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**

- **Sweden** (5.8%)
- **Germany** (12.8%)
- **Netherlands** (10.3%)
- **Ireland** (7.7%)
- **Spain** (5.9%)
- **Italy** (5.6%)

**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

- **Therapeutic products** 79.1%
- **Diagnostic products** 4.3%
- **Vaccines** 3.5%

- **Chemical entity-based medicines** 52%
- **Biologics** 13%
- **Advanced therapy medicinal products** 10%

- **Paediatric medicines** 10%
- **Orphan medicines** 27%
- **Generics** 19%

### 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

#### 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**

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#### Scientific advice
- 28% success rate
- 154 out of 545 requests from SMEs

#### Protocol assistance
- 33% success rate
- 39 out of 119 requests from SMEs

#### Scientific advice for PRIME products
- 29% success rate
- 11 out of 38 requests from SMEs

#### Qualification of novel methodologies
- 39% success rate
- 7 out of 18 requests from SMEs

#### Veterinary scientific advice
- 25% success rate
- 6 out of 24 requests from SMEs

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#### 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

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### Contact Us

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**Veterinary medicines**
- **4 initial submissions**
- **1 positive opinion**
- **0 negative opinion**
- **0 withdrawn applications**

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**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)