2023

SME office annual report

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

Highlights of 2023

- Sustained high figures of SMEs registered with EMA and regulatory assistance provided by the SME Office
- Increased number of SME briefing meetings
- Continued uptake of Scientific Advice and Protocol Assistance by SMEs, including on PRIME designated products
- Increased success rate for marketing authorisation applications for human medicines
- Strengthened collaboration with the European Innovation Council and SMEs Executive Agency
- Major update of the SME user guide

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.

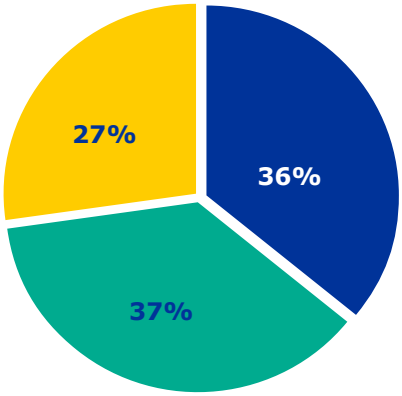
Regulatory assistance

220 Direct assistance by phone, email or teleconference

10 Briefing meetings on regulatory strategy of a medicinal product development

SME in numbers

1925 SMEs registered with EMA at the end of 2023



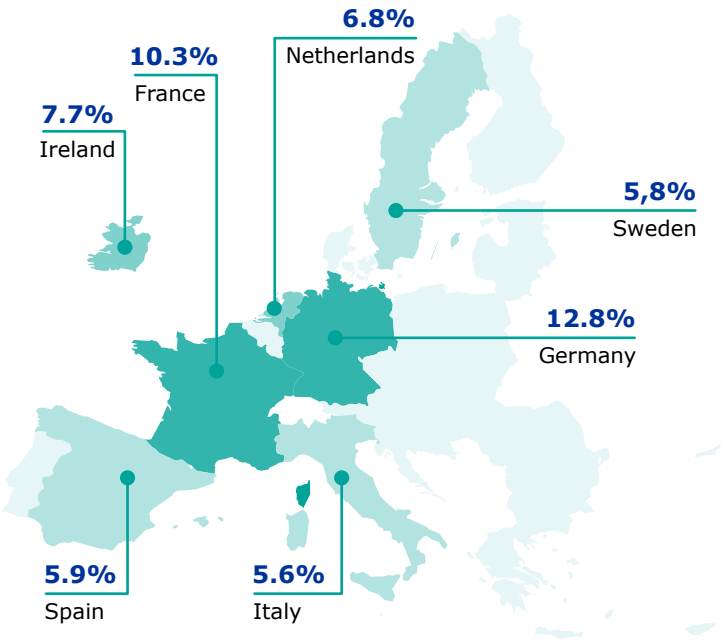
Micro-sized
Headcount <10; annual turnover or balance sheet total ≤€2 million

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

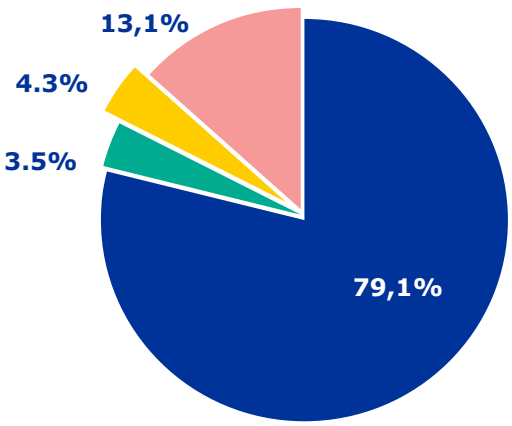


Non-EU based SMEs accessing incentives through EU SMEs service providers
United States of America 8.7% of registered SMEs

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

12% Academic spin-offs

8% SMEs incorporated over the last three years

79% of companies declared activities in the pharmaceutical sector

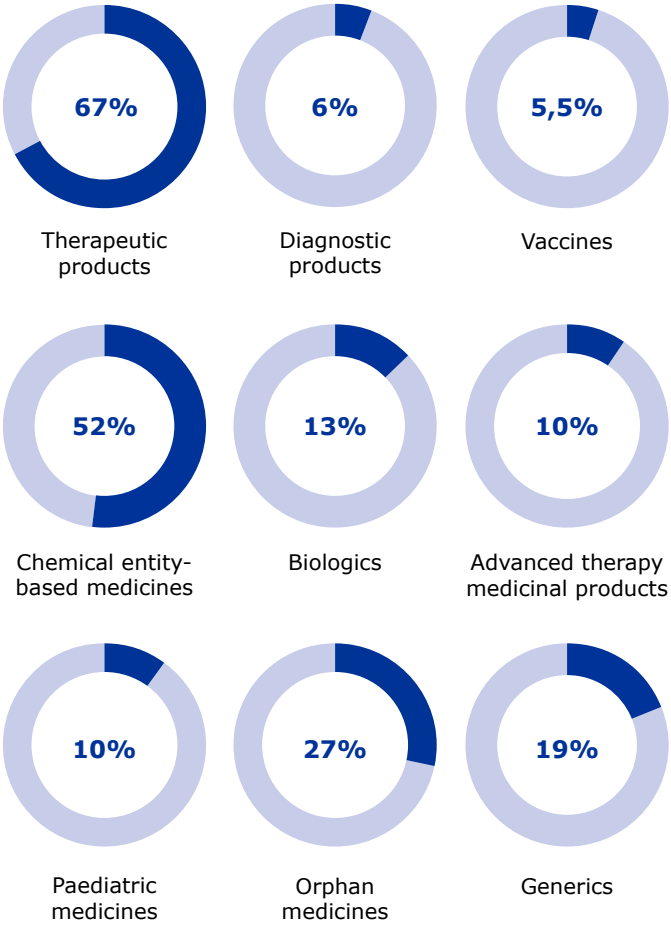
18% in the pharmaceutical and medical devices sectors

3% in the medical devices sector

67% of companies operating in the pharmaceutical sector have products at development stage

SMEs pipelines and portfolios

Of registered SMEs:



Research and development support

Scientific advice

28%

154 out of 545 requests from SMEs

Protocol assistance

33%

39 out of 119 requests from SMEs

Scientific advice for PRIME products

29%

11 out of 38 requests from SMEs

Qualification of novel methodologies

39%

7 out of 18 requests from SMEs

Veterinary scientific advice

25%

6 out of 24 requests from SMEs

Innovation Task Force (ITF)

10 out of **34 briefing meetings with ITF** from SMEs:
9 on human medicines
1 on veterinary medicine

PRIME

7 out of **18 PRIME positive** eligibility recommendations from SMEs

Advanced therapies

19 out of **52** recommendations for **advanced therapy classification for SMEs**

1 ATMP certification

Marketing authorisation applications

Human medicines

75% success rate

11 initial submissions

9 positive opinions of which
3 for new active substances,
3 for orphan medicines

Therapeutic areas: 4 in neurology and 3 in cardiovascular diseases

Significant therapeutic advances:

- **Pedmarqsi** for the prevention of ototoxicity induced by cisplatin chemotherapy in children
- **Aqumeldi** for the treatment of heart failure in children
- **Loargys** for the treatment of hyperargininaemia

1 negative opinion

2 withdrawn applications

Veterinary medicines

4 initial submissions

1 positive opinion

0 negative opinion

0 withdrawn application

Engagement with stakeholders and partners

- Newsletters highlighting news, documents and activities in the EU regulatory environment
- Major update of the SME user guide on the veterinary, clinical trials and medical devices regulations
- Regulatory and scientific conferences on RNA-based medicines and the new pharma legislation
- Collaboration with the European Innovation Council (support and training of beneficiaries, first EIC EMA Infoday for SMEs and academic researchers)

Contact Us

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