

2021 SME office annual report

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



Highlights of 2021

- Continued uptake of scientific advice by SMEs particularly for orphan drugs, PRIME designated medicines and qualification advice of novel methodologies
- Continued advice on Covid-19 developments by SMEs
- Significant increase in advanced therapies classifications
- Lower figures of dossiers submissions and positive opinions for human medicines
- Training, education and onboarding of SMEs on Clinical Trials Information System (CTIS) and veterinary legislation

Support to SMEs

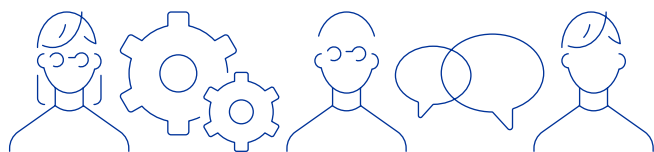
The Office has dedicated personnel who can help SMEs by:

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

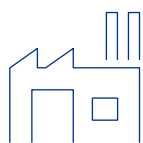
SMEs receive help on how to navigate the array of services available at EMA, support in identifying the most relevant guidance, and advice on regulatory strategy for a product development or authorisation.

Communication & Engagement

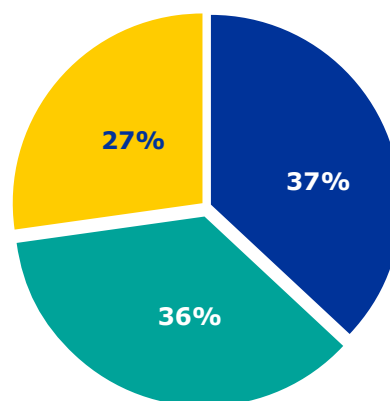
- Newsletters highlighting news, documents and activities in the EU regulatory environment
- Support to CTIS and veterinary legislation preparedness (training and education events, assistance to SMEs, targeted communications)



SME in numbers

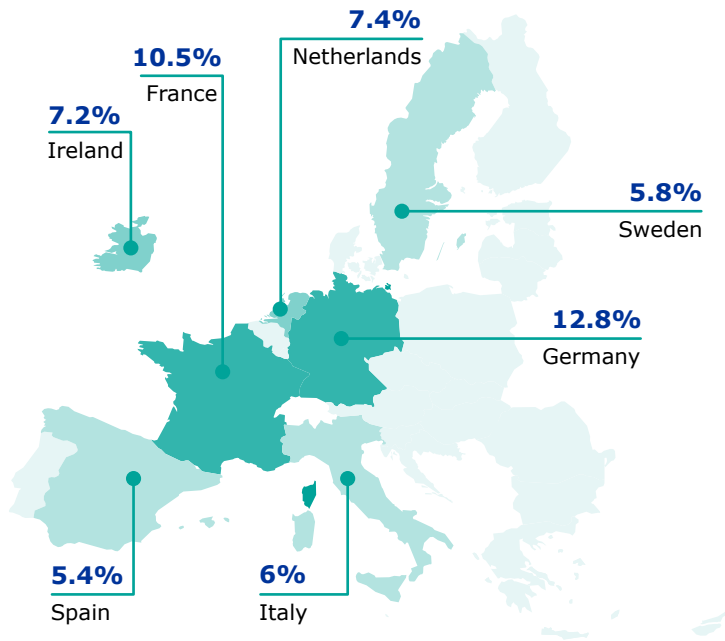


1780 SMEs registered with EMA at the end of 2021



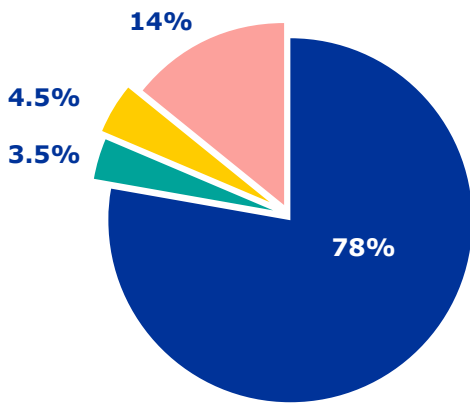
- Micro-sized**
Headcount <10; annual turnover or balance sheet total ≤€2 million
- Small-sized**
Headcount <50; annual turnover or balance sheet total ≤€10 million
- Medium-sized**
Headcount <250; annual turnover ≤€50 million or balance sheet total ≤€43 million

Member States with >5% of EMA-registered SMEs



Company activity

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



Regulatory assistance



175 Direct assistance by phone, email or teleconference



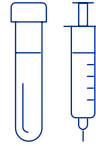
5 Briefing meetings on regulatory strategy

Profile



11% Academic spin-offs

13% SMEs incorporated over the last three years:
31% newly created entities
69% new subsidiaries



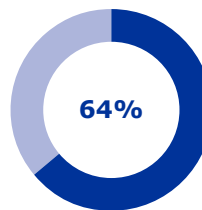
77% of companies declared activities in the pharmaceutical sector
20% in the pharmaceutical and medical devices sectors
3% in the medical devices sector



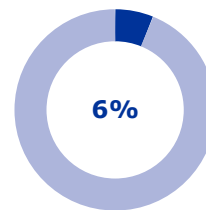
64% of companies operating in the pharmaceutical sector have products at development stage

SMEs pipelines and portfolios

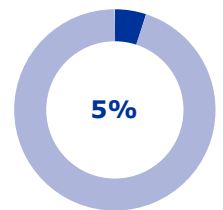
Of registered SMEs:



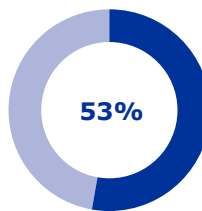
Therapeutic products



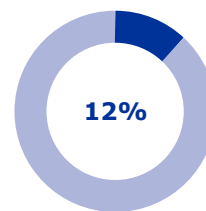
Diagnostic products



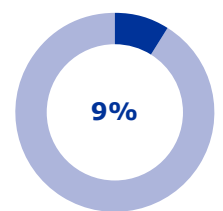
Vaccines



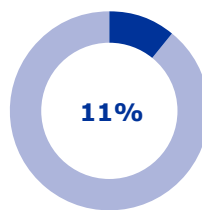
Chemical entities



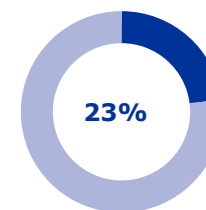
Biological substances



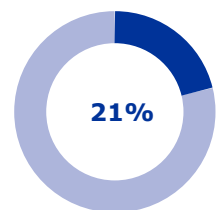
Advanced therapy medicinal products



Paediatric medicines



Orphan medicines



Generics

Research and development support

Scientific advice

19%

118 out of 611 requests from SMEs

Protocol assistance

36%

58 out of 163 requests from SMEs

Scientific advice for PRIME products

25%

15 out of 59 requests from SMEs

COVID-19

11%

9 out of 79 requests from SMEs

Qualification of novel methodologies

48%

12 out of 25 requests from SMEs

Veterinary scientific advice

26%

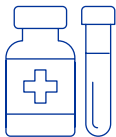
6 out of 23 requests from SMEs



Innovation Task Force (ITF)

11 briefing meetings with ITF

10 on human medicines
1 on veterinary medicine



PRIME

3 out of 11 PRIME positive eligibility recommendations from SMEs



Advanced therapies

26 recommendations for advanced therapy classification

Marketing authorisation applications



73%

Success rate

Human medicines



10 initial submissions of which
4 for new active substances

11 positive opinions of which
8 for new active substances
4 orphan medicines

0 negative opinion

4 withdrawn applications

Veterinary medicines



1 initial submission

2 positive opinions for new active substances

0 negative opinion

0 withdrawn application

Useful links

[SME Office](#)

[Pre-authorisation](#) (Human medicines)

[Pre-authorisation](#) (Veterinary medicines)

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