EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 September 2012
EMA/587764/2012
Press Office

Press release

Over 1000 SMEs now registered with European Medicines Agency SME office

For the first time since the launch of its SME initiative in December 2005, there are now more than 1000 micro, small and medium-sized enterprises (SMEs) registered with the European Medicines Agency.

Companies registered as SMEs with the Agency have access to a number of incentives, including regulatory assistance from the SME office, and reduced fees for certain Agency procedures such as scientific advice and inspections. The Agency recognises the fact that SMEs are a major driver of innovation in the pharmaceutical industry.

SME applicants currently account for around 10% of centralised marketing-authorisation applications for human medicines and 20% of veterinary applications.

2012 has seen a surge in the number of companies submitting SME declarations to the Agency, with a 48% increase since the end of last year. This indicates a high level of activity in the pharmaceutical sector, but is also a reflection of the new pharmacovigilance legislation coming into operation.

A high proportion of companies registering recently have sought SME status in relation to EudraVigilance, the European Union information system for the management of safety reports. A Medical Dictionary for Regulatory Activities (MedDRA) fee waiver is available to micro and small enterprises, and there are reduced fees for EudraVigilance training for all SMEs.

SME profiles

The majority of registered SMEs (76%) have medicines for human use under development, 4% are developing medicines for veterinary use, 6% are developing products for both human and veterinary use and 14% are service providers.

Further information on the companies registered with the Agency's SME office is available in the publicly available SME register, which has been designed to facilitate and promote interaction amongst SMEs.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

Product pipeline

Together, the registered SMEs have approximately 2600 medicines at various stages of development. Approximately half of the products developed by SMEs are chemical entities and a quarter are biological medicines, including advanced therapies.

SMEs are strongly encouraged to seek scientific advice on the data required for marketing authorisation for medicines from the Agency early in development. For help and guidance on how to obtain scientific advice, SMEs can turn to the Agency's SME office.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. A summary of experience to date was published by the SME office at the end of 2011 in its 'Report on the SME initiative 2006-2011: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/12/WC500119970.pdf
3. The SME register is available here: http://fmapps.emea.europa.eu/SME/
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Monika Benstetter or Martin Harvey Allchurch

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu