

2022 SME office annual report

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



Highlights of 2022

- Higher figure of SMEs registered with EMA
- SME registered in 2022 more active in the development of biologics
- Increased regulatory assistance, PRIME eligibility recommendations and uptake of scientific advice for human and veterinary medicines developments
- Positive opinions for human medicines intended for Hutchinson-Gilford progeria syndrome/processing-deficient progeroid laminopathies, multiple myeloma, primary immunoglobulin A nephropathy and hepatitis B (vaccine)
- Increased figures of dossiers submissions for human and veterinary medicines
- EMA engagement with EU executive agencies supporting SMEs and academic researchers

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



200 Direct assistance by phone, email or teleconference

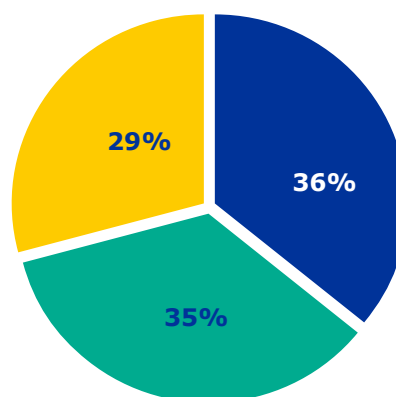


7 Briefing meetings on regulatory strategy

SME in numbers



1922 SMEs registered with EMA at the end of 2022



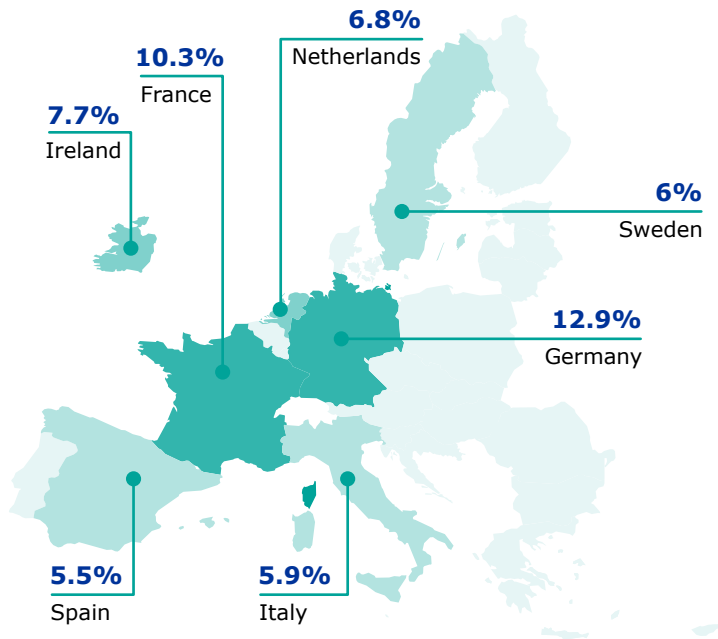
Micro-sized
Headcount <10; annual turnover or balance sheet total ≤€2 million

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

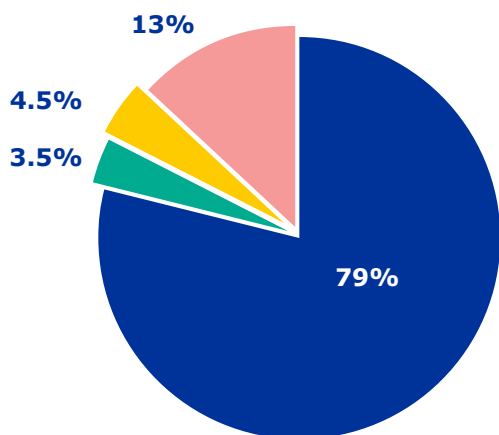
United States of America 8.4% of registered SMEs

Other countries <5%

Australia, Canada, China, 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



11% Academic spin-offs

11% SMEs incorporated over the last three years:
39% newly created entities
61% new subsidiaries



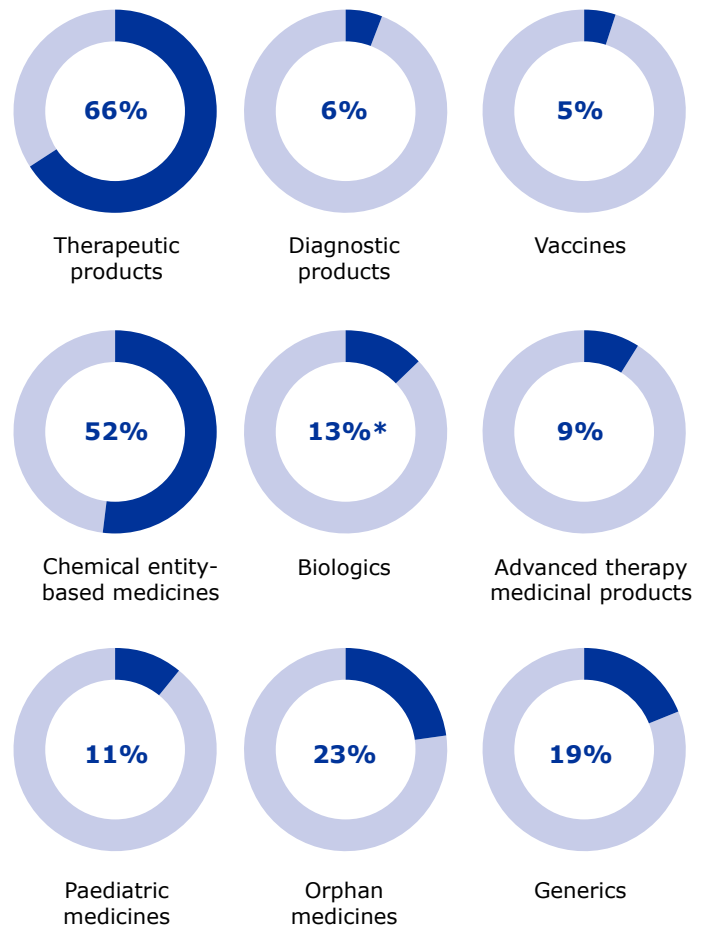
78% of companies declared activities in the pharmaceutical sector
19% in the pharmaceutical and medical devices sectors
3% in the medical devices sector



66% of companies operating in the pharmaceutical sector have products at development stage

SMEs pipelines and portfolios

Of registered SMEs:



* 21% for SMEs registered in 2022

Research and development support

Scientific advice

22%

144 out of 657 requests from SMEs

Protocol assistance

29%

37 out of 129 requests from SMEs

Scientific advice for PRIME products

19%

7 out of 37 requests from SMEs

COVID-19

8.5%

4 out of 47 requests from SMEs

Qualification of novel methodologies

43%

9 out of 21 requests from SMEs

Veterinary scientific advice

31%

12 out of 39 requests from SMEs



Innovation Task Force (ITF)

8 out of **38** briefing meetings with **ITF** from SMEs:

7 on human medicines
1 on veterinary medicine



PRIME

7 out of **13** PRIME positive eligibility recommendations from SMEs



Advanced therapies

21 out of **46** recommendations for **advanced therapy classification** from SMEs

Marketing authorisation applications

Human medicines

42% success rate



13 initial submissions of which 5 for new active substances

5 positive opinions of which 1 for new active substances and 2 for orphan medicines (55% less than in 2021)

4 negative opinions

3 withdrawn applications

Grounds for refusal related to deficiencies in the quality and clinical documentation.

Veterinary medicines



3 initial submissions

2 positive opinions, of which 1 for a new active substance

0 negative opinion

0 withdrawn application

Engagement with stakeholders and partners

- Newsletters highlighting news, documents and activities in the EU regulatory environment
- Engagement with EU executive agencies (Research Executive Agency, European Innovation Council and SMEs Executive Agency) on the EU SME definition, innovation foresight and training of EU-funded SMEs and academic researchers

Contact Us

[SME Office](#)

Tel: +31 (0)88 781 8787

E-mail: SME@ema.europa.eu

