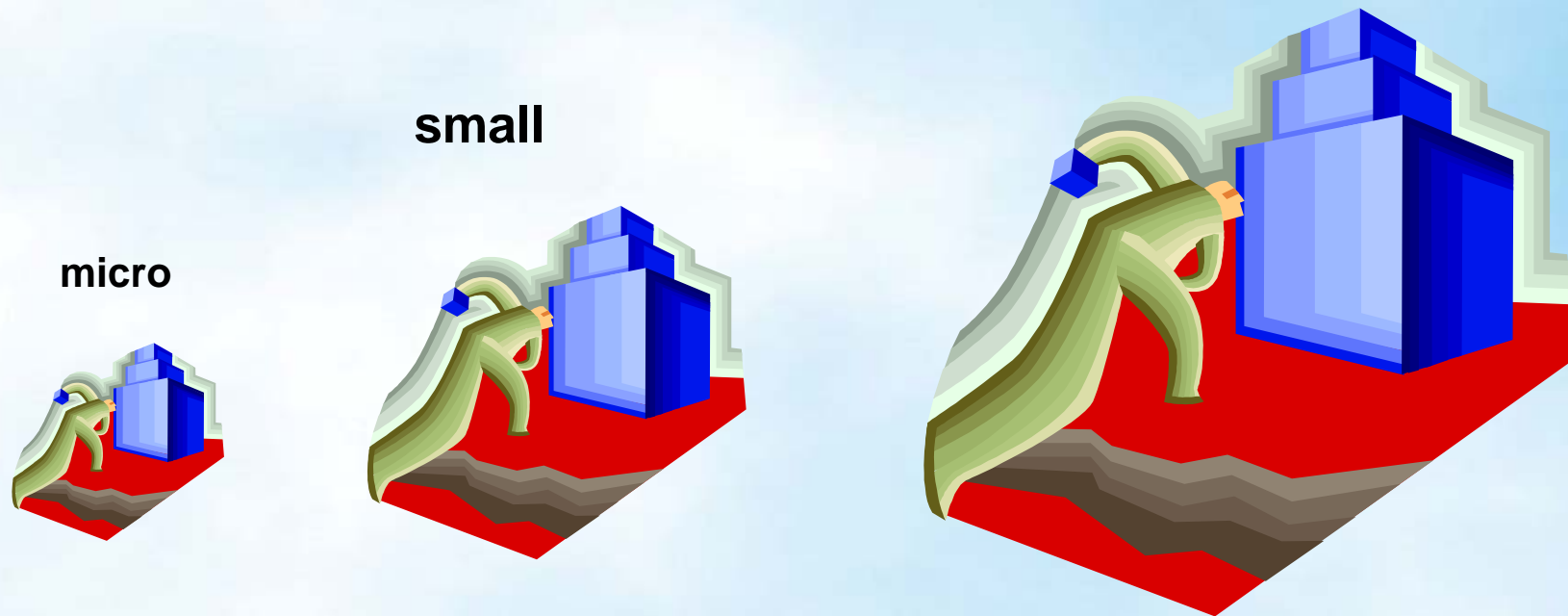




Update from “SME Office” for

& medium-sized enterprises



EMEA Workshop, 8.2.08





Agenda

- Introduction
- SME Regulation and Incentives
- Type of companies assigned SME status
- What has SME Office delivered?
- Scientific advice & application marketing authorisation



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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



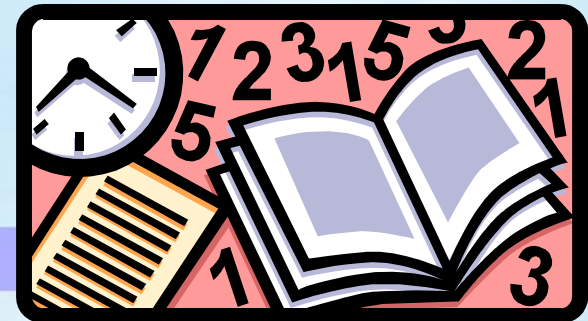


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Incentives for SMEs

- 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 workshops/training sessions



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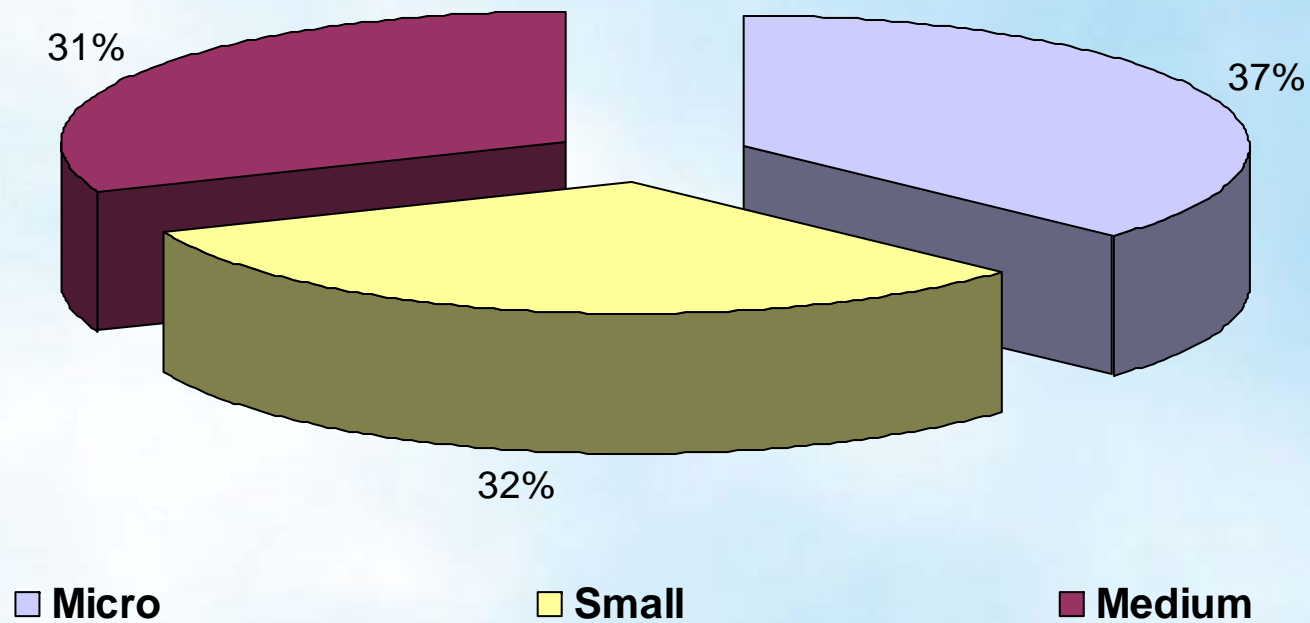


.. SMEs at end of 2007....

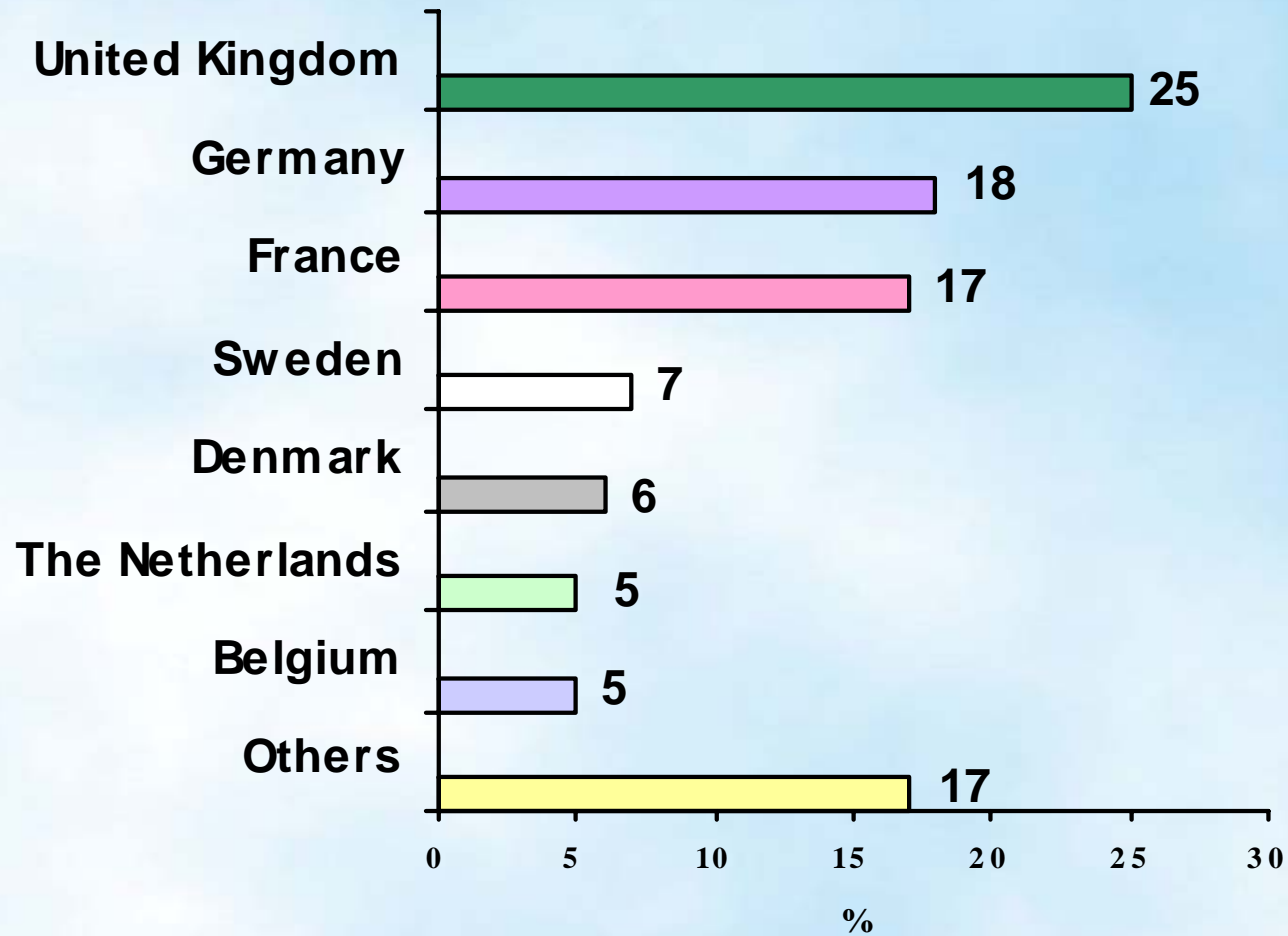
- 246 companies assigned SME status
- from 21 countries across EEA
- majority human, 9 vet, 8 human/vet & 19 consultants

- 40% increase in requests since 2006

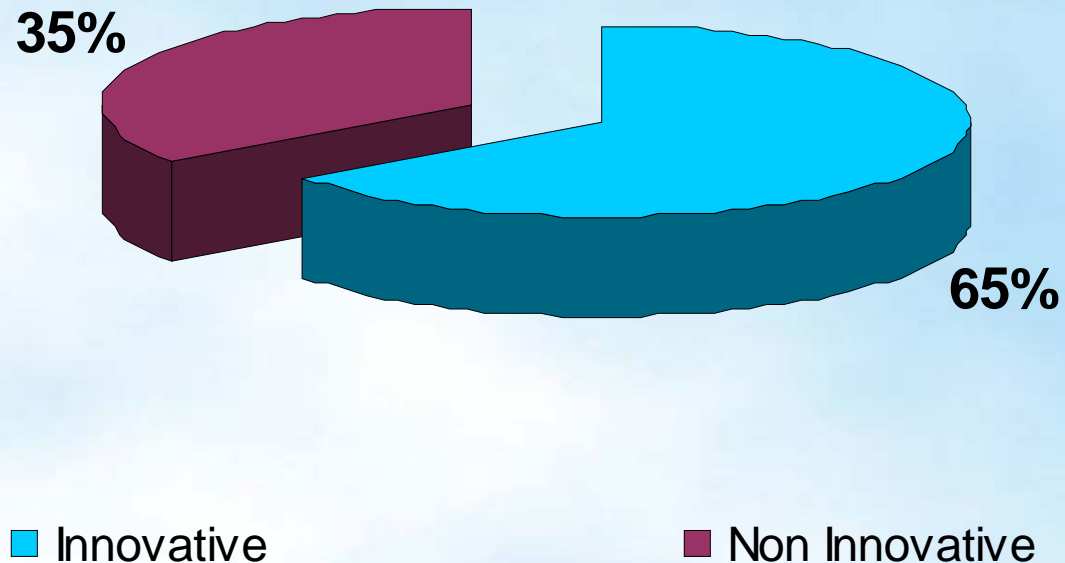
...micro, small or medium..



...geographical distribution...



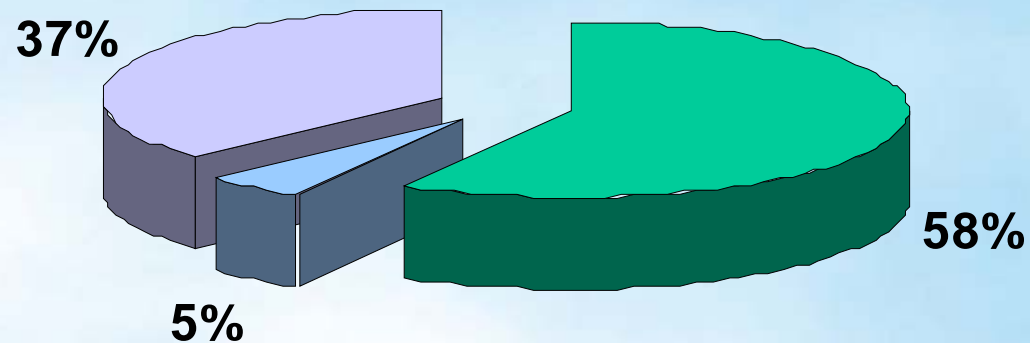
Development pipeline of registered SMEs



Innovation:

- 46 % therapeutic innovation (e.g. new target disease, mechanism of action)
- 36 % technical innovation (e.g. new delivery methods/formulation)
- 18 % scientific innovation (e.g. new R&D methods/tools, biomarkers)

Type of products developed by SMEs



■ Chemicals

■ Others

■ Biologics

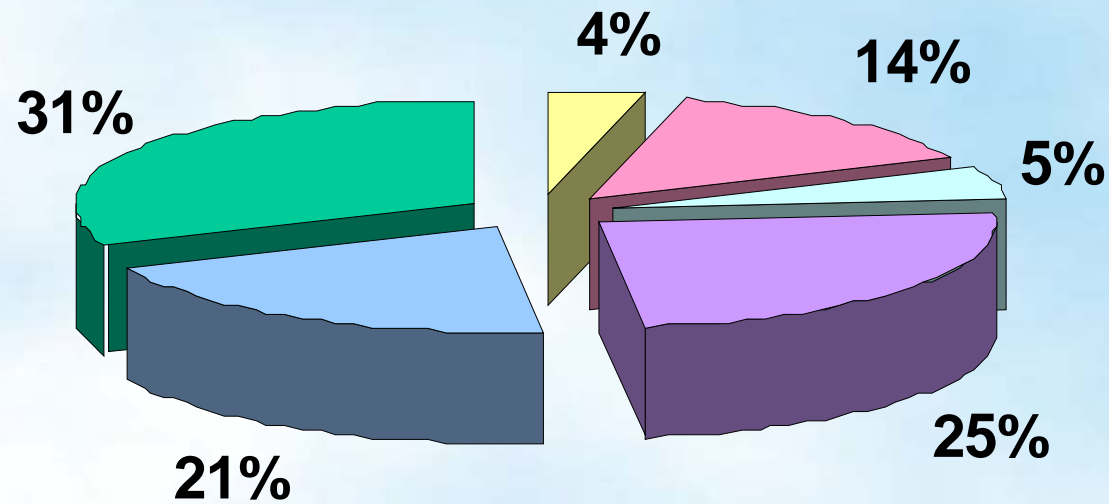
Chemicals:

- 57% new chemical entities
- 18% new formulations
- 11% oligopeptides
- 3% generics

Biologics:

- 50% recomb DNA derived products
- 20% cell-based products
- 11% classical biological products
- 10% nucleic acid-based compounds
- 7% tissue engineering

Most advanced Phase of Development of assigned SMEs



- Exploratory
- Preclinical
- Clinical Phase 1
- Clinical Phase 2
- Clinical Phase 3
- Marketing

Therapeutic Areas

- 27% anti-neoplastic &/or immunomodulating
- 12% alimentary tract & metabolism
- 10% central nervous system
- 10% general anti-infectives for systemic use
- 9% dermatologicals
- 8% musculo-skeletal system



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- **What has SME Office delivered?**
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Fee Reductions

- 90% reduction on :
 - scientific advice
 - inspections
 - scientific services
 - maximum residue limits (veterinary medicines)
- 100% 'waiver' on administrative services (except for parallel distribution)
- To date processed fee reductions totalling €4.2 million for scientific advice



Fee deferrals

- For MAA & inspections - fees deferred until end of MA procedure
- Conditional Fee Exemption - if scientific advice sought & followed: payment only in case of success (MA granted)
- To date, €2.6 million of deferred fees for MAA & inspections

Translations

- EMEA provides for the translations of:
 - SmPC
 - Conditions on supply/use
 - Labelling/package leaflet
 - (MRL statement)
- Translation Centre in Luxembourg with check through Member States
- Experience gained with 2 SME's to date





SME User Guide

- EMEA to publish detailed guide on aspects of 726/2004
- Guide to reference existing national provisions for SMEs
- 1st release - Dec 2006
- Update published - Dec 2007

Training/Workshops

- 1st SME Workshop - 'Navigating the Regulatory Maze' - 2 Feb 2007
- 2nd SME Workshop - 'Focus on Quality' - 8 Feb 2008

Please complete feedback form



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..experience so far with SMEs....

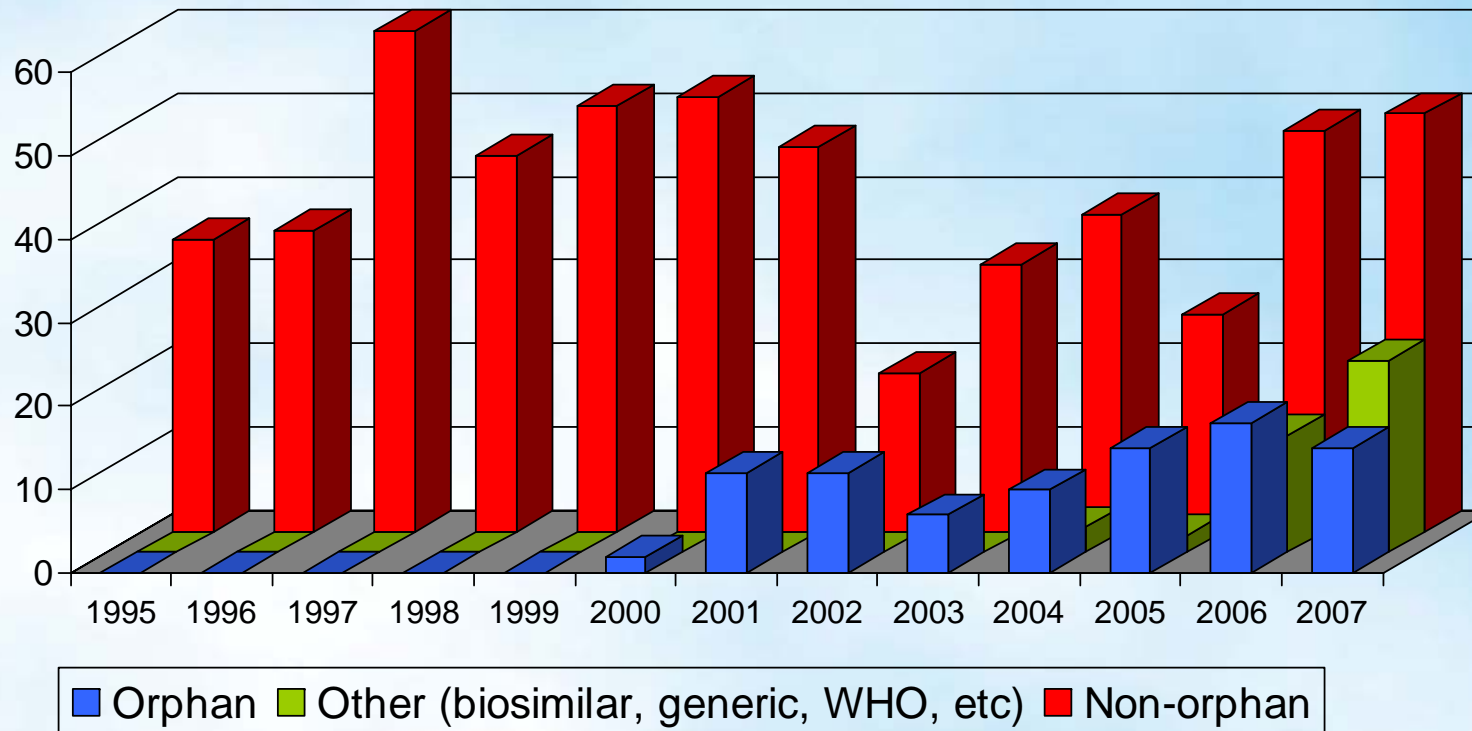
- 90 SMEs received regulatory assistance
- 71 SME's in scientific advice
- 23 submitted MAAs

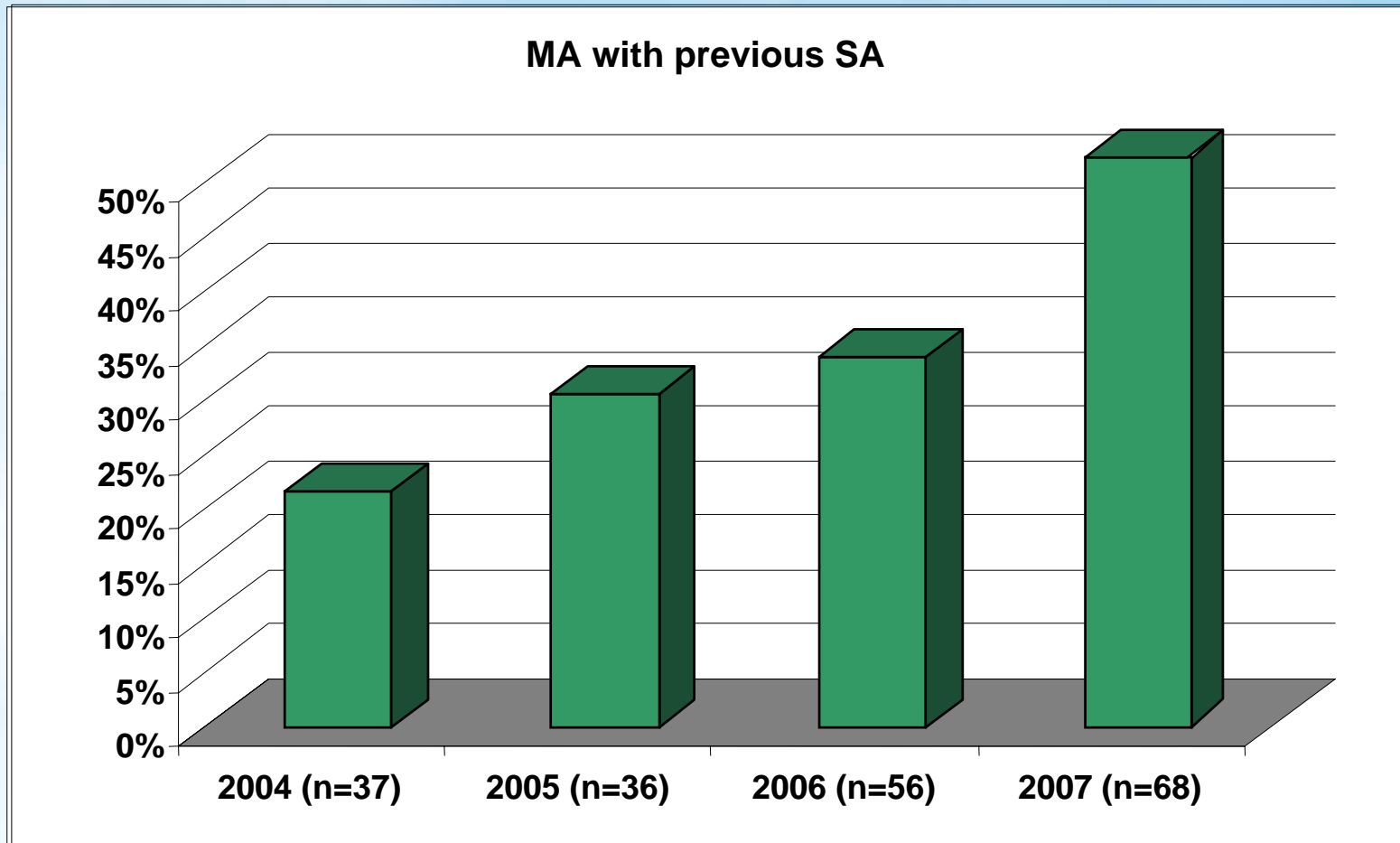


..experience so far with SMEs....

- 23 SME marketing authorisation applications (MAAs)
- 20 for human medicinal products (65% orphan)
 - 13 ongoing
 - 3 withdrawn
 - 3 negative (2 re-examination ongoing)
 - 1 marketing authorisation (Soliris) (accelerated timetable)
- 3 veterinary medicinal products.
 - 1 marketing authorisation (Rheumocam)
 - 2 ongoing

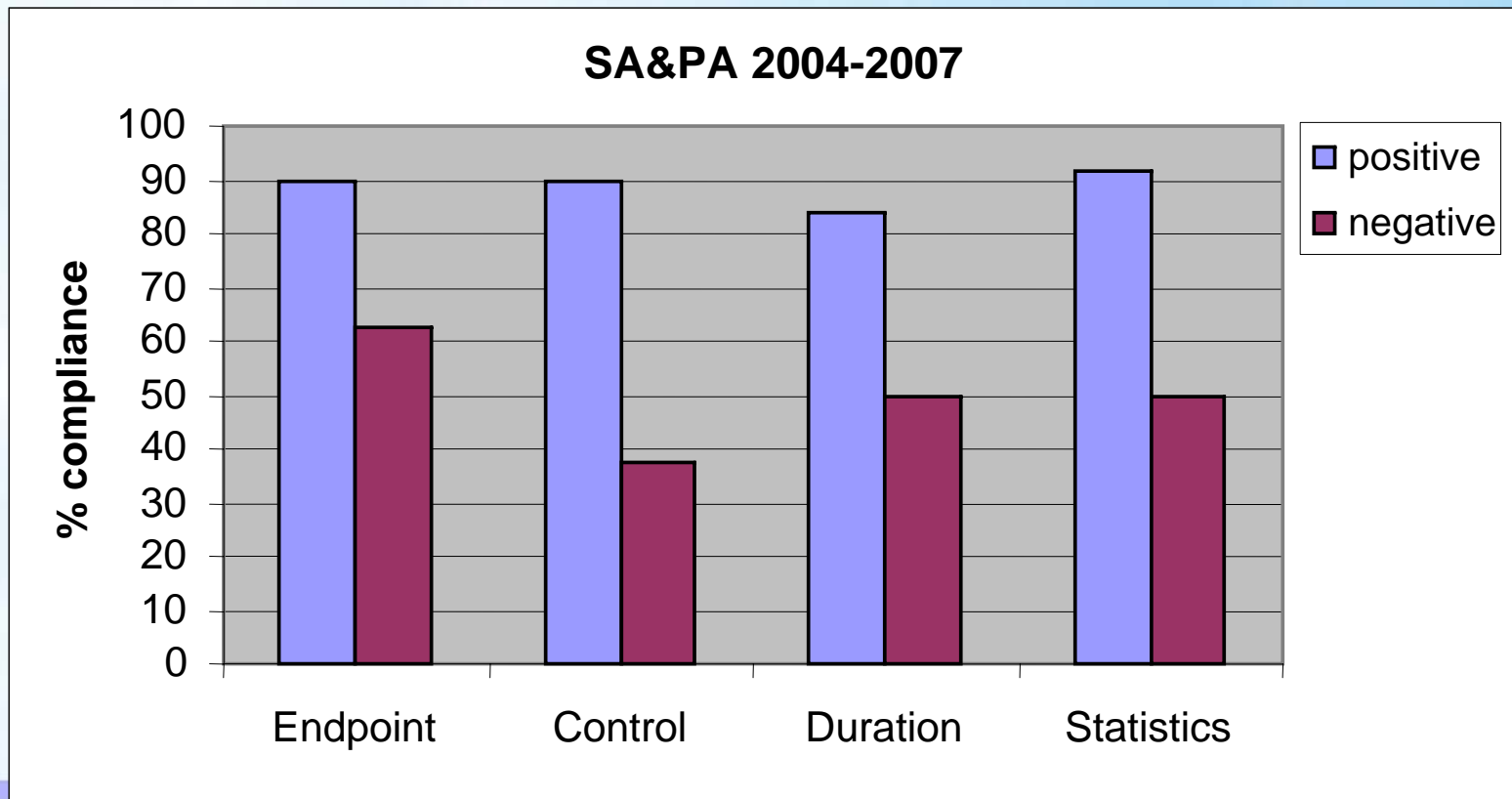
Initial centralised applications to EMEA 1995-2007*





..impact of scientific advice on MAAs...

- Overall in 2007, outcomes through centralised procedure:
 - 51 positive (of those 24 preceded by SA)
 - 17 negative (of those 10 preceded by SA)
- Analysis to look at adherence to SA & PA from 2004 to 2007





..impact of scientific advice on MAAs....

- Adherence to scientific advice or protocol assistance:
 - contributory factor to a successful outcome
 - less major objections from CHMP in areas of SA

Conclusion:

- Fee reductions facilitate SME access to SA
- Emphasise importance of adhering to advice & seek follow-up advice if necessary



For further information : SME Web-pages

European Medicines Agency Home - Microsoft Internet Explorer

Address: <http://www.emea.europa.eu/>

European Medicines Agency
New website address: emea.europa.eu

Home | Sitemap | Links | Help | All documents | Search | Advanced Search | Search Tips

About Us | What's New | Human Medicines | Veterinary Medicines | Inspections | General Reporting |

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](#)

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

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

Date	Category	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

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
- Veterinary Website

NEW EU LEGISLATION

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

ROADMAP 2010

Local intranet

Start | docu... | Note... | Inbo... | SME ... | Micr... | Euro... | 14:12





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

The screenshot shows a Microsoft Internet Explorer browser window displaying the SME Office overview page. The browser's address bar shows the URL: http://www.emea.europa.eu/SME/SMEoverview.htm. The page header includes the EMEA logo and navigation links such as 'Home', 'Sitemap', 'Links', and 'help'. A search bar is also present. The main content area is titled 'SME Office: Addressing the needs of small and medium-sized enterprises (SMEs)'. It features a left sidebar with links for 'Overview', 'Background', 'How to apply', and 'Related information sources'. A central text block explains the agency's commitment to SMEs and provides contact information. A right sidebar contains a 'Contact point' section with the email address smeoffice@emea.europa.eu and contact details for Ms. Melanie Carr. A bottom sidebar highlights a '1st EMEA Workshop for Micro, Small and Medium-Sized Enterprises (SMEs)' held on 2 February 2007 in London, UK. The browser's taskbar at the bottom shows several open windows and the system clock at 14:07.

SME Office - Overview - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address http://www.emea.europa.eu/SME/SMEoverview.htm

European Medicines Agency **emea** New website address: emea.europa.eu | Home | Sitemap | Links | help |

About Us | What's New | Human Medicines | Veterinary Medicines | Inspections | General Reporting |

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
smeoffice@emea.europa.eu
Ms Melanie Carr
Tel.: (44-20) 7418 8575
Fax: (44-20) 7523 7040
For further contact information see [Contact points](#)

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Send all queries regarding the Web content to: info@emea.europa.eu
Send all queries regarding the Web functionality to: EMEAwebservices

Start | docu... | Note... | Inbo... | SME ... | Micro... | SME ... | Local intranet | 14:07





Thank you for your attention

E-mail queries: smeoffice@emea.europa.eu