



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update from SME Office

Veterinary SME Workshop
"Veterinary regulatory support for SMEs"
07 November 2013

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An agency of the European Union





SME Initiative at EMA

Objective:

To promote innovation and development of new medicines by SMEs

SME Office:

- A single interface
- Fee reductions and deferrals
- Advice on regulatory issues
- Translation of product information
- Workshop / training sessions



Tailoring assistance for SMEs

To promote innovation & development of new medicinal products by SMEs

THE NEW THRESHOLDS (Art. 2)

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



Assignment of SME Status

- Applicant must be established in the EEA
- Applicant must meet SME criteria defined in Recommendation

2003/361/EC:

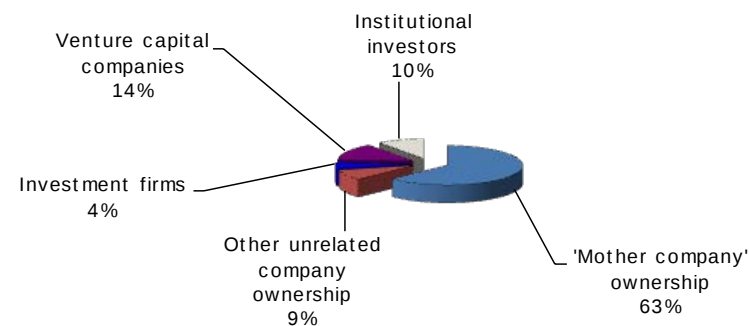
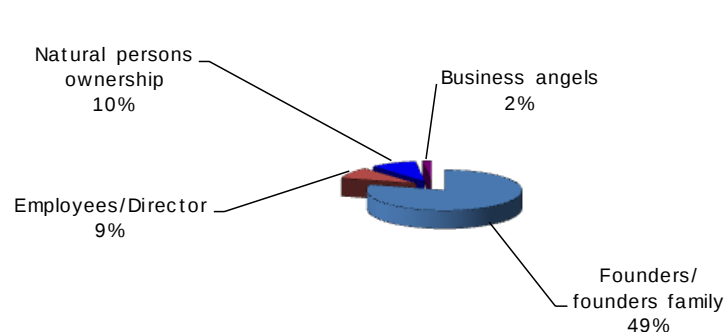
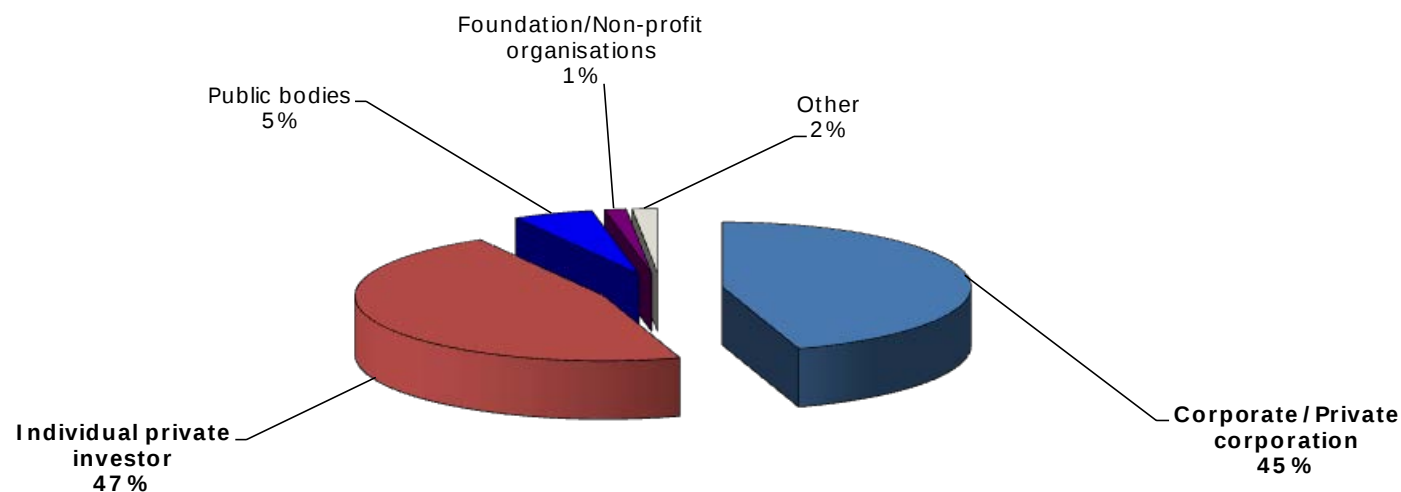
- Headcount < 250 and annual turnover not more than € 50 mil or balance sheet not more than € 43 mil
- Submit information to show compliance with criteria
- SME status valid for 2 years from date of closure of accounts. Can be renewed prior to expiry

<http://www.ema.europa.eu/ema> - regulatory page



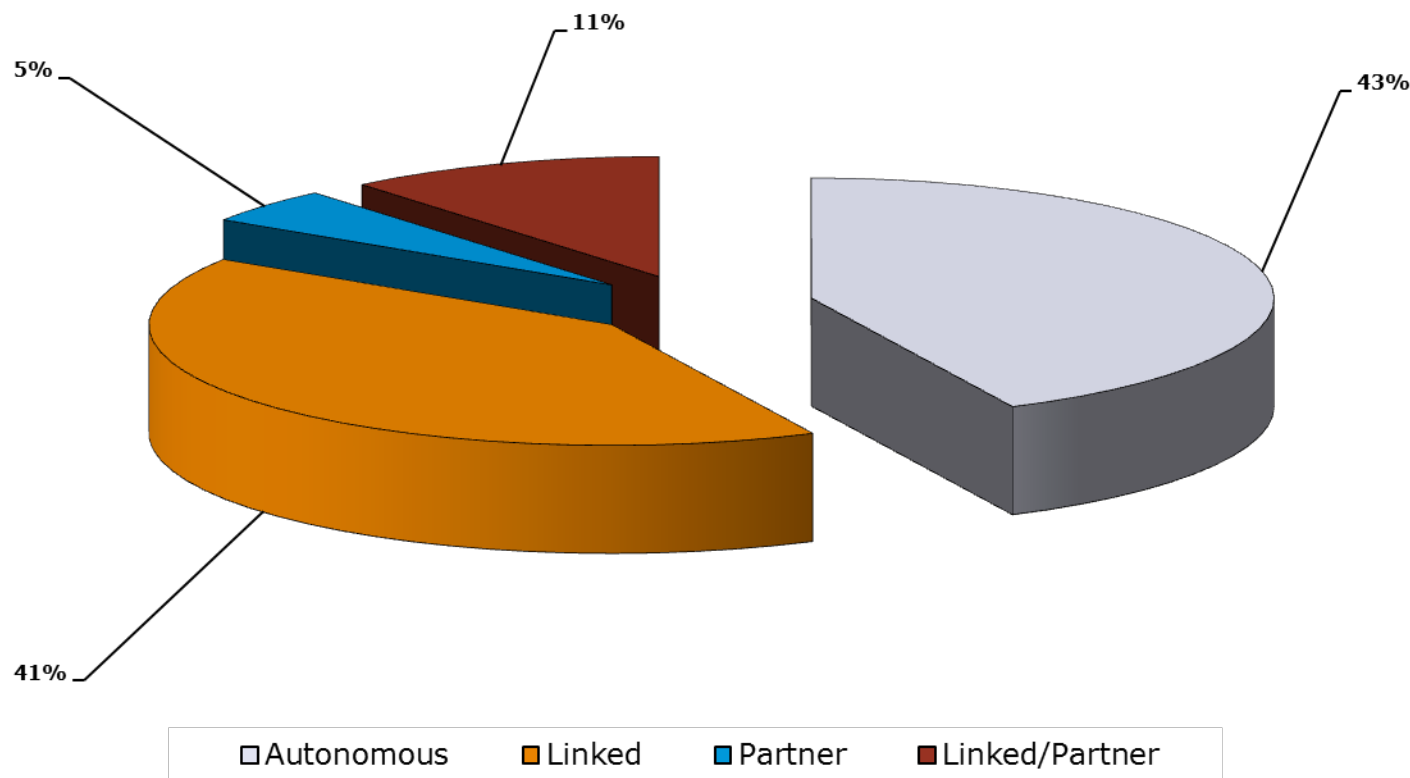


Ownership



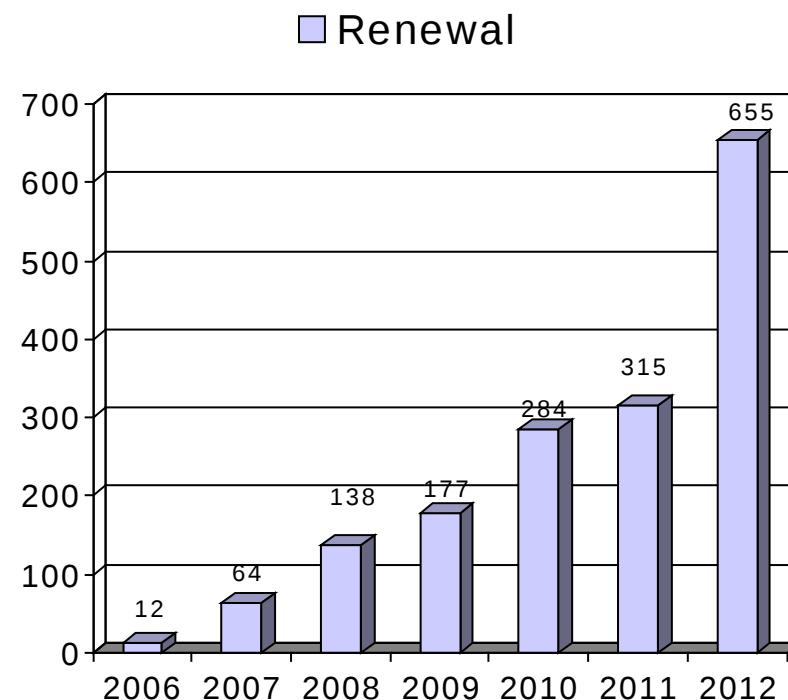
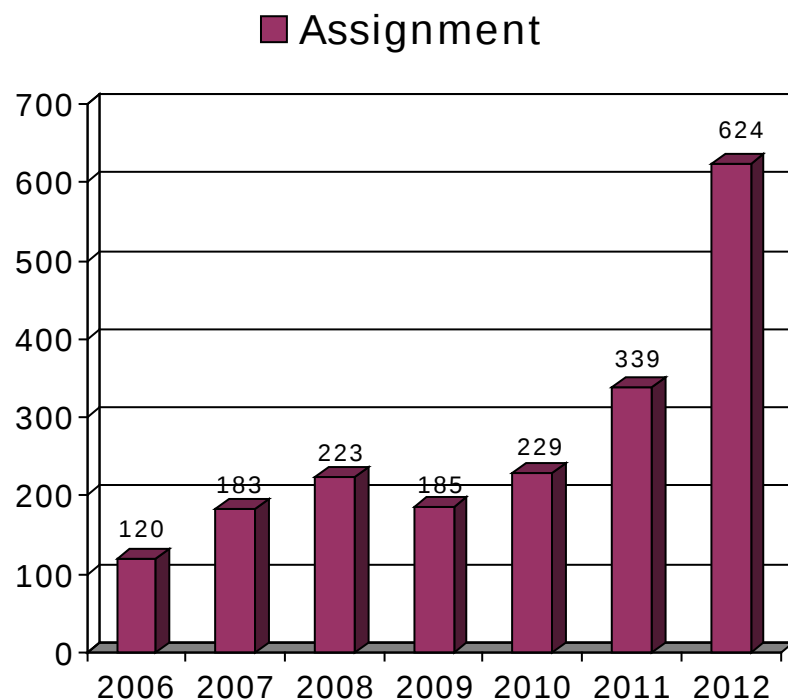


Types of enterprises





Number of SME Assignments / Renewals 2006-2013 (All)





Improvements to SME Assignment & Renewal process

- Electronic checklist on ownership information
- Electronic submission of all documentation (no paper)
- Risk-based approach to finance check by EMA for initial assignments
- Automatic renewal for majority of SMEs, limited review by EMA
- Confirmation of SME assignment / renewal via e-mail



Further process simplification planned in 2014



Experience with Veterinary SMEs to date

1234 companies assigned SME status currently from 28 countries across EEA (All)

126 (10%) in veterinary field, and combined human/veterinary

- **76** Human/Veterinary
- **50** Veterinary

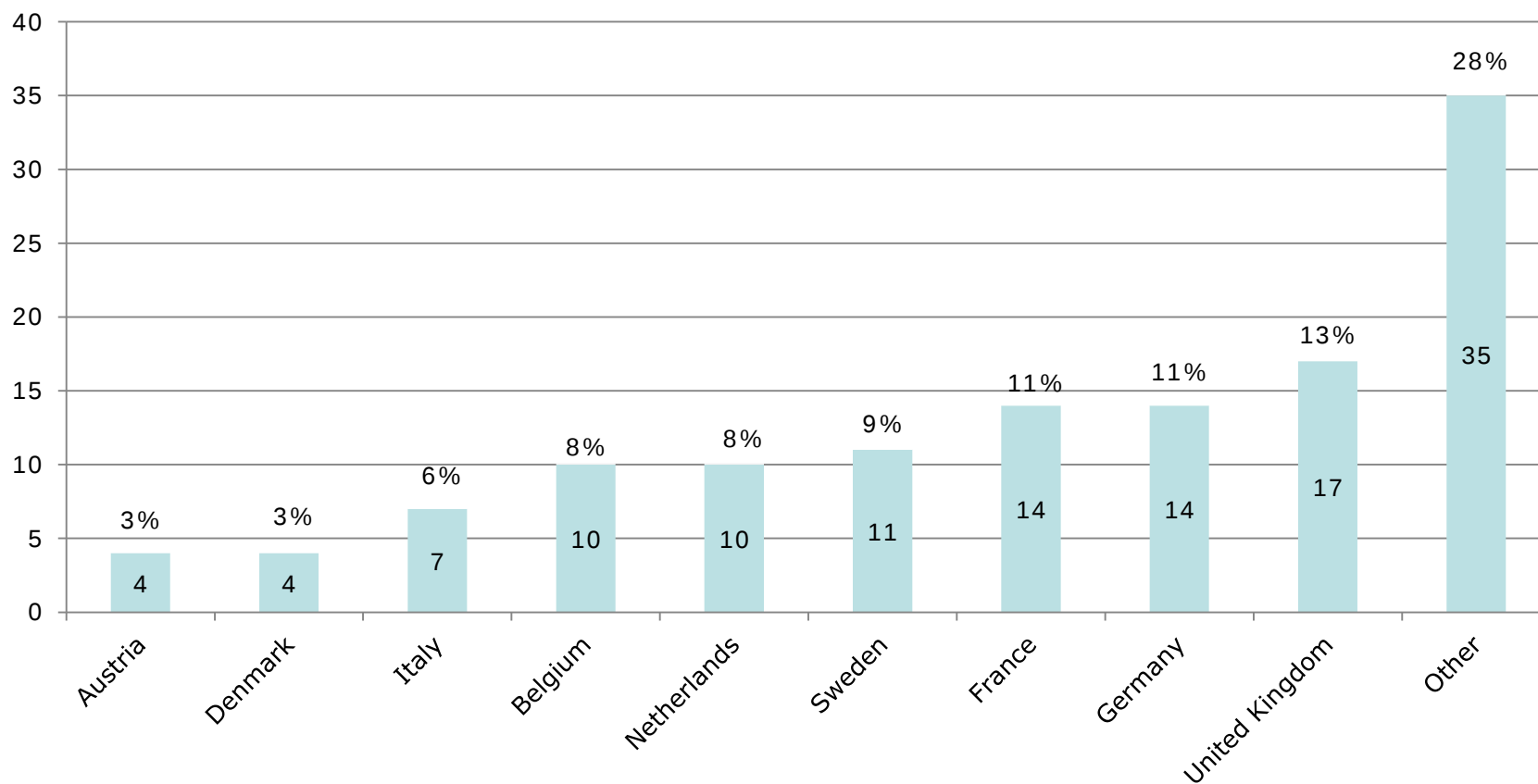
39% micro-sized, 32% small-sized, 29% medium-sized (Av. Headcount: 43; Av. Turnover: 8.5 mil €; Av. Balance sheet: 14 mil €)

34 newly created since 2009

Public register of companies on EMA website



Geographical Distribution





Company profile and development stage

■ Medical device and technology
16%

□ (Bio)Pharmaceutical
84%

Commer-
cialisation/
Marketing
stage
42%

Develop-
ment stage
58%

Commer-
cialisation
/
Marketing
stage
18%

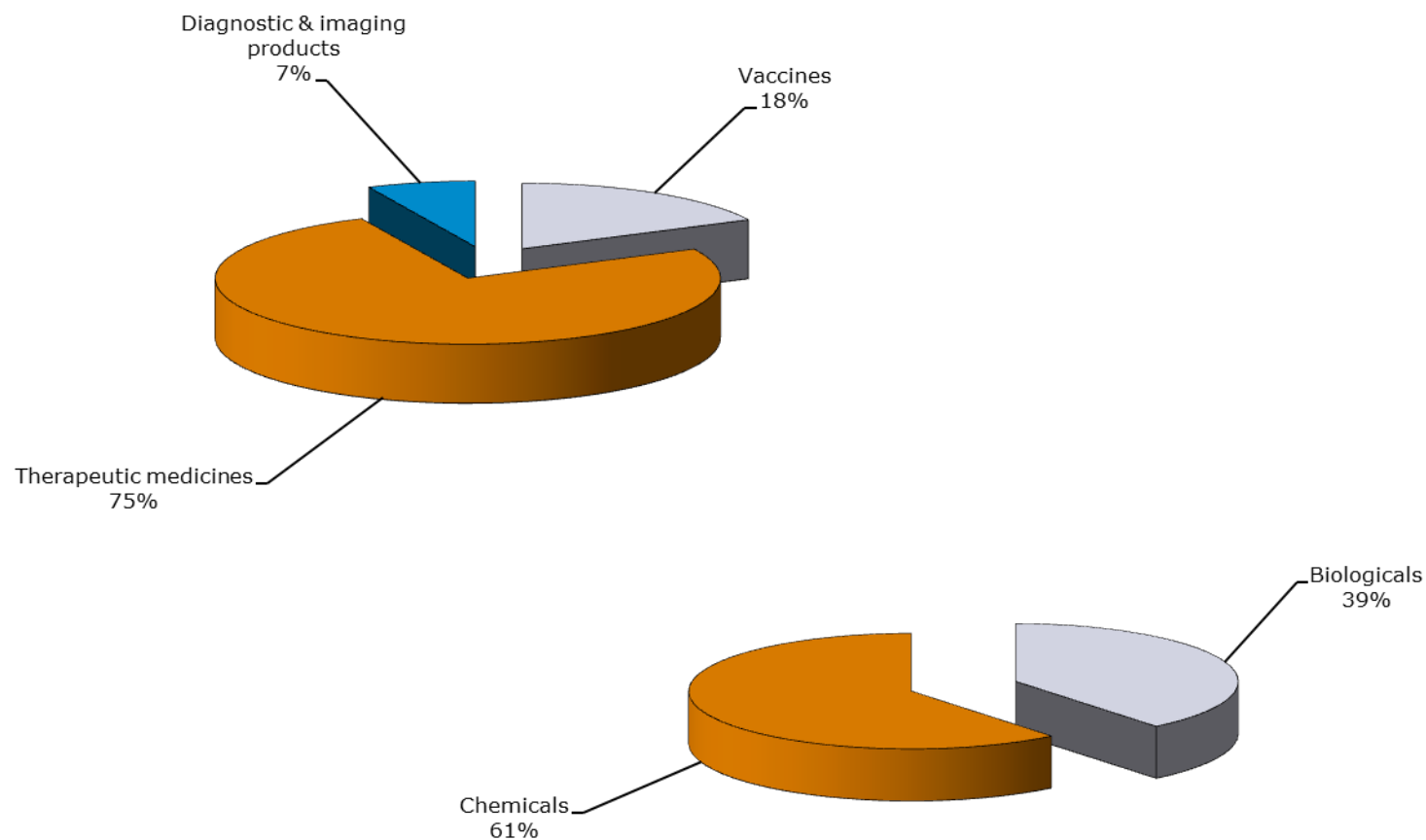
Developm
ent stage
33%

Manufact
uring
20%

Research/
Discovery
stage
27%

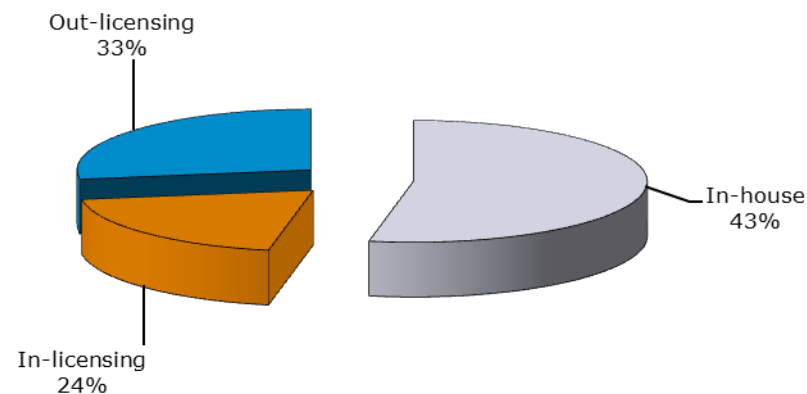
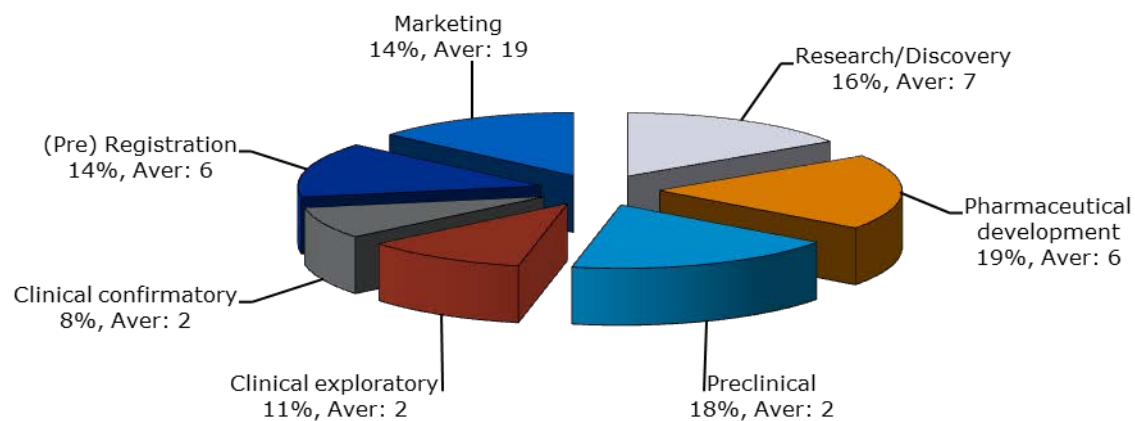


Product pipeline





Product development stages





Support to SMEs

Regulatory assistance (66 SMEs have received direct regulatory assistance from the SME Office)

Scientific advice (SA)

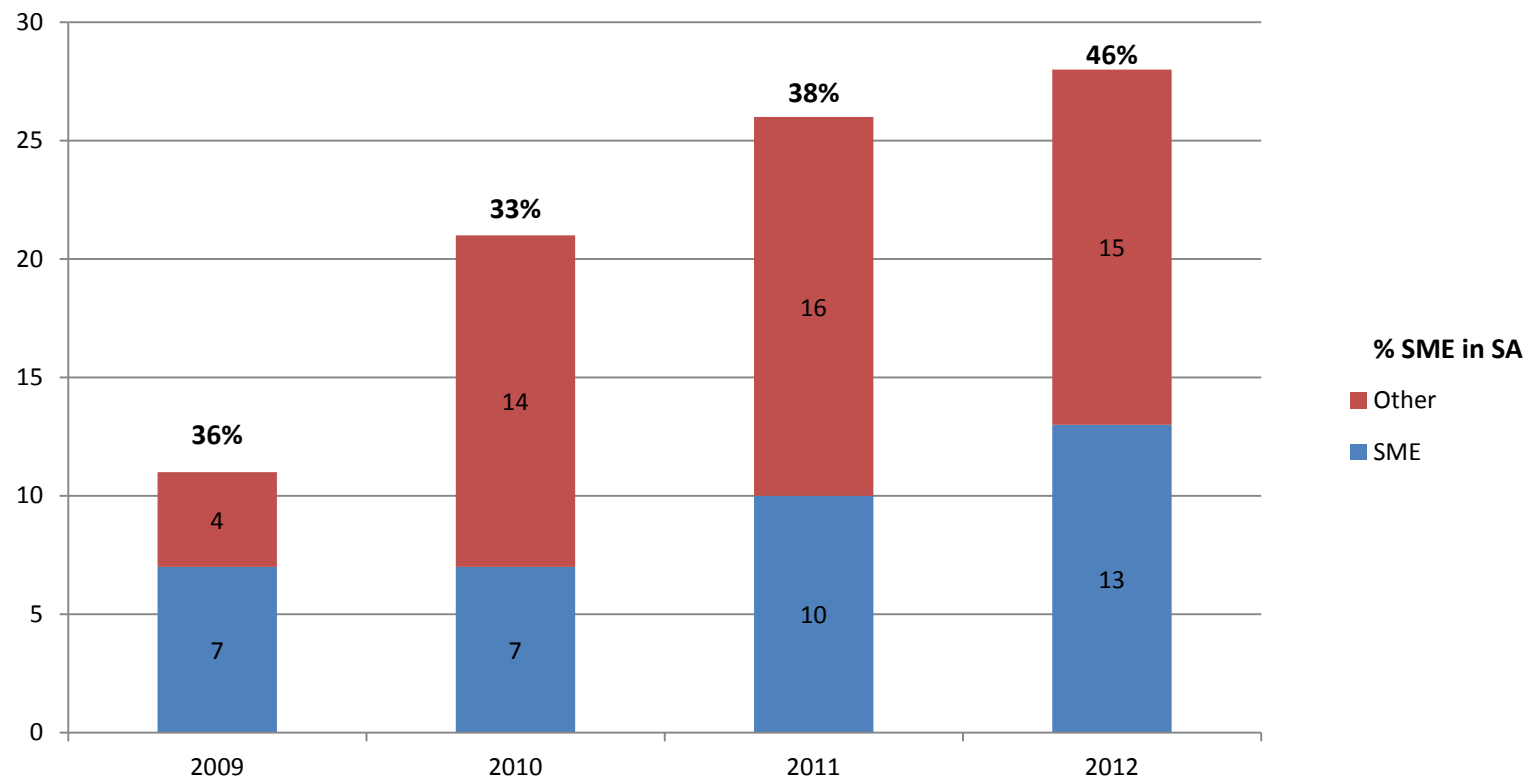
Applications for marketing authorisation (MAA)

Provision of translations for SMEs

Communication (SME User guide, newsletters, public consultations, workshops)

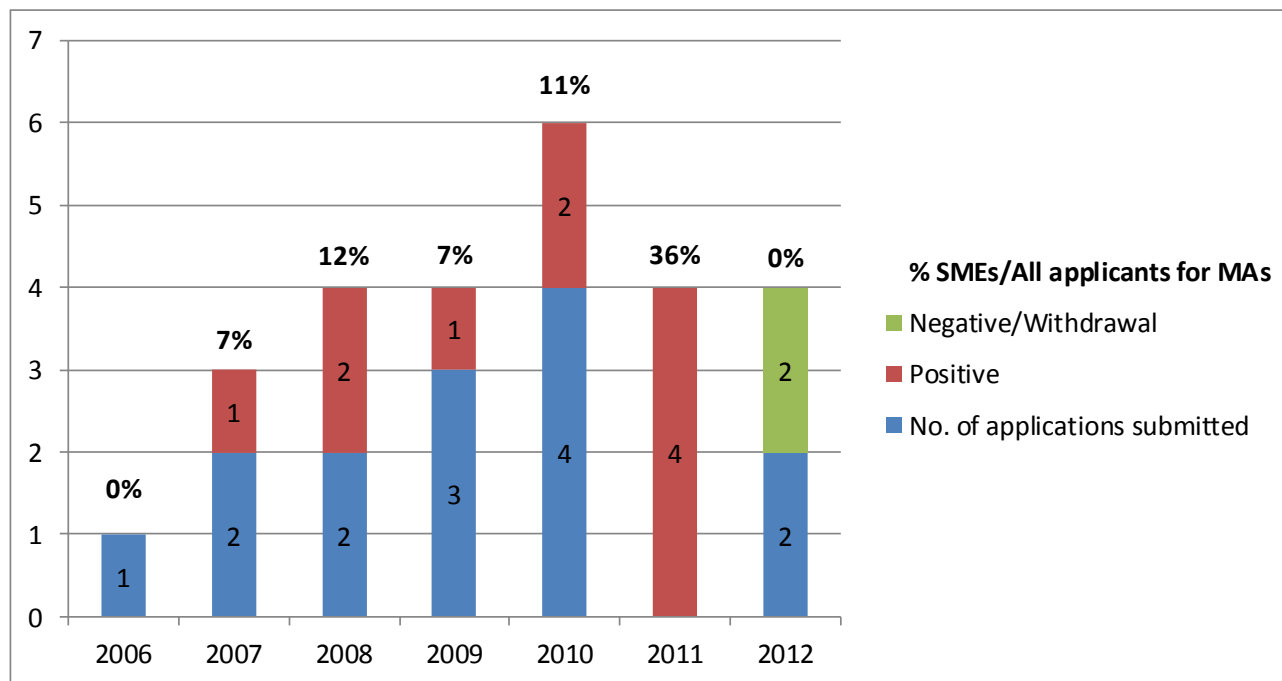


Veterinary Scientific Advice 2009-2012





Status of SME Applications for Marketing Authorisation for Vet Medicines



Vet MAs:

- 1 new chemical entity
- 2 vaccines
- 7 generics

Dec 2005- Dec 2012



Thank you for your attention!

SME Office, Stakeholder & Communication Division