

Support to Small and Medium Enterprises at EMA

PCWP and HCPWP meeting,
24 September 2025

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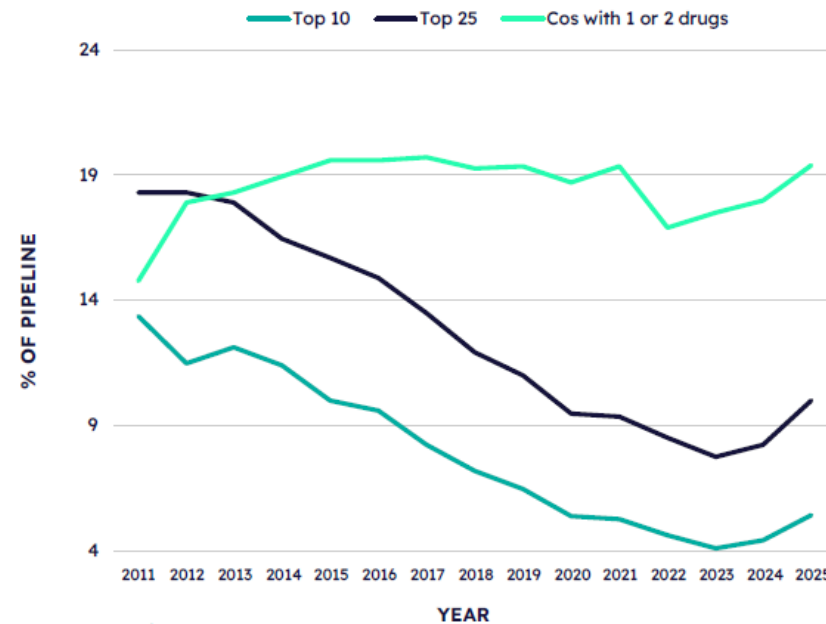


SMEs are pivotal to driving innovation in the life sciences sector



Out-licensing of medicines from SMEs to large or intermediate size companies
[Pharmaceutical innovation sourcing, Nature reviews drug discovery, 2022](#)

Figure 4: Share of pipeline contributed by top 10 companies, top 25 companies, and companies with just 1 or 2 drugs, 2011-25



Source: Pharamaprojects, January 2025

Small companies make up more of the pharma ecosystem than ever, comprising 19.4% of drugs in development [Pharma R&D Annual Review 2025 Citeline](#)

SMEs as a source of innovation

Scientific advice (H)

29%

182 out of 625 requests from SMEs

Protocol assistance (H)

39%

51 out of 131 requests from SMEs

Qualification of novel methodologies

36%

5 out of 14 requests from SMEs

Innovation Task Force (ITF)



16 out of **34** briefing **meetings**
with ITF from SMEs

PRIME



6 out of **18** **PRIME positive**
eligibility recommendations from
SMEs

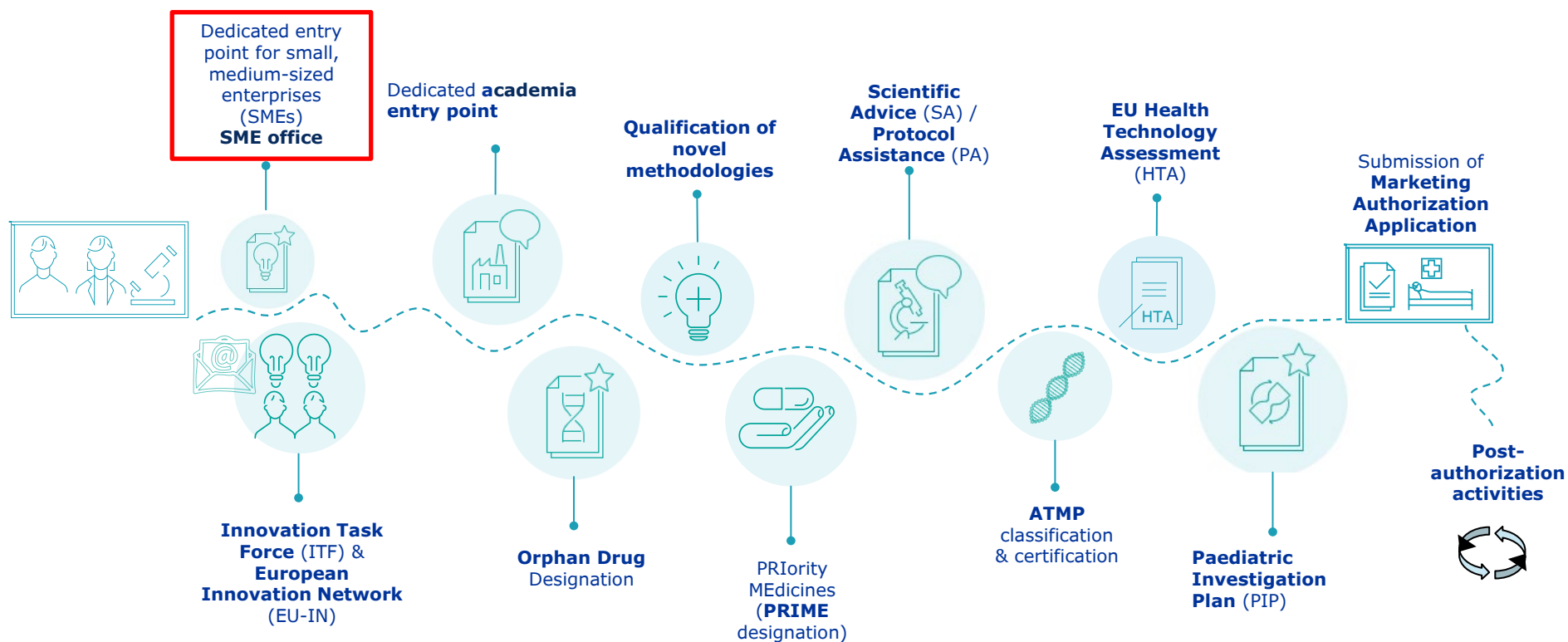
Advanced therapies



15 out of **39** recommendations for
advanced therapy classification
for SMEs

Support to innovation

Opportunities to interact with EMA



SME office



Set up by [Commission Regulation \(EC\) No 2049/2005](#) (SME Regulation)



Provides dedicated advice, guidance and assistance to SMEs to support the development of medicines in the European Union (EU) and the European Economic Area (EEA).



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SME Helpline : +31 (0)88 781 8787



[Support to SMEs | European Medicines Agency \(EMA\)](#)



EU SME Definition - Commission recommendation 2003/361/EC

Size and ownership structure

Size

- micro,
- small,
- medium-sized

Ownership structure

- autonomous
- partner
- linked



[How to apply](#)

Dedicated SME support



Assignment and renewal of
SME status
Compliance review of applications



Regulatory assistance
Guidance & advice



SME briefing meetings
Early dialogue and
discussion on regulatory
strategy for product
development



Fee incentives
Scientific advice, inspections,...



Translation of product information in
all EU languages
Free of charge, at time of marketing
authorisation



Training and
engagement
Info days, SME newsletters
and targeted mailings to
SMEs

Support from SME Office



Regulatory assistance

- SME definition and incentives
- Early development advice (scientific advice, ITF, PRIME...)
- Regulatory topics (e.g. legal basis, data protection)
- Criteria for orphan designation, market exclusivity
- Paediatric requirements
- Clinical trials, CTIS



SME briefing meetings

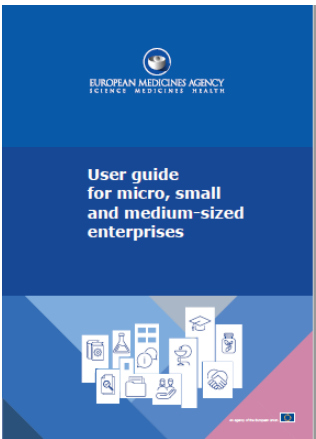
- Discussion on regulatory strategy of one or several products
- Platform for early and informal dialogue
- Interdisciplinary EMA team
- 90 minutes
- Free of charge

Training and engagement

Training and awareness

Facilitating access to regulatory and scientific information

SME user guide



Info days

SME newsletter, mailings



Engage

with **EU** bodies and **industry stakeholders**

Participation to conferences



SME Register



2005-2025: 20 years supporting SMEs



Roundtable with representatives from European Commission, European Investment Bank, Industry associations, incubators and private investment.

- Highlight **achievements** of the SME regulation and its impact on SMEs
- Present **EU policy initiatives** supporting SMEs
- Present **survey** on the SME regulation
 - Positive impact
 - Regulatory burden
 - Access to finance and regulatory fees
- Discuss about **challenges and future opportunities**

EMA roundtable with stakeholders
on the 20th anniversary of the SME
Regulation – Draft agenda

17 October 2025, 09:30 – 13:30 (CET)
Hybrid meeting - EMA, Amsterdam

Collaboration

EMA - European Innovation Council (EIC) collaboration

Support for Breakthrough Technologies
Funding to start-ups and SMEs

EMA collaboration

- Training and assistance of EIC beneficiaries on EMA regulatory support services
- Cooperation on horizon scanning activities

EU Biotech & Biomanufacturing Hub

Easy and accessible information on the relevant **EU legislation, financing opportunities** and **business support networks**.

Find out more by scanning the QR code



A large iceberg floats in a blue ocean under a clear sky. The visible tip of the iceberg is on the left, while the much larger, submerged part extends across the middle and right of the frame. A semi-transparent white rectangle is overlaid on the submerged part of the iceberg.

Thank you for your
attention



Constantinos
Ziogas



Helene
Casaert



Leonor Enes



Thomas Ballotti



Malika Holleyman



Tatjana Molodcova



Eglantine Legros



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

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