SME office

Annual report 2018

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

Highlights of 2018

- 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 protocol assistance, parallel consultations with regulators and health technology assessment bodies, and qualifications of novel methodologies
- Two thirds of SMEs amongst sponsors receiving PRIME eligibility recommendations
- Highest number of positive opinions for human medicines and steady success rate
- Attendance at SME info day at record level
- Dedicated support to human and veterinary SMEs for Brexit preparedness

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

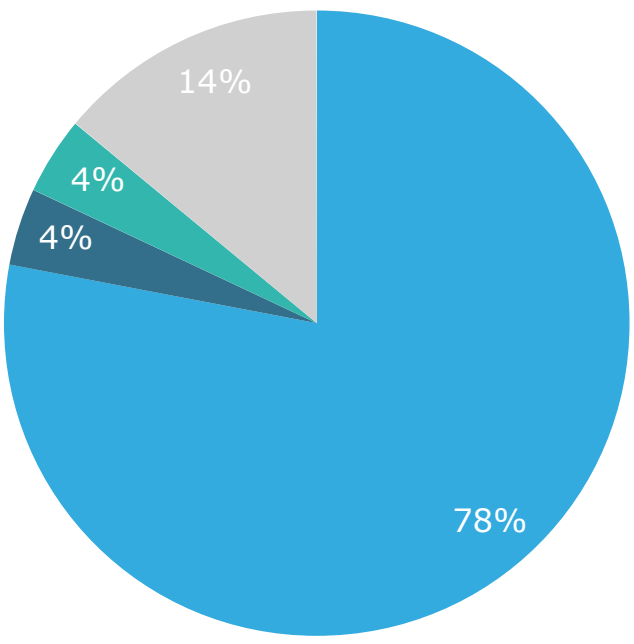
175 Direct assistance by phone, email or teleconference
19 Briefing meetings

SMEs in numbers

1922

SMEs registered with EMA at the end of 2018

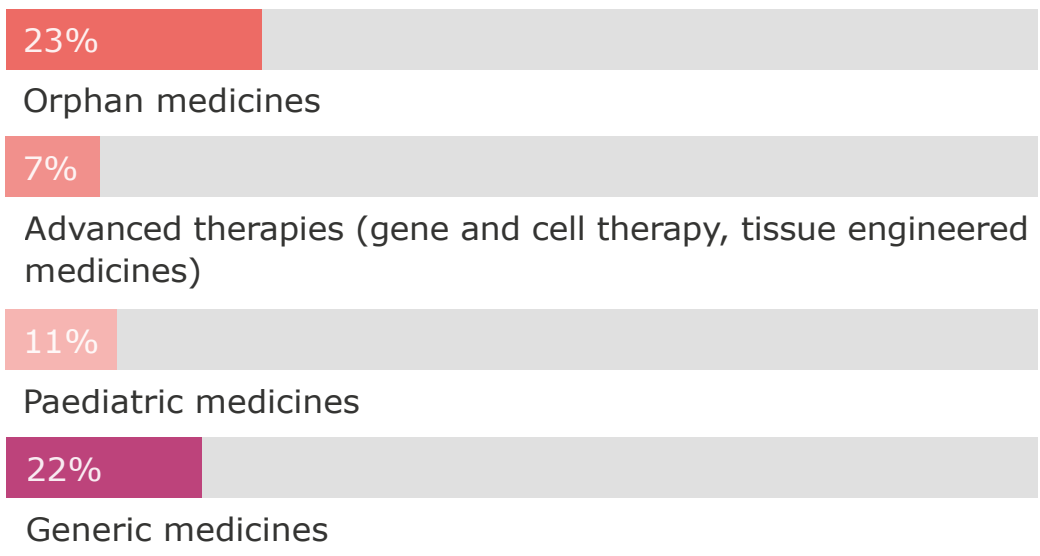
40%	35%	25%
Micro-sized (Headcount <10; annual turnover or balance sheet total ≤€2 mil)	Small-sized (Headcount <50; annual turnover or balance sheet total ≤€10 mil)	Medium-sized (Headcount <250; annual turnover ≤€50 mil or balance sheet total ≤€43 mil)



10% Academic spin-offs

10% SMEs incorporated over the last three years: 42% newly created entities; 58% new subsidiaries.

Out of 1922 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

634 requests for scientific advice and protocol assistance

198, 31% from SMEs

168 requests for protocol assistance

76, 45% from SMEs

27 requests for parallel consultations with HTA

8, 30% from SMEs

9 requests for qualification of novel methodologies

5, 56% from SMEs

25 requests for scientific advice for veterinary medicines

8, 32% from SMEs

Innovation Task Force (ITF)

9 briefing meetings with the ITF
(8 human medicines/1 veterinary medicine)

PRIME

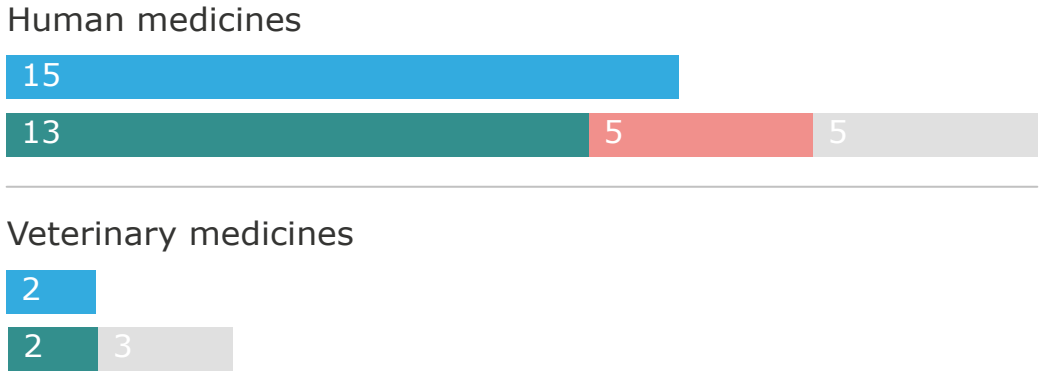
9 out of 14 PRIME eligibility
recommendations from SMEs

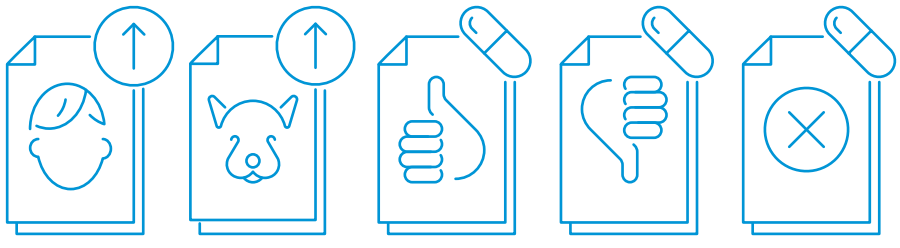
Advanced therapies

8 recommendations for advanced therapy classification
1 advanced therapy certification

Marketing authorisation applications

Success rate 57%; Average time to opinion 207 days.





- 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 plans for SMEs, advanced therapies and academia
- Quarterly newsletters highlighting news, documents and activities in the EU regulatory environment
- Support to Brexit preparedness (information sessions, mailings and assistance to SMEs)

SME Office

Pre-authorisation (human medicines)

Pre-authorisation (veterinary medicines)

Training

- Info day for micro-, small- and medium-sized enterprises: regulatory toolbox for medicines and combined devices developers (125 attendees on-site and 235 via webcast)
- 3 webinars on IRIS platform (new secure online portal for sponsors to submit applications for orphan medicinal product designation and to manage post-designation activities) (159 attendees)