European Medicines Agency

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Report from SME Office on its 1st year of Operation

On 15 December 2005, the EMEA launched an "SME Office" to provide financial and administrative assistance to micro, small and medium-sized enterprises (SMEs), pursuant to Commission Regulation (EC) No 2049/2005[1] (hereafter referred to as the SME Regulation). As the office celebrates its first anniversary, an update on its activities is provided here, together with a list of companies that currently have SME status assigned by the agency.

Background:

The aim of the initiative is to promote innovation and the development of new medicinal products by SMEs. Incentives available from the EMEA for SMEs, include:

- administrative and procedural assistance from a dedicated group of people within the SME Office within the agency;
- fee reductions (90%) for scientific advice, inspections and for the establishment of maximum residue limits (veterinary medicines);
- fee exemptions for certain administrative services (excluding parallel distribution);
- deferral of the fee payable for a centralised application for marketing authorisation or related inspection until after the grant of the marketing authorisation;
- conditional fee exemption where scientific advice is followed and the marketing authorisation application is unsuccessful;
- assistance with translations of the product-information documents submitted in a centralised application for marketing authorisation.

In determining which companies are eligible for SME incentives, the EMEA is applying the EU-definition of an SME provided in Commission Recommendation 2003/361/EC[2]. Companies are classified according to their size (micro, small or medium):

- micro enterprises employ less than 10 persons and have an annual turnover or balance sheet total not exceeding € 2 million;
- small enterprises have fewer than 50 employees and an annual turnover or balance sheet total of not more than € 10 million;
- medium enterprises have less than 250 employees and an annual turnover of not more than € 50 million or an annual balance sheet total of not more than €43 million.

and according to their category (autonomous, partner or linked):

- an autonomous enterprise holds less than 25% (capital or voting rights) in another company and/or another company holds less than 25% in it;
- a partner enterprise holds at least 25%, but no more than 50% in another company, and/or another company holds at least 25% but no more than 50%, in it;
- a linked enterprise holds more than 50% of the shareholders' or members' voting rights in another and/or another holds more than 50% in it.

A declaration of SME status (form available on EMEA web-site[3]) should be submitted to the SME Office prior to requesting financial or administrative assistance from the agency.

[1] *Official Journal L 329, 16/12/2005 pp. 4-7*
[2] *Official Journal L 124, 20/5/2003 pp. 36-41*
[3] Further information on the SME initiative is available on the EMEA website: http://www.emea.europa.eu/SME/SMEoverview.htm

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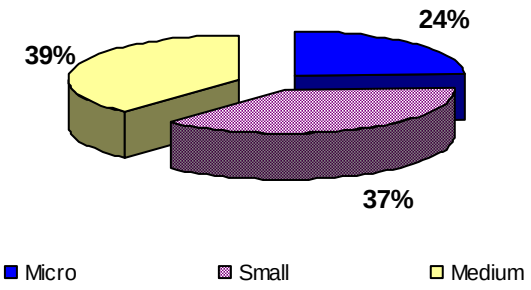
The first SME companies:

Companies' interest in the SME initiative, in its first year of operation, has exceeded expectations. To date, 136 companies have submitted SME declarations to the agency. Of those: 108 currently have SME status assigned by EMEA (for list of companies see Annex), 25 are under review, two have been withdrawn and one has expired[4]. The large majority of companies are developing medicinal products for human use, three are veterinary companies, and three are regulatory consultants[5].

Access to the incentives is the same regardless of whether a company is classified as micro, small or medium.

Information on the types of companies that are requesting assistance from the agency has been collected and is presented in figure 1.

Figure 1: Size of companies assigned SME status by EMEA – Dec. 2006

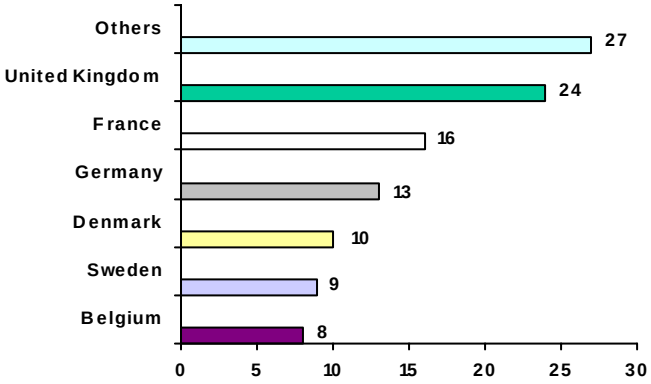


The substantial number of micro-enterprises (24%), which includes many start-up companies originating out of university research projects, is very encouraging.

The majority (58%) are 'linked' companies, i.e. are part of a group of enterprises linked through the direct or indirect control of the majority of voting rights or through the ability to exercise a dominant influence on the enterprise(s), 37% are autonomous, 2% are partner enterprises and 3% are both partner and linked enterprises.

Companies from across Europe have contacted the SME office, with declarations received from 17 different countries. The majority of companies assigned SME status, to date, are based in the UK, France, Germany, Denmark, Sweden and Belgium (figure 2).

Figure 2: Geographical distribution of companies assigned SME status by EMEA – Dec. 2006



[4] A company's SME status will expire two years after the date of closure of the accounts on which the declaration has been based. SME status may be maintained by submitting the latest annual accounts to the EMEA.

[5] Regulatory consultancies, which fulfil the definition of an SME and are established in the Community, may benefit from the provisions of the SME Regulation on behalf of SME clients. It is necessary for the regulatory consultancy to obtain SME status and the client to fulfil the definition of an SME within the meaning of Recommendation 2003/361/EC.

Experience to date:

Regulatory assistance:
The SME Office has given regulatory assistance to 14 companies. In 8 cases meetings or teleconferences have been organised. Regulatory assistance has been provided on a wide variety of topics including: general regulatory strategy for obtaining a marketing authorisation, eligibility to EMEA procedures as a medicinal product[6], applications for orphan designation, and by responding to detailed queries from companies in the run up to the filing of an application for marketing authorisation.

Scientific advice:
Twenty-three SME companies have requested scientific advice. Of those, 40% have sought advice on all areas of development (quality, non-clinical and clinical), 30% on both non-clinical and clinical, and in 30% of cases advice was limited to just one area. With SME companies benefiting from a 90% fee reduction, companies will be encouraged to seek follow-up advice as development proceeds. To date, a total of € 1.4 million in SME fee reductions has been processed for scientific advice.

Applications for marketing authorisation:
Eight SME companies have submitted marketing authorisation applications (MAAs), 7 for human medicinal products and 1 for a veterinary medicinal product. Of the human medicinal products that have been subject of MAAs, 6 out of 7 them are designated orphan medicinal products. One of the MAAs is currently being reviewed to an accelerated timetable. Payment of fees totalling € 1 million for MAAs and inspections have been deferred by SMEs to date.

Next steps:

Translations:
A procedure for providing SMEs with translations of the product information[7] within the scope of a centralised MAA is currently being delineated. It is envisaged that the English version of the product information will be translated by the Centre for Translation in Luxembourg just prior to the CHMP/CVMP opinion on the application. The translations would then be checked as the National Competent Authorities in the Member States in the usual manner. As no practical experience in handling SME translations has been gained yet, the procedure may be subject to change as experience is gained.

SME User Guide:
The SME Regulation requires the agency to publish a detailed 'User Guide' for SMEs on the administrative and procedural aspects of medicines legislation that are of particular relevance to smaller companies. The EMEA has completed the first draft of the Guide, which is currently with the European Commission for agreement. The draft User Guide will be published on the EMEA website for a 3-month consultation period.

Training/Workshop for SMEs:
The 1st SME Workshop, titled 'Navigating the Regulatory Maze', will take place on 2 February 2007. Registration for participation in this workshop, which has been limited to company's assigned SME status by the EMEA and representatives of stakeholder organisations, has now closed. Information and presentations coming from this workshop, as well as details of future workshops once organised, will be published on the EMEA web-site.

Future Updates from the SME Office
The SME office will publish regular updates on its activities in 2007.

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[6] This is done through the Innovation Task Force.
[7] Summary of product characteristics, package leaflet and label

Annex 1

List of companies that currently have SME status assigned by the EMEA
(status on 15 December 2006)

AB Science	France
Abigo Medical AB	Sweden
Action Pharma A/S	Denmark
Active Biotech AB	Sweden
ActoGenix N.V.	Belgium
Affibody AB	Sweden
Affymax Pharma Limted	United Kingdom
Alexion Europe SAS	France
Algeta ASA	Norway
Alimentary Health Limited	Ireland
Alizyme Therapeutics Limited	United Kingdom
Alliance Pharmaceuticals Limited	United Kingdom
Amarin Corporation plc	United Kingdom
AM-Pharma Holding B. V.	The Netherlands
Amro Biotech plc	United Kingdom
Antisoma Research Ltd	United Kingdom
AplaGen GmbH	Germany
Ardana plc	United Kingdom
Ark Therapeutics Ltd	United Kingdom
Arpida A/S	Denmark
AS Biotech GmbH	Austria
Astion Pharma A/S	Denmark
Barrier Therapeutics NV	Belgium
Bavarian Nordic A/S	Denmark
Bioalliance Pharma SA	France
BioInfoBank	Poland
Biolitec Pharma Ltd	Ireland
Biomay AG	Austria

Biotec Pharmacon ASA	Norway
BruCells SA	Belgium
Cardio3 S.A.	Belgium
Cellerix, S.L.	Spain
Chanelle Pharmaceuticals Manufacturing Ltd	Ireland
Chemisch-Pharmazeutische Fabrik Göppingen Carl Müller, Apotheker GmH & Co. KG	Germany
Clavis Pharma ASA	Norway
Crusade Laboratories Limited	United Kingdom
Curacyte AG	Germany
DBV Technologies	France
Diatos SA	France
DuoCort AB	Sweden
Elbion AG	Germany
Erytech Pharma	France
Exosect Limited	United Kingdom
Genmab A/S	Denmark
Génopoîétic	France
Genta Development Limited	United Kingdom
GPC Biotech AG	Germany
GW Pharma Ltd	United Kingdom
Hartington Pharmaceutical, SLU	Spain
Heidelberg Pharma GmbH	Germany
H-Phar	Belgium
Hungarotrial Ltd.	Hungary
I-Med Krebsimmuntherapie GmbH	Austria
Immatics Biotechnology GmbH	Germany
Immuno-Designed Molecules SA	France
Immunservice GmbH	Germany
INFAI GmbH - Institut für biomedizinische Analytik & NMR Imaging GmbH	Germany
Insmed Europe Ltd	United Kingdom

Intercell AG	Austria
Ipsat Therapies Oy/Ltd	Finland
Italchimici S.p.A.	Italy
Jerini AG	Germany
Jylland Pharma	Denmark
La Jolla Limited	United Kingdom
Laboratoire HRA Pharma	France
Laboratories SMB S.A.	Belgium
Lipomed GmbH	Germany
Medicure Europe Ltd	United Kingdom
Nanobiotix S.A.	France
Navamedic ASA	Norway
Neurochem Luxco II Sarl	Luxembourg
NeurogesX UK Limited	United Kingdom
NeuTec Pharma plc	United Kingdom
Newron Pharmaceuticals SPA	Italy
Novacea Europe Limited	United Kingdom
Novagali Pharma	France
NovaThera Ltd	United Kingdom
Oasmia	Sweden
Opi SA	France
Orphan Europe SARL	France
Oxxon Therapeutics Ltd	United Kingdom
OY Fennopharma Ltd	Finland
P.R.P. Tymofarm	Poland
Paion Deutschland GmbH	Germany
Pelias Biomedizinische Entwicklungs AG	Austria
Pharmasav Ltd	United Kingdom
Pharmathen S.A	Greece
Pharmexa A/S	Denmark
Pharming Group NV	The Netherlands

Renovo Ltd	United Kingdom
Resistentia Pharmaceuticals AB	Sweden
Rheoscience AS	Denmark
SantoSolve Pharma AS	Norway
Scancell Limited	United Kingdom
ScentoClone AB	Sweden
Swedish Orphan AB	Sweden
Symphogen A/S	Denmark
Synvolux Therapeutics B.V.	The Netherlands
The Weinberg Group LLC	Belgium
Theraptosis	France
TiGenix NV	Belgium
Trophos SA	France
VasTox plc	United Kingdom
Vitrolife Sweden AB,	Sweden
Voisin Consulting SARL	France
Wilex AG	Germany
Zealand Pharma A/S	Denmark