

2024 SME office annual report

The SME Office was set up to address the particular needs of smaller companies



Highlights of 2024

- Increased success rates for marketing authorisation applications for human and veterinary medicines.
- Greater figures of SMEs in the veterinary medicines sector registered with EMA.
- Higher figures of regulatory assistance provided by the SME Office.
- Increased support to innovative developments through Innovation Task Force (ITF) briefing meetings.
- Higher figures of PRIME designations and uptake of scientific advice for orphan designated medicines.
- Continued training & education of SMEs including EIC-funded beneficiaries.

Support to SMEs

The Office has dedicated personnel who can help SMEs by:

- Responding to regulatory, procedural and administrative enquiries
- Setting up briefing meetings to discuss their regulatory strategy

SMEs receive help on how to navigate the array of services available at EMA, support in identifying the most relevant guidance, and advice on regulatory strategy for a product development or authorisation.

Regulatory assistance



246 Direct assistance by phone, email or teleconference

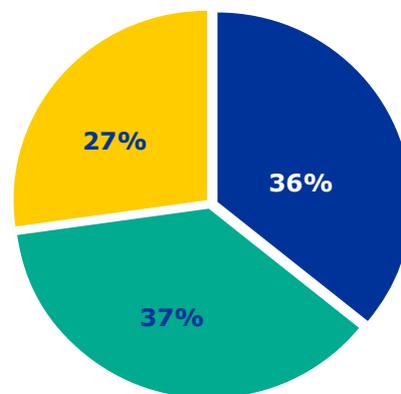


3 Briefing meetings on regulatory strategy

SME in numbers



1896 SMEs registered with EMA at the end of 2024



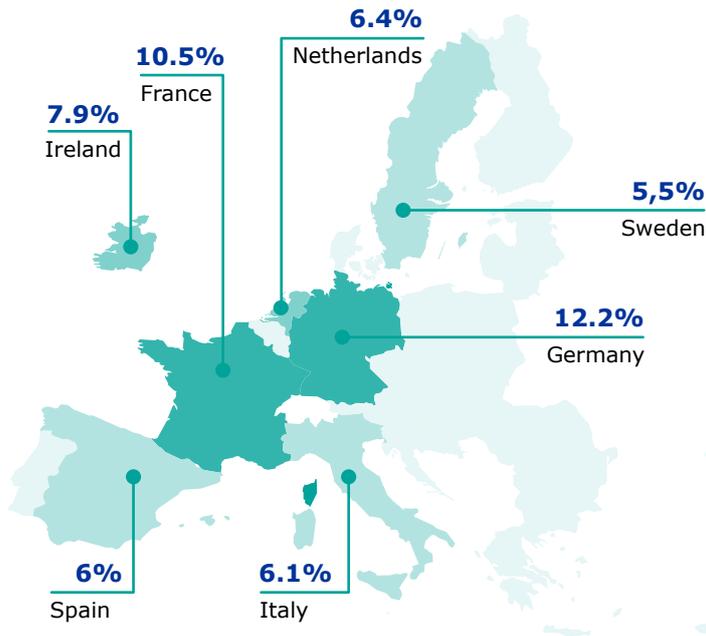
Micro-sized
Headcount <10; annual turnover or balance sheet total ≤€2 million

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

Location

Member States with >5% of registered SMEs



Non-EU based SMEs accessing incentives through EU SMEs service providers

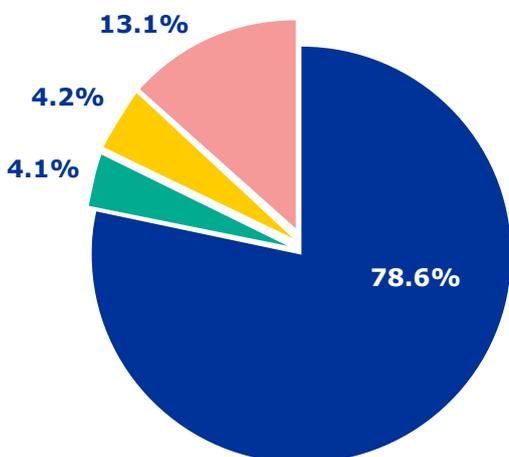
United States of America: 9.1% of registered SMEs

Other countries <5%:

Australia, Canada, China, Hong-Kong, Israel, Japan, Singapore, South Korea, Switzerland, Taiwan, United Kingdom

Company activity

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

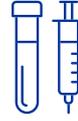


Profile



12.5% Academic spin-offs

6% SMEs incorporated over the last three years



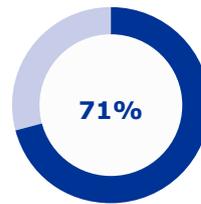
79.8% of companies declared activities in the pharmaceutical sector
17.4% in the pharmaceutical and medical devices sectors
2.8% in the medical devices sector



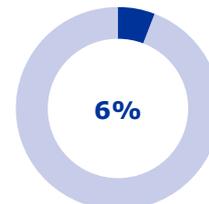
59% of companies operating in the pharmaceutical sector have products at development stage

SMEs pipelines and portfolios

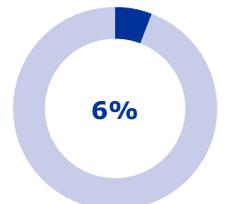
Of registered SMEs:



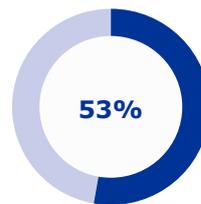
Therapeutic products



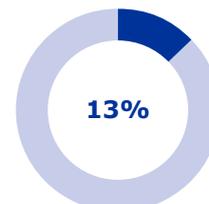
Diagnostic products



Vaccines



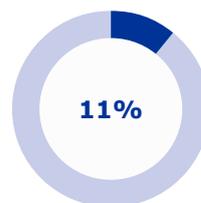
Chemical entity-based medicines



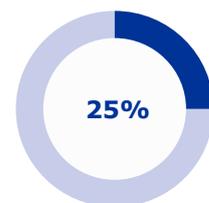
Biologics



Advanced therapy medicinal products



Paediatric medicines



Orphan medicines



Generics

Scientific advice

29%

182 out of 625 requests from SMEs

Protocol assistance

39%

51 out of 131 requests from SMEs

Scientific advice for PRIME products

14%

6 out of 42 requests from SMEs

Qualification of novel methodologies

36%

5 out of 14 requests from SMEs

Veterinary scientific advice

26%

7 out of 27 requests from SMEs



Innovation Task Force (ITF)

16 out of **34** briefing meetings with ITF from SMEs:

14 on human medicines
2 on veterinary medicines



PRIME

6 out of **14** PRIME positive eligibility recommendations for SMEs



Advanced therapies

15 out of **39** recommendations for advanced therapy classification for SMEs

1 ATMP certification

Contact Us

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Human medicines

87.5% success rate



10 initial submissions

7 positive opinions of which

2 new active substances,

1 orphan medicine

1 authorisation under exceptional circumstances

Therapeutic areas: oncology, endocrinology, pneumology/allergology, ophthalmology, cardiovascular diseases

Significant therapeutic advances:

- **Eurneffy** (epinephrine): first emergency treatment against allergic reactions administered as a nasal spray, not as an injection
- **Emcitate** (tiratricol): first treatment for peripheral thyrotoxicosis in patients with Allan-Herndon-Dudley syndrome, an ultra-rare, chronic and severely debilitating disease caused by mutations in the gene coding for the thyroid hormone transporter MCT8 protein

1 negative opinion

0 withdrawn application

Veterinary medicines

100% success rate



6 initial submissions

3 positive opinions

0 negative opinion

0 withdrawn application

Engagement with stakeholders and partners

- Redesigned newsletter highlighting news, documents and activities in the EU regulatory environment
- Training & education of SMEs (relaunch of in-person SME infodays; training on EMA's New Fee Regulation)
- Continued collaboration with the European Innovation Council and SMEs Executive Agency (support and training of EIC beneficiaries, participation to EIC Summit 2024)