



European Medicines Agency

SME Office

Constantinos Ziogas
September 2009



Agenda

- Introduction
- Current incentives for SMEs
- Type of companies assigned SME status
- What has SME Office delivered thus far?
- Closing remarks



The European System

- “One European system: two procedures”
 - Centralised procedure
 - Mutual recognition and decentralised procedures
- EMA is focal point of centralised procedure
- Rapid and EU-wide authorisation
- 1 evaluation, 1 authorisation



Support to Innovation & Access to Market

- Scientific advice procedure
- Orphan Initiative
- Paediatric Medicines
- Support to Small & Medium sized companies (SMEs)
- New legislation for Advanced Therapy Medicinal Products
- Accelerated assessment
- Conditional authorisation/Exceptional circumstances

SME

Orphan

Paediatric

Scientific
Advice

Advanced
Therapies

**Incentives/Assistance
to drug development**





Small & Medium sized Enterprises (SMEs)

Objective of SME Initiative

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



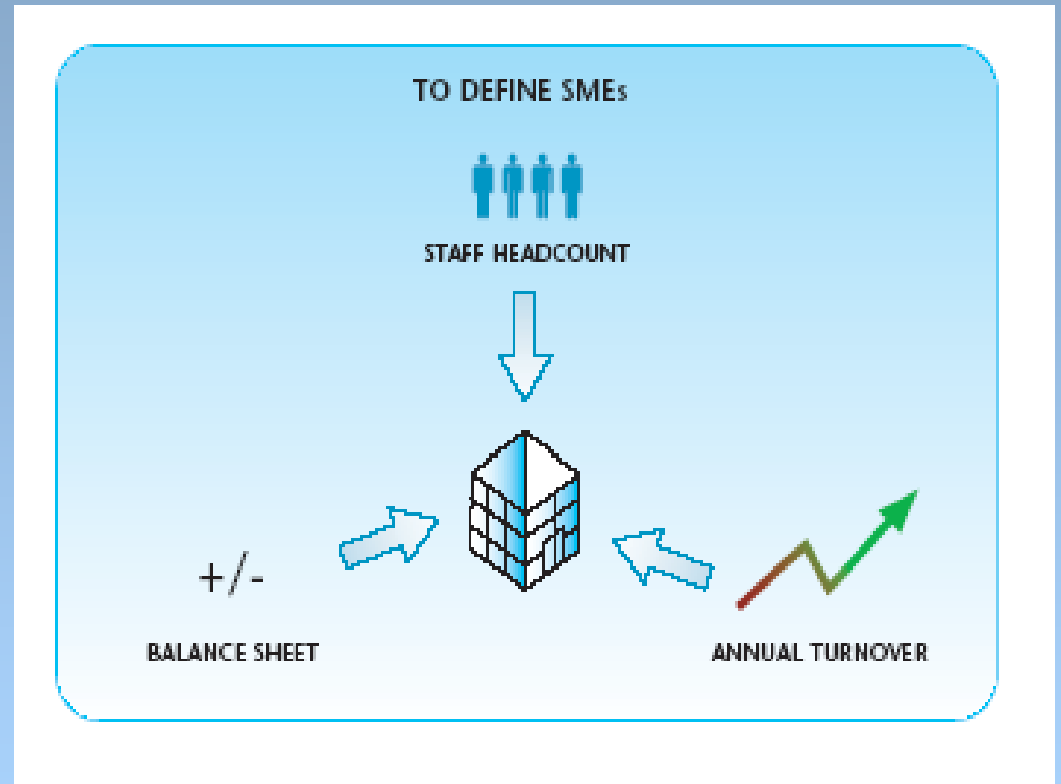
Definition of SME

Enterprise:

- any entity engaged in an economic activity irrespective of its legal form

New thresholds based on:

- Staff headcount
- Annual turnover
- Annual balance sheet



Definition of SME

THE NEW THRESHOLDS (Art. 2)

Enterprise category	Headcount: Annual Work Unit (AWU)	Annual turnover	or	Annual balance sheet total
Medium-sized	< 250	≤ €50 million <small>(In 1996 € 40 million)</small>	or	≤ €43 million <small>(In 1996 € 27 million)</small>
Small	< 50	≤ €10 million <small>(In 1996 € 7 million)</small>	or	≤ €10 million <small>(In 1996 € 5 million)</small>
Micro	< 10	≤ €2 million <small>(previously not defined)</small>	or	≤ €2 million <small>(previously not defined)</small>

Assignment of SME Status

- Applicant must be established in the Community
- Meet SME criteria defined in Recommendation 2003/361/EC
- Submit information necessary to demonstrate compliance with the criteria



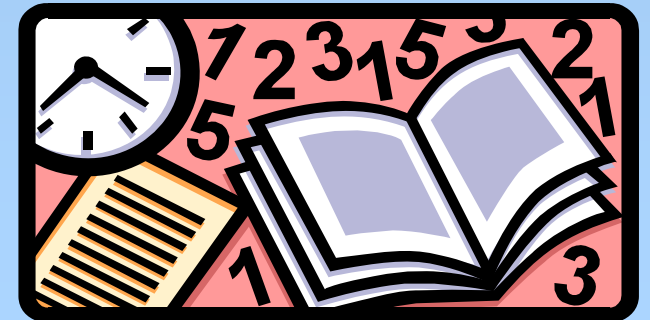


Agenda

- Introduction
- Current incentives for SMEs
- Type of companies assigned SME status
- What has SME Office delivered thus far?
- Closing remarks

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



New Incentives for SMEs developing advanced therapies

- Medicinal products based on genes / cells / tissues
- 50% reduction for SME/hospitals
 - centralised MAA where public health interest in Community until 2011-2012
 - 1st year post-authorisation fees
- Certification of Quality / Non-clinical data
 - Optional tool to potentially facilitate further development
 - Same scientific evaluation standards as for MAA





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
 - and a cross-Agency network



Role of SME Office

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



Agenda

- Introduction
- Current incentives for SMEs
- Type of companies assigned SME status
- What has SME Office delivered thus far?
- Closing remarks

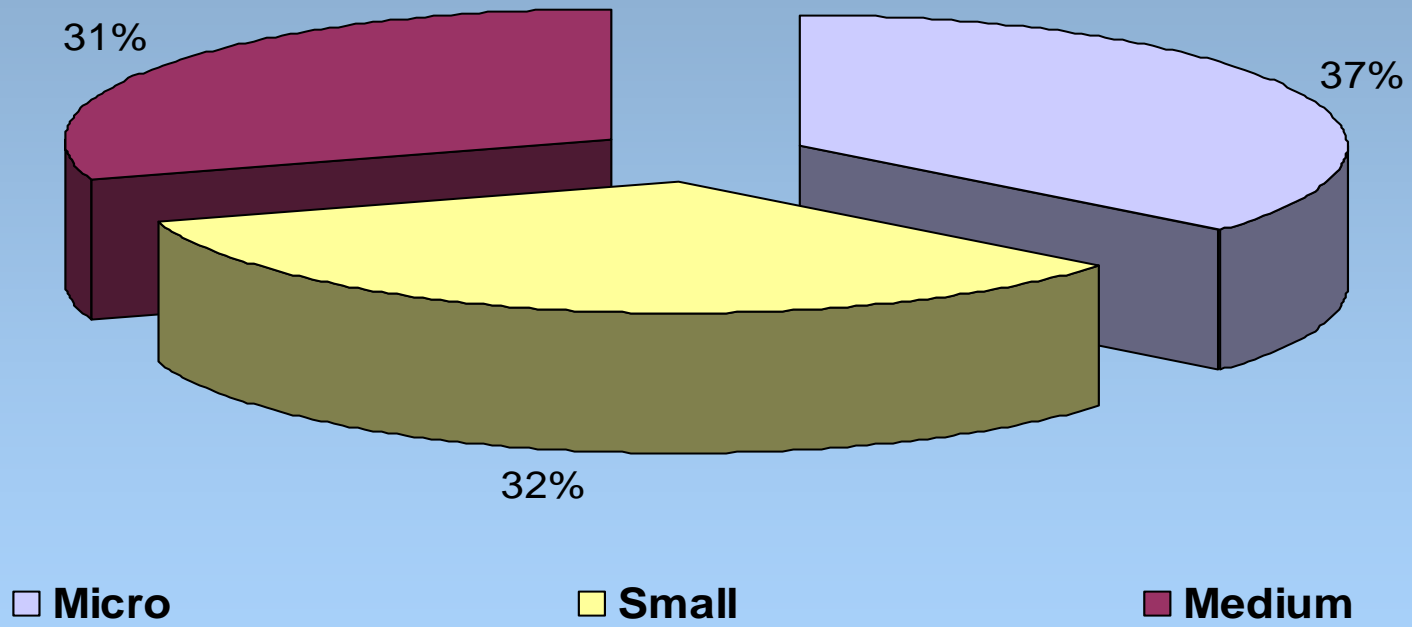


... SMEs to date....

- 414 companies assigned SME status
- 50% increase from 2007 to 2008
- 36% micro, 34% small, 30% medium
- Majority human, 16 vet, 18 human/vet & 43 consultants

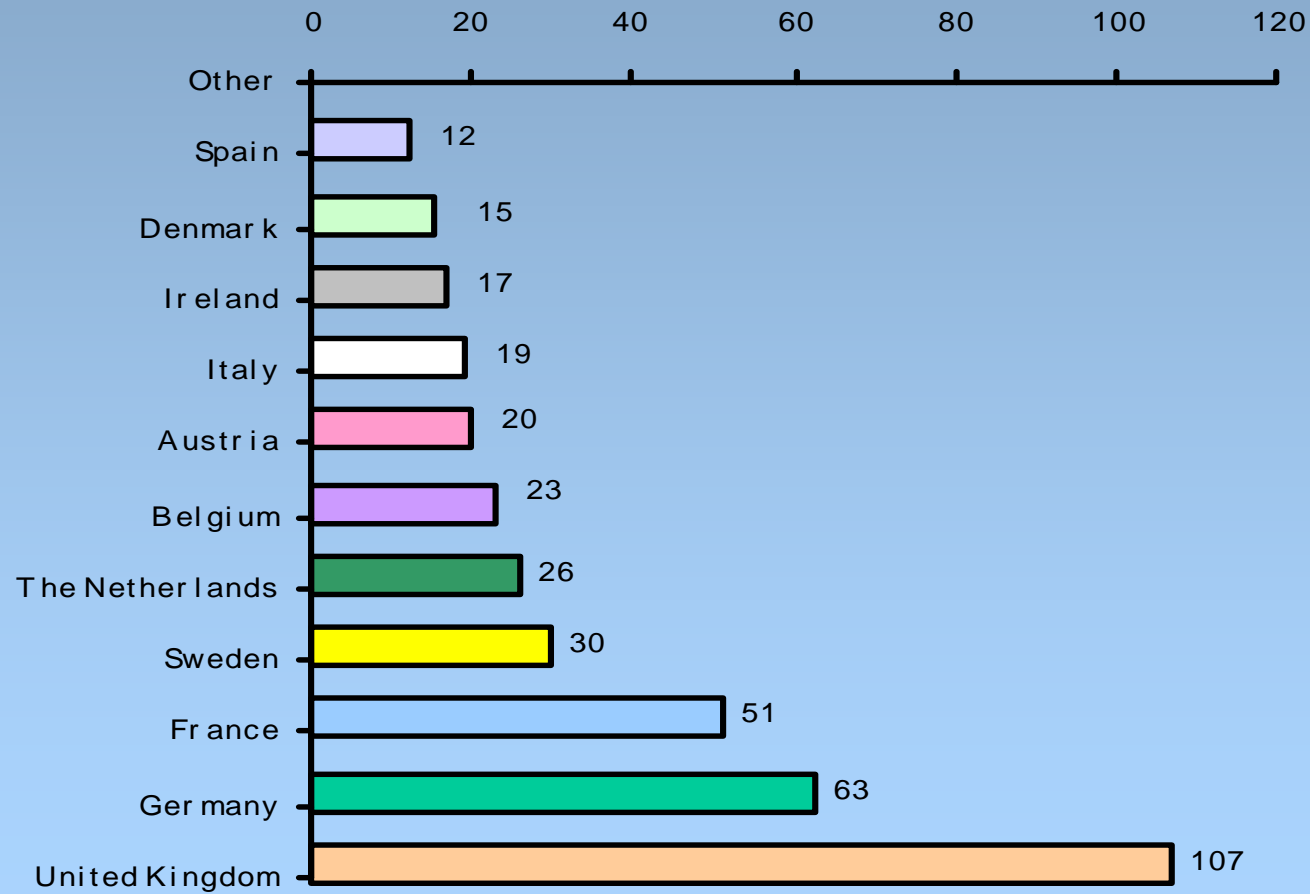


...micro, small or medium..

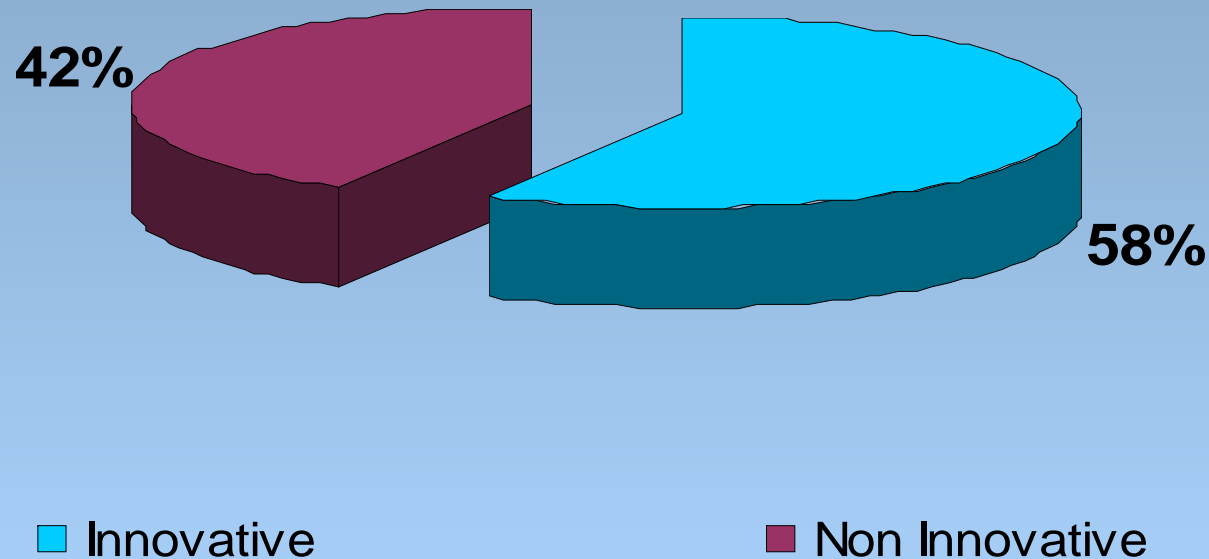




...geographical distribution...



Development pipeline of registered SMEs

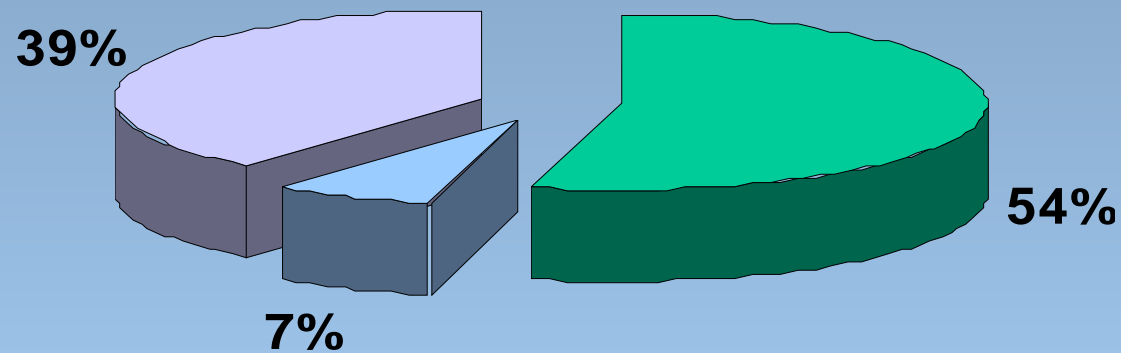


Innovation:

- 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:

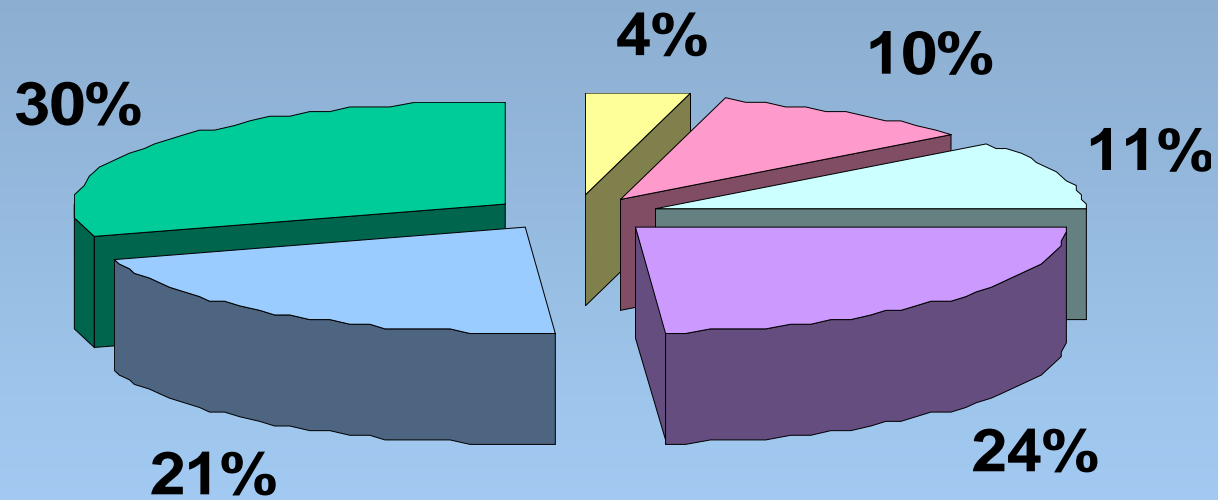
- 57% new chemical entities
- 18% new formulations
- 11% oligopeptides
- 3% generics

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



Agenda

- Introduction
- Current incentives for SMEs
- Type of companies assigned SME status
- What has SME Office delivered thus far?
- Closing remarks



Tailoring assistance for SMEs

Regulatory assistance:

- > 200 SMEs received direct regulatory assistance
- Published SME User Guide on regulatory procedures
- SME News bulletin to update companies
- Annual training/workshops tailored for SMEs



Encourage early dialogue and Scientific Advice

- Advice on development & agreement of future strategy
- 70 day procedure, possibly 40 days
- Pre-submission meetings involve working party's coordinators
- Face to face meetings for 50% of scientific advice
- Fee-related activity (reduction for SMEs, fee waiver for orphan products)



Experience to date

Scientific advice (SA):

- >130 SME's in scientific advice, 11 follow-up advice
- To date, processed fee reductions totalling € 6.9 million

Applications for marketing authorisation (MAA)

- 40 submitted MAAs
- Deferred € 6.1 million in fees for MAA & inspections
- Provision of translations for 12 SMEs



Agenda

- Introduction
- Current incentives for SMEs
- Type of companies assigned SME status
- What has SME Office delivered thus far?
- Closing remarks



Closing remarks

During Development:

- Consider contact through Innovation Task Force, SME, Orphan, if applicable
- Seek (multidisciplinary) scientific advice early in development
- Follow-up advice if necessary

During MAA pre-submission:

- Contact EMA to discuss filing strategy
- Come early for formal EMA pre-submission meeting
- Meet with assessment teams once appointed
- Any questions contact SME Office

Thank you for your attention



**Contact SME Office:
Tel +44 207 418 8575
smeoffice@emea.europa.eu**

Visit EMEA web-site:

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