The European Agency for the Evaluation of Medicinal Products
Directorate

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PRESS RELEASE
EMEA forecasts modest increase in applications in its 2004 budget and Management Board elects new chairman

The EMEA Management Board elected a new chairman and vice-chairman at its 18 December 2003 meeting. Dr Philippe Duneton (France), who was previously the Board's vice-chairman, was elected as chairman and Dr Jytte Lyngvig (Denmark) was elected as the new vice-chairman.

The Board adopted the EMEA work programme and budget for 2004. The budget totals € 84 224 000 (2003: € 78 081 000) and includes forecast fee revenue of € 52 700 000 (2003: € 48 142 000). About 40 new applications for marketing authorisations for human medicines are forecast, which is an increase on 2002 and 2003 levels (31 and 38), but below numbers seen in previous years. The work programme will be published on the EMEA web site in early 2004. A summary of EMEA priorities for 2004 is given below.

The budget also includes a basic contribution from the EU general budget of € 17 500 000 (2003: € 15 500 000), an orphan drugs fund of € 3 500 000 (2003: € 3 300 000) and a special contribution of € 7 500 000 (2003: € 7 000 000) for implementation of the EU information technology strategy.

The Board also approved the recruitment of 27 additional EMEA staff members, taking the total maximum head count to 314 in 2004 (2003: maximum of 287). It is intended that recruitment will focus on improving the scientific competence of the Agency, in line with the growing scientific role the EMEA will be asked to play in the European regulatory system.

The Board noted the results of the 2003 joint performance indicators surveys conducted with the European trade associations of the human and veterinary pharmaceutical industry, EFPIA and IFAH-Europe. One important finding in the survey is the positive impact of EMEA scientific advice on applications, both in terms of quicker procedures and higher chance of a successful outcome. Both documents will be published on the EMEA web site early in 2004.

EMEA priorities in 2004

In addition to the core business the Agency has set itself seven priorities in 2004:

1. EU enlargement

The first of these priorities is enlargement, which will extend the European medicines system to twenty-eight countries within the European Economic Area. The coordinating role of the Agency within the European network will become more complex and intensive.

- The main objective will be to ensure a smooth transition as we welcome the new members into our activities. This will of course also mean more meetings and more delegates coming to the EMEA

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2. Medicines for human use

The Agency's structures and procedures for medicines for human use need to be of the highest calibre.

- Independently of any future legislative changes, the objective is to put in place a programme of improvements for the Committee for Proprietary Medicinal Products
- Improving the provision of scientific advice continues to be an important objective and the Agency will focus here on the scientific expertise needed for this and the process by which it is done
- Surveillance of the safety of medicines is another critical activity for the Agency, particularly with regard to progressing the implementation and upgrading of the EudraVigilance system
- The CPMP must be in a position to give the best possible scientific opinions with regard to medicines for human use. Greater use of external expertise will be made to help the CPMP in its tasks, in particular therapeutic advisory groups established in 2003. In addition, specialised experts will be involved in the scientific evaluation process, both pre- and post-authorisation, in order to allow for a more proactive conduct of pharmacovigilance

3. Medicines for veterinary use

The Agency's structures and procedures for veterinary medicines also need to be of the highest calibre.

- Antimicrobial resistance continues as a critical issue for both animal and human health. Determining the Agency's contribution to facing this challenge this will be an objective in 2004
- The availability of veterinary medicines, especially for minor uses and minor species, will continue as a major objective for the Committee for Veterinary Medicinal Products in 2004
- The surveillance of veterinary medicines is also an important activity for the Agency, particularly with regard to progressing the implementation of the EudraVigilance system in the veterinary sector

4. International

The regulation of pharmaceuticals has become increasingly international in response to the globalisation of the pharmaceutical industry. It is important that regulators share their experience and best practices as part of meeting the international challenge.

- The Agency will continue to play a role with its scientific contribution to the European Union presence in a number of international forums, in particular the trilateral EU-Japan-US ICH and VICH international harmonisation conferences, and to the mutual recognition agreements with third countries
- Implementation of the confidentiality agreement with the US Food and Drug Administration will also be an objective in 2004, together with the conclusion of a similar agreement with the US Department of Agriculture for veterinary biological medicinal products

5. Networks

The European medicines system rests firmly on the network of the national competent authorities of the Member States. The operation and maintenance of that network is of prime importance to the EMEA.

- The main objective here will be to fulfil the Agency's responsibilities for the implementation of the EU telematics strategy for the pharmaceuticals sector
- The exchange of information is central to the networks and there are a number of key European databases for which the EMEA has responsibility, including the clinical trials database

6. Strengthening the EMEA

The Agency plays a central role in the European system. It is important that EMEA staff have the highest competence and the organisation and structures allow it to meet future challenges.

- Significant efforts will be made to improve staff competence, development and training
- A new group will be created in the Agency with responsibility for external communications and internal management support
- It is also an objective to bring the Agency's legal staff together into a new group in order to provide more coordinated legal support to all parts of the EMEA. A head of the legal staff will be appointed

7. Planning for the future

The EMEA and the medicines system are entering a period of significant change. Preparation and planning for the future is a priority activity for the EMEA.

- A high-level strategy document outlining the vision of the Agency for the future will be presented for discussion with all stakeholders.

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NOTES:

1. Dr Philippe Duneton is a medical doctor. After having served as a member of cabinet for two French health ministers, Dr Duneton joined the French Agence du Médicament in 1998 as Secretary-General. He was appointed Director-General of the new Agence Française de Sécurité Sanitaire des Produits de Santé in 1999 and joined the Management Board in 1999.
2. Dr Jytte Lyngvig is a chemical engineer. Beginning as a lecturer at the Technical University of Denmark, she went on to work in the Danish Environment Ministry and later in the Copenhagen Agency of Environmental Protection. Dr Lyngvig has 12 years' private sector experience in the transport and consultancy industries and was appointed Chief Executive Office of the Danish Medicines Agency in 2000. She joined the EMEA Management Board in the same year.
3. As part of discussions on the EU budget and the impact of enlargement, the European Parliament has placed € 2.9 million of the EMEA budget into reserve, pending re-negotiations in April 2004.
4. 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
5. The next meeting of the Management Board is on 11 March 2004.

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