European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

London, 8 May 2009
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1st European SME Week 2009
EMEA Roundtable with SME Stakeholder Organisations

To coincide with the launch of the 1st "SME week" by the European Commission (Link to EC website), the EMEA held a meeting with representatives of SME stakeholder organizations on 7 May 2009. The aim of the meeting was to take stock of the Agency's SME initiative and invite roundtable discussion on the scheme and how it might be improved in the future.

The SME Office presented a profile of its activity since its inception in 2005. Stakeholders acknowledged the significant role the Office now plays as a service provider. Focussing on long-term activities, the EMEA will move to a paperless system this year with electronic submission and notification to speed up the assignment process. The Agency will continue to provide 'early' development support through briefing meetings, offer scientific advice at a reduced fee and direct regulatory assistance. An additional workshop will be organized in 2009 on the paediatric initiative. More detailed information on SME companies developing medicines will be published.

The meeting was also an opportunity to promote the establishment of a network of Offices within the European regulatory framework. Representatives from two national competent authorities described measures to support SMEs and innovation. In France support is provided through the Innovation Office of AFSSAPS which provides User guides for medicines and medical devices, newsletters, and scientific advice. An SME office with the Paul Ehrlich Institute in Germany is in its planning phase.

An update on SME experience with marketing authorisation applications for human and veterinary medicines was presented. For veterinary medicinal products, there have been 3 outcomes since the SME initiative started, all positive. For medicinal products for human use, of the 21 outcomes, 8 (38%) positive and 13 (62%) resulting in negative opinion or withdrawal with SMEs having a much lower success rate compared to non-SME companies. In this context the need to prevent premature filings in particular was highlighted. Although the impact of the SME initiative will only be seen in the coming years, it is clear from the limited experience gained so far that there is a need to further encourage the uptake of 'early' support at the scientific advice stage, in particular on chemical, pharmaceutical and biological aspects, as well as 'later' support during MAA preparation.

Further the EMEA presented an overview of the use of the Scientific Advice procedure by SMEs. Although it is too early to assess the impact of compliance with scientific advice on the success rate of marketing authorisation applications, preliminary data indicate that following scientific advice is a predictor of a positive outcome.

European Biopharmaceutical Enterprises (EBE) presented the conclusions of its recent report (Link to report) which aimed at assessing the impact of the global economic downturn on small biopharmaceutical companies in Europe. A significant finding of the report was that up to 20% of European Biotech SMEs could be facing bankruptcy by year end 2009 due to reduced credit access to public and private financing. Solutions suggested include coordinated actions at European and Member State level to introduce tax credits and reduce operating expenses for start-ups.

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The roundtable discussion was an opportunity to openly debate how to further support SMEs in the regulatory framework:

- reinforcing the provision of information on SME initiatives in particular to veterinary companies through stakeholders or events,
- increasing dialogue with companies on the product pipeline following SME assignment,
- further supporting translational work and raising awareness of the biomarker qualification process,
- further engaging SMEs and their stakeholders to provide feedback on new regulations, guidelines and procedures (e.g. for Advanced Therapy Medicinal Products),
- strengthening pre- and post-MAA support, with strategy briefing meetings prior to MAA submission, eCTD support, and de-briefing meetings at major milestones in the approval process.

The roundtable discussion was felt to be extremely useful by all parties and will be built on in the future as a measure to receive feedback from SMEs and their stakeholders to continually improve the services provided by the Agency's SME Office.

Annex

List of Participants
EMEA Roundtable with SME Stakeholder Organisations
7 May 2009, 14.00 to 17.00

Chairperson:

Agnés Saint Raymond	Head of Sector, Scientific Advice and Orphan Drugs

Organisations Representatives

Emmanuel Chantelot	European Biopharmaceutical Enterprises (EBE)
Anna Thomas	EBE (PregLem)
Julie Kjestrup	EuropaBio
Linda Lebon	EuropaBio (Voisin Consulting)
Tim Kievits	EuropaBio (PamGene BV)
Alain Verrijdt	Europharm smc
Ariadna Olle	European Generics Association (Combino Pharm)
Leslie Galloway	Ethical Medicines Industry Group
Derval O'Carroll	Ethical Medicines Industry Group
Stephen Dawson	International Federation for Animal Health
Klaus Hellmann	Association of Veterinary Consultants

National Competent Authorities

Bettina Ziegele	Paul-Ehrlich-Institut, Germany
Stéphane Palies	AFSSAPS, France

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Patrick Le Courtois	Head of Unit, Human Pre-Authorisation
Melanie Carr	SME Office
Constantinos Ziogas	SME Office
Cathrin Budnik	SME office
Spiros Vamvakas	Acting Deputy Head, Scientific Advice and Orphan Drugs
Marisa Papaluca Amati	Deputy Head of Sector, Safety and Efficacy Sector
Bo Aronsson	Safety and Efficacy Sector
Patrick Celis	Regulatory Affairs and Organisational Support
Hilde Boone	Regulatory Affairs and Organisational Support
Enrico Tognana	Business Pipeline
Karen Quigley	Veterinary Marketing Authorisation Procedures