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

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Report from SME Office on its 2nd Anniversary

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). Two years on, an update on SME related activities is provided here, together with an overview of the companies that have shown interest in the initiative thus far.

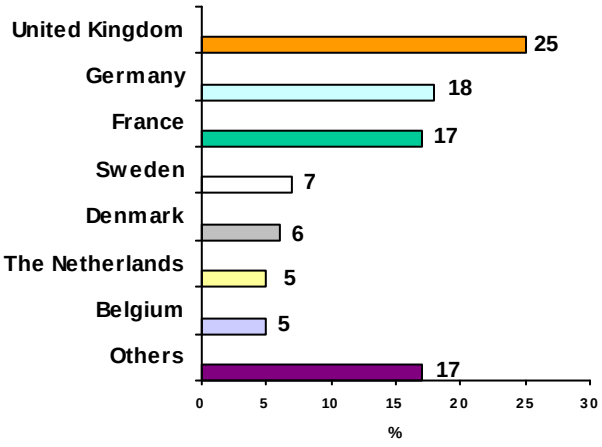
SME companies registered with EMEA

To date, 339 have submitted SME declarations to the agency. Of those: 246 currently have SME status assigned by EMEA (for current list of companies see Annex), 53 are under review, 21 have been withdrawn and 19 have expired[2]. The large majority of companies are developing medicinal products for human use, 9 are veterinary companies, 8 companies are developing products for both human and veterinary use and 19 are regulatory consultants [3].

In 2007, the number of companies requesting SME status from the agency increased by 40% compared to the previous year. The number of renewal requests increased 3-fold compared to 2006.

The majority of companies assigned SME status, to date, are based in the UK, Germany, France, Sweden, Denmark, Belgium (figure 1). Companies from 21 countries across the EEA have contacted the SME office to date.

Figure 1: Geographical distribution of companies assigned SME status by EMEA – Dec. 2007



Information on the size of companies that are requesting assistance from the agency is presented in figure 2. The relative proportion of micro-enterprises (37%), including many spin-offs from university research projects, increased in 2007.

[1] *Official Journal L 329, 16/12/2005 pp. 4-7*
[2] 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.
[3] 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.

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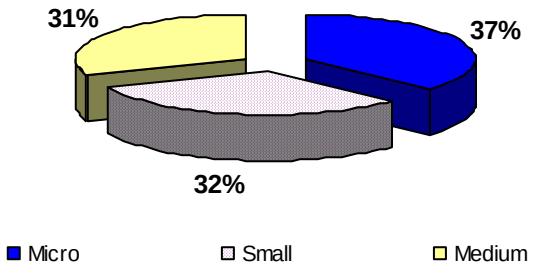
Figure 2: Size of companies assigned SME status by EMEA – Dec. 2007

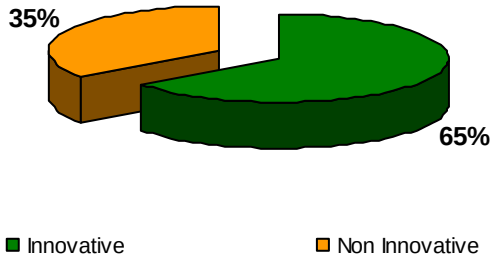


Development pipeline of registered SMEs

As the aim of the SME initiative within the EMEA is to promote innovation and the development of new medicinal products by SMEs, in November of this year the agency conducted a survey of SME assigned companies to gain more insight into their interests/product pipeline.

Of the assigned companies, the large majority of companies are developing products for therapeutic use. A small number 9% are operating in the area of diagnostic/imaging and 8% in preventive medicine, including vaccines. The level of innovation[4] amongst assigned SME companies was found to be very high (figure 3 below).

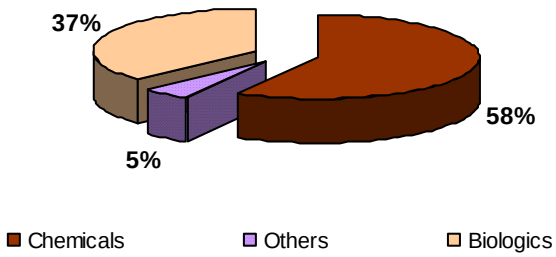
Figure 3: Level of innovation amongst companies assigned SME status by EMEA – Dec. 2007



Looking at the types of product under development, the broad breakdown into chemical entities vs. biologics is presented in figure 4 below.

[4] Innovation, as defined in the survey, comprised therapeutic innovation (e.g., new target disease, new mechanism of action, new compound types, new treatment modalities), technical innovation (e.g. new delivery methods/formulation, new manufacturing techniques, nanotechnology) and scientific innovation (e.g. new research and development methods/tools, pharmacogenomics, biomarkers).

Figure 4: Type of products developed by assigned SMEs – Dec. 2007

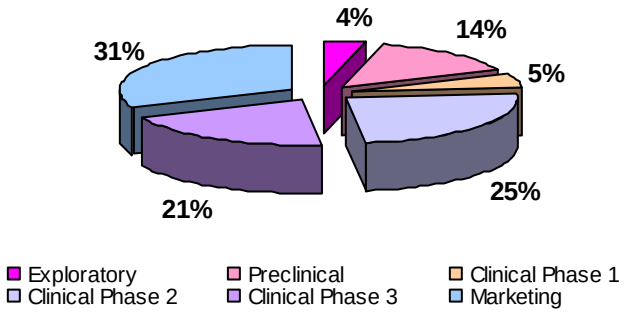


Of those companies developing biologics, the majority (50%) are recombinant DNA derived products (e.g. cytokines, monoclonals, transgene-derived, fusion proteins). Twenty percent (20%) are developing cell-based products (e.g. autologous, allogeneic, xenogeneic, stem cells); 11% classical biological products (e.g. blood-derived, vaccine, enzymes, live organisms); 10% nucleic acid-based compounds (e.g. gene therapy, DNA vaccines) and some 7% tissue engineering.

Of those companies developing chemical compounds, more than half (57%) are developing new chemical entities. Eighteen percent (18%) are developing new formulations or delivery methods, 11% oligopeptides, and 3% generics.

To gain some insight into the stage of development of the SME companies and their experience with marketing approval procedures, companies were asked to indicate the phase of development of the most advanced product in their respective pipelines. Although the large majority of companies were yet to place a product on the market, just over half had reached the clinical phase of development – with some 21% in late phase clinical trials.

Figure 5: Most advanced Phase of Development of assigned SMEs – Dec. 2007



In terms of the therapeutic areas, just over a quarter of companies (27%) are developing products which are classified under the category of: anti-neoplastic and/or immunomodulating, 12% alimentary tract and metabolism, 10% central nervous system, and 10% general anti-infectives for systemic use.

Financial and Administrative Assistance offered to SMEs

Scientific Advice

With SME companies benefiting from a 90% fee reduction, companies are encouraged to seek scientific advice from the agency as development proceeds. In 2007, forty-six (46) SME companies requested scientific advice from the agency, almost double that seen in 2006 (25). Of those, 60%

sought advice on more than one area of development (quality, non-clinical and/or clinical) and 16% were seeking follow-up advice. To date, a total of € 3.8 million in SME fee reductions has been processed for scientific advice.

Applications for marketing authorisation
Since the start of SME initiative in December 2005, twenty-three SME companies have submitted marketing authorisation applications (MAAs), 20 for human medicinal products and 3 for veterinary medicinal products. Of the human medicinal products that have been subject of MAAs, 13 out of 20 of them are designated orphan medicinal products. One has been reviewed to an accelerated timetable and has gone on to receive a marketing authorisation (Soliris). Thirteen are ongoing, three have been withdrawn and three have received negative opinions.

Of the veterinary medicinal products that have been subject of MAAs, one has received a positive opinion recommending the grant of a marketing authorisation (Rheumocam) and two are ongoing.

Payment of fees totalling some € 2.6 million for MAAs and inspections have been deferred by SMEs to date.

Translation assistance

In 2007, first experience was gained in providing translations for the two SME companies that received marketing authorisation referred to above. Through the Translation Centre in Luxembourg, the translations required for the purposes of granting a Community marketing authorisation, were provided by the EMEA at no cost to the applicant enterprises. Translations were provided on time and quality was deemed to be good following review by the national competent authorities in the Member States. The applicant enterprises remained responsible for the Norwegian and Icelandic translations.

Regulatory Assistance

The provision of regulatory assistance to companies through the SME office increased in number and in scope in 2007. To date, more than 90 requests for assistance were processed by the SME office. Regulatory assistance was provided on a wide variety of topics including: orphan designation, scientific advice, general regulatory strategy for obtaining a marketing authorisation, and pharmacovigilance.

Training/Workshop for SMEs:

Ninety four representatives of SME companies and their stakeholders participated in the 1st SME Workshop, titled 'Navigating the Regulatory Maze', on 2 February 2007.

The next SME Workshop will take place on 8 February 2008 and will focus on Quality, with an overview of data requirements for new chemical entities and biologicals from an EU assessor's perspective. Registration in the workshop, has once again been limited to company's assigned SME status by the EMEA and representatives of stakeholder organisations. Further information is available on the EMEA web-site.

Future Updates from the SME Office
The SME office launched a News Bulletin in May 2007 and will continue to publish regular updates on its activities in 2008.

Contacts for further information

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List of companies that currently have SME status assigned by the EMEA
(status on 20 December 2007)

AB Science	France
Abigo Medical AB	Sweden
ACE Pharmaceutical B.V.	The Netherlands
Action Pharma A/S	Denmark
Active Biotech AB	Sweden
ActoGeniX N.V.	Belgium
Acure Pharma AB	Sweden
Adventrx (Europe) Ltd	United Kingdom
Affibody AB	Sweden
Affimed Therapeutics AG	Germany
Affymax Pharma Limited	United Kingdom
Agennix Limited	United Kingdom
AGT Sciences Limited	United Kingdom
AKELA Pharma Oy (Ltd.)	Finland
Algeta ASA	Norway
Alizyme Therapeutics Limited	United Kingdom
Alliance Pharmaceuticals Limited	United Kingdom
Alloksys Life Sciences BV	The Netherlands
Amarin Corporation plc	United Kingdom
Anaconda Pharma	France
AplaGen GmbH	Germany
Apogenix GmbH	Germany
Applied Regulatory Consulting Ltd	United Kingdom
Archivel Farm, S.L.	Spain
Ardana Bioscience Ltd	United Kingdom
Ark Therapeutics Ltd	United Kingdom
Arpida A/S	Denmark
AS Biotech GmbH	Austria
Astex Therapeutics Ltd	United Kingdom
Astion Pharma A/S	Denmark
Avir Green Hill Biotechnology Research Development Trade AG	Austria
Avontec GmbH	Germany
Axxonis Pharma AG	Germany

Barrier Therapeutics	Belgium
Bavarian Nordic A/S	Denmark
Bioalliance Pharma SA	France
Bioenvision Limited	United Kingdom
BioInfoBank	Poland
Biolek Sp. z.o.o.	Poland
Biolipox AB	Sweden
Biomay AG	Austria
BioMedisinsk Innovasjon AS	Norway
Biomedizinische Forschungsgesellschaft m.b.H.	Austria
Bioprojet Pharma	France
Biotec Pharmacon ASA	Norway
BioTech Tools	Belgium
Biotie Therapies Corp.	Finland
Bioxell S.p.A.	Italy
Bone Therapeutics SA	Belgium
BruCell SA	Belgium
Campharm Ltd	United Kingdom
Cardio3 SA/NV	Belgium
Cellartis AB	Sweden
Cellerix, S. L.	Spain
CellGenix Technologie Transfer GmbH	Germany
CellMed AG	Germany
CellTran Ltd	United Kingdom
Celogos	France
Chanelle Pharmaceuticals Manufacturing Ltd	Ireland
Chemisch-Pharmazeutische Fabrik Göppingen Carl Müller, Apotheker GmbH und Co. KG	Germany
Chevita Tierarzneimittel GmbH	Germany
Clavis Pharma ASA	Norway
CLL Pharma	France
Co.don AG.	Germany
Colithin GmbH	Germany
Crusade Laboratories Limited	United Kingdom
Curacyte AG	Germany
Curalogic A/S	Denmark

Cytheris S A	France
DanDrit Biotech A/S	Denmark
DBV Technologies	France
Develco Pharma GmbH	Germany
Diamond BioPharm Limited	United Kingdom
Diatos SA	France
DNA Therapeutics SA	France
Dopharma Research BV	The Netherlands
Dorian Regulatory Affairs BV	The Netherlands
Dr. Ebeling & Assoc. GmbH	Germany
DREHM Pharma GmbH	Austria
DuoCort AB	Sweden
ECBio	Portugal
elbion AG	Germany
EleosInc Limited	United Kingdom
Ellen AB	Sweden
Envestia Limited	United Kingdom
EpiCept GmbH	Germany
Epidyme Limited	United Kingdom
EPMC Pharma (European Paediatric Medicine Company)	Belgium
Erytech Pharma	France
euroderm GmbH	Germany
European Medical Advisory Services Limited	United Kingdom
EUSA Pharma	France
Faron Pharmaceuticals Ltd.	Finland
Fibrex Medical Research and Development GmbH	Austria
Galpharm International Ltd	United Kingdom
Genetic Immunity	Hungary
Genetic Research S.r.l.	Italy
Genfit SA	France
Genitrix Ltd	United Kingdom
Genmab A/S	Denmark
Génopoîétic	France
Genta Development Limited	United Kingdom
GPC Biotech AG	Germany

Gregory Fryer Associates Ltd	United Kingdom
Gruenwalder Gesundheitsprodukte GmbH	Germany
GW Pharma Ltd	United Kingdom
Hartington Pharmaceutical, SLU	Spain
Heidelberg Pharma GmbH	DE
Hepa Wash GmbH	Germany
Hungarotrial Ltd	Hungary
I.Q.A. a.s.	Czech Republic
IDEA AG	Germany
Immatics Biotechnologies GmbH	Germany
ImmunoBiology Ltd	United Kingdom
Immuno-Designed Molecules SA	France
Immunomedics GmbH	Germany
Immunservice GmbH	Germany
INFAI Institut für biomedizinische Analytik und NMR- Imaging GmbH	Germany
Inmunologia y Genetica Aplicada S.A.	Spain
Innate Pharma	France
Innovata Biomed Limited	United Kingdom
Insmed Europe Ltd	United Kingdom
Inspiration Biopharmaceuticals EU Limited	Ireland
Instituto Biomar S.A.	Spain
Intercell AG	Austria
Interface International Consultancy Ltd.	United Kingdom
Ipsat Therapies Oy/Ltd	Finland
ISA Pharmaceuticals B.V.	The Netherlands
Isotechnika Ltd	United Kingdom
Istituto Biochimico Italiano, Giovanni Lorenzini S.p.A.	Italy
Italchimici S.p.A.	Italy
Jerini AG	Germany
JJGConsultancy Ltd	United Kingdom
Karo Bio AB	Sweden
Kiadis Pharma B.V.	The Netherlands
Kuros Biosurgery International AG	Liechtenstein
Laboratoire HRA Pharma	France
Laboratoire Philippe Davioud	France

Laboratories SMB S.A	Belgium
Laboratorios Ovejero S.A.	Spain
Lay Line Genomics S.p.A.	Italy
LIDDS AB	Sweden
Lionpharm Regulatory Consulting GmbH	Germany
Lipomed GmbH	Germany
LipoNova AG	Germany
Löns Pharma AG	Germany
Lux Biosciences GmbH	Germany
Mapreg	France
MediGene AG	Germany
Medikalla Oy	Finland
Medivir AB	Sweden
Movetis NV	Belgium
Nanobiotix S.A.	France
Napo UK Limited	United Kingdom
Navamedic ASA	Norway
NDA Group AB	Sweden
Neuraxo Biopharmaceuticals GmbH	Germany
Neurochem Luxco II Sarl	Luxembourg
NeurogesX UK Limited	United Kingdom
Neuropharm Ltd	United Kingdom
NeuroProgen GmbH	Germany
Newport Pharmaceuticals Limited	Ireland
Nexatio Limited	United Kingdom
Novacea Europe Limited	United Kingdom
Novagali Pharma SA	France
NovaThera Ltd	United Kingdom
NsGene A/S	Denmark
Oasmia Pharmaceuticals AB	Sweden
Octagon Research Solutions Limited	United Kingdom
OctoPlus N.V.	The Netherlands
Omnipharm Limited	United Kingdom
OMRIX biopharmaceuticals S.A.	Belgium
Oncoscience AG	Germany

Only for children pharmaceuticals	France
Orexo AB	Sweden
Orphan Europe SARL	France
Orphix Consulting GmbH	Germany
Oxagen Limited	United Kingdom
Oxxon Therapeutics Ltd	United Kingdom
Oy Fennopharma Ltd	Finland
P.R.P. Tymofarm W. Brzosko M. Brzosko	Poland
PAION Deutschland GmbH	Germany
PanGenetics BV	The Netherlands
Pantarhei Bioscience BV	The Netherlands
Parabolic Biologicals S.P.R.L.	Belgium
PepTcell Limited	United Kingdom
Pharmafar S.r.l.	Italy
PharmaKodex Limited	United Kingdom
Pharmasav Ltd	United Kingdom
Pharmathen S.A.	Greece
Pharmaxis Pharmaceuticals Limited	United Kingdom
Pharmexa A/S	Denmark
Pharming Group N.V.	The Netherlands
Photocure ASA	Norway
PKB Consulting Sas	Italy
Prana Biotechnology UK Limited	United Kingdom
Praxis Pharmaceutical SA	Spain
PregLem SA	France
Promefarm S.r.l.	Italy
Prosensa B. V.	The Netherlands
Prospero Therapeutics Ltd	United Kingdom
ProtAffin Biotechnologie AG	Austria
Protherics PLC	United Kingdom
QEDetal Limited	United Kingdom
QuadraMed Limited	United Kingdom
Rada-Pharma Uk Ltd.	United Kingdom
Regulatory Pharma Net srl	Italy
Regulon AE	Greece

Renovo Ltd	United Kingdom
Resistentia Pharmaceuticals AB	Sweden
Rheoscience A/S	Denmark
Santaris Pharma A/S	Denmark
Santhera Pharmaceuticals (Deutschland) GmbH	Germany
SantoSolve Pharma AS	Norway
Scan Aqua AS	Norway
SentoClone AB	Sweden
Summit Corporation plc	United Kingdom
Sunesis Europe Ltd	United Kingdom
SuppreMol GmbH	Germany
Swedish Orphan International AB	Sweden
Symphogen A/S	Denmark
Synta Limited (UK)	United Kingdom
Synvolux Therapeutics B.V.	The Netherlands
Systems Biology Laboratory UK Ltd	United Kingdom
TBF – Genie Tissulaire	France
Tecnifar Indústria Técnica Farmacêutica S.A.	Portugal
The Weinberg Group LLC	Belgium
Therakind Limited	United Kingdom
TiGenix NV	Belgium
Topaz Pharmaceuticals (UK) Limited	United Kingdom
TopoTarget A/S	Denmark
Trimed Biotech GmbH	Austria
Trio Medicines Ltd.	United Kingdom
Triskel EU Services, LTD	United Kingdom
Trophos SA	France
TxCell	France
Vaxon Biotech	France
Vectura Group PLC	United Kingdom
Vernalis Plc	United Kingdom
Vita (Europe) Ltd	United Kingdom
Vitrolife Sweden AB	Sweden
Voisin Consulting SARL	France
Wilex AG	Germany

Yes Pharmaceutical Development Services GmbH	Germany
Zealand Pharma A/S	Denmark
Zentaris GmbH	Germany