SME office

Annual report 2019

The SME Office was set up within the European Medicines Agency to address the particular needs of smaller companies

Highlights of 2019

- Highest figure of EMA registered SMEs since the launch of the SME Regulation
- Continued high levels of regulatory support provided to SMEs
- Uptake of scientific advice remains high, in particular qualifications of novel methodologies, innovative developments and veterinary medicines
- Lower number of positive opinions for human medicines
- Overall higher success rate at stage of marketing authorisation and shorter review times
- Higher number of dossiers submissions, with more than half for orphan medicines
- Increase in numbers of positive opinions for veterinary medicines

Support to SMEs

The Office has dedicated personnel who can help SMEs by:

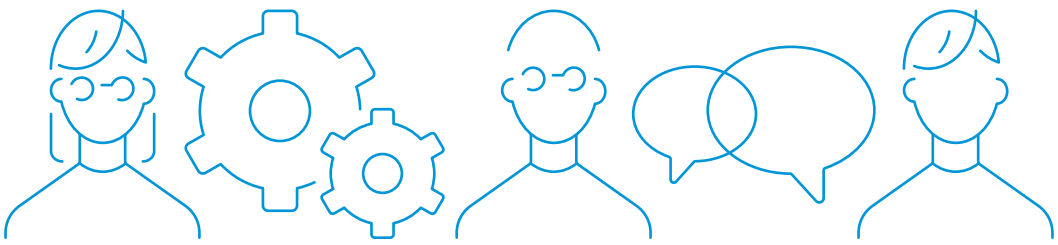
- Responding to regulatory, procedural and administrative enquiries
- Setting up briefing meetings to discuss their regulatory strategy

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

188 Direct assistance by phone, email or teleconference

7 Briefing meetings on regulatory strategy

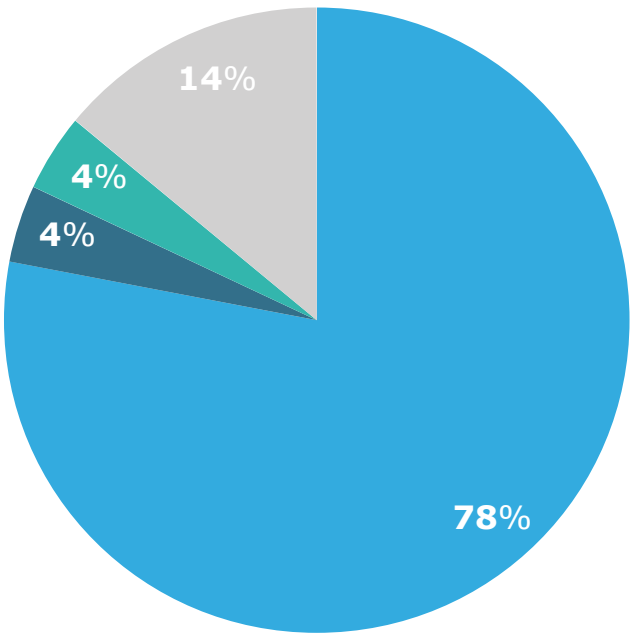


SMEs in numbers

1951

SMEs registered with EMA at the end of 2019

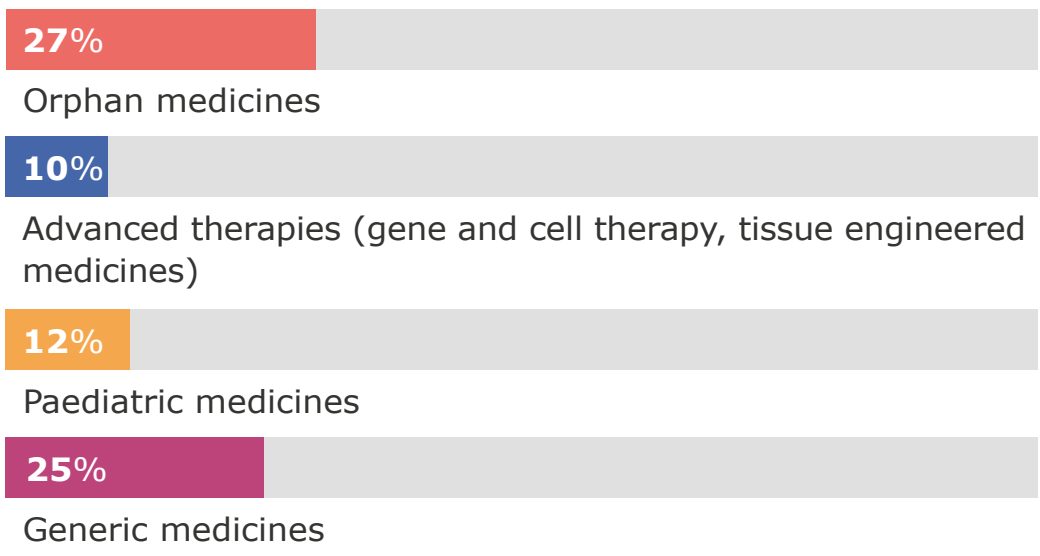
40%	34%	26%
Micro-sized (Headcount <10; annual turnover or balance sheet total ≤€2 mil)	Small-sized (Headcount <50; annual turnover or balance sheet total ≤€10 mil)	Medium-sized (Headcount <250; annual turnover ≤€50 mil or balance sheet total ≤€43 mil)



12% Academic spin-offs

12% SMEs incorporated over the last three years:
- 31% newly created entities
- 69% new subsidiaries

Out of 1951 SMEs registered, the product pipelines comprise:



SME office

Contact the SME Office at EMA
E-mail: sme@ema.europa.eu
Tel: +31(0)88 781 8787

Research and development support

549 requests for scientific advice

144, 26% from SMEs

125 requests for protocol assistance

41, 33% from SMEs

20 requests for parallel consultations with HTA

3, 15% from SMEs

16 requests for qualification of novel methodologies

11, 69% from SMEs

21 requests for scientific advice for veterinary medicines

14, 67% from SMEs

Innovation Task Force (ITF)

14 briefing meetings with the ITF
(13 human medicines/1 veterinary medicine)

PRIME

7 out of 16 PRIME positive eligibility recommendations from SMEs

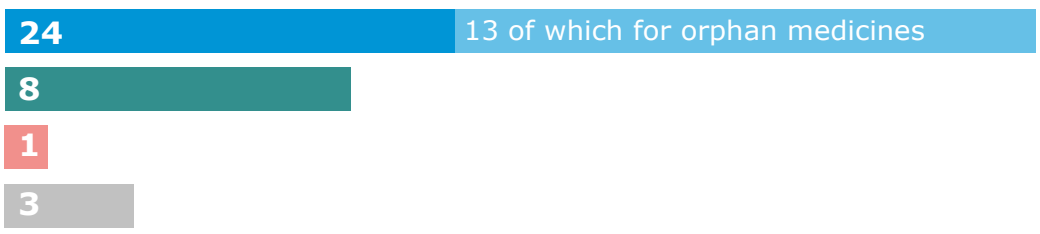
Advanced therapies

12 recommendations for advanced therapy classification
1 advanced therapy certification

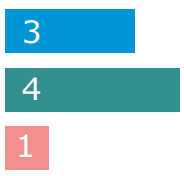
Marketing authorisation applications

Success rate 67%;
Average time to opinion 192 days;
Average company clock-stop 178 days.

Human medicines



Veterinary medicines



- Initial submissions
- Applications with a positive opinion from CHMP/CVMP
- Applications with a negative opinion from CHMP/CVMP
- Withdrawn applications

Communications and engagement

- Ongoing implementation of EMA's action plan for SMEs
- Newsletters highlighting news, documents and activities in the EU regulatory environment
- Support to Brexit preparedness (mailings and assistance to SMEs)

Useful links

SME Office

Pre-authorisation (human medicines)

Pre-authorisation (veterinary medicines)