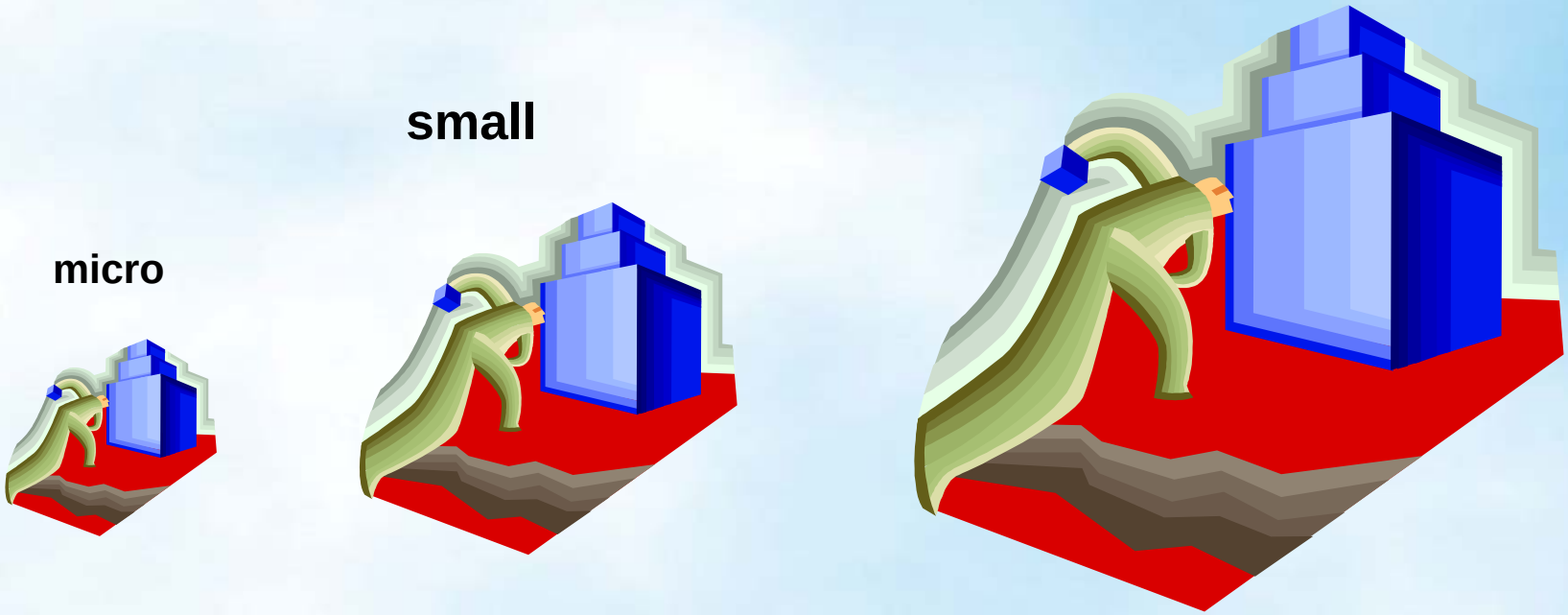
Update from “SME Office”
for
& medium-sized enterprises

small

micro



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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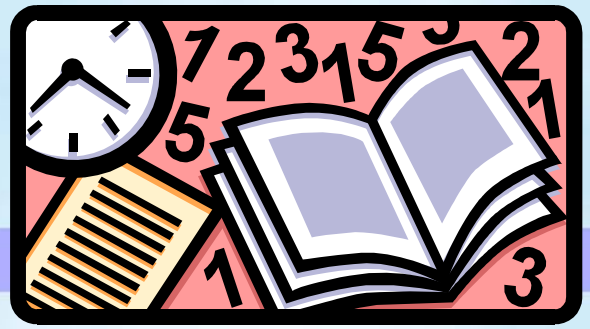
Incentives for SMEs

- 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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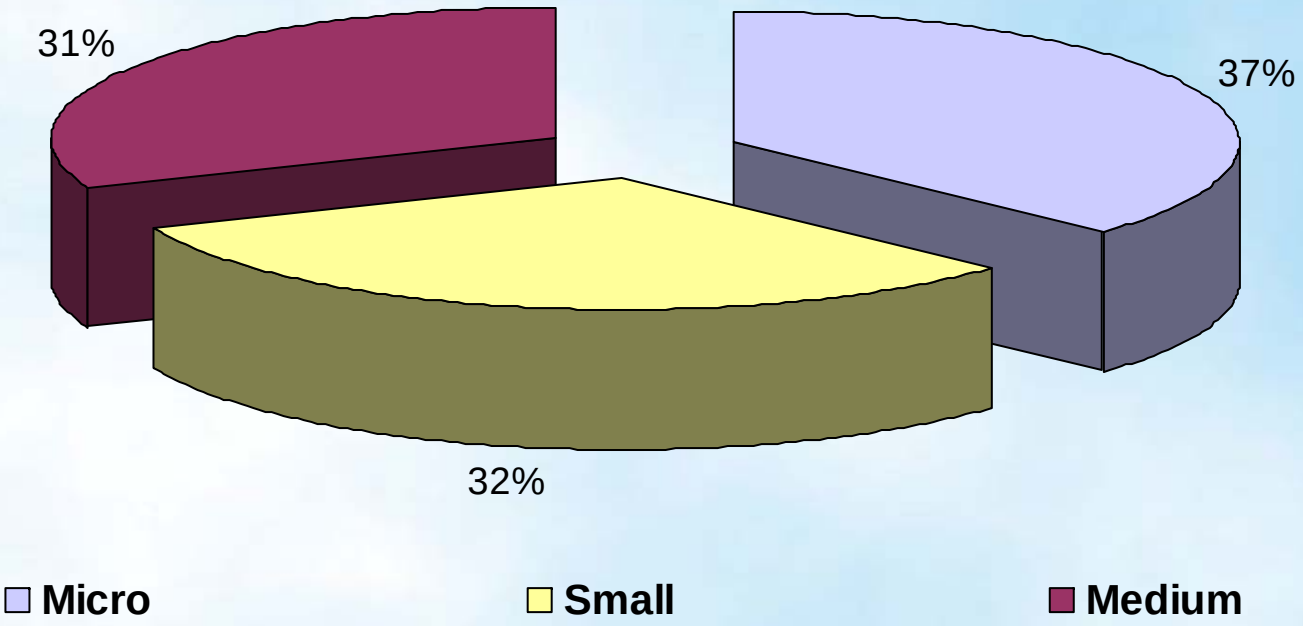
.. SMEs at end of 2007….

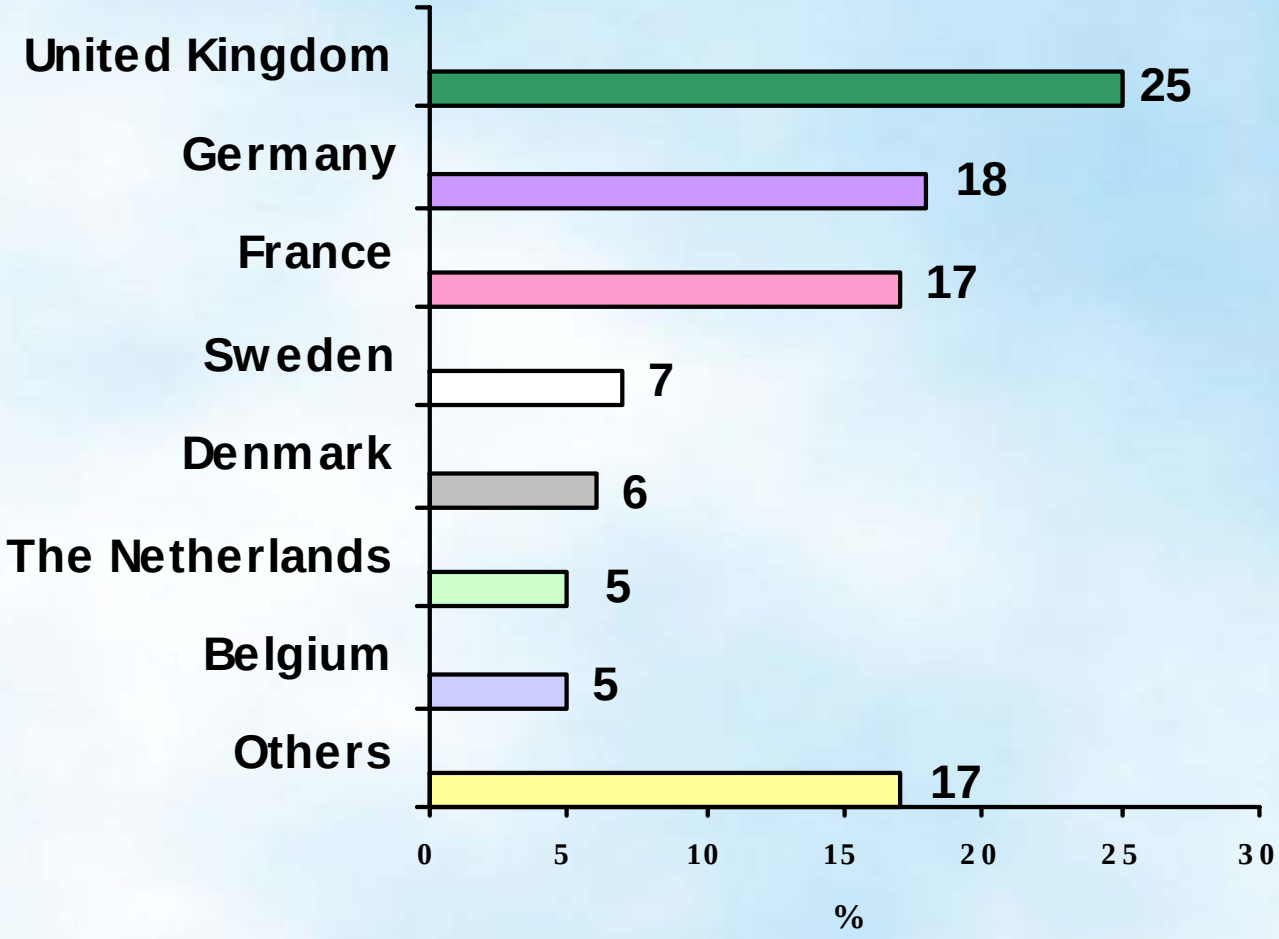
- 246 companies assigned SME status
- from 21 countries across EEA
- majority human, 9 vet, 8 human/vet & 19 consultants

- 40% increase in requests since 2006

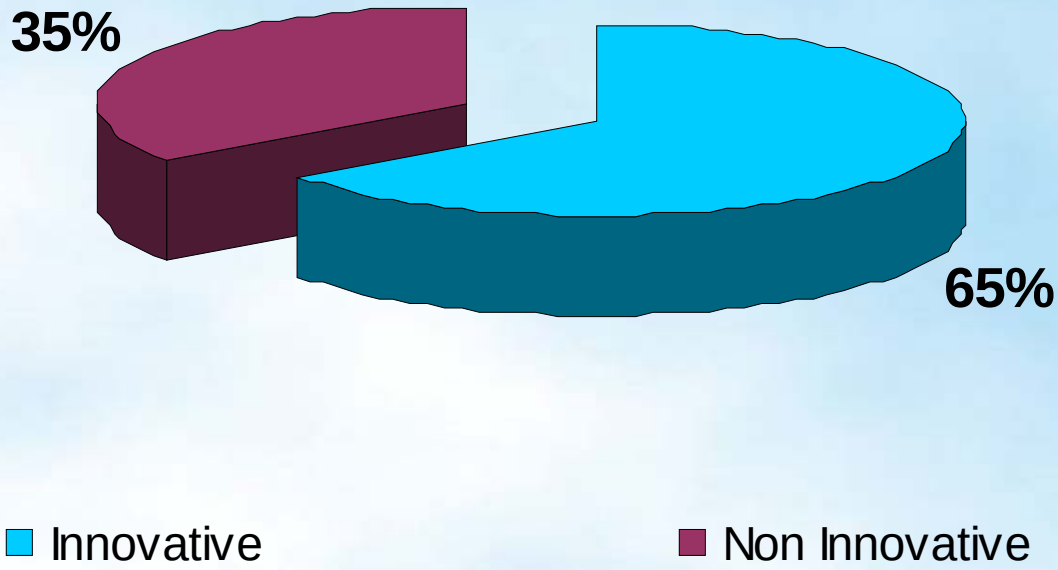
…micro, small or medium..



…geographical distribution…



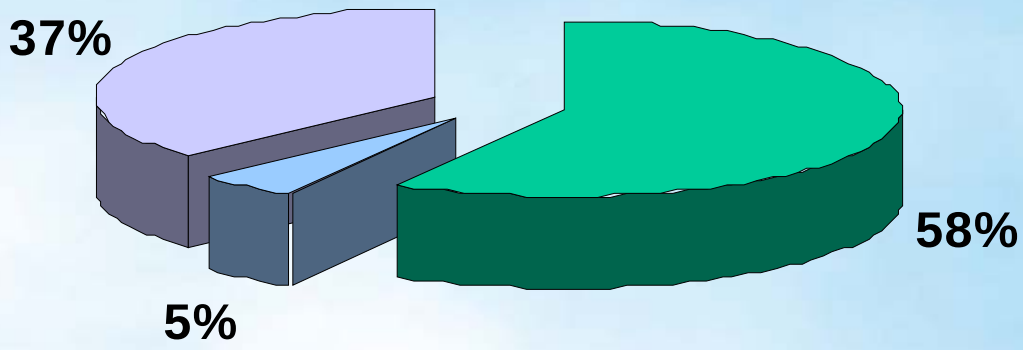
Development pipeline of registered SMEs



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)

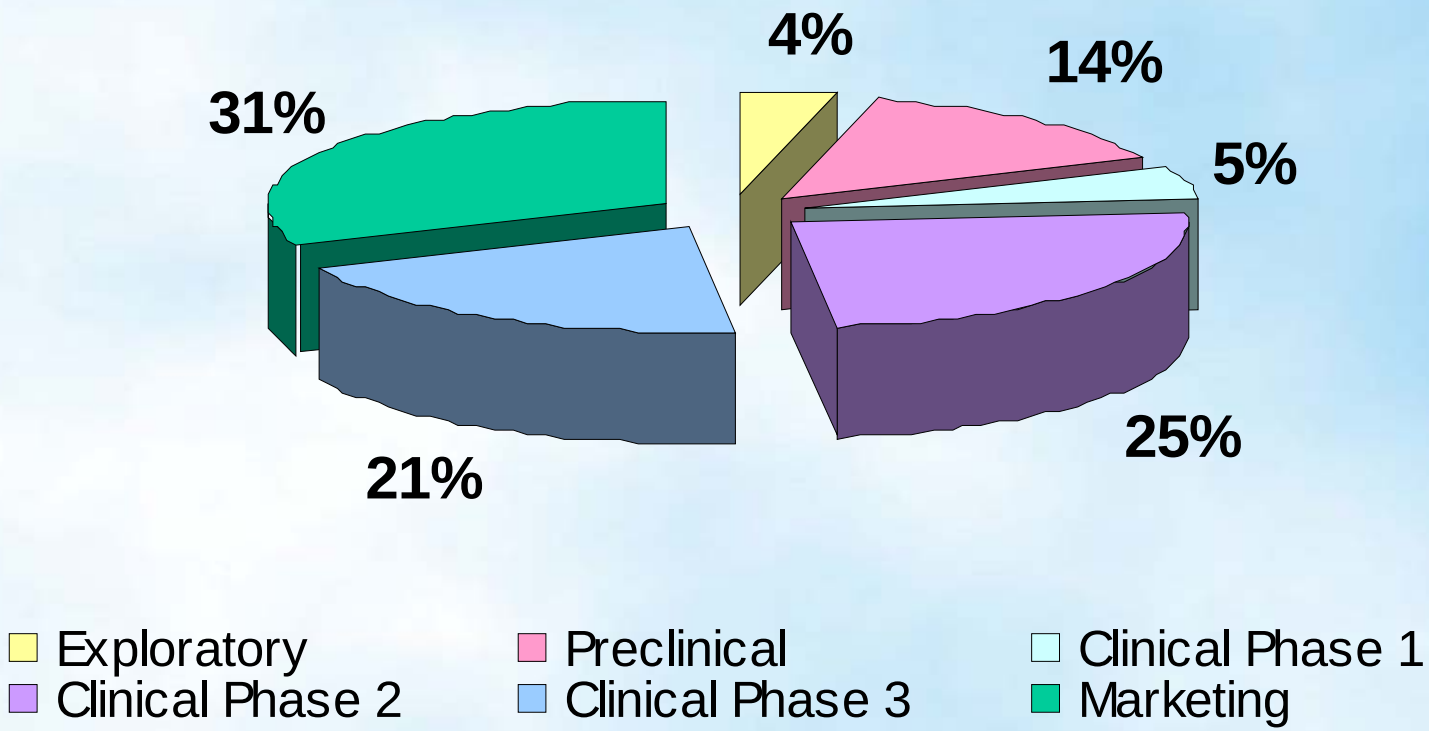
Type of products developed by SMEs



Chemicals:
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



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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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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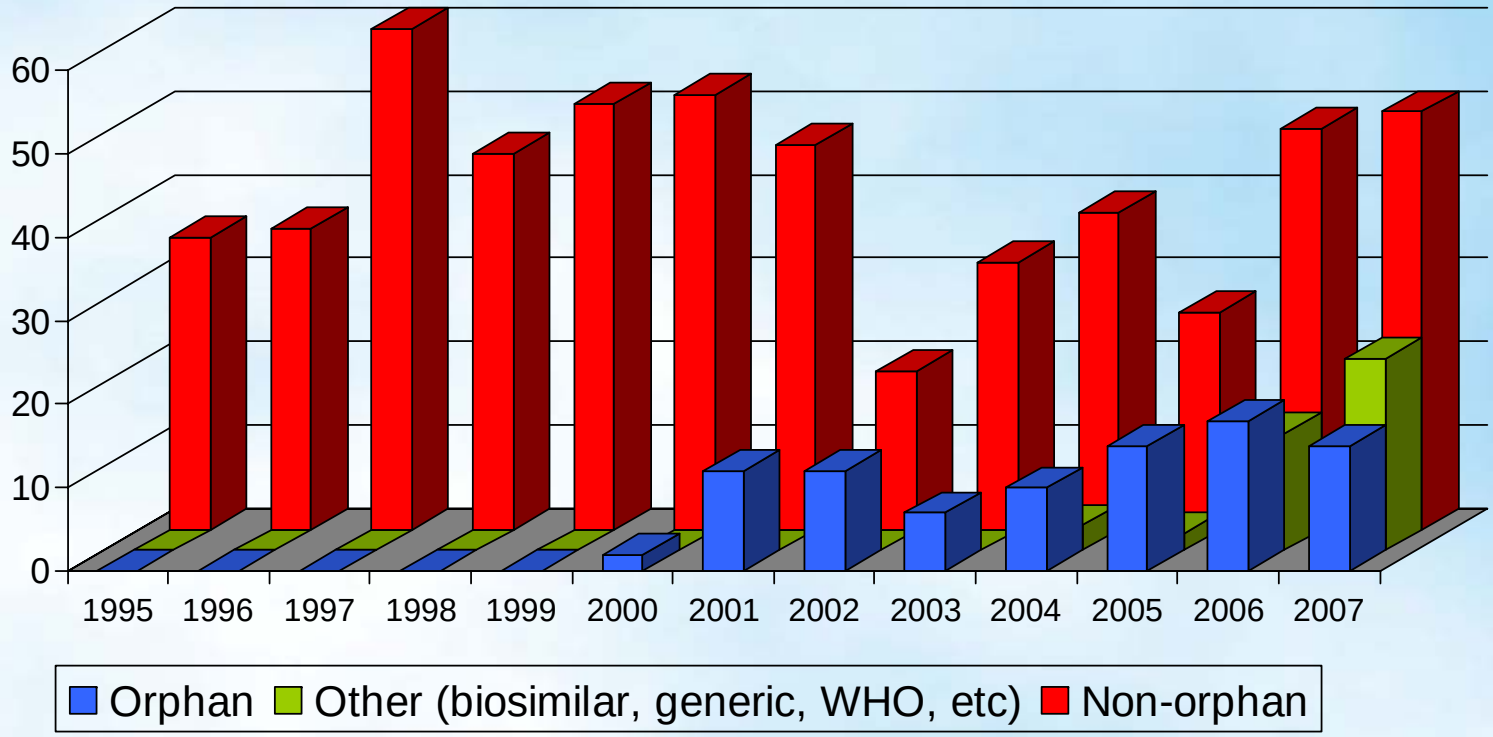
..experience so far with SMEs….

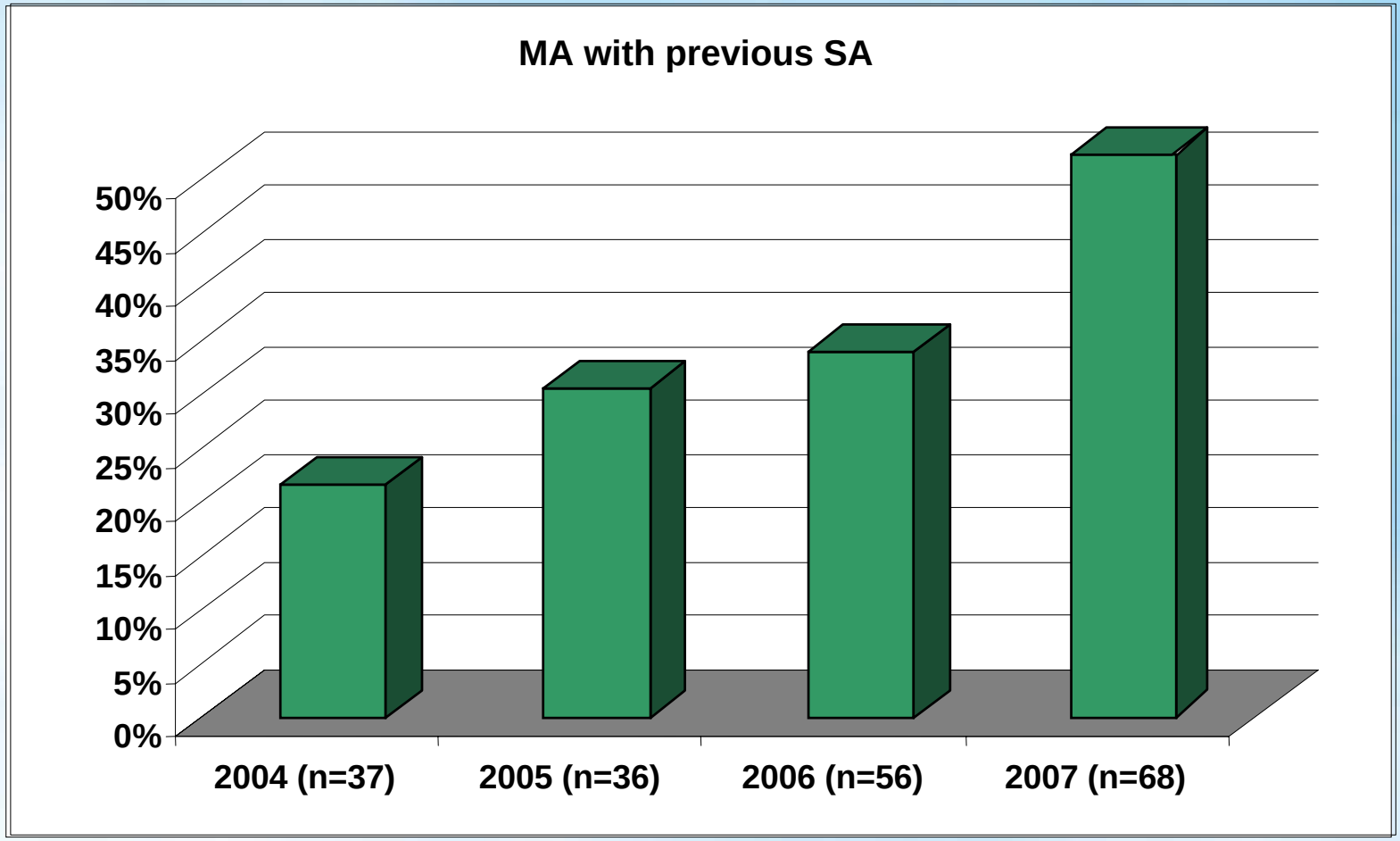
- 90 SMEs received regulatory assistance
- 71 SME’s in scientific advice
- 23 submitted MAAs

..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*

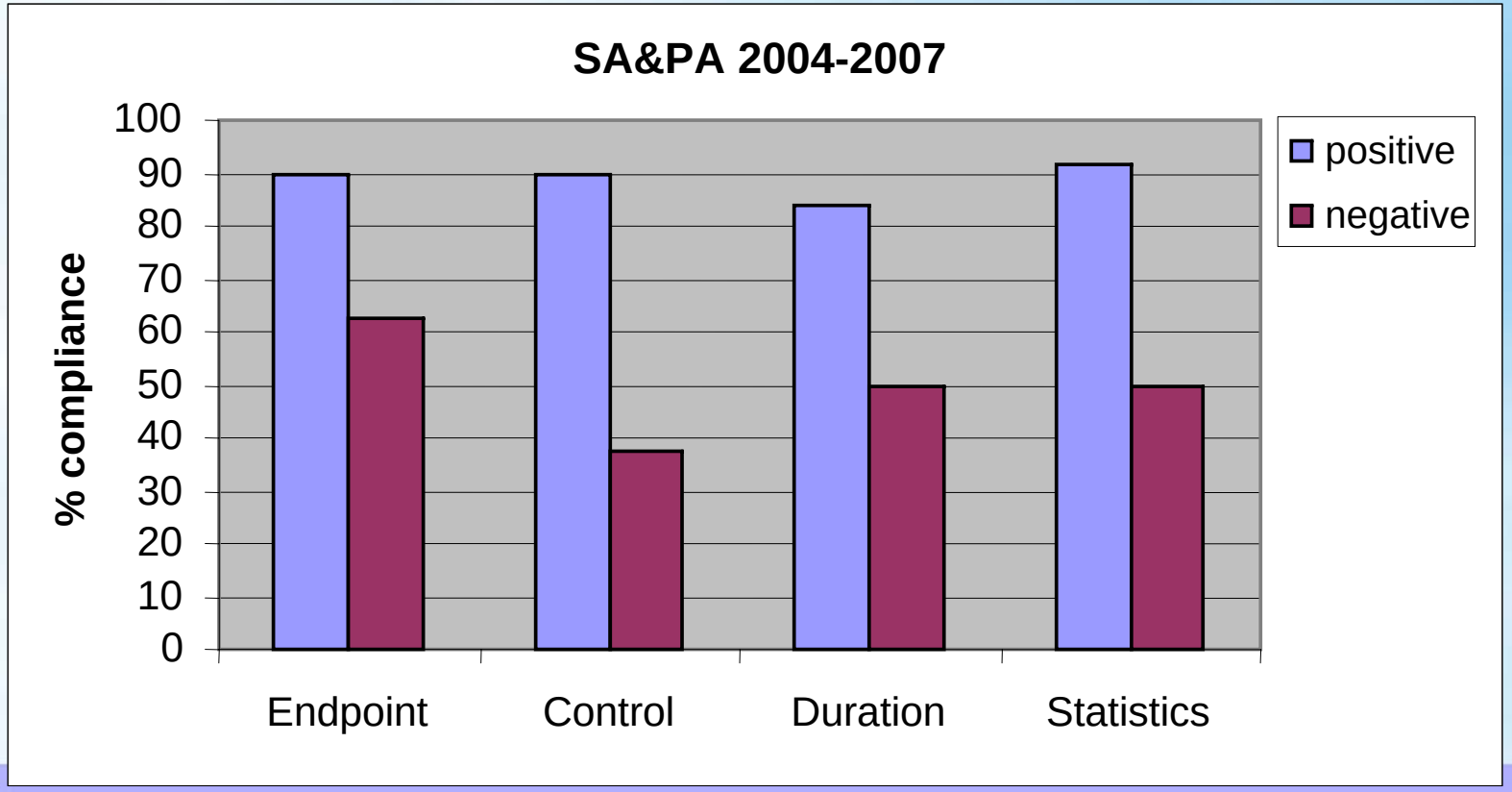



MA with previous SA
50%
45%
40%
35%
30%
25%
20%
15%
10%
5%
0%
2004 (n=37)
2005 (n=36)
2006 (n=56)
2007 (n=68)

..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….

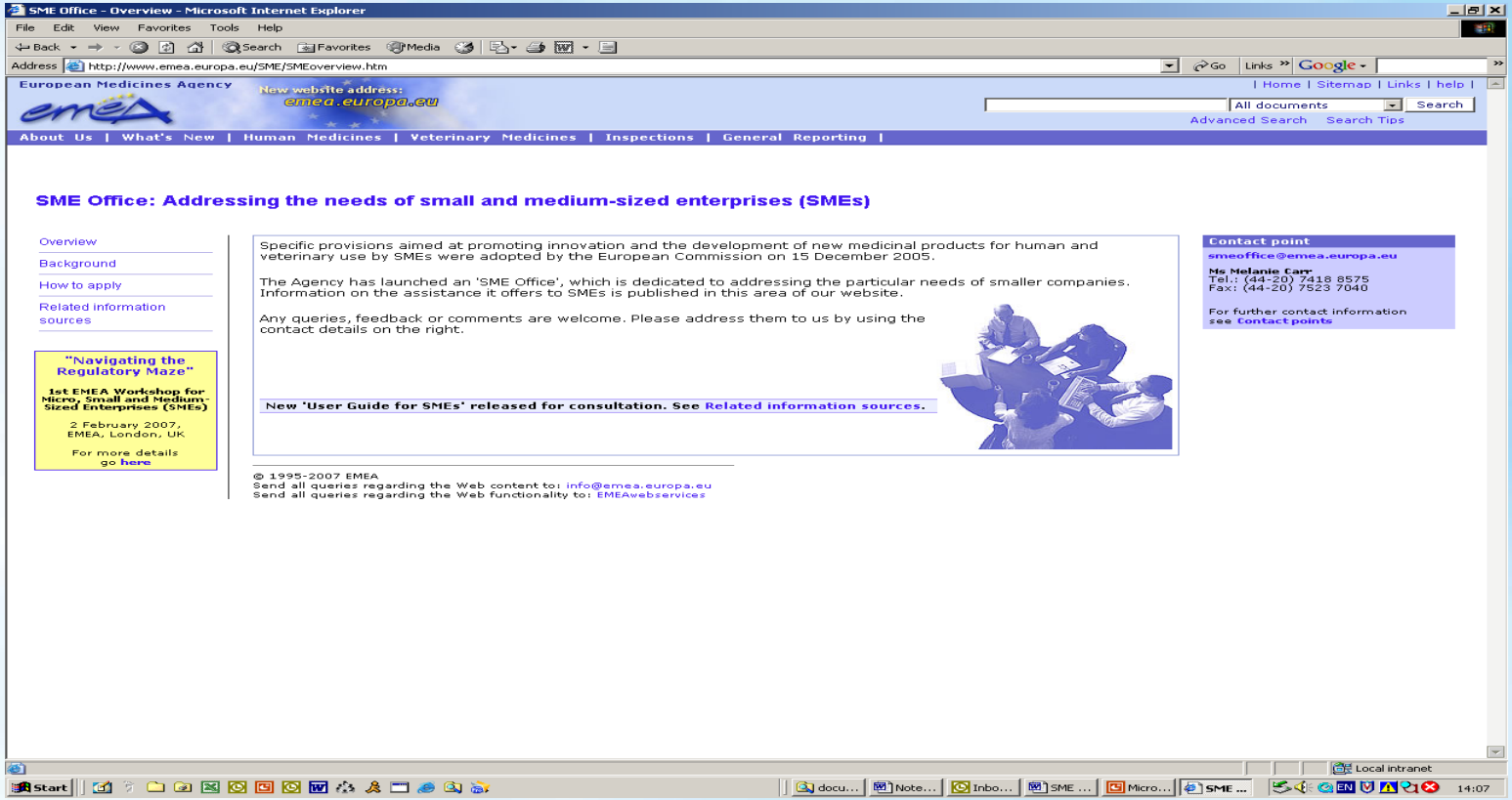
- Adherence to scientific advice or protocol assistance:
  - contributory factor to a successful outcome
  - less major objections from CHMP in areas of SA

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

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



Thank you for your attention

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