This report reviews the experience with the SME initiative on the 15-year anniversary of the SME Regulation and highlights achievements of EMA support to SMEs over 2016-2020. The SME Regulation was adopted in December 2005 to promote innovation and the development of new medicines for human and veterinary use by SMEs. Its main objective is to provide financial and administrative assistance to micro, small and medium-sized enterprises (SMEs) through a dedicated instrument, the SME Office, and address the needs of smaller companies in the pharmaceutical sector.

**Achievements**

- Gradual increase in the number of EMA registered SMEs with record levels reached in 2019-2020.
- Continued high levels of support to SMEs on regulatory, administrative and procedural matters and assistance for translations for marketing authorisation applications.
- Significant uptake of EMA’s PRIME scheme by SMEs.
- Continued significant use of development support tools by SMEs, including scientific advice, protocol assistance, Innovation Task Force briefing meetings for human and veterinary medicines.
- High interest from veterinary SMEs in scientific advice and Minor-use/Minor species policy.
- Increased number of positive opinions and success rate for marketing authorisation applications for human medicines developed by SMEs, with a majority for new active substances.
- Increased number of positive opinions for marketing authorisation applications for veterinary medicines developed by SMEs.
- Continued training and education of SMEs on the EU regulatory framework for pharmaceuticals.
- Importance and relevance of EMA’s SME regulation and its incentives acknowledged by SMEs and stakeholders with suggested measures identified on awareness, incentives, training and engagement.

**SMEs in numbers in 2020**

1904 SMEs registered with EMA at the end of 2020

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

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**Small-sized**
Headcount <50; annual turnover or balance sheet total ≤€10 million

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

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**Company activity**

- Human medicines: 15%
- Veterinary medicines: 4.5%
- Human and veterinary medicines: 3.5%
- Service providers and regulatory consultancies: 77%

* No significant change compared to 2016
At the end of 2020, the highest number of companies were based in Germany and France. Following UK’s withdrawal from the EU, an increase in SMEs registered in Ireland and the Netherlands was noted. The figure below shows Member States with more than 5% of EMA-registered SMEs.

**Location of EU-based SMEs**

- Germany: 12.9%
- France: 8.5%
- Netherlands: 6.5%
- Ireland: 6.8%
- Spain: 5.4%
- Italy: 5.3%
- Sweden: 5.1%
- Netherlands: 6.5%
- France: 8.5%

**Profile**

- **9.5% academic spin-offs**
- **12% SMEs incorporated in 2018–2020**
  - 31% newly created entities
  - 69% new subsidiaries
- **77.5% of companies declared activities in pharmaceutical products**
- **19.5% in pharmaceutical products and medical devices**
- **3% in medical devices**
- **64% of companies operating in the pharmaceutical sector have products at development stage**

**SME pipelines and portfolios**

- **Therapeutic products**: 65%
- **Diagnostic products**: 6%
- **Vaccines**: 5%
- **Chemical entities**: 51%
- **Biological products**: 12%
- **Advanced therapy medicinal products**: 8%
- **Paediatric medicines**: 10.5%
- **Orphan medicines**: 23%
- **Generics**: 21%

**SME Office support**

**Regulatory assistance**

- **2016 – 2020**
  - 943 Direct assistance by phone, email or teleconference
  - 66 SME briefing meetings

**Topics**

- SME DEFINITION AND INCENTIVES
- SCIENTIFIC ADVICE AND PROTOCOL ASSISTANCE
- PRIME DESIGNATION
- ORPHAN AND PAEDIATRIC REQUIREMENTS AND INCENTIVES
- REGULATORY STRATEGY
- DATA PROTECTIONS AND EXCLUSIVITIES
- PACKAGING AND LABELLING REQUIREMENTS
- CLINICAL TRIAL REQUIREMENTS

* No significant change compared to 2016
Support to innovation for SMEs

- 54 of 248 Innovation Task Force (ITF) briefing meetings (22%)
- 36 of 84 products granted PRIME designation (43%)
- 701 of 2728 finalised scientific advice procedures (26%)
- 307 of 717 finalised protocol assistance procedures (43%)
- 36 of 73 requests for qualification of novel methodologies (49%)
- 20 of 101 requests for parallel consultation with HTA bodies (20%)

Covid-19 developments

- 18 of 127 companies involved in Covid-19 scientific advice were SMEs (14%)

Marketing Authorisation Application (MAA) outcomes

- Positive opinions
  - 2016: 5
  - 2017: 12
  - 2018: 13
  - 2019: 3
  - 2020: 1
- Negative opinions
  - 2016: 1
  - 2017: 2
  - 2018: 2
  - 2019: 1
  - 2020: 8
- Withdrawals
  - 2016: 1
  - 2017: 1
  - 2018: 1
  - 2019: 1
  - 2020: 16

MAAs success rate

- 5-year success rate
  - 2016: 40%
  - 2017: 57%
  - 2018: 57%
  - 2019: 67%
  - 2020: 89%

7 Advanced Therapy Medicinal Products certifications finalised

An agency of the European Union
SMEs and pharmaceutical innovation

An EMA analysis showed that over 2016-2019:

- 11% of positive opinions for new medicines were from SMEs
- 22% of SMEs were at the source of new medicines developments
- Acquisitions of SME-originated new medicines by large or intermediate-sized companies represented 60% of the overall out-licensing activity

Highest number of positive opinions in 2020 (16; 8 orphan medicines)

Highest proportion of positive opinions by SMEs in 2020 (18% of all positive opinions)

Positive opinions for SMEs

- 7% of products received a conditional marketing authorisation
- 4% of products were authorised under exceptional circumstances
- 9% received an accelerated assessment (versus 3% in 10-year report)
- 39% of products were new active substances
- 24% were orphan designated products (versus 42% in 10-year report)
- 52% of products received scientific advice prior to filing (average number of advice per product: 2.5)
- 35% of generic or hybrid applications (versus 19% in 10-year report)
- 55% of full applications (versus 67% in 10-year report)

Type of products

- 79.5% medicines containing chemical entities
- 15% biological medicines
- 5.5% advanced therapy medicinal products

Most products authorised in oncology, alimentary tract and metabolism, central nervous system conditions and infectious diseases.

SMEs and pharmaceutical innovation

An agency of the European Union
Support to innovation for SMEs

- 50 of 115 scientific advice procedures (43.5%)
- 9 of 21 ITF briefing meetings (43%)
- 51 of 151 requests for classification under the Minor-use/Minor species policy (MUMS) (34%)

Positive opinions for SMEs

- 43% of products are Minor-use/Minor species products
- 43% of products received scientific advice prior to filing
- 43% of products were new active substances
- 50% of full applications (versus 37.5% in 10-year report)

MAA outcomes for veterinary medicines and success rate

- 5-year success rate: 83%, 80%, 70%, 50%
Training and education

The SME Office continued to address regulatory training and education needs of SMEs through info days, a revised EMA SME User Guide, SME newsletters and targeted communications.

EMA SME Action plan 2017–2020

The plan achieved its objectives to:

- Raise awareness of the EMA SME initiative to stakeholders in the innovation lifecycle
- Develop regulatory knowledge base of SMEs in the pharmaceutical sector
- Foster pharmaceutical innovation for human and veterinary medicines
- Engage with SMEs, partners and stakeholders

Actions delivered: engagement at meetings, conferences or events organised by EMA, EU partners and stakeholders, communication activities, training and education, support and incentives.

EMA SME survey and roundtable

An SME survey conducted in 2020 confirmed that the SME Regulation continues to successfully deliver on its intended objectives, which are to promote innovation and the development of new medicines for human and veterinary use by SMEs. Challenges faced by SMEs were:

- Administrative and regulatory burden
- Access to finance
- Regulatory fees

A roundtable with stakeholders on the 15-year anniversary of the SME Regulation acknowledged the relevance of the SME initiative and supported measures suggested in the survey to increase awareness of the program, expand assistance, training and regulatory fees incentives.

Future priorities

Promoting the SME and innovation agendas, enhancing education and training and facilitating engagement with SMEs and their stakeholders will be key themes to be considered in future actions targeting SMEs taking into account the EU pharmaceutical and SME strategies, and the EU Network and Regulatory Science strategies to 2025.

Find out more

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