European Medicines Agency
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PRESS RELEASE

Management Board finalises its long-term plan and adopts work programme and budget for 2005

EMEA long-term plan, work programme and budget for 2005

After an extensive public consultation exercise, the Management Board endorsed the long-term plan for the EMEA (EMEA Road Map to 2010) that sets out the direction for the Agency to 2010, including implementation of the new pharmaceutical legislation. The first wave of actions from the plan will be put into force in 2005 and are included in the 2005 work programme that was adopted by the Management Board, together with the budget for 2005. In his introduction to the work programme, EMEA Executive Director Thomas Lönngren sets out three main priority areas for 2005 (see below for details):

- Implementation of the new pharmaceutical legislation and EMEA long-term plan
- Optimisation of the Agency's core business and existing activities
- Implementation of the EU telematics strategy for the pharmaceutical sector

The 2005 budget totals € 110 160 000 (2004: € 99 089 103) and includes forecast fee revenue of € 77 455 000 (2004: € 67 000 000). Some 52 new applications for marketing authorisations for human medicines are forecast for 2005, which suggests a potential return to the numbers of applications seen before the shortfall in 2002 and 2003 (2000=54, 2001=59, 2002=31, 2003=39, 2004=47). Growth is also expected for veterinary medicines with 11 new applications forecast compared to 7 in 2004.

The budget also includes a basic contribution from the EU general budget of € 17 900 000 (2004: € 17 500 000), an orphan drugs fund of € 3 700 000 (2003: € 3 500 000) and a special contribution of € 7 500 000 (2004: € 7 500 000) for implementation of the EU information technology strategy.

The overall workload of the Agency is expected to increase substantially. As a result of this the Board also approved the recruitment of 65 additional EMEA staff members, taking the total maximum head count to 379 in 2005 (2004: maximum of 314). A large number of these staff will be recruited for the preparation and implementation of the new pharmaceutical legislation, as well as to cope with the anticipated increased number of applications.

Code of conduct and declaration of interests

The Management Board adopted a new 'Code of Conduct' for staff members, European experts and members of EMEA scientific committees and working parties. The revised Code provides important guidance to staff, experts and committee members on conflicts of interest and the declaration of those interests, confidentiality and discretion, as well as guidance on the acceptance of gifts and invitations.

EMEA priorities for 2005

The detailed priorities for the EMEA in 2005 given in the Executive Director's introduction to the work programme are as follows:

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1. Implementation of the new pharmaceutical legislation and EMEA long-term plan

Some aspects of the new pharmaceutical legislation came into force in 2004, while fundamental changes to the European regulatory system will have their first effects in 2005.

- ✓ In 2005 the Agency will focus on preparation for the full entry into force of the new legislation in the last part of the year
- ✓ Particular attention will be attributed to the implementation of provisions reinforcing safety of medicines, accelerating availability of medicines to EU patients and creating the right environment to stimulate research. These initiatives include implementation of the concept of risk management plans, expansion of the scope of medicines to be authorised through the centralised procedure, establishment of the accelerated assessment, conditional authorisation, compassionate use procedures as well as procedures for authorisation of biosimilar and generic products and support to small and medium-sized enterprises
- ✓ High importance will be attributed to initiatives aimed at increased communication and provision of information to patients, health care professionals and the general public

2. Optimisation of the Agency's core business and existing activities

Safety of medicines and improvement of the Agency's core activities will remain a priority in 2005.

- ✓ To provide for safe use of medicinal products, the Agency will reinforce its activities in the area of pharmacovigilance, in particular the EudraVigilance database and the implementation of the EMEA risk management strategy for medicines for human use. The Agency will improve handling of referral procedures to provide faster opinions on questions related to safety of medicines.
- ✓ The Agency will remain committed to managing effectively and efficiently its increased tasks and responsibilities ensuring that patients and users of medicines have access to safe and effective medicinal products within the timelines laid down in the legislation
- ✓ The Agency will work for greater transparency of its operations and activities
- ✓ EMEA will further extend its capacity to provide scientific advice and the quality of that advice
- ✓ It will strive to increase availability of veterinary medicines intended for minor uses and minor species

3. Implementation of the EU telematics strategy for the pharmaceutical sector

EMEA was given the responsibility to implement the EU telematics strategy and projects agreed by the European Commission, Member States and the Agency, which once implemented will increase efficiency of the network, provide better information to the users of medicinal products and will contribute to safe and effective use of medicinal products. The Agency plans to undertake further implementation and expansion of these projects in response to legislative requirements in 2005. As part of this plan:

- ✓ The Agency will carry out additional work to considerably enlarge the original scope of the EuroPharm database of all medicines authorised in the EU. This will allow the general public to access information in the database in all languages and it will include more information
- ✓ The Agency will continue to develop the EudraVigilance database and will add a new component on suspected unexpected serious adverse reactions
- ✓ EMEA will also prepare and design a database of manufacturing authorisations and good manufacturing practice certificates required under the new Directive on human medicines

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NOTES:

1. This press release, together with other information about the work of the EMEA, may be found on the EMEA web site at the following location: http://www.emea.eu.int
2. The final 'EMEA Road Map 2010', work programme for 2005 and revised Code of Conduct will be published on the EMEA website in January 2005.
3. The next meeting of the Management Board is on 10 March 2005.

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