

20 December 2010
EMA/784834/2010
Press Office

Press release

European Medicines Agency facilitates interaction between small and medium-sized enterprises (SMEs)

Agency launches public SME registry

The European Medicines Agency has launched a public SME registry providing information on companies which are registered as SMEs with the Agency. The registry aims at facilitating and promoting interaction amongst SMEs. In the first phase this registry will include contact details of individual companies, their area of activity and headcount. In the second phase, available from the end of March 2011, this registry will also include information on the company pipeline and product profile.

This initiative is in line with the overall transparency policy of the Agency. Following discussions with stakeholders it was decided to increase the public information on SMEs to give a more complete picture of the registered SMEs in Europe and to support their growth in the EU through partner search and cooperation. Previously the Agency published only a list of SMEs with their country of origin.

The 20 million SMEs within the EU are a key driver for economic growth, innovation, employment and social integration. The Agency supports SMEs developing new medicines for human and veterinary use through its dedicated SME Office – a 'one-stop shop' that helps SMEs with practical or procedural issues relating to the development and authorisation of their medicinal products.

Incentives available to SMEs from the Agency include regulatory assistance, assistance with translations, fee reductions, exemptions, deferrals and the certification procedure for advanced therapy medicinal products.

SME seeking advice on the support provided by the Agency should contact the SME Office at: smeoffice@ema.europa.eu.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The SME registry is available on the Agency's website. The register includes companies established in the European Economic Area that have submitted a SME declaration with the meaning of Recommendation 2003/361/EC and to whom the Agency has assigned SME status.

3. A document answering frequently asked questions relating to the assignment and maintenance of SME status by the European Medicines Agency is available on the Agency's website.
4. The user guide for micro, small and medium-sized enterprises on the administrative and procedural aspects of the provisions, laid down in Regulation (EC) No 726/2004 that are of particular relevance to SMEs, updated on 17 December 2010, is available on the Agency's website.
5. The report from the SME Office on its 5th year of operation is available on the Agency's website.
6. The December 2010 issue of the news bulletin for small and medium-sized enterprises is available on the Agency's website. The news bulletin aims to bring to the attention of SMEs, and their stakeholders, documents and activities related to the European regulatory environment.
7. 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 Sabine Haubenreisser

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu