Overview of EMA initiatives supporting SMEs

Info Day for SMEs: EMA support for SMEs under the new Veterinary Medicinal Products Regulation

Presented by Clément Provansal on 28 October 2021
Scientific Officer | SME Office | Regulatory Science and Innovation Task Force (TRS)

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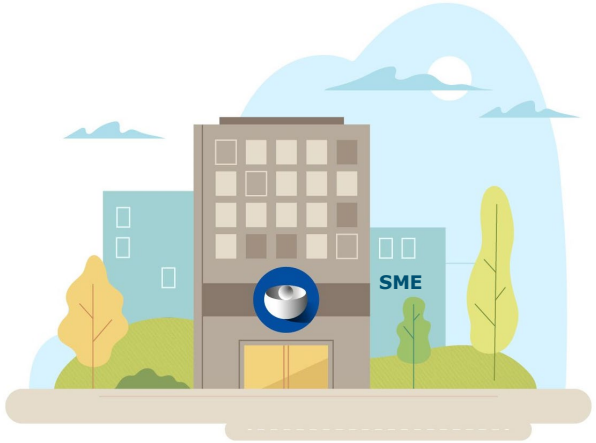
1. EMA SME office



SME regulation(EC) No 2049/2005 of 15 December 2005

- Aims to promote innovation and development of new medicines by SMEs

EMA SME Office launch in December 2005

➔ Dedicated contact point (a single interface)

➔ Assistance to SMEs
Regulatory, administrative and procedural support

➔ Facilitates communication with SMEs

➔ Engage with EU bodies, SME partners and industry stakeholders

Important milestones

15-year anniversary
SME survey 2020
Roundtable meeting
SME office report 2016-2020

- Assignment of SME status
- Regulatory assistance
- Fee incentives

SME office activities

- Translation Assistance
- Training & Awareness
- Partnering & Networking

Registration as an SME with EMA

Assignment of SME status

EU SME Definition - Commission recommendation 2003/361/EC

Size:

- *micro,*
- *small,*
- *medium-sized*

Ownership structure:

- *autonomous*
- *partner*
- *linked*

SME thresholds

Size and ownership structure

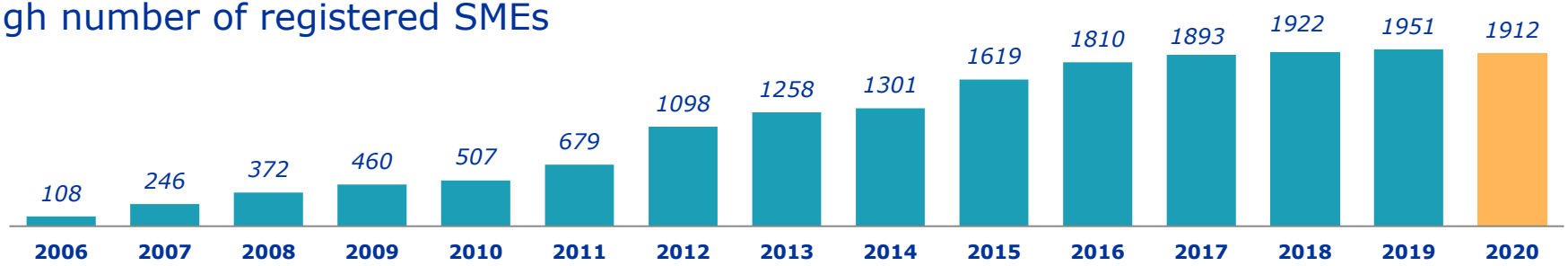
Assignment of SME status

Review of SME application by EMA SME Office

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

SMEs registered with EMA – Profile in 2020

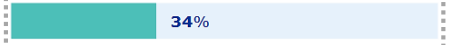
High number of registered SMEs



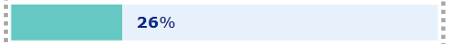
2020

Micro-sized*
Headcount <10; annual turnover or balance sheet total ≤€2 million

Small-sized*
Headcount <50; annual turnover or balance sheet total ≤€10 million

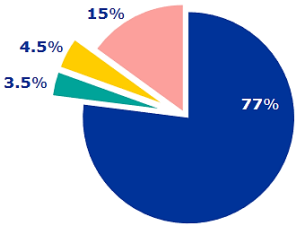


Medium-sized*
Headcount <250; annual turnover ≤€50 million or balance sheet total ≤€43 million



Company activity*

- Human medicines
- Veterinary medicines
- Human and veterinary medicines
- Service providers and regulatory consultancies

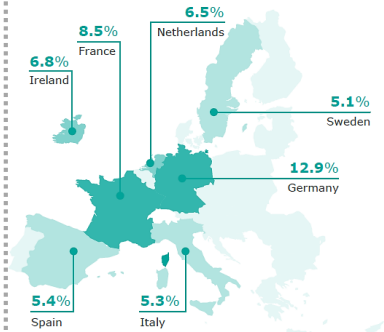


Profile*

9.5% academic spin-offs

12% SMEs incorporated in 2018–2020
- **31%** newly created entities
- **69%** new subsidiaries

Location of EU-based SMEs



Breakdown for Veterinary (V) and H/V companies:
- 151 companies: 66 V | 85 H/V
- Micro (41.8%) | Small (27.9%) | Medium (30.3%)

SME Office support – Regulatory assistance

Regulatory assistance

Administrative, regulatory and procedural queries from SMEs

SME@ema.europa.eu

SME Helpline :
+31 (0)88 781 8787

Response by email or phone

Interaction with other EMA offices

Meetings → SME briefing meetings

Example of topics addressed

- SME definition, SME incentives and translation assistance;
- Scientific advice: how/when to apply?
- Regulatory strategy (e.g. eligibility to centralised procedure, legal basis, data protections and exclusivities);
- Packaging and labelling requirements.

2016 – 2020 (Veterinary and Human)

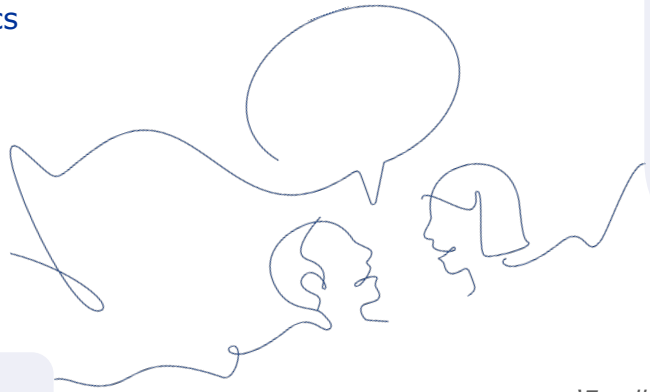
943 Direct assistance by phone, email or teleconference

66 SME briefing meetings

Breakdown for V and H/V companies:
45/943 (5%) direct assistance
3/66 (5%) SME BM

SME briefing meetings

- Platform for early dialogue with SMEs
- Discuss the regulatory strategy of a medicinal product development
- Navigate the range of procedures and incentives available
- Multidisciplinary EMA group
- Veterinary and human topics
- Free of charge



Topics covered

- Scientific advice (quality, non-clinical, clinical) including procedural and types of advice available
- Regulatory and procedural aspects
- Access to SME incentives
- Pre/post-licensing evidence generation

Stage of development

Majority at early stage.

'Feedback from companies shows high level of satisfaction'

Fee incentives for SMEs

Fee incentives

Full detail on fee incentives is available here

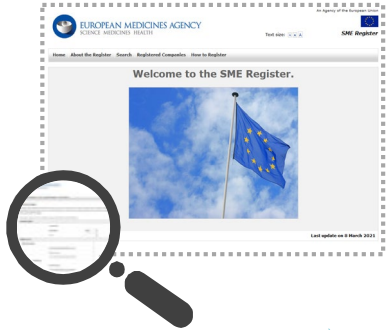
- SME incentives provided by SME Regulation are maintained.
- New Veterinary Medicinal Products Regulation related information to be set out in revisions of EMA Explanatory notes on fees.

Other SME incentives

Training, regulatory awareness and engaging

Training & awareness
Facilitating access to regulatory information

- EMA SME Info days
- SME newsletters
- Mailings / announcements
- SME user guide



- SME Register
  - *Increase information available on SMEs*
  - *Facilitate and promote interaction, partnering and networking between SMEs*
  - *Provide a source of information for EU institutions, agencies and Member States*

Engage
with EU bodies and industry stakeholders

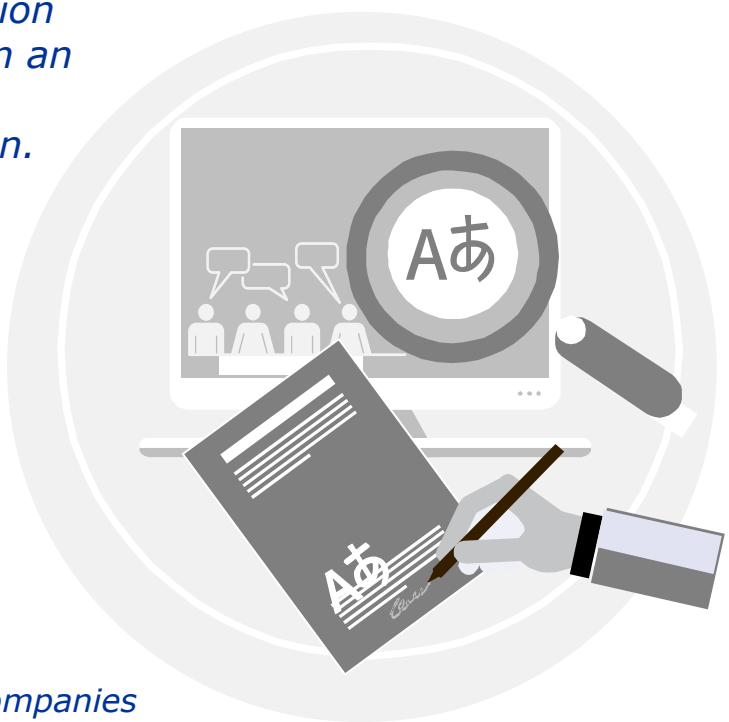
- Participation to conferences and events

Product information translation

Assistance with translations of the product information documents submitted in an initial marketing authorisation application.

23 *Product translations (2020 – V&H)*

At no cost to applicant

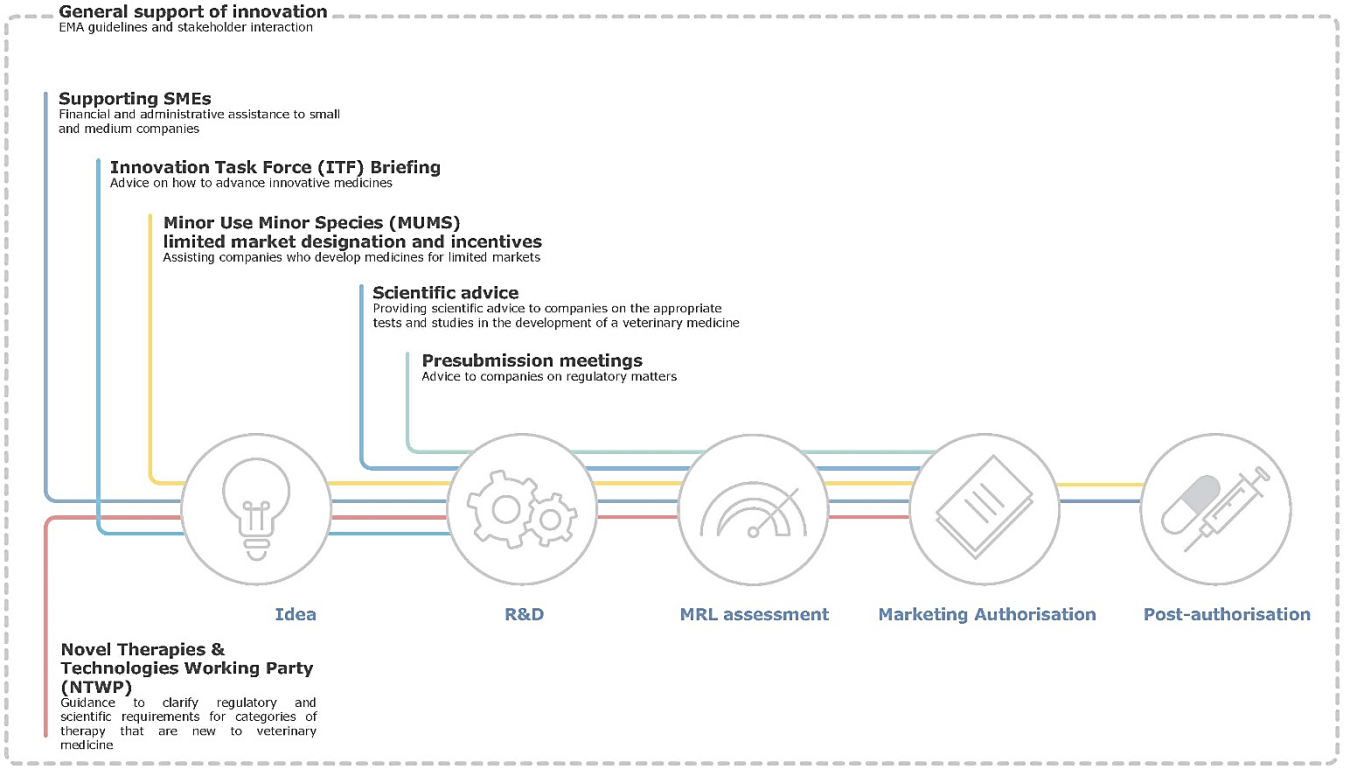


→ *Important incentive for companies in terms of workload and money*

"At time of opinion, EMA will provide translations of product information required to grant an EU marketing authorisation. Translation into EU official languages will be provided free of charge by the Agency."

2. Support to innovation

Support to innovation and opportunities to interact with EMA



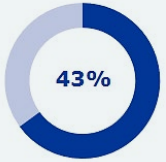
Early support to innovation

Innovation task force (ITF)

- Multidisciplinary group, works in co-operation with EMA's working parties
- Scientific, legal and regulatory aspects competences
- Forum for early dialogue with applicants on innovative aspects of medicine development
- Emerging therapies, novel technologies and borderline products

EU Innovation Network

- Strengthened cooperation between Innovation Offices and EMA
- Make the regulatory support for medicines developers that is available at national and EU levels more visible and attractive to innovators



9 of 21 **ITF briefing meetings**

2016-2020:

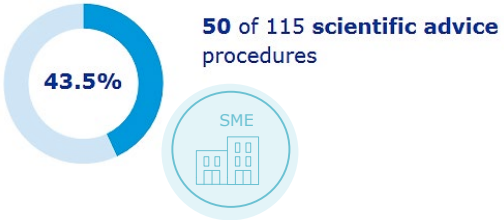
21 *ITF briefing meetings for veterinary products*

9 *for SME (43%)*

Scientific Advice

- Scientific advice can be provided on ANY scientific question ⇔ quality, non-clinical and clinical
- At any time point of the development (early advice with subsequent follow-up is recommended)
- Advice on eligibility of the proposed development for a conditional approval/under exceptional circumstances

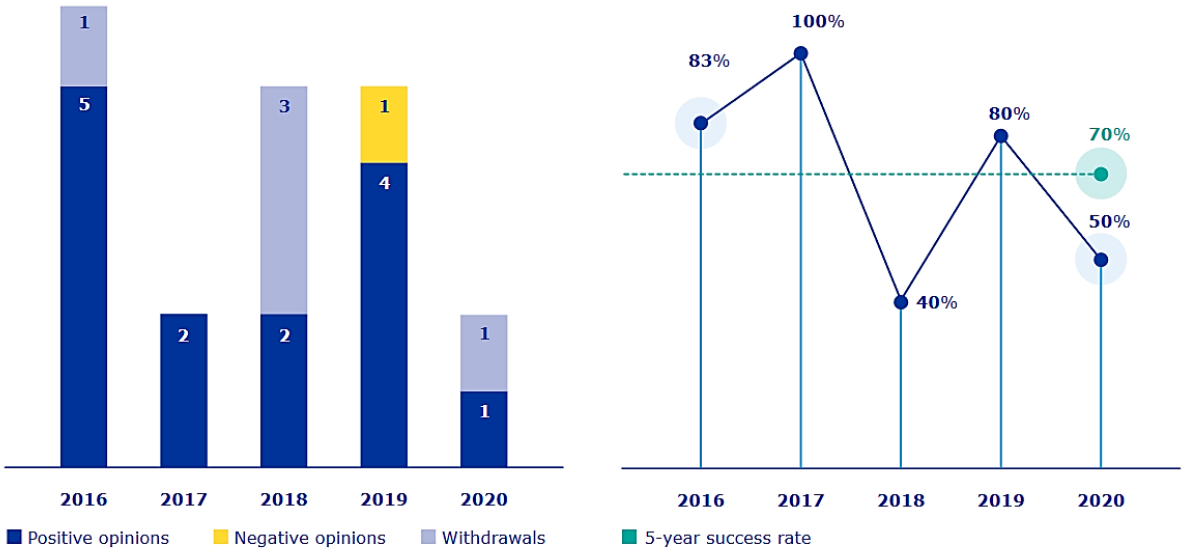
➔ **Maximise the chances of success at the time of MAA**



50 of 115 **scientific advice** procedures

Experience with the centralised procedure over the last 5 years

MAA outcomes for veterinary medicines and success rate



Positive opinions for SMEs

43% of products are **Minor-use/ Minor species products**

43% of products received **scientific advice** prior to filing

43% of products were **new active substances**

50% of **full applications** (versus 37,5% in 10-year report)

3. Conclusion

Specific support

- Qualify as SME to benefit from SME incentives.
- Specific fee incentives for SMEs
- Regulatory assistance to SMEs including SME briefing meeting

Look for guidance

- European Public Assessment Reports are useful source of information.
- Consult available guidance (procedural and scientific) and SME User Guide.

Come early and come often

- Make use of available support (ITF, EU innovation network, scientific advice…)
- Importance of early regulatory and scientific advice to minimising the most frequent hurdles, especially on quality aspects.
- Early pre-submission dialogue in run up to MAA filing.
- Discuss pre- and post-licensing evidence generation plans for approval and access.

Any questions?

Further information

clement.provansal@ema.europa.eu
SME@ema.europa.eu

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
Telephone +31 (0)88 781 6000
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