EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 years supporting SMEs at EMA

EMA SME Office

An agency of the European Union

20 years supporting SMEs at EMA

EMA SME Office

Table of contents

Foreword by Emer Cooke and Constantinos Ziogas

Welcome to this special edition of the SME report marking the 20th anniversary of the EU SME regulation, a key driver for innovation within the EU's pharmaceutical sector.

Since its adoption in 2005, the SME Regulation has supported thousands of small and medium-sized enterprises through tailored guidance, regulatory and scientific advice and fee incentives, enabling the development and authorisation of medicines and contributing to improved public and animal health across the EU.

We mark this milestone as we are preparing for the new pharmaceutical legislation, the proposed medical devices legislation and Biotech Act, while advances in science, technology and artificial intelligence are transforming health care. SMEs are at the forefront of this transformation and EMA remains committed to engage with them to enable the translation of these advances into tangible benefits for public and animal health.

SMEs continue to face hurdles in advancing promising ideas from early concept to patient access. EMA's vision is to foster a regulatory environment that effectively supports SMEs while upholding the highest standards of safety and public trust.

Looking ahead, our shared ambition is clear: to make Europe the most attractive and dynamic environment for SMEs, boosting competitiveness and ensuring that scientific innovation translates into meaningful benefits for patients and animal health across the EU.

Emer Cooke, Executive Director, European Medicines Agency

As we mark 20 years of the SME Regulation, I would like to recognise the contribution of the SME Office team. Over this time, the Office has become a trusted source of guidance for innovators, supported by collaboration across the Agency, the European medicines regulatory network and EU institutions and agencies. Together, we ensure SMEs receive clear, consistent and timely support throughout their development journey. Looking ahead, we remain committed to further strengthening this collaboration and enhancing the support available to SMEs, enabling them to drive innovation across the EU.

Constantinos Ziogas, Head of Small and Medium-sized Enterprise Office, European Medicines Agency

20 years of the EMA SME Regulation

The SME Regulation was introduced in 2005 to support small and medium-sized enterprises developing human and veterinary medicines. Recognising both their innovative potential and the specific challenges they face, it also established the SME Office as a dedicated structure within EMA designed to guide and support SMEs in the pharmaceutical sector.

The SME Office acts as the main entry point for SMEs, offering guidance and support across the product lifecycle. Its services include direct assistance, dedicated briefing meetings and support in navigating regulatory pathways and developments support tools.

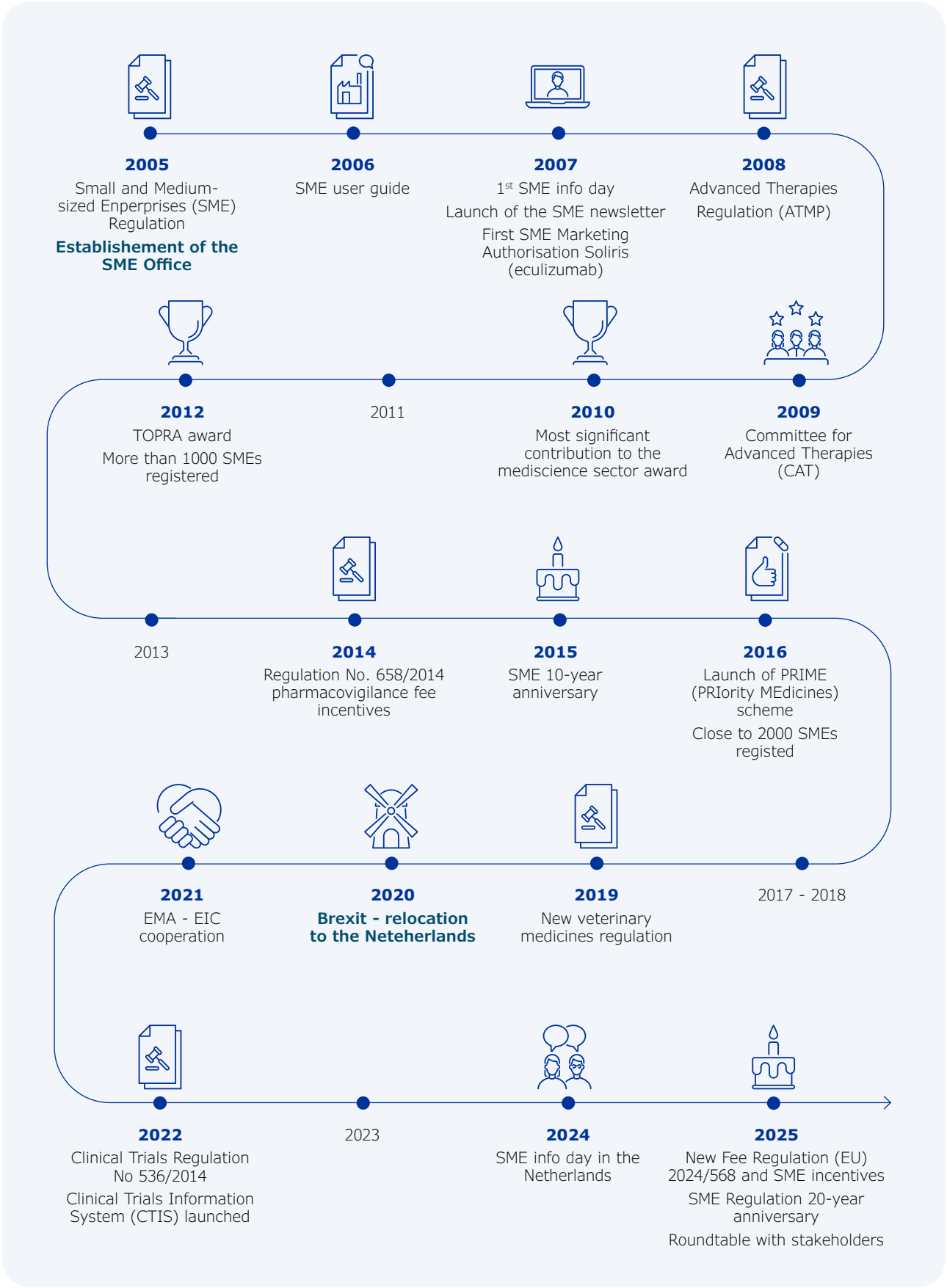
The Office also provides regulatory fee incentives, coordinates the translation of product information into all EU languages and delivers training.

The SME Office plays a key role in facilitating early engagement with regulators, helping SMEs better understand regulatory requirements, anticipate challenges and design robust development programmes. Through regular communications including newsletters, guidance material and outreach activities it ensures SMEs remain informed of regulatory requirements.

Since 2005: at a glance

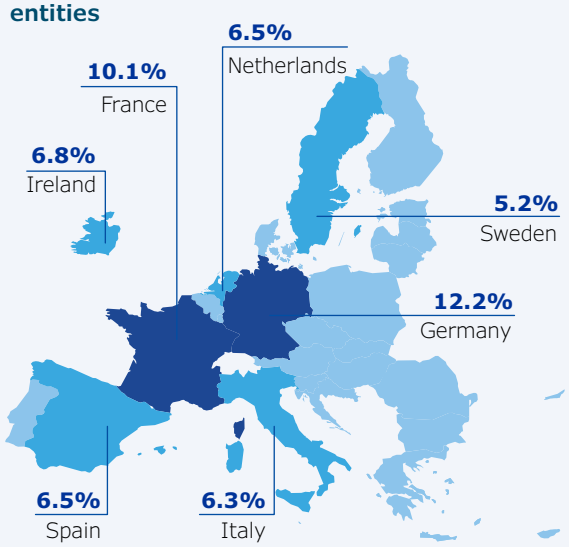
- Over 5000 SMEs have successfully applied for SME status at EMA.
- More than 3000 SMEs have received direct assistance and support.
- Over 3000 have benefitted from scientific advice, including a significant share developing orphan medicines, PRIME-designated products and advanced therapy medicinal products.
- 297 marketing authorisation applications for human and veterinary medicines have been submitted by SMEs.
- Substantial fee incentives supported SMEs across the product lifecycle.
- Extensive training and education activities have been delivered through info days, webinars and targeted guidance and communications to support SMEs in navigating the EU regulatory framework.
- Support has been provided to SMEs through major transitions, such as the general pharmaceutical legislation, pharmacovigilance, paediatric medicines, clinical trials and veterinary medicines regulations.
- Engagement with partners and stakeholders have reinforced the broader support for SMEs in the life-sciences ecosystem.

Timeline with key milestones in EMA support to SMEs (2005-2025)



SMEs at EMA: in figures

1922 SMEs registered with EMA in 2025

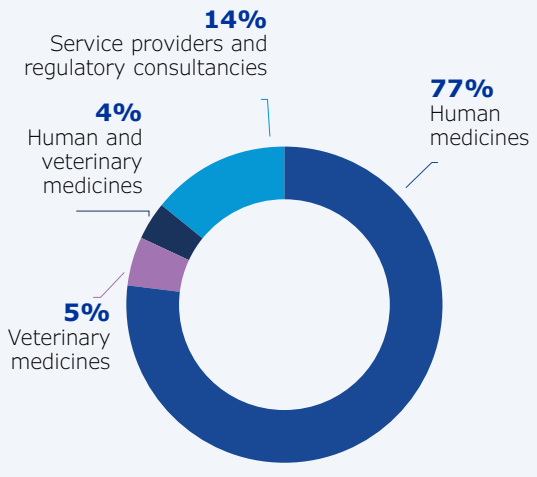


Micro-sized: 38%
Headcount <10; annual turnover or balance sheet total ≤€2 million

Small-sized: 35%
Headcount <50; annual turnover or balance sheet total ≤€10 million

Medium-sized: 27%
Headcount <250; annual turnover ≤€50 million or balance sheet total ≤€43 million

SMEs sectors



SMEs profile

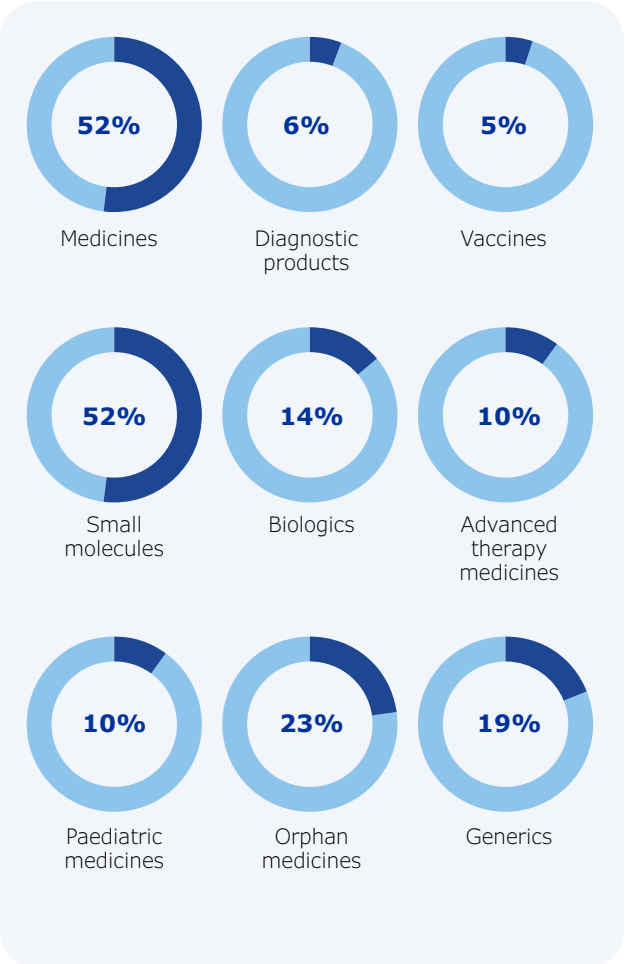
13% Academic spin-offs
7.5% SMEs incorporated over the last three years

81% of SMEs operate in the pharmaceutical sector
16% operate across the pharmaceutical and medical devices sectors
3% operate in the medical devices sector

67% of SMEs operating in the pharmaceutical sector have products in development

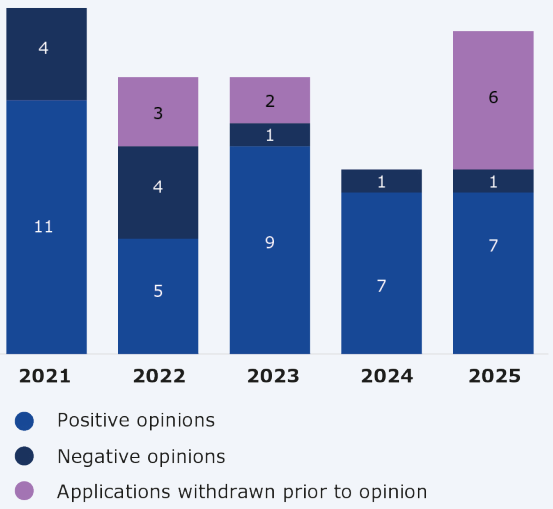
SMEs pipelines

Of registered SMEs:

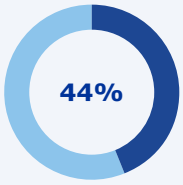


SME marketing authorisations at EMA: a snapshot

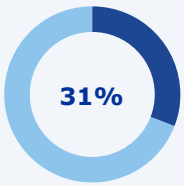
Outcome of initial applications for human medicines



2021-2025 success rate: **64%**



Positive opinions for new active substances

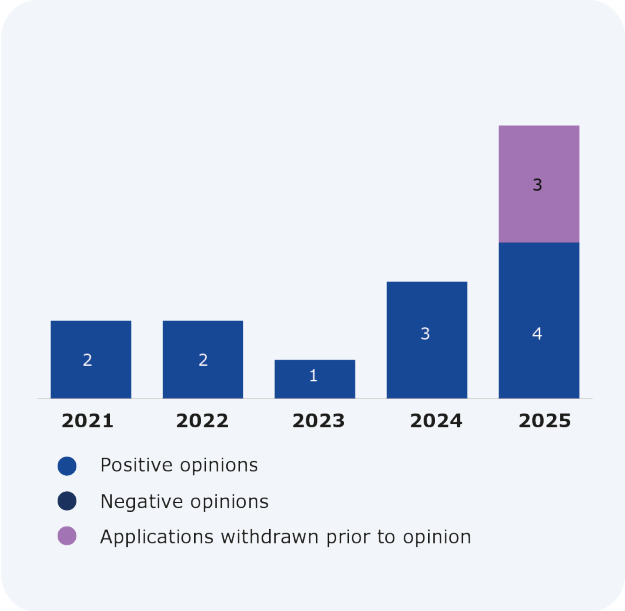


Positive opinions for orphan medicines

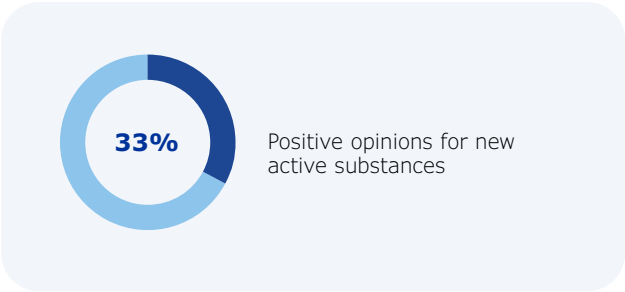
SMEs are a key source of innovative medicines, accounting for around 20% of initial marketing authorisation applications. Products authorised between 2021 and 2025 have delivered significant advances and addressed important unmet medical needs. The significant uptake of EMA's development support services highlights the central role of regulatory and scientific advice in helping SMEs prepare robust development programmes, anticipate potential challenges, reduce assessment times and maximise their chances of success.

Bruno Sepodes,
Chair of the Committee for Human Medicinal Products (CHMP)

Outcome of initial applications for veterinary medicines



2021-2025 success rate: **80%**



SMEs play a significant role in driving innovation in animal health. There are inherent challenges to veterinary innovation related to smaller markets and the need to generate evidence across multiple animal species. Early engagement with regulators is essential to support development of veterinary medicines, and the path to successful authorisation and introduction to the market."

Ivo Claassen,
Deputy Executive Director, European Medicines Agency

Innovative medicines from SMEs: highlights

SMEs are a key source for innovation. Medicines authorised between 2021 and 2025 have delivered significant advances across a range of therapeutic areas, addressing important unmet medical needs.

Human medicines

- **Zemcelpro, PRIME/Orphan/Advanced therapy,** treatment of adults with haematological malignancies requiring allogeneic haematopoietic stem cell transplantation following myeloablative conditioning where no suitable donor is available.
- **Emcitate, Orphan/Paediatric,** first treatment for peripheral thyrotoxicosis in patients with Allan-Herndon Dudley syndrome.
- **Eurneffy, Paediatric,** first nasal spray for the emergency treatment of allergic reactions, offering an alternative to injections.
- **Aqumeldi, Paediatric,** treatment of heart failure in children.
- **Loargys, Orphan/Paediatric,** treatment of hyperargininaemia, a rare disease with neurological clinical signs.
- **Pedmarqsi, Paediatric,** prevention of cisplatin-induced ototoxicity in children from one month up to 18 years with localised, non-metastatic, solid tumours.
- **Zokinvy, Orphan/Paediatric,** first treatment for children with progeroid syndromes, an ultra-rare genetic disease which causes premature aging and death.
- **Imcivree, PRIME/Orphan/Paediatric,** treatment of obesity and the control of hunger associated with genetic deficiencies of the melanocortin 4 receptor (MC4R).
- **Bylvay, PRIME/Orphan/Paediatric,** first treatment for progressive familial intrahepatic cholestasis (PFIC) in patients aged 6 months or older.

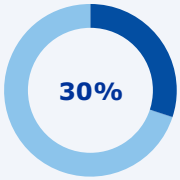
Veterinary medicines

- **Biobhyo**, first vaccine authorised in Europe against swine dysentery disease.
- **Strangvac, MUMS (Minor use/Minor Species),** vaccine for horses from 8 months of age to reduce clinical signs of strangles.

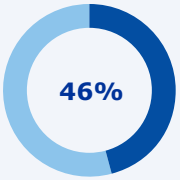
Supporting innovative SMEs at EMA: the numbers

Between 2021 and 2025, the SME Office played a key role in supporting SMEs by providing guidance and advice and help them access EMA's development support tools. Support covered a wide range of topics, such as SME eligibility and incentives, early advice on development and regulatory pathways, guidance on legal bases for marketing authorisation, data exclusivity and market protection, orphan designation and paediatric requirements and incentives.

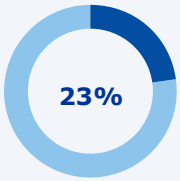
Uptake of EMA development support services by SMEs remained consistently high. SMEs accounted for a substantial share of Innovation Task Force briefings, PRIME designations and scientific advice requests, supported by significant fee incentives. This strong engagement underscores the central role of regulatory and scientific advice in enabling SMEs to advance the development of innovative medicines across both the human and veterinary sectors.



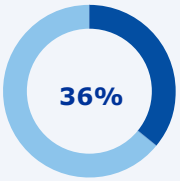
54 of 180 **Innovation Task Force (ITF)** briefing meetings for SMEs



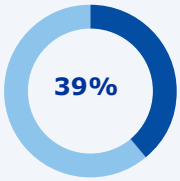
33 of 72 of granted **PRIME designation** from SMEs



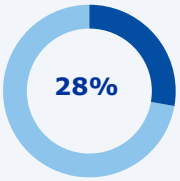
710 of 3085 requests for **scientific advice** from SMEs



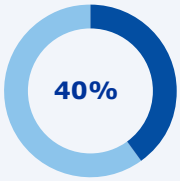
243 of 675 requests for **protocol assistance** from SMEs



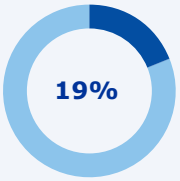
35 of 89 requests for **qualification of novel methodologies** from SMEs



39 of 141 requests for **scientific advice for veterinary medicines** from SMEs



92 of 230 recommendations for **advanced therapy classification** from SMEs



46 of 244 requests for **requests for scientific advice for PRIME products** from SMEs

Empowering SMEs: training, education and communication

Between 2021 and 2025, the SME Office supported SMEs in navigating the EU regulatory framework through webinars, info days and targeted guidance. Themes and topics included clinical trials (CTR-CTIS), the veterinary regulation, scientific advice, the new general pharmaceutical legislation and dedicated training for SMEs funded by the European Innovation Council (EIC).

Looking ahead, training activities will be further strengthened to support SMEs in preparing for upcoming developments such as the new general pharmaceutical legislation, the planned Biotech Act and medical devices legislation.

SME info day on veterinary medicines, 28 October 2021

EMA support for SMEs developing innovative veterinary medicines, impact of the Veterinary Medicinal Product Regulation (EU) 2019/6, and the Union Pharmacovigilance Database.

SME and academia webinar on CTR-CTIS, 29 November 2021

Update on changes brought by Clinical Trials Regulation (EU) No 536/2014 and CTIS.

EMA-EIC infoday, 31 January 2023

Support services provided by EMA to researchers and SMEs funded by the EIC.

Awareness session for SMEs new pharma legislation, 24 November 2023

Update on changes brought by the new pharmaceutical legislation and their impact on SMEs.

SME info day, 18 October 2024

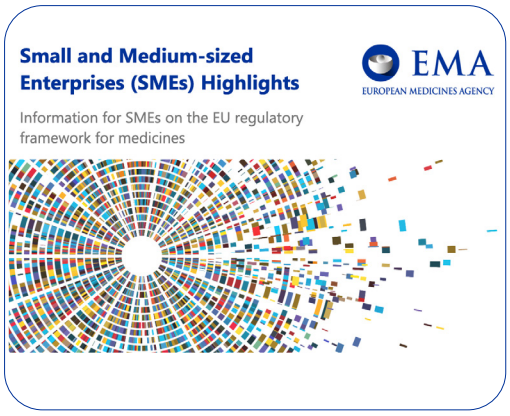
Updates on EMA Scientific Advice, management of medicines shortages, the new EMA Fee Regulation, Health Technology Assessment, Clinical Trials and Medical Devices.

EMA roundtable on the 20th anniversary of the SME regulation, 27 October 2025

Exchange of views on current challenges and future opportunities to foster innovation and support SMEs in the pharmaceutical and MedTech sectors with public and private investors, life science incubators, patients' organisations and industry organisations.

SME newsletter

The newsletter, published quarterly, provides SMEs with key regulatory updates, as well as information on relevant initiatives, support measures and activities. Subscriber uptake has continued to grow steadily.



SME user guide

The guide supports companies in navigating regulatory requirements, procedures and incentives available throughout the lifecycle of a medicinal product. Its regular updates provided practical information to help SMEs understand key regulatory pathways, access available support mechanisms and make informed decisions from early development through to marketing authorisation.

In a rapidly evolving regulatory environment, SMEs need clarity and support more than ever. Over its 20-year history, the SME Office has risen to this challenge, ensuring that SMEs remain at the forefront of medicine development for the benefit of patients and animal health across Europe. As we work to strengthen Europe's position as a global hub for medicine innovation, our commitment remains unwavering: the SME Office will continue to provide tailored guidance, foster innovation, and empower SMEs to navigate regulatory pathways with confidence.

Emmanuel Cormier,
Head of Regulatory Science and Innovation, European Medicines Agency

Working together: engagement with partners and stakeholders

The EMA SME Office engaged with institutional partners, including the European Commission, its executive agencies, decentralised agencies and national regulatory authorities, to strengthen the support framework for SMEs. In parallel, it engaged with public and private stakeholders including industry organisations and entities across the life sciences ecosystem such as universities, incubators, research organisations, funding bodies and international organisations.

These exchanges provided valuable insights into the evolving needs and challenges faced by SMEs, helping inform and further develop EMA SME support. In particular, cooperation and joint initiatives with the European Innovation Council (EIC) and SMEs Executive Agency (EISMEA) supported innovative SMEs developing breakthrough innovations and help them navigate regulatory pathways and frameworks.

Looking ahead

Marking 20 years of the SME Regulation, EMA organised a stakeholder roundtable in 2025 that brought together representatives from the European Commission, the European Medicines Regulatory Network, public and private investors, life science incubators and industry organisations. Reflecting on two decades of progress, participants looked ahead to how support for SMEs can evolve to meet future needs and challenges. Discussions highlighted the need to build more integrated support structures, simplify administrative procedures, and strengthen training and awareness of available tools and incentives, fostering a more enabling environment in which innovative SMEs can deliver the next wave of public health breakthrough innovations.

European Medicines Agency

Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

+31 (0)88 781 6000

www.ema.europa.eu