European Medicines Agency
Press office

London, 15 December 2005
Doc. Ref. EMEA/261632/2005

PRESS RELEASE

European Medicines Agency opens SME Office to support small and medium-sized enterprises

The European Medicines Agency today launched an SME Office to provide administrative and procedural assistance to small and medium-sized enterprises (SMEs) seeking to develop and market new medicines. The launch follows the adoption of a new Commission Regulation aimed at promoting innovation and the development of new medicinal products by SMEs.

Once the Regulation comes into effect, SME companies that are developing medicinal products for human or veterinary use will be able to benefit from a number of incentives, including:

- Administrative and procedural assistance from a dedicated group of people within the SME Office at the Agency;
- Fee reductions for scientific advice, inspections and (for veterinary medicines) establishment of maximum residue limits;
- Fee exemptions for certain administrative services of the EMEA;
- Deferral of the fee payable for an application for marketing authorisation or related inspection;
- Conditional fee exemption where scientific advice is followed and a marketing application is not successful;
- Assistance with translations of the product-information documents submitted in the application for marketing authorisation.

To determine which companies are eligible for SME incentives, the EMEA will apply the definition of micro, small and medium-sized enterprises provided in Commission Recommendation 2003/361/EC.

The new Commission Regulation was adopted by the Standing Committees for Medicinal Products for Human Use and for Veterinary Medicinal Products in order to implement provisions relating to SMEs in the new EU pharmaceutical legislation (Article 70(2) of Regulation (EC) No 726/2004).

Further information on the assistance available to SMEs can be found on the new SME Office section of the EMEA website at http://www.emea.eu.int/SME/SMEoverview.htm

--ENDS--

NOTES

1. Commission Regulation (EC) No 2049/2005 laying down the specific provisions aimed at promoting innovation and the development of new medicinal products by SMEs will be published shortly on the website of the European Commission's pharmaceuticals unit: http://pharmacos.eudra.org/F2/
2. The Commission press release on the adoption of the Regulation can be found here.
3. Commission Recommendation 2003/361/EC on the definition of SMEs can be found here.
4. Information about EMEA implementation of the new EU pharmaceutical legislation is available here.

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

Queries regarding the EMEA's SME Office to:
Melanie Carr
Tel.: (44 20) 74 18 85 75, Fax: (44 20) 75 23 70 40, E-mail: smeoffice@emea.eu.int