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PRESS RELEASE

Thirty-third meeting of the Management Board

The EMEA Management Board met on 21 February 2002, chaired by Dr Keith Jones. Items discussed included:

1. The Management Board considered a programme of work for the Agency as part of the Community-wide IT strategy for the pharmaceuticals regulatory sector. The strategy is aimed at supporting regulatory bodies and the pharmaceutical industry, but also includes initiatives to give patients and health professionals access to information on medicines throughout the European Union. Important initiatives forming part of that strategy include:
 - Continued development and enhanced operation of the EudraVigilance system for the reporting and monitoring of safety of medicines across the EU.
 - Development of 'EuroPharm' – a European pharmaceuticals database giving access to information on all medicines authorised throughout the EU.
 - Development and operation of 'eSubmissions' – an IT platform to allow electronic submission by companies (as part of implementation of the ICH electronic common technical document).
 - Development and management of the European database for information on clinical trials conducted in the EU.
 - Management of the 'EudraNet' – the EU drug regulatory authorities' network that links the national competent authorities, European Commission and EMEA.
 - Preparation for extension of this system to acceding Member States on enlargement.

The cost of the three-year programme (2003-2005) is forecast at € 36 million. Implementation of the strategy will depend on the availability of appropriate funding from the European Commission and will be decided at the end of 2002 as part of the EU budgetary process.

2. The Board approved the draft work programme and budget request for 2003. In addition to the forecast increase in current workload, the work programme takes into account a number of new tasks for the Agency in 2003, preparation for enlargement and strengthening of certain aspects of the Agency's public health related activities. The budget requested totals € 94 113 000.

The Management Board considered the balance between fee revenue and EU subsidy in the Agency's budget. The level of general EU subsidy has gradually fallen as a proportion of EMEA revenue and the Board has proposed that a minimum 6 % increase in fee levels is needed in 2003 in order to meet the Agency's work programme. The actual increase proposed will depend on several factors including the final outcome of the EU subsidy discussions. The Board also proposed that the EMEA should offer up to 100 % fee reductions for orphan medicines, to meet the expectations of patient groups and sponsor companies.

An additional 62 posts are requested, that would take the total staff complement to 313. The budget and work programme are now submitted to the EU institutions and will be finally adopted at the end of 2002 after voting by the European Parliament and Council of Ministers.

3. The next meeting of the Management Board is on 6 June 2002.

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Elements of the EMEA draft budget 2003

Revenue side includes:

- Fee revenue of € 54 280 000 (58 % of revenue), with an increase to 70 applications for new human medicines in 2003, including 20 applications from designated orphan medicines. Applications in the veterinary sector are expected to increase to 11 applications for new veterinary medicines, with 6 applications for maximum residue limits.
- General EU subsidy of € 16 000 000 (17 % of budget), plus € 12 106 100 for the IT strategy in 2003 (13 % of revenue).
- Orphan drug fund of € 6 200 000 representing a doubling of the 2002 orphan drug fund to allow for greater fee reductions (6.5 % of revenue).
- Other revenue includes € 2 600 000 for the third phase of the Pan-European Regulatory Forum (PERF) programme with the regulatory authorities of central and eastern European countries (3 % of revenue).

Expenditure side includes:

- Payment of € 26 770 000 to national competent authorities for rapporteur, co-rapporteur and inspection services (28.5 % of expenditure).
- Staff salaries and other costs of € 36 661 000 (39 % of expenditure).
- Building and equipment costs of € 21 079 200 (22.5 % of expenditure).
- These 2 items include expenditure of € 12 106 000 for the Community IT strategy.

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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>

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