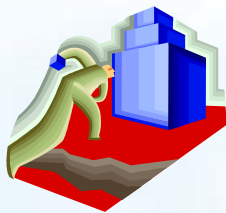


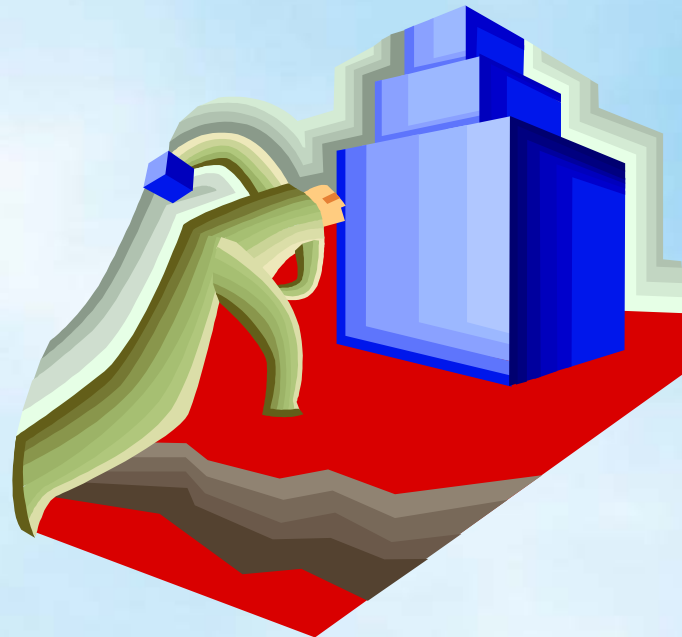
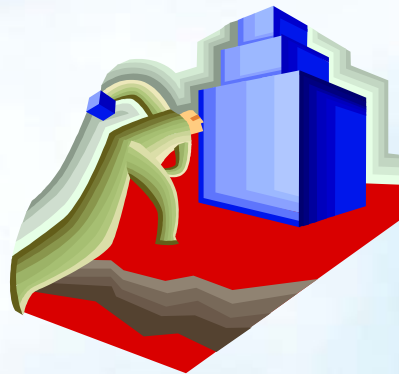


Update from “SME Office” for & medium-sized enterprises

micro



small



EMEA Workshop, 2.2.07



Agenda

- Introduction
- Look back at 2005 survey of SME stakeholders
- SME Regulation and Incentives
- What has SME Office delivered?
- Some facts & figures

Agenda

- Introduction
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Objective of SME Incentives

- To promote innovation and the development of new medicinal products by SMEs



Legal Background

- Article 70.2 of Regulation 726/2004 of 31 March 2004 introduced a provision for financial and administrative assistance for SMEs
- Implementing Regulation (EC) No 2049/2005 adopted on 15 December 2005





Agenda

- Introduction
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Activities to prepare for Regulation

- Survey of Pharmaceutical Industry: expectations/needs circulated through stakeholder organisations in September 2005
- 1st meeting with representatives of stakeholder organisations held on 17 November 2005





Survey of SME Stakeholders

- Circulated on 16 September 2005
- Sent to the following organisations:
 - Emerging Biopharmaceutical Enterprises (EBE) EFPIA
 - The European Association for Bioindustries (EuropaBio)
 - Europharm SMC
 - European Generic Medicines Association (EGA)
 - Association of the European Self-Medication Industry (AESGP)
 - International Plasma Fractionation Association (EPFA)
 - European Animal Health Industry (IFAH-Europe)
 - Association of Veterinary Consultants (AVC)
 - European Group for Generic Veterinary Products (EGGVP)
 - European Federation of Associations of Health Product Manufactures (EHPM)
- Deadline for response: 28 October 2005



Survey of SME Stakeholders

SME office

1. Administrative assistance
2. Procedural assistance
3. Other issues

Workshop/Trainings

7. Topics

User Guide & Communication

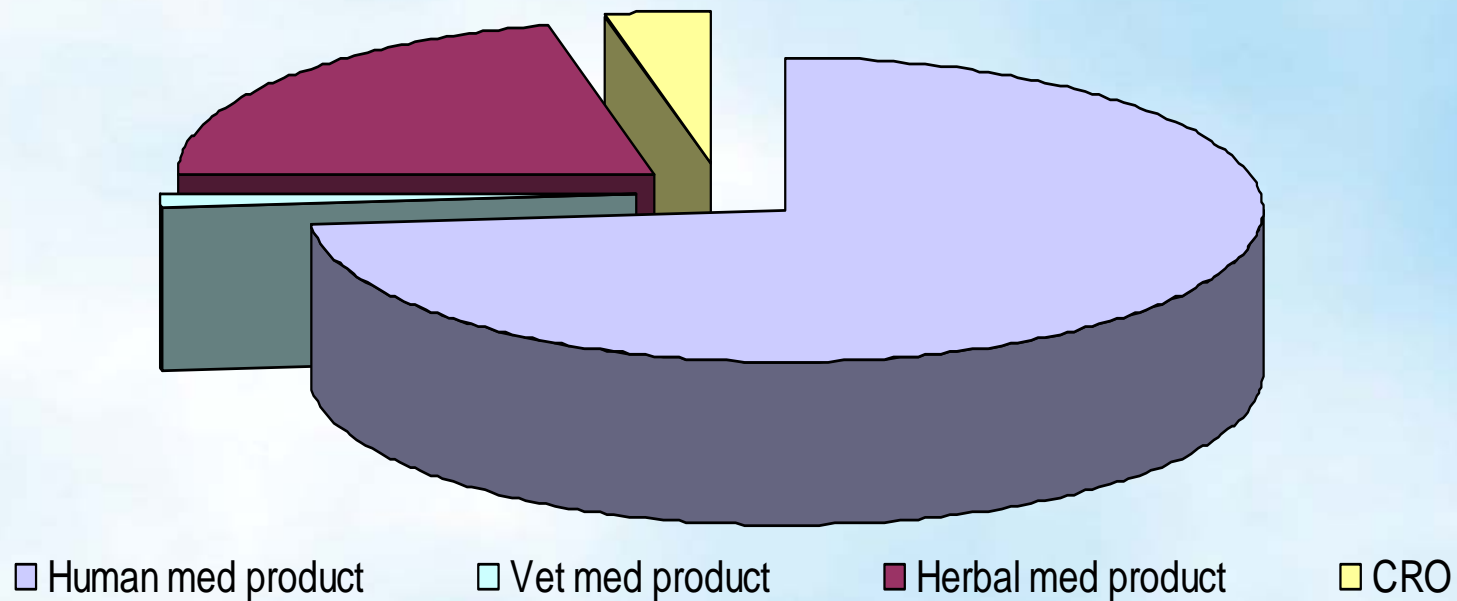
4. Topics
5. Distribution
6. Other information

Other

8. Other interested organisations
9. Other comments

Response to Survey

- 56 individual companies
- 3 stakeholder organisations





Feedback on Administrative & Procedural difficulties

Problems faced or anticipated in following areas:

- Contact with EMEA
- Regulatory issues
- Clinical Trials
- Scientific Advice
- Translations
- Fees
- Electronic Submissions
- Other (compassionate use, herbals, pharmacovigilance, funding R&D, pricing & reimbursement)



User Guide & Communication

Suggested topics:

- flow chart to Regulations that apply & links to one another
- advice on clinical trials across several EU countries
- regulatory overview from OD to MA & beyond
- procedure for SA, OD, PhVig reporting for SME, text handling for SME (PIM)
- build up in chronological order of company submission
- include self-assessment questionnaire
- questions & responses

To be kept simple for ease of understanding

Consultation on draft



Proposals for Workshops/Training

- SME initiative
- Orphan Designation & Scientific Advice
- Innovative medicines
- Regulatory (practical management, centralised procedure, Article 58)
- CTD, e-CTD, PIM
- Quality (stability/GMP standards)
- Alternatives to animal testing
- Clinical Trials
- Statistics
- Pharmacovigilance



Conclusions from 2005 Survey

- Excellent response
- Detailed feedback addressed to relevant sectors in EMEA
- Aimed to tailor SME service to meet needs
- Further feedback required in future

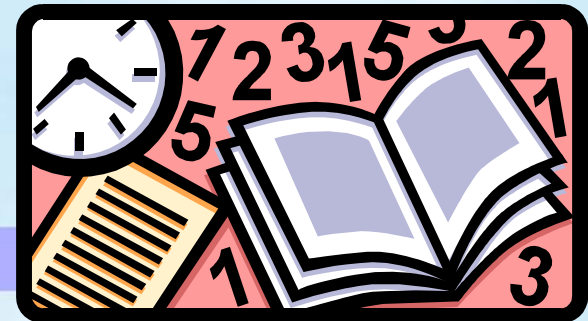


Agenda

- Introduction
- Look back at 2005 survey of SME stakeholders
- **SME Regulation and Incentives**
- What has SME Office delivered?
- Some facts & figures

Incentives for SMEs

- Administrative and procedural assistance
- Fee reductions
- Fee exemptions for certain administrative services
- Deferral of fee for application for marketing authorisation or inspection
- Conditional fee exemption
- Translation of product information





SME Office Established

- A single interface ('One stop shop')
- A dedicated structure within the Agency Secretariat
 - Three full-time staff + representatives in all relevant sectors
 - A cross-Agency activity



SME Office – Cross Agency Activity





Role of SME Office

- Advise applicants on administrative and procedural issues
- Facilitate communication
- Organise workshop/training sessions



Agenda

- Introduction
- Look back at 2005 survey of SME stakeholders
- SME Regulation and Incentives
- What has SME Office delivered?
- Some facts & figures

Fee Reductions

- 90% reduction on :
 - scientific advice
 - inspections
 - scientific services
 - maximum residue limits (veterinary medicines)
- 100% 'waiver' on administrative services (except for parallel distribution)

Fee deferrals

*Granting of the
Marketing Authorisation*

Marketing Authorisation Application
+
Inspections (pre-authorisation)

Post-authorisation



***Payment deferred until
the end of the
marketing authorisation
procedure***



TIME

Conditional Fee Exemption



IF scientific advice used:
=> Payment only in case of success
(Marketing Authorisation Granted)

Example

	<i>Standard application non-SME</i>	Standard application SME	
Scientific Advice	<i>70 000 EUR</i>	7 000 EUR (-90%)	
Inspection	<i>17 000 EUR</i>	1 700 EUR (-90%)	} <i>Payment deferred until the end of the procedure</i>
Marketing Authorisation Application	<i>232 000 EUR</i>	232 000 EUR if success 0 EUR (-100%) if failure	
Total	<i>320 000 EUR</i>	241 000 EUR if success (-25%) 8 700 EUR if failure (-97%)	



Fee Reductions/Deferrals

- Similar to Procedure for Orphan Fee Reductions
- Applicant to submit simple e-mail request for fee reduction/deferral
- Information required outlined on EMEA website
- SME Fee reductions/deferrals in 2006
 - processed fee reductions totalling €1.4 million for scientific advice
 - deferred payment of €1 million in MAA + inspection

Translations

EMA provides for the translations of:

- SPC
- Conditions on supply/use
- Labelling/package leaflet
- (MRL statement)



Procedure for Handling Translations

- Objective to carry out the translations required for MA on the applicant's behalf
- Procedure being delineated within EMEA in liaison with Centre for Translation in Luxembourg
- No practical experience to date

SME User Guide

- EMEA required to publish detailed guide on administrative/procedural aspects of 726/2004
- Guide to reference existing national provisions for SMEs
- Internal drafting group convened in May 2006





User Guide – Proposals from Survey

Suggested topics:

- flow chart to Regulations that apply & links to one another
- advice on clinical trials across several EU countries
- regulatory overview from OD to MA & beyond
- procedure for SA, OD, PhVig reporting for SME, text handling for SME (PIM)
- build up in chronological order of company submission
- include self-assessment questionnaire
- questions & responses

Kept simple for ease of understanding

Consultation on draft



SME User Guide

- ☐ Introduction
- ☐ SME Initiative
- ☐ Scientific advice
- ☐ Medicinal product development human (*vet pending*)
- ☐ Application for centralised marketing authorisation
- ☐ Other useful information
- ☐ Annex – national provisions for SMEs

- Final draft released to EC end Nov 2006
- 1st release for consultation Dec 2006

Please comment by end Mar 2007

Training/Workshops

- EMEA will organise a series of training sessions /workshops for SMEs
- Feedback received from survey useful in identifying topics of interest



Workshops/Training – Proposals from Survey

- SME initiative
- Orphan Designation & Scientific Advice
- Innovative medicines
- Regulatory (practical management, centralised procedure, Article 58)
- CTD, e-CTD, PIM
- Quality (stability/GMP standards)
- Alternatives to animal testing
- Clinical Trials
- Statistics
- Pharmacovigilance



Training/Workshops

- 1st SME Workshop titled 'Navigating the Regulatory Maze' - 2 Feb 2007
- Feedback/proposals for future workshops welcome
- Depending on topic may be organised in the margins of expert meetings at EMEA or in sessions at external conferences/symposia

Please complete feedback form



Agenda

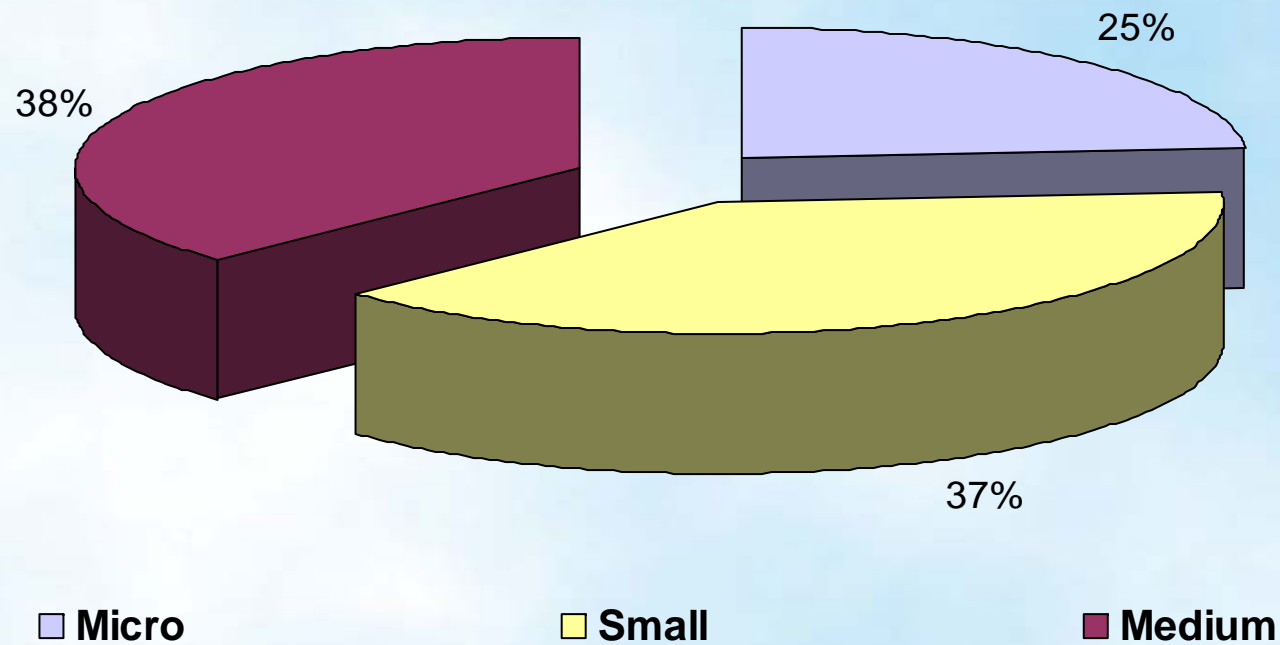
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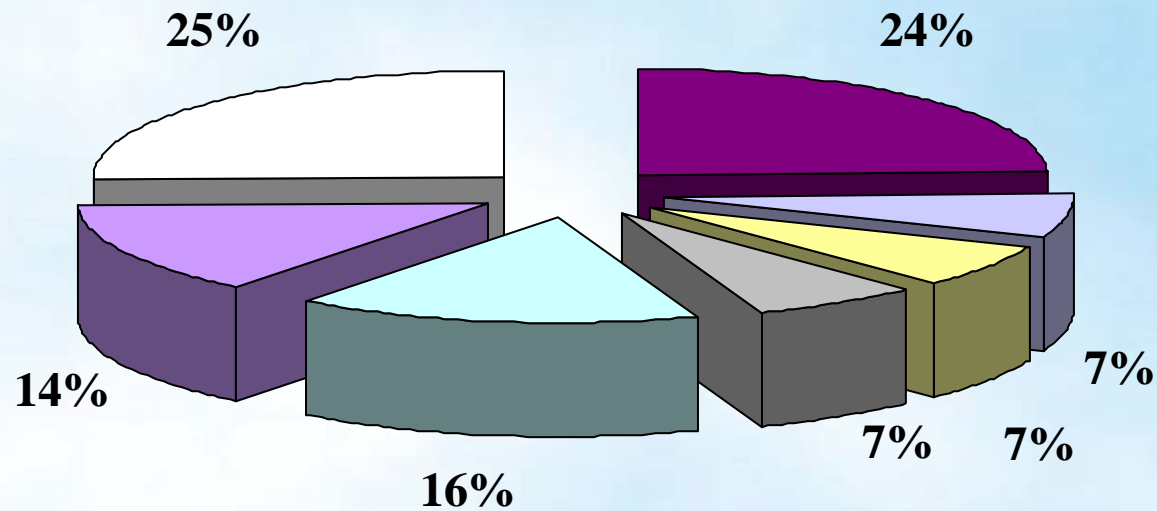
..the first SMEs....

- 116 companies assigned SME status
- 28 under review
- 2 withdrawn
- Majority human, 7 vet, 4 consultants

...micro, small or medium..



...geographical distribution...



■ United Kingdom
■ Denmark
□ Others

■ Sweden
■ France

■ Belgium
■ Germany



..experience so far....

Financial/administrative assistance:

- 25 SME companies in scientific advice
- 8 submitted MAAs
- 14 received regulatory assistance

Report from SME Office, including list of SME companies, published in Dec 06



For further information : SME Web-pages

European Medicines Agency Home - Microsoft Internet Explorer

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Whatever you do... Main EMEA contact details and Product Emergency Hotline

EMEA STRUCTURE

- Overview
- Mission Statement
- Organigramme
- Management
- Staff
- European Experts

EMEA COMMITTEES

- Management Board
- CHMP
- CVMP
- COMP
- HMPC

CONTACT & LOCATION

- General Enquiries
- Press Office
- Pharmacovigilance
- Product Defects
- EMEA Certificates
- Documentation
- European Experts
- IQN/Audits
- Business Hours
- EMEA holidays 2006
- How to Find Us

MEETINGS & EVENTS...

- EMEA Calendar
- Conferences & Events

RECRUITMENT...

- Recruitment Policy
- Job Opportunities

PUBLISHING SERVICES

- Online Mailing service
- Copyright Notice
- Copyright Policy
- Copyright Fees

SEE ALSO...

- Calls for Tender
- Fees Payable to EMEA

Improved access to veterinary scientific guidelines on EMEA website

Published 18/01/2007

Following the recent success of efforts to improve access to scientific guidelines relating to human medicines on its website, the EMEA has now completed a similar process for guidelines relating to veterinary medicines, updating and replacing the previous Volume 7.

The restructured compilation contains all currently valid guidelines relating to medicines for veterinary use previously published by the European Commission in Volume 7 of 'The rules governing medicinal products in the European Union' (EudraLex), all currently valid guidelines published by EMEA since 1995, plus any subsequent revisions and supplements. As well as adopted guidelines, it also includes concept papers, draft guidelines and overviews of comments received during the consultation on draft versions.

See the new compilation [here](#)

EMA prepares for entry into force of the Paediatric Regulation

Published 12/01/2007

Regulation (EC) No 1901/2006 - the Paediatric Regulation - enters into force in the European Union on 26 January 2007. This is an important new piece of legislation that aims to improve health amongst children in Europe through measures designed to stimulate the development of new medicines for use in the paediatric population, to ensure that they are appropriately tested and authorised, and to improve the availability of information about the use of these medicines.

As part of its ongoing action plan for implementing the Paediatric Regulation, the European Medicines Agency has prepared a document to address questions frequently asked by applicant companies about regulatory aspects of the new legislation.

Read the press release [here](#)

Read the FAQ (frequently asked questions) document [here](#)

Latest Press Releases

Date	Committee	Press Release
25/01/07	CHMP	Press Release from the January meeting
19/01/07	CVMP	Press Release from the January meeting
15/01/07	COMP	Press Release from the January meeting
12/01/07	EMEA	Press Release - EMEA prepares for entry into force of a new legislation on paediatric medicines
21/12/06	Management Board	Press Release: EMEA Management Board adopts the 2007 work programme and budget
15/12/06	EMEA	Press Release: European Medicines Agency adopts first positive opinion for mock-up pandemic influenza vaccine
08/12/06	EMEA	Press Release: Fournier Laboratories withdraws its marketing authorisation application for Synordia
06/12/06	EMEA	Press Release: EMEA launches EudraPharm - the European medicines database
28/11/06	EMEA	Press Release: EMEA workshop on homeopathic medicinal products concludes to strengthen harmonisation, but accept different national traditions
22/11/06	EMEA	Press Release: Defect in Herceptin vials identified but supply for patients is maintained
17/11/06	CVMP	Press Release: 2006 EMEA/IFAH-Europe Info day
15/11/06	EMEA	Press Release: The EMEA and CMD(h) review Europe-wide experience with user consultation in the readability testing of package leaflets

See [Press Office](#) for archived press releases

PRODUCT INFORMATION

- Human Medicines
- Veterinary Medicines
- Safety Announcements
- Product Withdrawals
- Summary of Opinions
- Opinions for Orphan Designation
- Opinions for medicines used outside the EU

PATIENT GROUPS

- Working with patients and consumers

SME OFFICE

- Addressing the needs of small and medium-sized enterprises (SMEs)

EU ENLARGEMENT

- Preparing for the accession of new member states

EU TELEMATICS

- EudraPharm Website
- EudraCT Website
- EudraCT Helpdesk
- PIM website
- eSubmission Website
- EudraVigilance Website
- EudraVigilance Veterinary Website

NEW EU LEGISLATION

- Overview
- Organisational changes
- Human Medicines
- Veterinary Medicines
- Herbal Medicines
- Telematics projects
- Parallel distribution

ROADMAP 2010

Local intranet

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<http://www.emea.europa.eu/SME/SMEoverview.htm>

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SME Office: Addressing the needs of small and medium-sized enterprises (SMEs)

[Overview](#)

[Background](#)

[How to apply](#)

[Related information sources](#)

"Navigating the Regulatory Maze"

1st EMEA Workshop for Micro, Small and Medium-Sized Enterprises (SMEs)

2 February 2007, EMEA, London, UK


For more details [go here](#)

Specific provisions aimed at promoting innovation and the development of new medicinal products for human and veterinary use by SMEs were adopted by the European Commission on 15 December 2005.

The Agency has launched an 'SME Office', which is dedicated to addressing the particular needs of smaller companies. Information on the assistance it offers to SMEs is published in this area of our website.

Any queries, feedback or comments are welcome. Please address them to us by using the contact details on the right.

New 'User Guide for SMEs' released for consultation. See [Related information sources](#).



Contact point

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Fax: (44-20) 7523 7040

For further contact information see [Contact points](#)

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Thank you for your attention

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