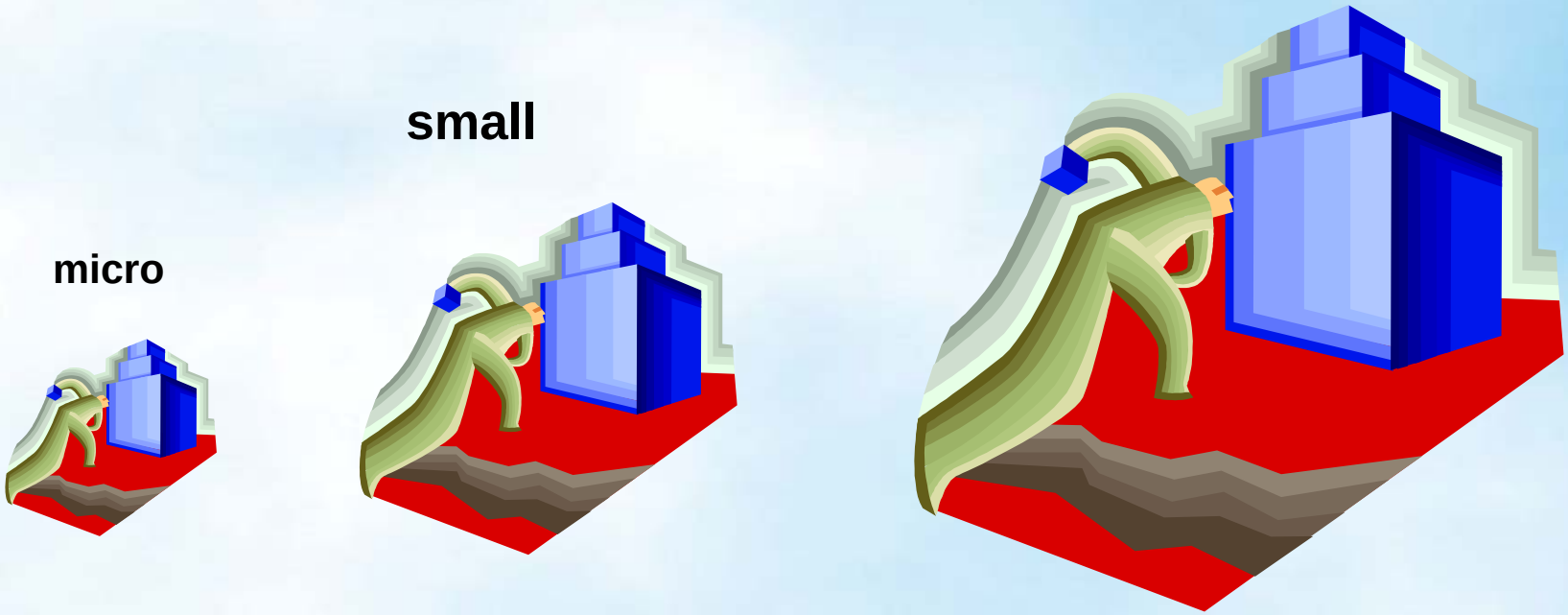
Update from “SME Office”
for
& medium-sized enterprises

small

micro



Agenda

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

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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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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

User Guide & Communication

4. Topics
5. Distribution
6. Other information

Workshop/Trainings

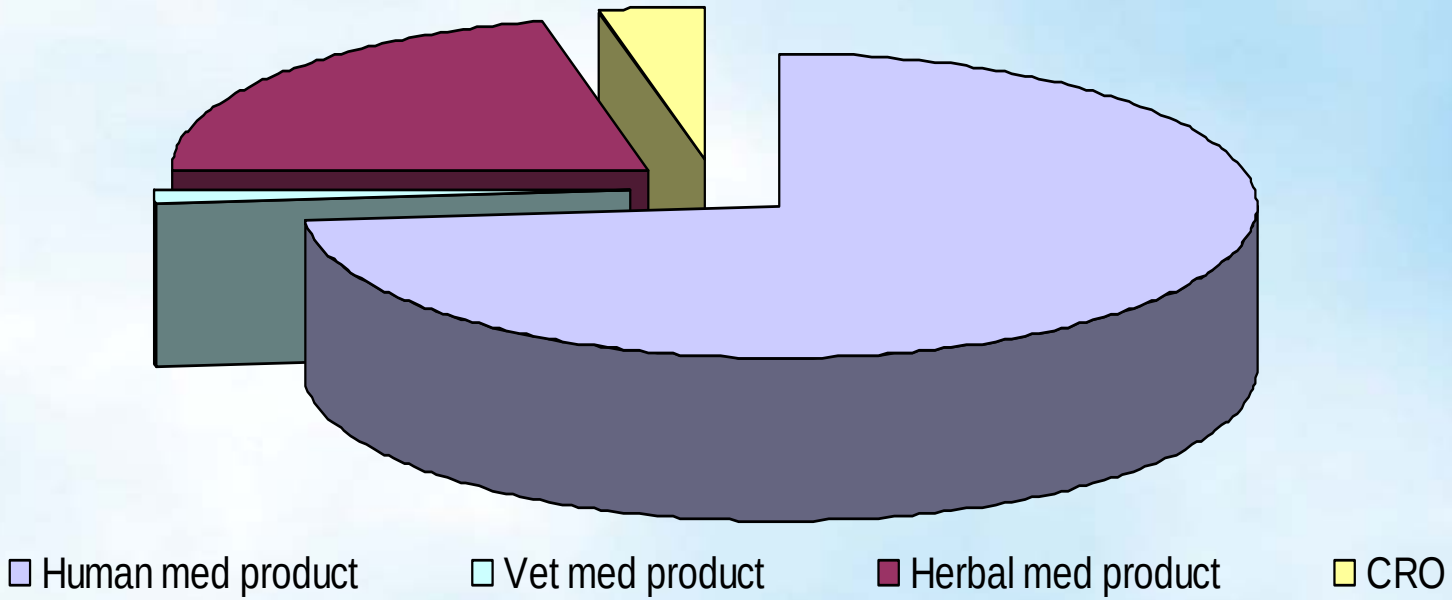
7. Topics

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 questionairre
- 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

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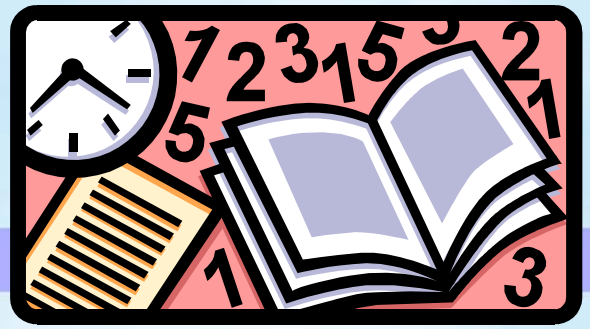
Incentives for SMEs

- 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 workshop/training sessions

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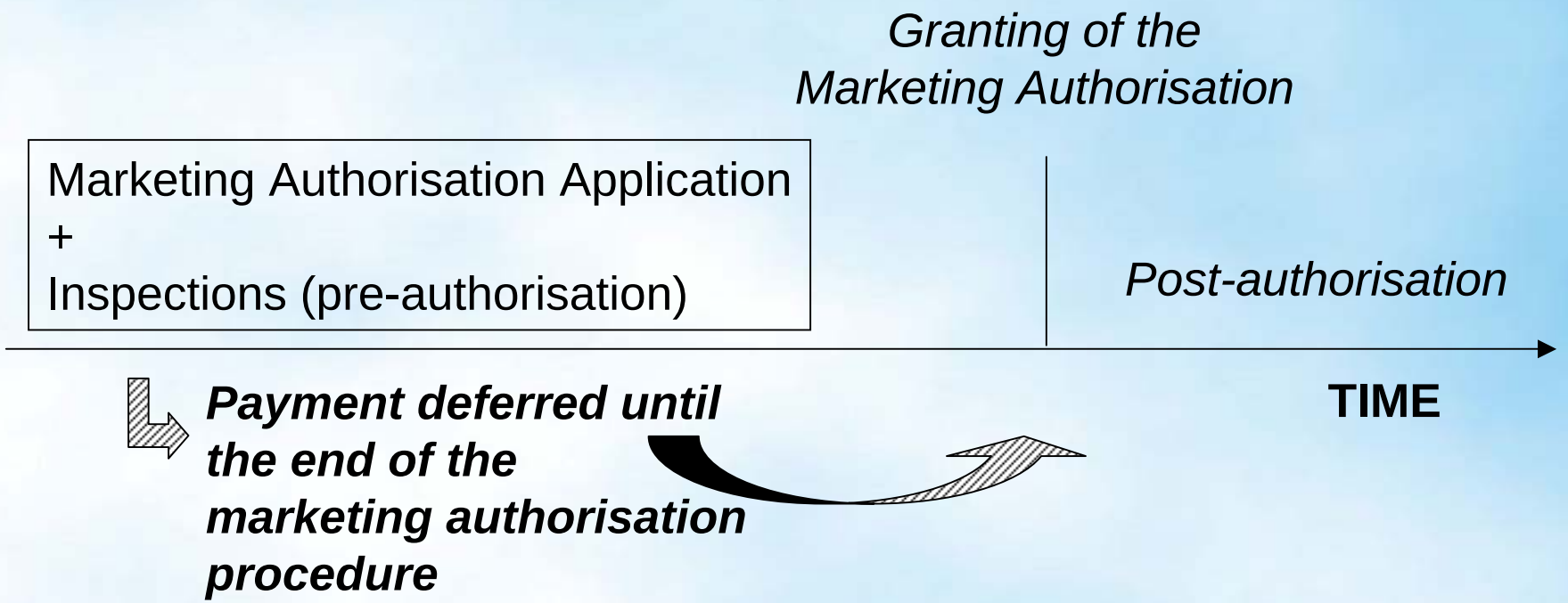
Fee Reductions

- 90% reduction on :
  - scientific advice
  - inspections
  - scientific services
  - maximum residue limits (veterinary medicines)

- 100% ‘waiver’ on administrative services (except for parallel distribution)

Fee deferrals



Conditional Fee Exemption

***IF** scientific advice used:*

=> Payment only in case of success

(Marketing Authorisation Granted)

Example

	Standard application non-SME	Standard application SME	
Scientific Advice	*70 000 EUR*	7 000 EUR **(-90%)**	
Inspection	*17 000 EUR*	1 700 EUR **(-90%)**	*Payment deferred until the end of the procedure*
Marketing Authorisation Application	*232 000 EUR*	232 000 EUR if success 0 EUR **(-100%)** if failure	
Total	*320 000 EUR*	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 web-site
- 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

EMEA 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
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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)
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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

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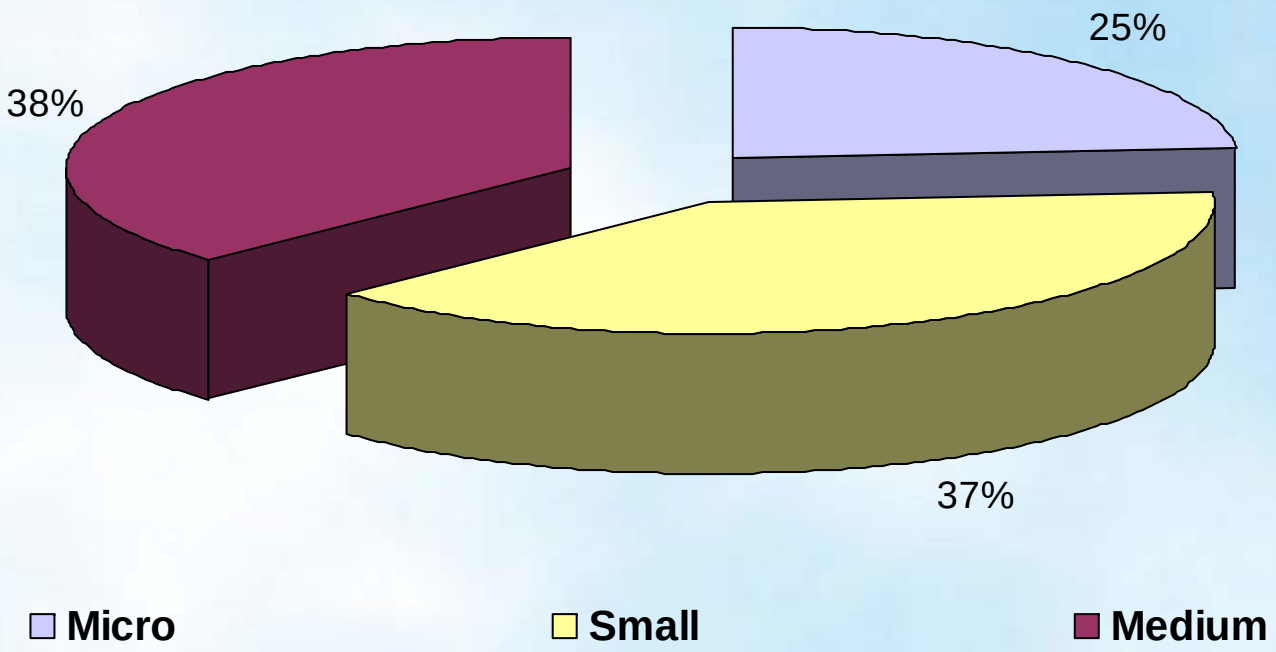
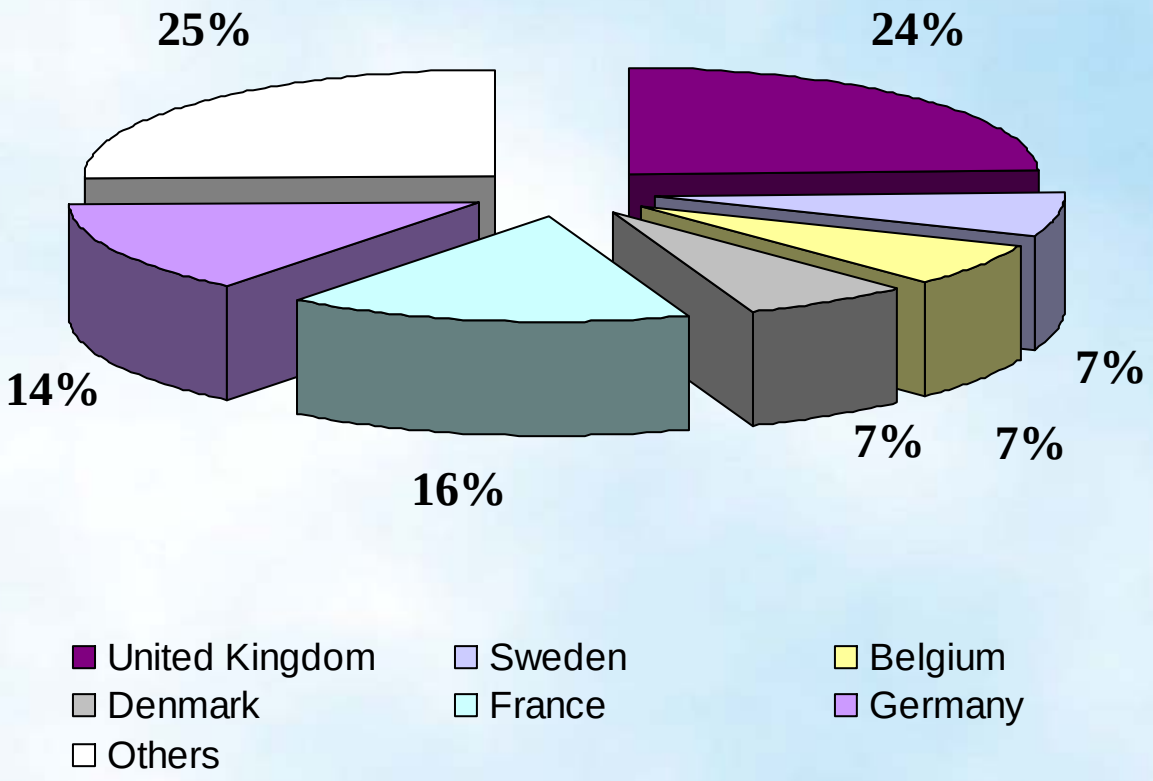
..the first SMEs….

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

…micro, small or medium..



…geographical distribution…



..experience so far….

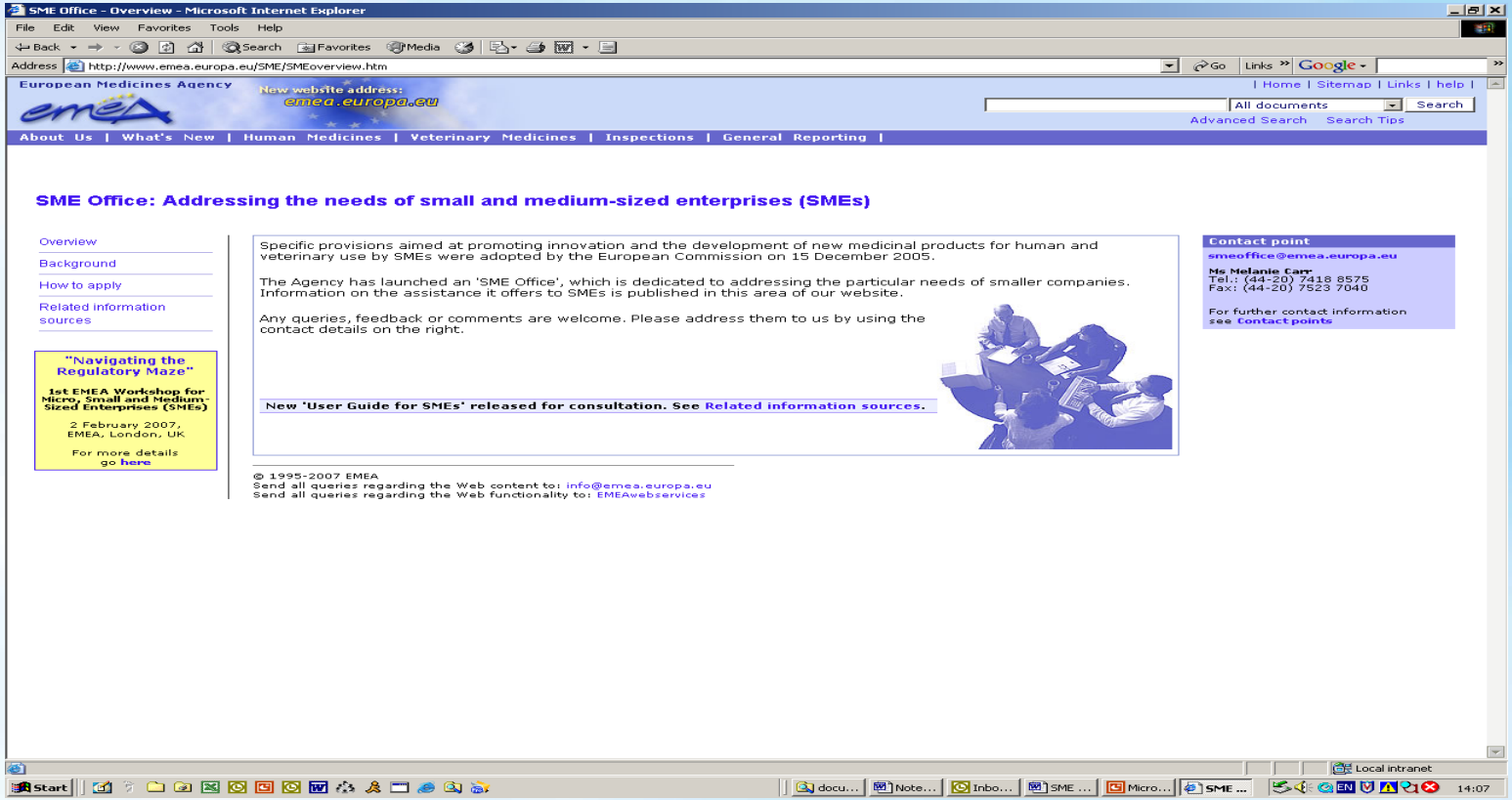
Financial/administrative assistance:

- 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

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



Thank you for your attention

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