EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

An overview of EMA initiatives supporting SMEs

SME info day „Supporting innovative medicines‘ development and early access“
17 November 2017, EMA

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An agency of the European Union

1. SME Regulation
2. What the SME Office does
3. SME action plan
4. Recommendations for SMEs

SME Regulation

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

***Aim**: to promote innovation and the 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
- Coordinating & networking
  Working closely with EU, SME partners and stakeholders

What the SME Office does

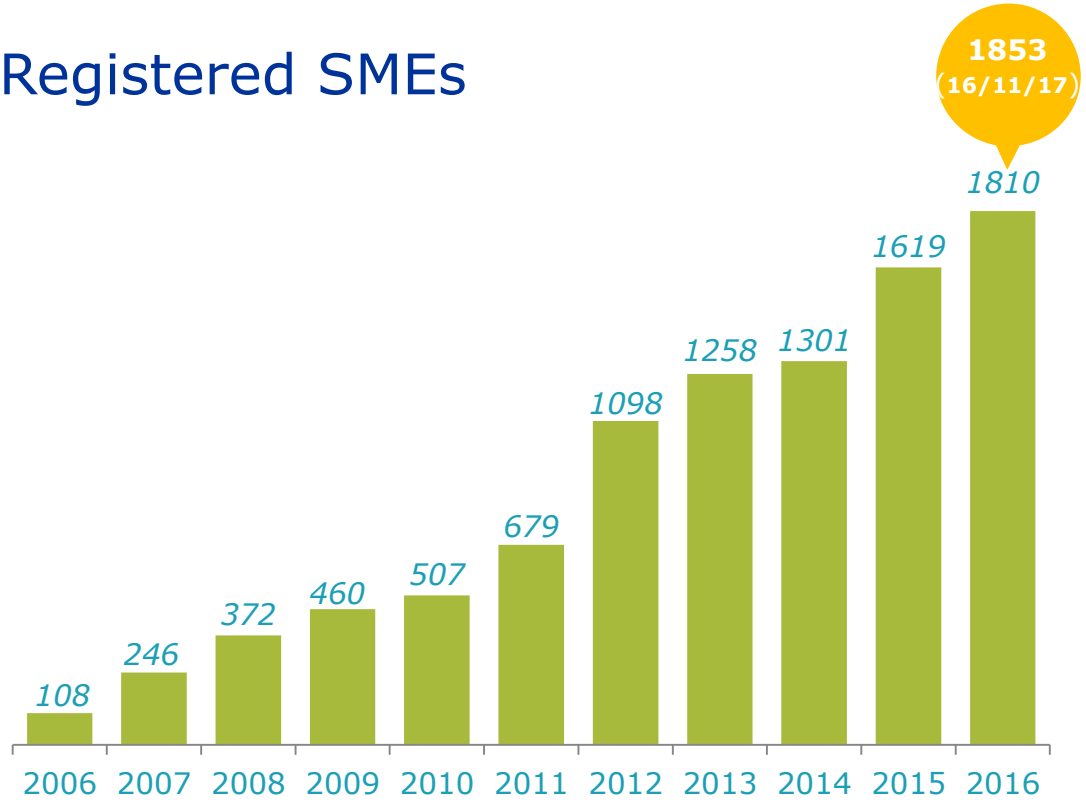
- Assignment of SME status
- Regulatory Assistance & SME briefing meetings
- Fee Incentives
- Translation Assistance
- Training and Awareness
- Partnering & Networking
  SME Register
- Reporting

01 Assignment of SME status

Commission Recommendation 2003/361/EC

1. *Submission*
2. *Review*
3. *Qualification*
4. *Renewal*

Registered SMEs



- From 28 countries across EU
- Top 5 countries : UK (17%), Germany (13%), France (9%), Italy (6%) and Spain (5%)
- 41% micro, 34% small, 25% medium
- Majority human (78%), 4% vet, 5% human/vet & 13% service providers
- Information on registered companies available in the SME public register

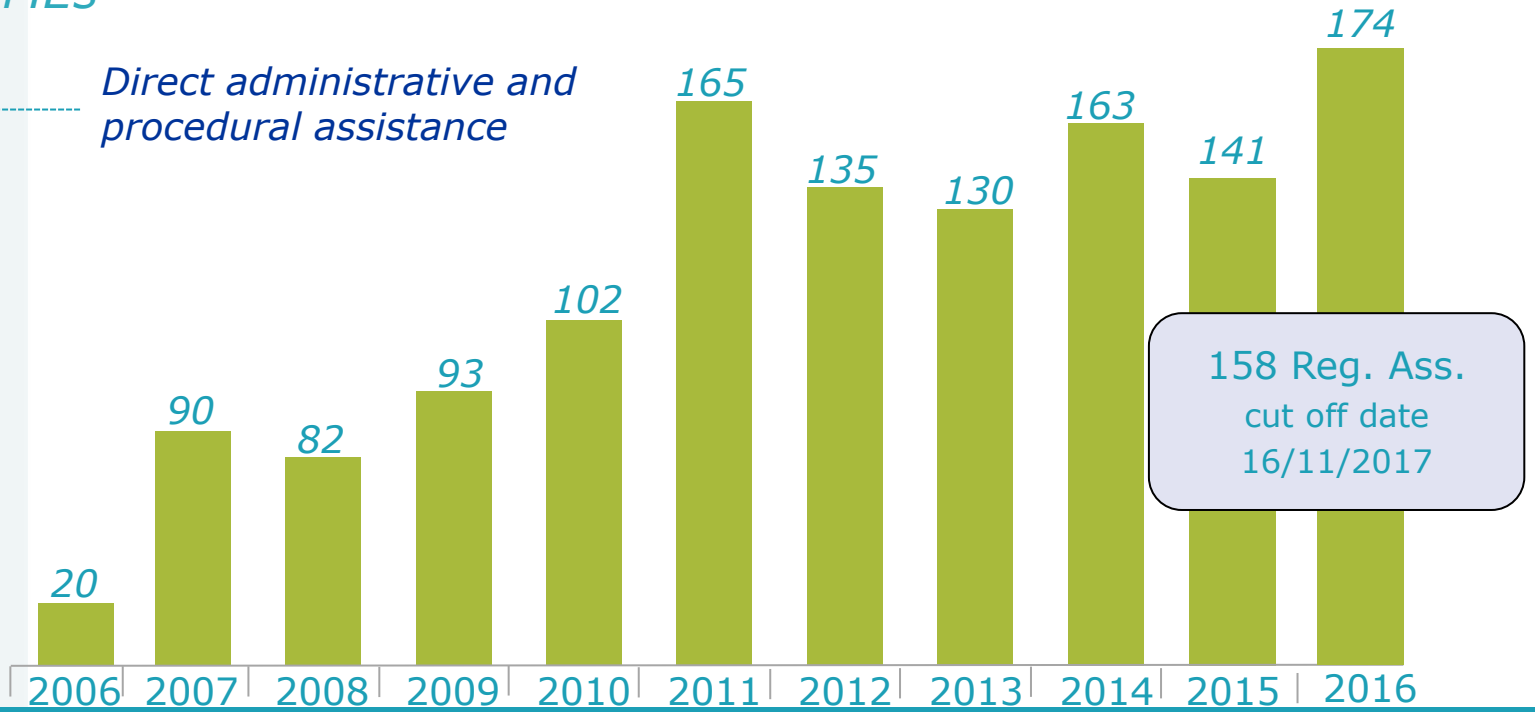
02 Regulatory assistance & SME briefing meetings (1/3)

Administrative, regulatory and procedural queries are addressed by email, phone or in a briefing meeting

Regulatory assistance to SMEs (2/3)

Tailored to SMEs

Direct administrative and procedural assistance



158 Reg. Ass.
cut off date
16/11/2017

02 SME briefing meetings (3/3)

- 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, co-operation with other EMA offices (scientific advice, paediatrics, orphans, regulatory affairs, etc)
- Open to medicinal products for human and veterinary use
- Free of charge
- SME request to SME Office with background on the product on the product development
- Can be face to face or via TC

2005 - 2015: **65**
2016: **13**
2017 (Jan - Nov): **15**

03 SME fee incentives (1/2)

- Fee reductions and exemptions for scientific advice, scientific services, inspections & establishment of maximum residue limits
- Deferrals of the fee payable for an application for marketing authorisation or related inspection
- Conditional fee exemption
- Fee reductions and exemptions for post-authorisation procedures and pharmacovigilance activities
- Waiver of the MedDRA licensing fee for micro and small companies

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

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*

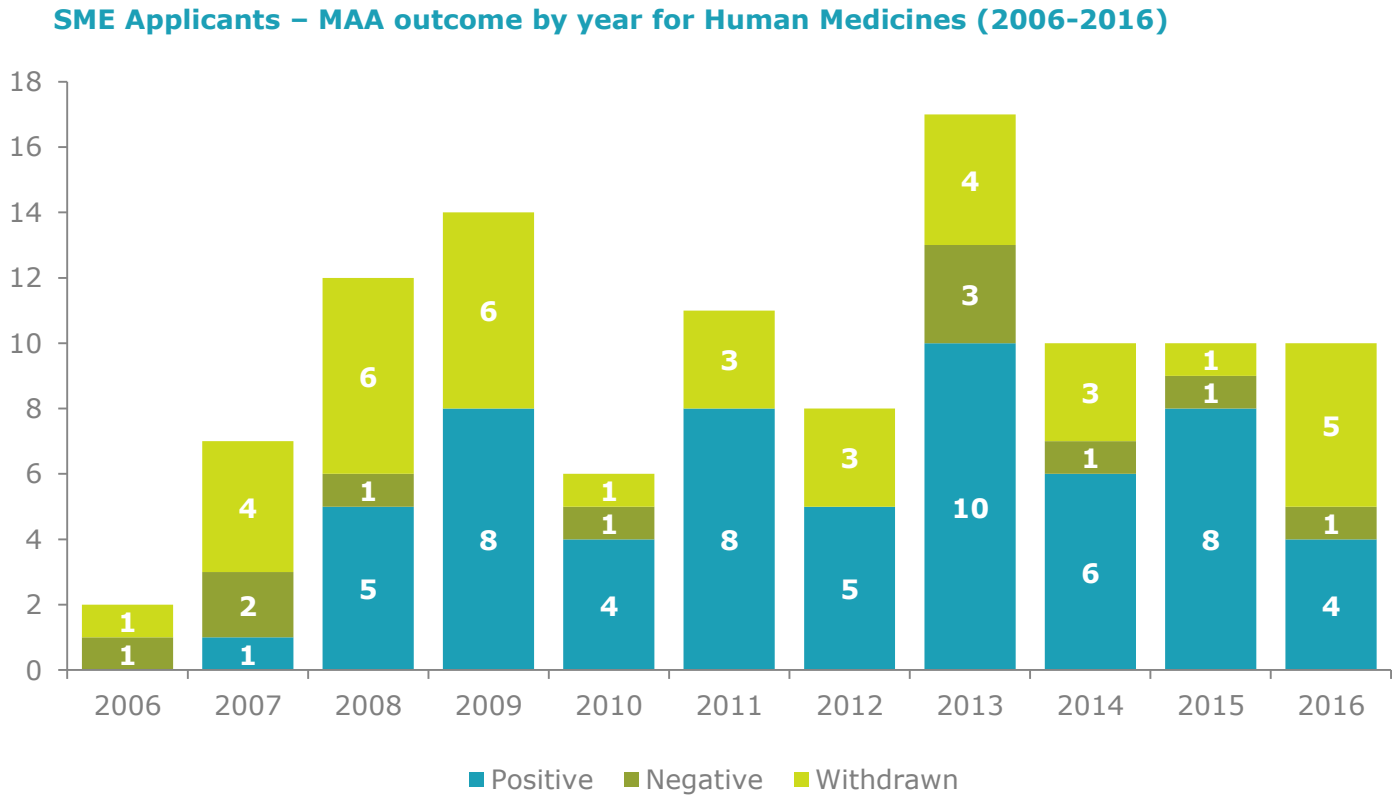
07 Reporting

SME Office annual report 2016

Overview of SME activities: platforms to advance innovative developments and regulatory strategies and SMEs experience with human and veterinary marketing authorisation applications

EMA SME 10 year report

Marketing authorisations



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

*1. **Awareness of EMA's SME initiative**: engagement with incubators, universities and investors.*
*2. **Training and education***
*3. **Support the development of innovative medicines**: maximising the use of regulatory tools to support the development of and access to medicines and enhancing cooperation with EU partners on projects subject to EU funding.*
*4. **Engagement with SMEs, EU partners and stakeholders**: EU Innovation Network, EU initiatives supporting SMEs and start-ups and interacting with international regulatory authorities.*

Recommendations for SMEs

- *Consult available guidance (procedural and scientific) and SME User Guide*
- *European Public Assessment Reports are useful source of information*
- *Regulatory assistance/briefing meeting with SME Office*
- *Informal dialogue through Innovation Task Force*
- *Early Scientific Advice (multidisciplinary)*
- *Eligibility to PRIME scheme*
- *Build timelines for paediatric investigation plan (PIP) and modification/compliance check, as appropriate*
- *Early pre-submission dialogue in run up to MAA filing*
- *Consider policy 70 on clinical data publication*
- *Take advantage of the various opportunities to enter in a dialogue with EMA*

Take home messages

- The SME initiative offers a broader range of incentives to SMEs
- The EMA remains committed to fostering an environment which provides incentives to SMEs: awareness of the EMA SME initiative, training and education, supporting innovative medicines' developments, and further engaging with SMEs, partners and stakeholders

Further information

See: supporting SMEs

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