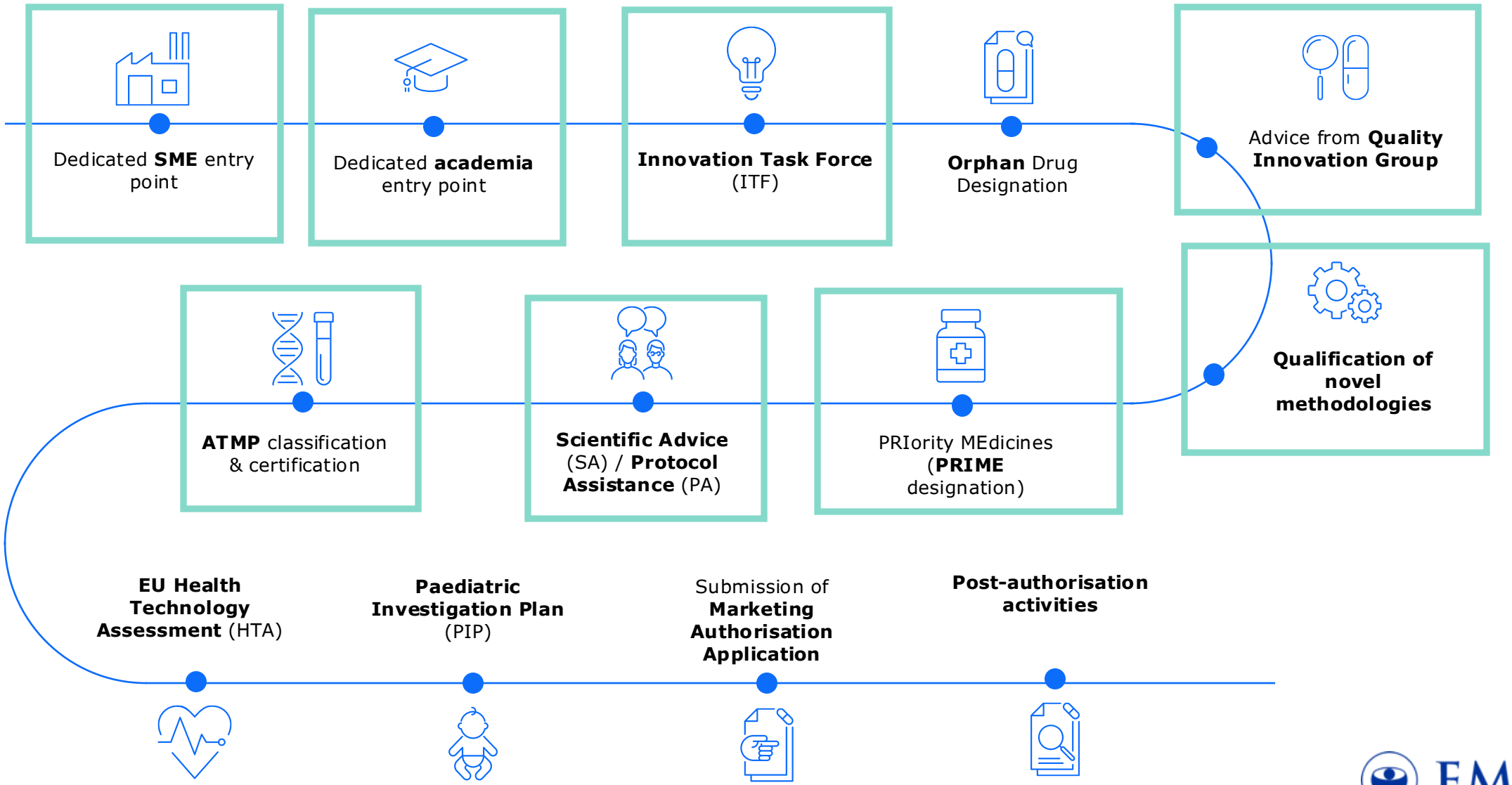
EMA
EUROPEAN MEDICINES AGENCY

European Medicines Agency's support to SMEs

European Access Academy
Fall Convention
Joint EAA & EUCOPE Preconvention SME
6 November 2025

Presented by **Constantinos Ziogas, Head of SME Office**
Regulatory Science and Innovation Task Force (TRS)
European Medicines Agency

EMA interactions across the medicine life cycle

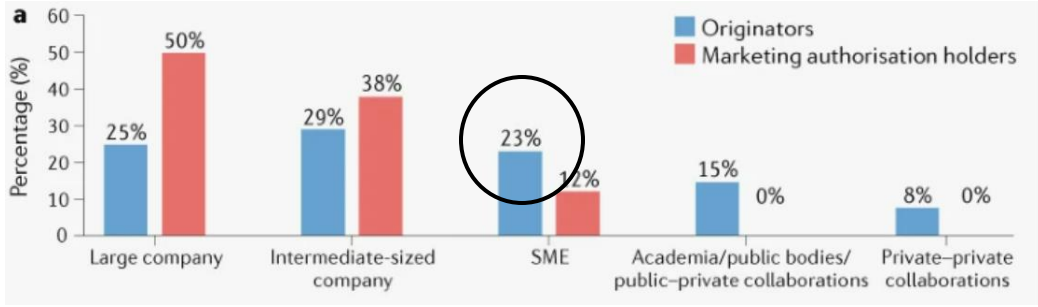


SME office

Set up by Commission Regulation (EC) No 2049/2005 (SME Regulation)

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

Pharmaceutical innovation sourcing: a 10 year analysis
Nature Reviews Drug Discovery September 2022



SME@ema.europa.eu

SME Helpline :+31 (0)88 781 8787

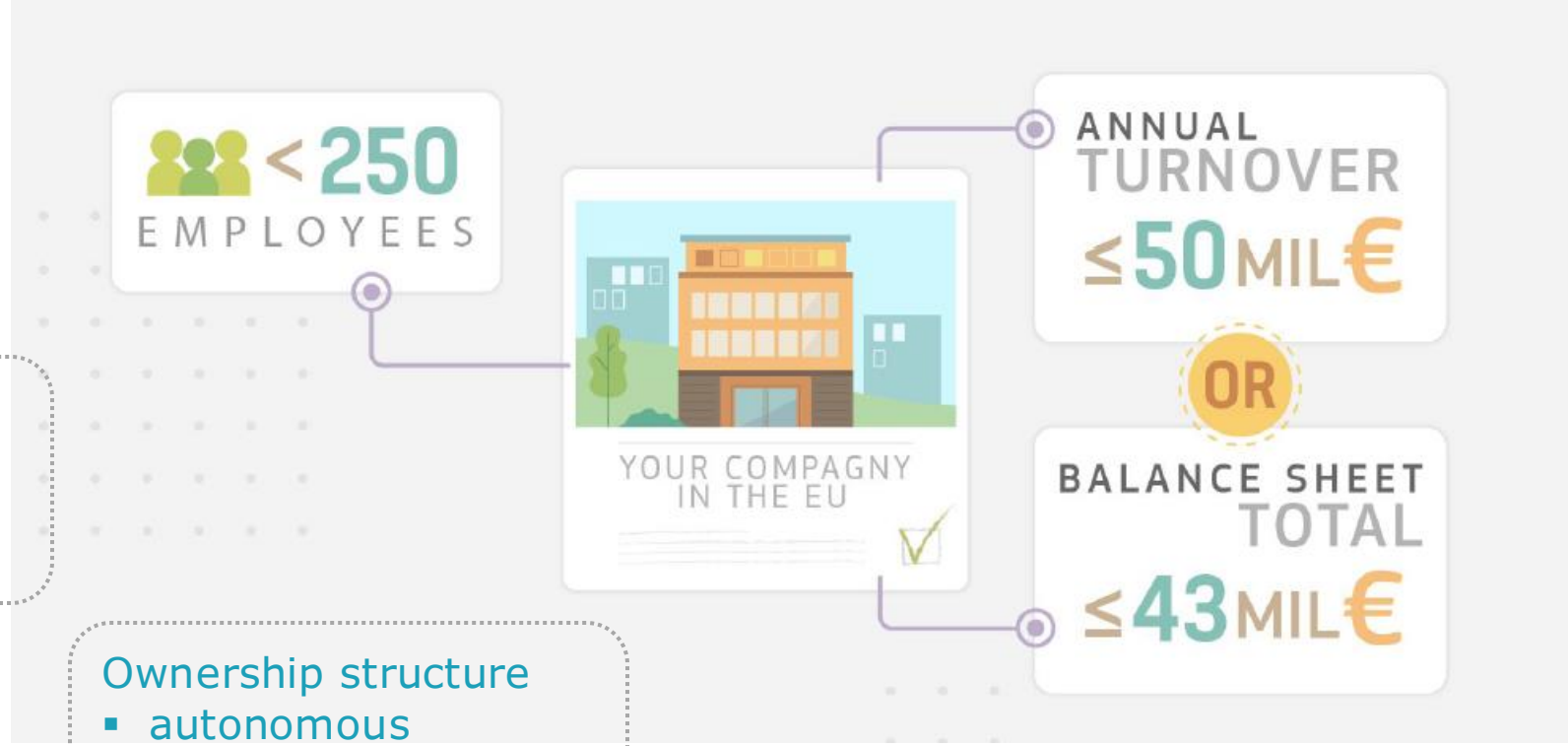
Support to SMEs | European Medicines Agency (EMA)

EMA SME status

EU SME Definition - Commission recommendation 2003/361/EC

Size and ownership structure

Size
- micro,
- small,
- medium-sized



Ownership structure
- autonomous
- partner
- linked

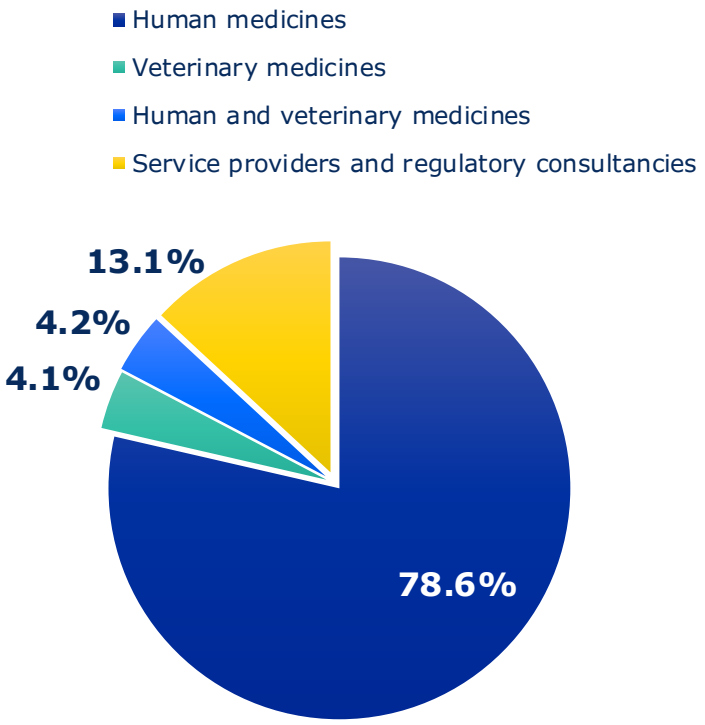
[How to apply]

2,000 SMEs registered – Facts and figures

Location

- **12.2%**
- **10.5%**
- **7.9%**
- **6.4%**
- **6.1%**
- **6%**
- **5.5%**
- **9.1%**

Company activity



Profile

12,5% **Academic spin-offs**

79,8% of companies' activities in the pharmaceutical sector

17,4% in the pharmaceutical and medical devices sector

2,8% in the medical devices sector

59% of companies operating in the pharmaceutical sector have products at development stage

*SME office annual report **2024***

SME Office activities

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, marketing authorisation dossiers

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

Regulatory assistance

Key topics

SME definition, incentives and services

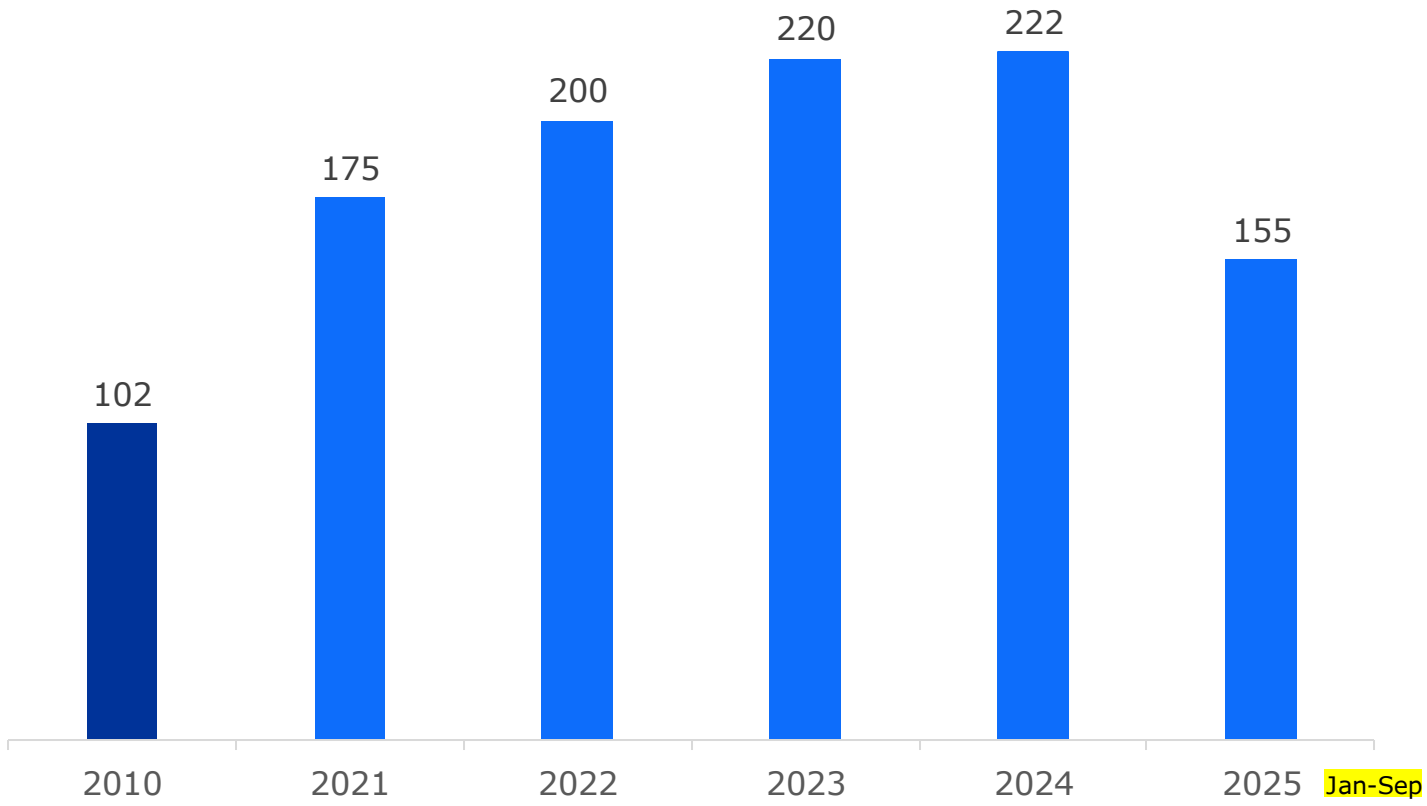
Early development advice and routing (scientific advice, ITF, PRIME)

Regulatory topics (e.g. legal basis, data protection)

Criteria for orphan designation, market exclusivity

Paediatric requirements

Clinical trials, CTIS



Tools

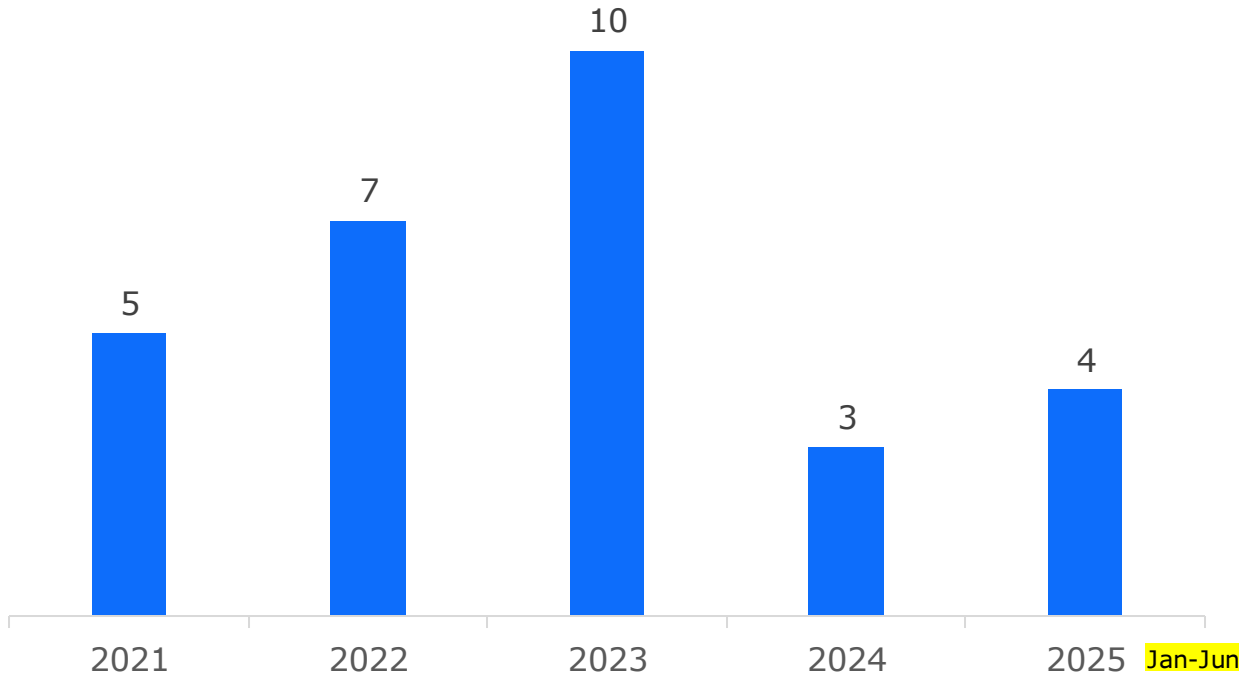
Via email SME@ema.europa.eu

Via SME helpline + 31 (0)88 781 8787

SME briefing meetings

- Discussion and guidance on regulatory strategy of one or several products
- Platform for early informal dialogue
- Interdisciplinary EMA team
- 90 minutes
- Free of charge
- Minutes with outcome of discussions and follow-up guidance

Topics: e.g. Scientific Advice, Orphan Drug Designation, Pediatric investigation plan, PRIME



Year	Average N. of meetings
2006-2010	5
2011-2015	9
2016-2020	13
2021-2024	6

Fee incentives for SMEs

Scientific advice : 90% fee reduction / 100% for designated orphan products

Marketing authorisation application :

Fee deferral until the outcome

100% fee reduction for designated orphan products

Conditional fee exemption

Inspections (pre-authorisation) :

90% fee reduction and deferral

100% fee reduction for designated orphan products

Inspections (post-authorisation) :

90% fee reduction

100% fee reduction for designated orphan products

Pharmacovigilance : 100% fee reduction for micro-sized enterprises, 40% fee reduction for small or medium-sized enterprises

Post-authorisation procedures : 100% fee reduction for micro-sized enterprises, 40% fee reduction for small or medium-sized enterprises

Use of EMA supporting tools for medicines development

Scientific advice (H)

154 out of 625 requests from SMEs

Protocol assistance (H)

51 out of 131 requests from SMEs

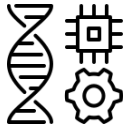
Qualification of novel methodologies

5 out of 14 requests from SMEs

Veterinary scientific advice

7 out of 27 requests from SMEs

Innovation Task Force (ITF)

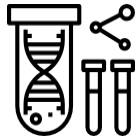


14 out of 34 briefing **meetings with ITF** from SMEs

PRIME

6 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 (3 submitted)

*SME office annual report **2024***

SME marketing authorisations (2024)

Human medicines

87.5% success rate

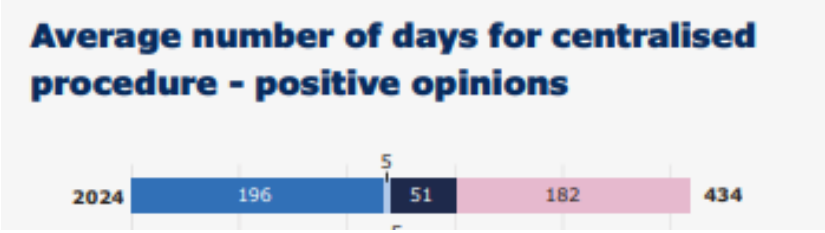
10 initial submissions

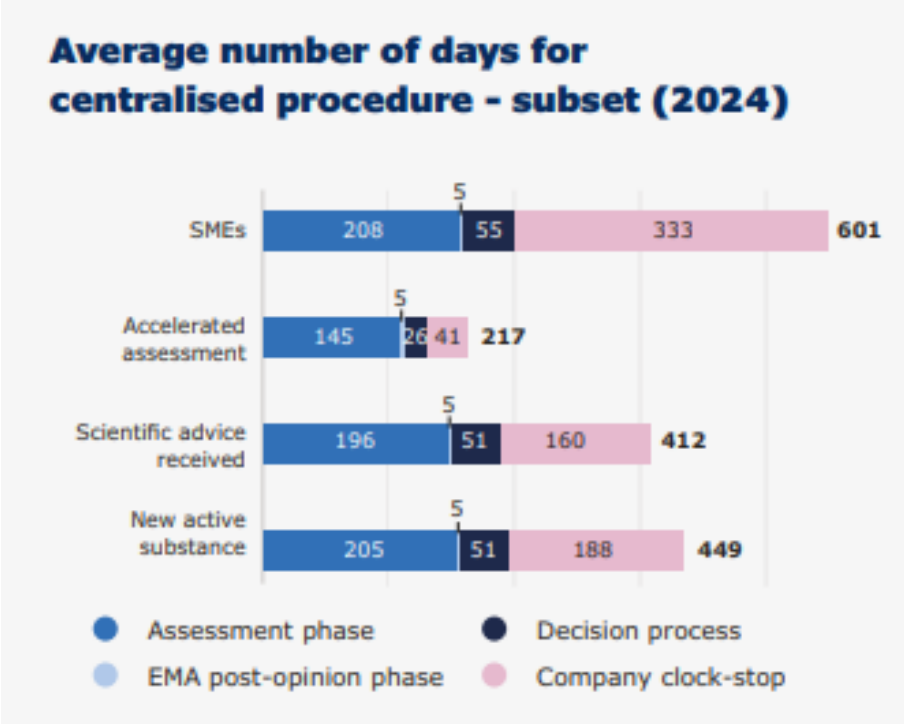
7 positive opinions of which
2 new active substances,
1 orphan medicine
1 authorisation under exceptional circumstances

Therapeutic areas: oncology, endocrinology, pneumology/allergology, ophthalmology, cardiovascular diseases

Longer approval times for SMEs applications (***ANNUAL REPORT 2024***)

➔ Use and follow Scientific Advice to increase success rate of marketing authorisation applications



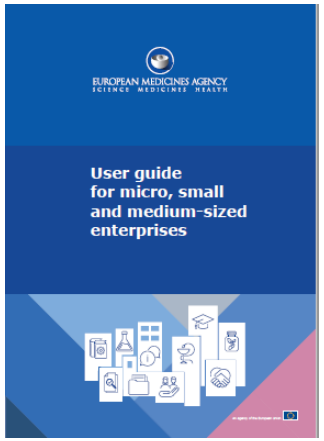


Training&education and engagement with partners and stakeholders

Training&awareness

Facilitating access to regulatory and scientific information

SME user guide



Info days &training material

Subscribe

SME newsletter, mailings

Engage

with **partners** and **stakeholders**

Participation to conferences

TOPRA | BERLIN Symposium 2025

EUROPEAN INNOVATION COUNCIL SUMMIT 25

Bio International Convention

SME Register

EMA

Training&education

Conferences and lectures to raise awareness

9 participations to conferences or lectures in 2024

The past 5 years:

SME Info Day on VETS
2021.10.28
EMA support for innovative veterinary medicines, vet regulation, PV, UPD

EMA-EIC Info day
2023.01.31
EMA support to innovation (PRIME, SA, ITF)

SME Info day
2024.10.18
Clinical trials, HTA, Medical devices, NFR, shortages

SME and academia webinar on CTR - CTIS
2021.11.29
CTR, CTIS functionalities

Awareness session for SMEs new pharma legislation
2023.11.24
Pharma package, impact on SMEs, Q&A

Engagement with partners&stakeholders

European Investment Bank

Health innovation

European Innovation Council

EIC EMA cooperation deliverables

Mutual exchange and support on SME definition

REA

Sharing experience on SME support

EFSA EUROPEAN FOOD SAFETY AUTHORITY

Mutual exchange and support on SME definition

ECHA EUROPEAN CHEMICALS AGENCY

enterprise europe network

EEN Annual Conference; meetings of the Friends of the EEN

European Commission

DG GROW/DG SANTE
Mutual exchange and support on SME definition and EU initiatives (e.g. revision of SME definition; EU Biotech and biomanufacturing Hub).

EMA

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SCIENCE MEDICINES HEALTH

Thank you

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