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PRESS RELEASE

New pharmaceutical legislation enters into force on 20 May 2004

The EMEA welcomes the publication of the new European pharmaceutical legislation in the Official Journal of the European Union on 30 April 2004. The revised legislative package introduces new responsibilities, a new administrative structure, and a new name for the Agency.

Implementation of some parts of the new legislation starts 20 days after publication, on 20 May 2004, with the remaining provisions coming into force 18 months later at on 20 November 2005.

Consequences for the EMEA

The revised Regulation and two Directives will have a significant impact on the Agency. Elements of the new legislation that come into force in May 2004 include a reinforced role for the Agency in the provision of scientific advice to companies, cooperation with the WHO in giving opinions for the use of medicines outside the EU, opinions on the compassionate use of unapproved medicines in Member States. The Agency will be given a stronger role in the provision of information to the patients and the public, including a mandate to develop a database of all medicines approved in the European Union ('EuroPharm'). There are also provisions for giving small and medium-sized companies administrative and scientific support.

Provisions that will enter into force in November 2005 include conditional approvals and fast-track reviews, in addition to an increase in the scope of the centralised procedure.

The name of the Agency also changes to reflect its broader responsibilities, to the European Medicines Agency. The acronym 'EMEA' will continue to be used. Other changes include:

- Committee for Medicinal Products for Human Use replaces the Committee for Proprietary Medicinal Products. The new Committee will be known as the CHMP. Membership of the Committee changes from two to one member per Member State (following EU enlargement this means 25 members) and in addition one member from Iceland and Norway.
- Committee for Medicinal Products for Veterinary Use replaces the Committee for Veterinary Medicinal Products. The new Committee will continue to be known as the CVMP. Membership of the Committee is similar to the CHMP.
- There are no changes to the Committee for Orphan Medicinal Products (COMP).
- A new Committee for Herbal Medicinal Products is created and is expected to begin activity later in 2004. The new Committee will be known as the HMPC.
- Composition of the Management Board changes from two to one member per Member State, in addition to two representatives each of the European Parliament and the European Commission. They are joined by two representatives of patient organisations, one representative of doctors' organisations and one representative of veterinarians' organisations. There are a total of 33 members of the Board.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 27 Fax (44-20) 74 18 84 09
E-mail: press@emea.eu.int http://www.emea.eu.int

Next steps

The new Management Board will meet for the first time on 24 May 2004. One of its first actions will be to consider the proposed composition of the CHMP and CVMP. Under the new pharmaceutical legislation, the Management Board has to be consulted on the composition of these two Committees before Member States can appoint the members.

In order to allow enough time for the consultation process the CHMP meeting scheduled for 25-27 May 2004 has been exceptionally postponed to 1-3 June 2004. The next CVMP meeting (11-13 May 2004) will be held in its current form together with representatives from the new Member States acting as full members. The June CVMP meeting will be held in its new composition.

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NOTES:

1. The EMEA was created in 1995 by Council Regulation (EEC) No 2309/93. The new Regulation (EC) No 726/2004 will replace this Regulation. The new Directives introduce amendments to the existing Community Codes on human and veterinary medicines (Directives 2001/83/EC and 2001/82/EC).
2. 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
3. The full text of the new legislation can be found in the Official Journal of the European Union on the following location: http://europa.eu.int/eur-lex/en/archive/2004/l_13620040430en.html

Media enquiries only to Martin Harvey Allchurch

Tel. (44-20) 74 18 84 27, Fax (44-20) 74 18 84 09, E-mail: press@emea.eu.int