EMA
EUROPEAN MEDICINES AGENCY

How EMA supports SMEs

EMA Veterinary Innovation Day

Thomas Ballotti
SME office - Regulatory Science and Innovation Task force

14 March 2025

140 medicinal products for Human use from SMEs approved by EMA in the last 20 years

Close to 40 medicinal products for veterinary use from SMEs approved by EMA in the last 20 years

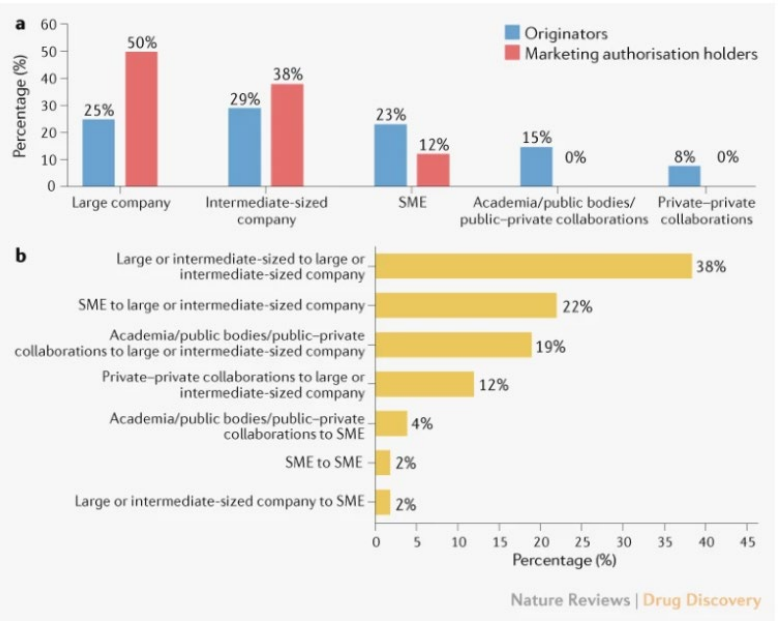


Fig. 1 | **Sourcing of pharmaceutical innovation: 2010–2019. a** | Originator and marketing authorisation holder for approved new and innovative medicines, divided according to organization type. **b** | Direction of product transfers between organization types during development. SMEs, small and medium-sized enterprises.

Large majority marketed by large or intermediate sized companies

SMEs and academia at the origin of innovation

EMA SME Office

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

- **Dedicated contact point**
- Assistance to SMEs
  Regulatory, administrative and procedural support
- Facilitates communication with SMEs
- Engage with EU bodies and industry stakeholders

Support to SMEs

SME status assignment
Upon request of the applicant

Regulatory assistance

SME briefing meeting
Early dialogue for regulatory strategy

Fee incentives
(scientific advice, inspections…)

Translation assistance for the product information in all EU languages

Training and awareness
via info days, SME newsletters and mailings targeted at SMEs

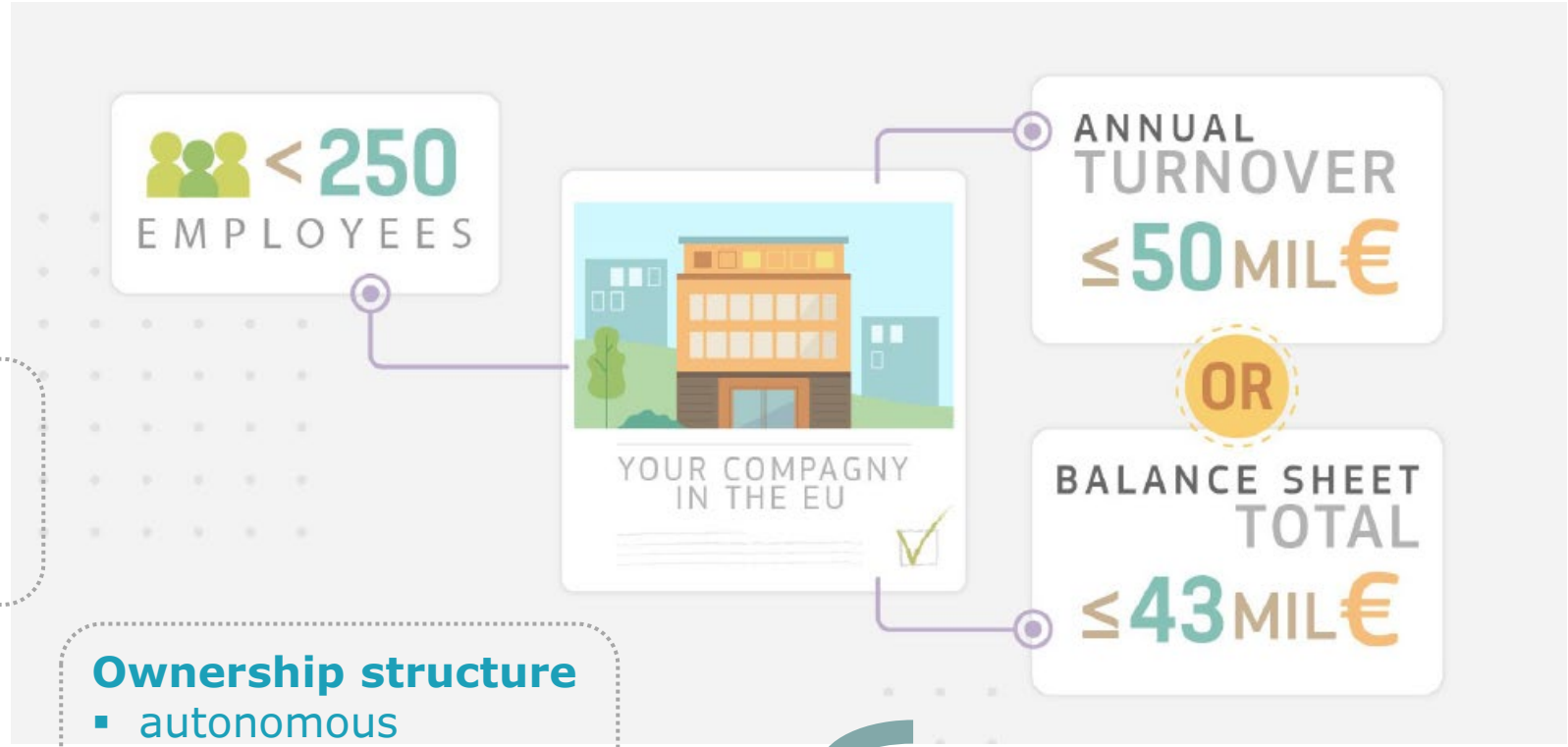
Assignment of SME status

EU SME Definition - Commission recommendation 2003/361/EC

Size
- micro,
- small,
- medium-sized

SME thresholds

Size and ownership structure



Ownership structure
- autonomous
- partner
- linked

[How to apply]

Regulatory assistance and SME briefing meetings

SME@ema.europa.eu

SME Helpline :
+31 (0)88 781 8787

Response by phone or email

- SME definition and incentives
- Procedural questions:

- *How/When to apply for scientific advice?*
- *What are the latest guidelines to consider?*
- *Is my product eligible for the centralised procedure?*
- *What will be the legal basis for my application?*

SME briefing meeting

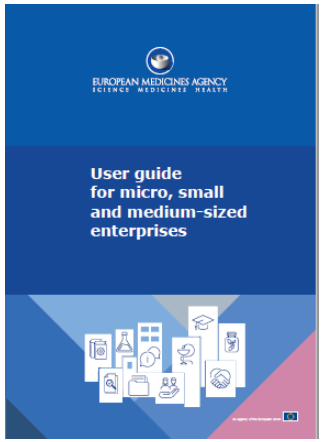
- Discussion on **full regulatory strategy** for one or several products

- *Platform for early and informal dialogue*
- *Interdisciplinary EMA team*
- *90 minutes, free of charge*
- *Generally, two months after request*

Training and awareness

Training and awareness
Facilitating access to regulatory and scientific information

SME user guide



Info days

SME newsletter, mailings

Subscribe

Engage
with **EU** bodies and **industry stakeholders**

Participation to conferences

TOPRA | BERLIN Symposium 2025

EUROPEAN INNOVATION COUNCIL SUMMIT 25

BIO-EUROPE SPRING®

SME Register

Translation assistance

- EMA provides **free-of-charge** translations of the product information into all EU languages for EU marketing authorisations (excluding Icelandic and Norwegian).
- For any practical question during the procedure: **SME@ema.europa.eu**

During MAA

SME Office send procedural details to the applicant

At opinion

- English PI sent to the **EU Translation Centre**
- **Timetable** sent to the applicant with the opinion

National competent authorities **check the quality** of the translations

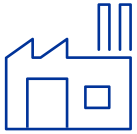
European Commission Decision

ONLY FOR

- ***INITIAL*** **MARKETING AUTHORISATION**
- ***CENTRALISED*** **PROCEDURE**

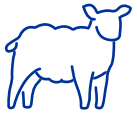
Fee incentives

Scientific advice : 90% fee reduction



Inspections (pre- and post-authorisation): 90% fee reduction

Marketing authorisation application: fee deferral until the outcome



Maximum residue limits (*establishment, extension, modification)*: 90% fee reduction

Annual fee: 100% fee reduction

Post-authorisation procedures: 100% fee reduction for micro-sized enterprises, 40% fee reduction for small or medium-sized enterprises

New fee regulation (NFR) effective from 1 January 2025

- All current **provisions in terms of SME fee incentives still apply.**
- **SME status incentives: SMEs must hold a valid SME status with EMA or have submitted the renewal of their SME status** (before its expiry) by the *'applicable fee level date*' of the service/procedure, indicated in the Appendix to the NFR working arrangements. For scientific advice and marketing authorisation, this date is the date of submission of an application for the procedure.
- **Pre-payment for scientific advice:** EMA will provide scientific advice only **after full payment** of the invoice.
- **Annual fees:** for annual fees of CAPs, the 'applicable fee level date' is **1 January**.

Check the veterinary Q&A

General fee enquiries: NFR@ema.europa.eu

SME specific questions: SME@ema.europa.eu

The EU Biotech & Biomanufacturing Hub is live!

- Supports companies, particularly **start-ups and SMEs,** in bringing innovative products to the EU market and increase their competitiveness.
- Helps **identify support at EU level**.
- Easy and accessible information on the relevant **EU legislation, financing opportunities** and **business support networks**.

Find out more by scanning the QR code

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EUROPEAN MEDICINES AGENCY

Your Europe

2005-2025: 20 years supporting SMEs

17 October 2025

Stakeholders' roundtable *with representatives from industry associations, the European Commission, the European Medicines Regulatory Network, public and private investors and life science incubators.*

- Highlight **achievements** of the SME regulation and its impact on SMEs
- Present **EU policy initiatives** supporting SMEs
- Discuss about **future opportunities and challenges**

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SCIENCE MEDICINES HEALTH

Thank you

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