An overview of EMA initiatives supporting SMEs

EMA Veterinary Medicines Innovation day – 19 April 2018

Presented by: Helene Casaert
SME Office, Corporate Stakeholders Department, Stakeholders & Communication Division

1. SME Office remit and activities
2. Focus on Veterinary applications by SMEs
3. EMA's action plan for SMEs
4. Conclusion

SME Office remit

SME Regulation

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COMMISSION REGULATION (EC) No 2049/2005 of 15 December 2005

***Aim**: to promote innovation and development of new medicines for human and veterinary use by SMEs*

SME Office launch in December 2005

- A single contact point
- Assistance to SMEs
  Regulatory, administrative and procedural support
- Facilitates communication
  With SMEs in veterinary and human pharma sector
- Coordination & networking
  Working closely with EU, SME partners and stakeholders

What the SME Office does

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- Assignment of SME status
- Regulatory Assistance
- Fee Incentives
- Translation Assistance
- Training and Awareness
- Partnering & Networking
  SME Register

01 Assignment of SME status (1/2)

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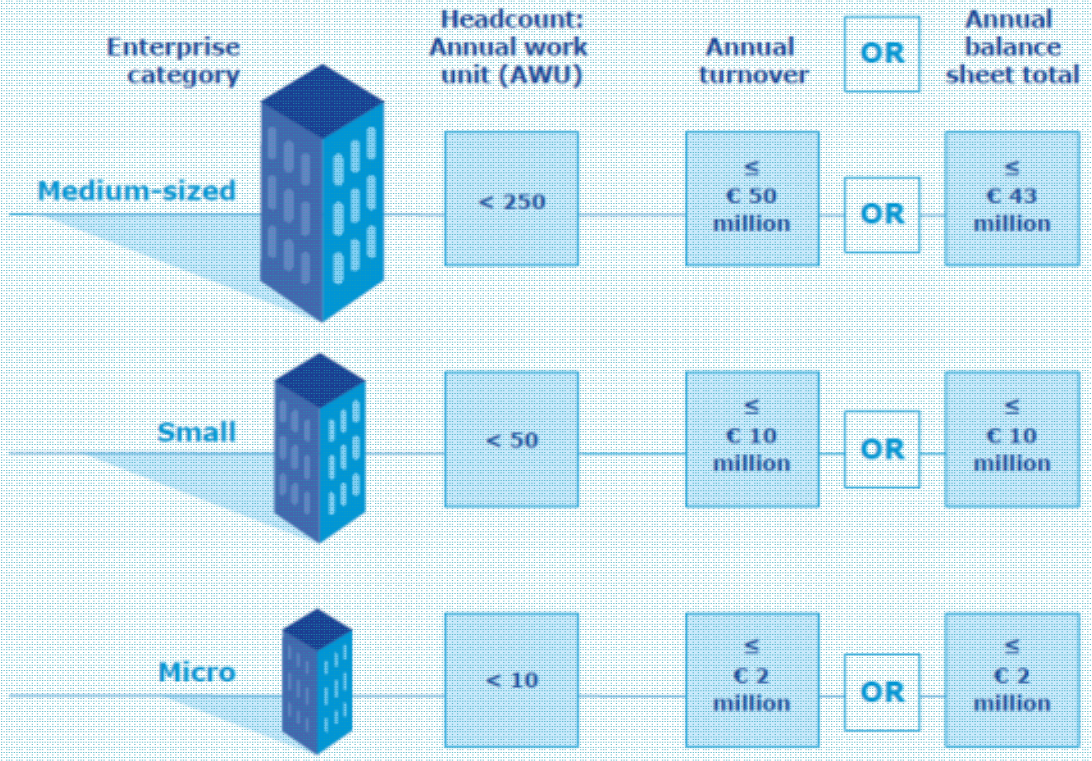
SME Thresholds - Commission Recommendation 2003/361/EC



01 Assignment of SME status (2/2)

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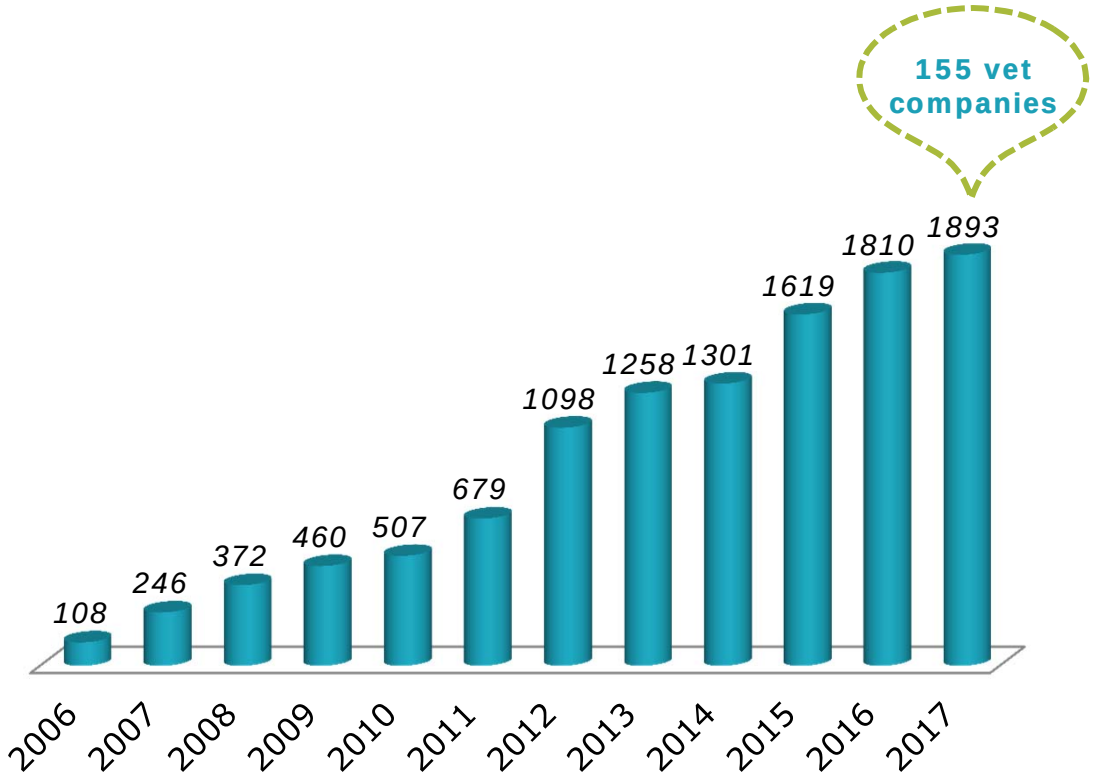
Registered SMEs (2006-2017)



- Majority human (78%), 4% vet, 4% human/vet & 14% service providers
- Top 5 countries for vet companies :

  UK (15%), Germany (13%), Spain (10%), Italy (9%) and France (7%),
- Size of vet companies :

  44% micro, 32% medium, 24% small

02 Regulatory assistance

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Administrative, regulatory and procedural queries are addressed by email (SME@ema.europa.eu), phone (SME Helpdesk) or in a briefing meeting.

SME briefing meeting

- *Provides a platform for early dialogue with SME*
- *to discuss regulatory strategy of medicinal product development and navigate the range of procedures and incentives available*
- *Multidisciplinary group*
- *Free of charge, can be face to face or via TC*
- *SME request to SME Office with background on the product and queries*

03 SME fee incentives (1/2)

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Procedure	Fee incentives for SMEs
Scientific advice	90% fee reduction
Establishment , extension or modification of Maximum Residue Limits (MRL)	90% fee reduction
Post - authorisation activities	100% fee reduction for micro enterprises 40% fee reduction for small or medium-sized enterprises
Inspection (pre-authorisation)	90% fee reduction + Fee deferral
Inspection (post-authorisation)	90% fee reduction
Marketing authorisation application	Fee deferral Conditional Fee exemption

Full details on all fees and fee reductions, are available in: Explanatory note on general fees payable to the European Medicines Agency

03 SME fee incentives (2/2)

Conditional fee exemption (SMEs)

- Applicant request to SME Office with supporting document and justification
- Review of compliance with SA by EMA/CVMP

04 Translation assistance

- *Assistance with translations of the product information and opinion annexes, in the event of a CxMP positive opinion*

- *No cost to SME applicant*

05 Training & awareness for SMEs

Info days
regulatory training course tailored for SMEs

Newsletters
Circulated quarterly; published on the EMA Website.

Announcements
Information sent by email to SMEs and stakeholders

SME User Guide
Updated regularly

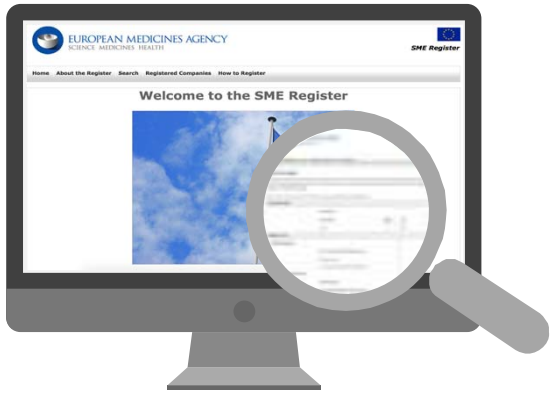
Provide training
&
ease the access to regulatory information

06 Partnering & networking

SME Register

Set up in consultation with SME stakeholders aiming:

- *to increase information available to SMEs and their stakeholders*
- *to facilitate and promote interaction, partnering and networking between SMEs*
- *to provide a source of information for EU institutions, agencies and Member States*



Focus on Veterinary applications by SMEs

Scientific advice

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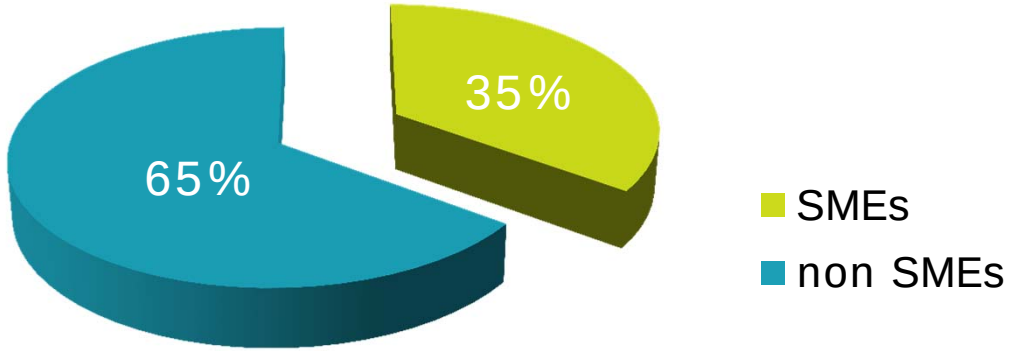
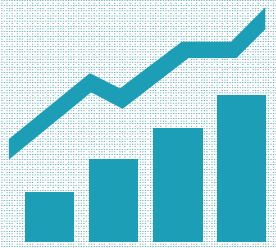
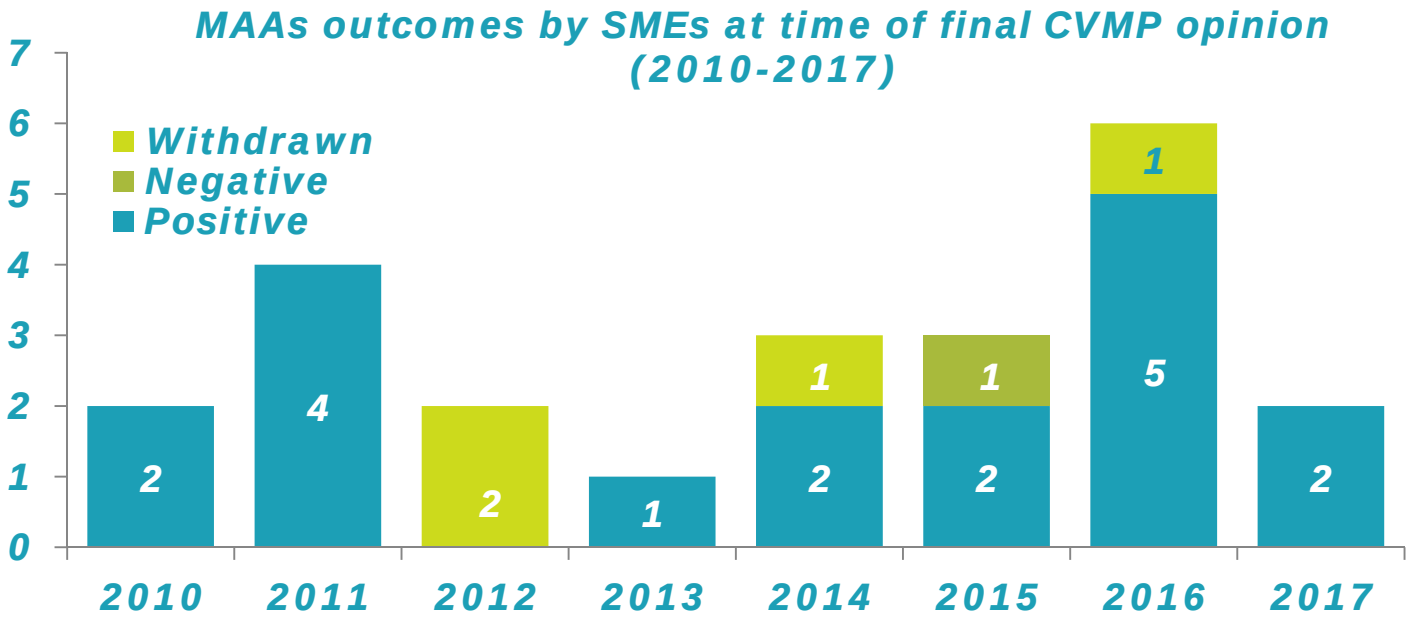
Scientific advice in 2017



- *In 2006, 21% of all requests for scientific advice came from SMEs*
- *Higher uptake than scientific advice for human medicinal products*
- *Important to start early dialogue*

Marketing authorisation applications





Veterinary medicinal products MAAs submissions in 2017 :

- *35 % of all veterinary MAAs submitted by SMEs*
- *Higher proportion than in the human field*

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EMA action plan for SMEs (2017-2020)

EMA SME action plan (2017-2020)

Outlines a series of objectives and actions grouped by theme, which were identified in the EMA 10-year report and the SME survey.

4 *key areas including 16 actions, across EMA*

Awareness of EMA's SME initiative

Enhance engagement with biotech incubators, universities and investors.

Training and education

Increase training through multiple channels.

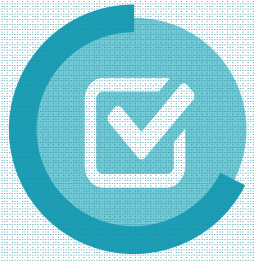
Support the development of innovative medicines

e.g. Promote the Innovation Task Force as a platform for early regulatory and scientific dialogue on innovative veterinary medicines.

Engagement with SMEs, EU partners and stakeholders

To conclude

Recommendations for SMEs



- *Consult available guidance (procedural and scientific)*
- *European Public Assessment Reports are useful source of information*
- *Regulatory assistance/briefing meeting with EMA (V-Division, SME Office)*
- *Informal dialogue through Innovation Task Force*
- *Early Scientific Advice (multidisciplinary)*
- *Early pre-submission dialogue in run up to MAA filing, in particular regarding regulatory aspects*
- ***Take advantage of the various opportunities to enter in a dialogue with EMA***

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Thank you for your attention

Further information

See: supporting SMEs

Contact us at: sme@ema.europa.eu

SME helpline 8787