19 December 2011
EMA/810583/2011
Human Medicines Development and Evaluation

European Medicines Agency roundtable with small and medium-sized enterprise (SME) stakeholder organisations

European SME Week – October 2011

To coincide with "SME week" (Link to EC website), the EMA held a meeting with representatives of SME stakeholder organizations on 3 October 2011. The aim of the meeting was to present the outcome of the SME survey conducted by the Agency in March 2011 and discuss the experience with the SME initiative, more than 5 years following its implementation. The Agency is required to report annually on the implementation of the SME Regulation so that feedback on the practical application of the various support measures is available.

The SME Office presented a profile of its activity since its inception in 2005. It included an overview of the companies registered with the Office, their profiles, experience with scientific advice and the centralised procedure, the issues faced during the review of the application for marketing authorisation and how these can be addressed through regulatory dialogue. A summary of experience with SMEs operating in the veterinary sector, including scientific advice and centralised application for marketing application, was also provided. Looking back over the experience to date, all stakeholders acknowledged the significant achievements of the SME office.

Following on from the success of the SME initiative in its first five years, the EMA is committed to continue supporting SMEs. The agency will continue to provide 'early' development support through briefing meetings, offer scientific advice at a reduced fee and direct regulatory assistance. To cope with the growing number of SMEs approaching the EMA for assistance, the SME office will move to a paperless system this year with electronic submission and notification to speed up the assignment process as well as introducing a risk based approach to review of initial SME assignments and renewals. The next SME workshop in 2012 will focus on the roll out of new pharmacovigilance legislation.

The results of the SME Survey conducted in March 2011 were presented. The survey provided valuable feedback on the level of general awareness of measures to support SMEs, the relevance and quality of the programme as well as highlighting emerging issues and challenges identified by respondents.

Antoine Mialhe from the European Commission provided an overview of EU support for SMEs in Health Research through the 7th Framework Programme (2007-2013). There is emphasis on innovation through SME targeted topics and continued support of clinical trials. Specific measures to support SMEs

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

include, the target of 15% of the EU contribution going to SMEs, with funding covering up to 75% of R&D costs and up to 100% of management and training costs.

Stephane Palies presented the work of the Innovation office in France, which provides a user guide, newsletters, and scientific advice covering medicinal products, devices and combination products. Stakeholders would be keen to see more initiatives like this at national level. The SME office will continue to promote the establishment of a network of Offices within the European regulatory framework and cooperation with international structures supporting innovation.

Following on from the survey, the roundtable provided an opportunity to openly debate how to further support SMEs in the five key areas that were flagged by respondents as challenging:

Theme I – Finance and funding

Stakeholders welcomed the additional support for SMEs available through FP7. There was discussion around the definition of innovation, whether it includes incremental research and how it is can supported from the regulatory perspective. The need for sponsors to be aware of the regulatory classification of their product and the regulatory framework were emphasised as well as the need for convergence of science and regulation in programmes aimed at supporting the development and marketing of medicinal products.

It was noted that the European Commission will be moving to a more integrated approach to funding research in its 2020 vision by merging some of the programmes.

With regard to fees from EMA procedures, some stakeholders considered that, particularly in the post-authorisation phase, the fees charged could be more proportional to level of service provided. It was felt that current fee levels might discourage some SMEs from submission of line extensions and variations.

Theme II – Regulatory

Stakeholders present emphasised the importance of conducting small firm impact assessment routinely prior to implementation of new legislative proposals and guidance documents. The variation regulation was highlighted as an area that SMEs find complex and challenging.

Areas where SME stakeholders called specifically for more information and advice were: review of the clinical trials directive, post-authorisation efficacy and safety studies, inspections of active product ingredient manufacturing sites, and health technology assessment. Concerns were raised around costs to SMEs in the area of anti-counterfeiting.

EMA was asked to promote the application of the “only once” principle from the ‘Small Business Act’, i.e. to refrain from requesting the same information, data, documents or certificates which have already been made available in other procedures. The Article 57(2) ‘database’ was discussed in this context as it appears to go beyond the legislative provisions and require information that is already available elsewhere within the agency. The reasons for this were clarified during the meeting, which relate to the link to Eudrapharm and the new ISO standard entry tool.

The impact of e-CTD requirements on SMEs was discussed with proposals mooted for further support in this area including: a checklist for software suppliers and a helpdesk on e-CTD. It was noted that the EMA can provide advice and technical assistance via the SME office and can also arrange testing of the e-CTD submission prior to filing. Providing information at the national level, training through webinars, and increasing the role of stakeholder organisations in informing about these issues were also suggested as tools to facilitate e-CTD submission by SMEs.

Theme III – Scientific advice

Stakeholders emphasised that regulatory feedback on the development plan is key for investors and that information and communication about the predictability of the regulatory framework and its requirements is the eventual aim.

The need to encourage 'early' scientific advice was emphasised, even prior to first in man clinical trials. There is also a need to raise awareness of 'late' stage regulatory activities such as scientific advice cooperation with HTAs, and advice on post-marketing authorisation issues related to the pharmacovigilance legislation.

Theme IV – Information and communication

Proposals to reinforce training of SMEs through e.g. webinars was strongly supported by stakeholders, particularly in new areas where there is a steep learning curve for both regulators and industry, such as with variations and pharmacovigilance legislation. There was also a suggestion to take into account different regions when communicating as there may be less experience with certain regulatory aspects in some member states.

CAT-Focus groups with interested parties were considered particularly useful and there was a call for more collaboration with EMA committees along these lines. The need to simplify language when communicating on regulatory matters was noted. It was considered that the level of awareness of SME incentives may be lower in the veterinary sector. To reinforce this, the introduction of a web-link to the SME office from national competent authority websites was suggested.

Theme V – Regulatory authorities

The need for reinforcing communication and improving links with national competent authorities was mentioned as an important area for development.