applications for new medicines for human use, in addition to 13 new orphan medicines and 39 generic applications (2011: 47, 13 and 45 respectively). Some 9 applications for new veterinary medicines are expected, with 3 generic applications (2011: 8 and 3 respectively). The Board noted the 10% increase in expected requests for scientific advice for human medicines, which includes an increasing number of joint scientific advice with health technology assessment bodies (HTAs).

The work programme is accompanied by a budget of €222.5 million, an increase of 6.5% over 2011, that includes fee revenue of €173.2 million (2010: €161 million) and an EU contribution of €23 million (2010: €28). The special orphan medicines fund given by the EU has been increased from €4.9 million to €6 million. The workforce foreseen for 2012 remains at the level for 2011, with the staff ceiling fixed at 737.

In 2012 the Agency will continue to review its activities and processes with the aim of identifying areas where efficiency gains, re-allocation of resources and re-prioritisation of activities may be possible. This should put the Agency in a position to manage the increased responsibilities with existing resources.

In line with the Road Map implementation plan, the Agency will strengthen, where needed, the quality and the regulatory and scientific consistency of the assessment process and its outputs in both the

* The figures for the fee revenue and EU contribution now reflect the revised budget

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
E-mail press@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

human and veterinary fields; increase transparency; advance initiatives in the area of communication and interaction with stakeholders; deliver on public health needs; support the availability of veterinary medicines and undertake initiatives in the context of the review of veterinary legislation.

New pharmacovigilance legislation

The Management Board endorsed an implementation plan for the new pharmacovigilance legislation starting in July 2012 that takes into account the restricted resources and budget available to the Agency. Activities contributing to public health are given the highest priority, followed by activities increasing transparency and improving communication, followed by simplification measures.

The implementation plan foresees the establishment of the Pharmacovigilance Risk Assessment Committee (PRAC) with an inaugural meeting in July 2012 and the establishment and operation of the revised Coordination Group from September 2012. The Agency will operate the new urgent Union procedure from September 2012 and plans to introduce public hearings.

Implementing revised policies on handling of conflicts of interests

Following the successful implementation of the revised policy on the handling of conflicts of interest for scientific-committee members and experts and Agency staff, aimed at achieving a more robust system, the Board discussed a proposal for a revised policy on the handling of conflicts of interests for members of the Management Board. The Board welcomed the proposed improvements and plans to adopt the policy at its next meeting in March 2012.

Ethical and good clinical practice (GCP) aspects of clinical trials

The Management Board endorsed the 'Reflection paper on ethical and GCP aspects of clinical trials of medicinal products for human use conducted outside of the EU/EEA and submitted in marketing authorisation applications to the EU regulatory authorities'.

The paper sets out practical steps to be taken during the evaluation of marketing authorisation applications submitted to the Agency or national competent authorities and when providing advice on clinical trials conducted outside of the EU/EEA in the medicine development phase. The paper, which emphasises the role of international cooperation, aims at assuring, at the time of assessment of marketing authorisation applications, that clinical trials conducted in countries outside the EU/EEA have been conducted in accordance with GCP and ethical standards equivalent to those applying in the EU.

Progress of Agency interaction with healthcare professionals

The Management Board welcomed and endorsed a framework for interaction between the Agency and healthcare professionals, who have been an integral part of the Agency's work since its establishment. The framework ensures that healthcare professionals support the Agency in its work in order to access the best possible independent expertise on the use of human medicines in clinical practice and to contribute to a more efficient and targeted communication to healthcare professionals. The framework will also enhance healthcare professionals' organisations' understanding of the role of the Agency and the EU regulatory network.

The framework foresees the transformation of the current CHMP Working Group with healthcare professionals into an Agency working party with links to all scientific committees dealing with medicines for human use.

The framework is accompanied by criteria to be fulfilled by healthcare professionals' organisations in order to be involved in Agency activities. This will ensure that the Agency establishes contact with the most suitable organisations representing European healthcare professionals in a transparent manner.

Supply shortages of medicines caused by insufficient good manufacturing practice (GMP) compliance

In the light of recent GMP/manufacturing problems leading to supply shortages, the Management Board agreed that ensuring the security of the manufacturing supply chain of medicines is an important aspect of maintaining the availability of medicines. Disruption in the supply of medicines can lead to a failure to treat, the use of less desirable alternative medicines, increased potential for errors and poorer patient outcomes, caused by absent or delayed treatment or incidence of preventable adverse reactions associated with alternative medicines or dosage forms.

The Management Board initiated the discussion on a 'Reflection paper on medicinal product supply shortages caused by manufacturing/GMP compliance problems', which summarises the lessons learned from previous crises where the Agency had a supporting or co-ordinating role and presents short and mid-term actions that may allow the EU network to prevent, mitigate and manage shortages of important medicines.

Notes

1. This press release, together with all relevant documents adopted at the Management Board meeting are available on the Agency's website.
2. More information on the new pharmacovigilance legislation is available on the Agency's website.
3. The detailed implementation plan for the new pharmacovigilance legislation will be published on the Agency's website in mid-January 2012.
4. The 'Reflection paper on ethical and GCP aspects of clinical trials of medicinal products for human use conducted outside of the EU/EEA and submitted in marketing authorisation applications to the EU regulatory authorities' will be presented to the Heads of Medicines Agencies for endorsement in February 2012 as a final step.
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Monika Benstetter or Sabine Haubenreisser

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu