EMA
EUROPEAN MEDICINES AGENCY

EMA SME survey 2024

20th anniversary of the SME Regulation

Presented by Thomas Ballotti on 17th October 2025

SME Office | Regulatory Science and Innovation Task Force (TRS)

Survey objectives and scope

What did we aim to achieve?

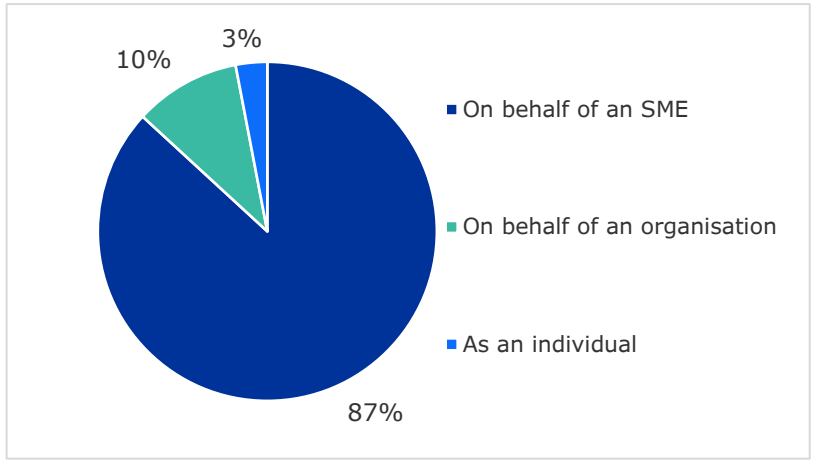
- **Evaluate the experience** from SMEs and stakeholder organisations on the operation of the SME Regulation.
- **Receive feedback** on the support provided to SMEs at the EMA.
- **Better understand** current challenges faced by SMEs.
- **Tailor** our future activities to better meet the needs of SMEs.

5-month period : 266 responses

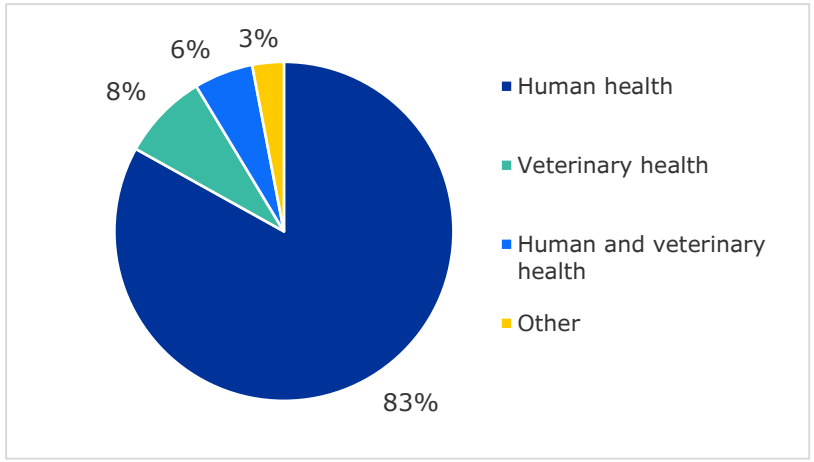
Public report

Profile of respondents

Are you completing this survey as:



Entity's field of activity:

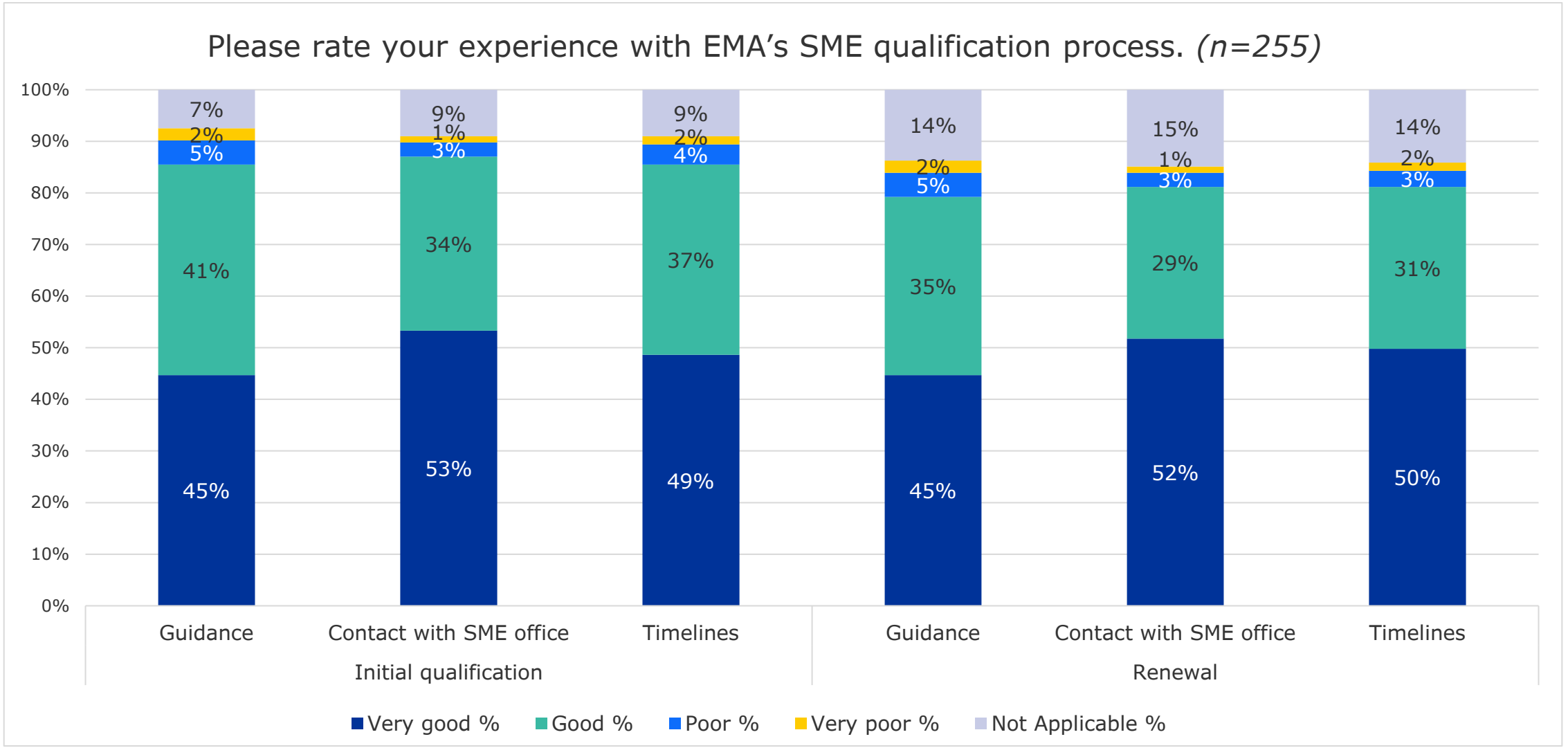


Business activity:

- Development, manufacturing or marketing of pharmaceuticals (67%)
- Service providers to the pharmaceutical industry (16%)
- Operating in the medical device and technology field (7%)

96% of all respondents have at some point held SME status with EMA.

EMA’s SME qualification process



Nine out of ten SMEs satisfied *with the overall process of registration with the SME office.*

EMA’s support for SMEs – Overview

Financial fee incentives (pre-authorisation)

Financial fee incentives (post-authorisation)

Regulatory assistance

SME briefing meetings

Translation assistance

Support to EMA’s clinical data publication (Policy 0070)

Advanced Therapies incentives (certification)

Public SME register

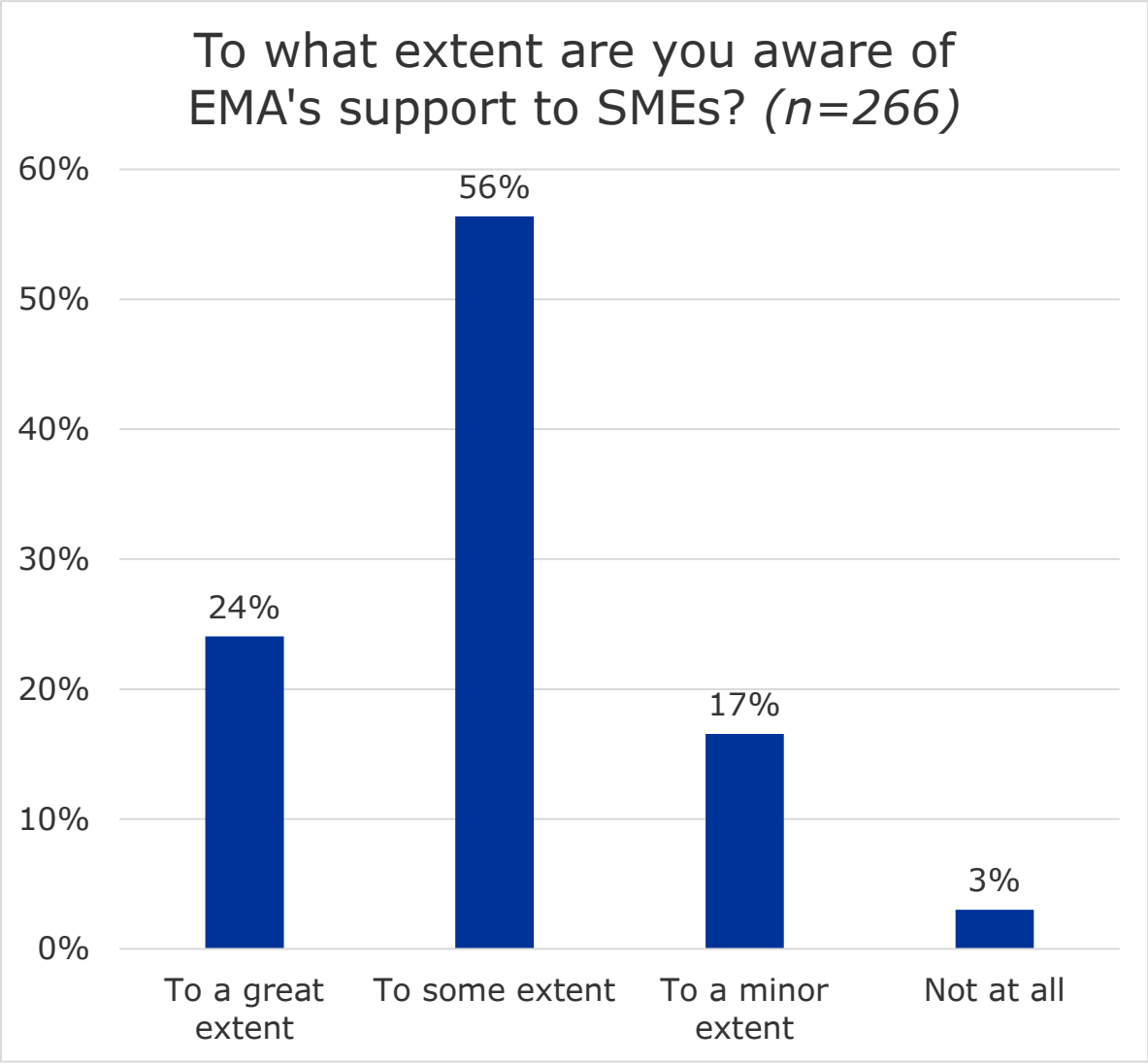
Training events (Workshops and info days)

SME user guide

SME newsletter

Support to Priority medicines scheme (PRIME)

EMA’s support for SMEs – Awareness of support services



Most respondents (**80%**) indicated that they were **aware** of EMA’s support for SMEs to **a great and some extent**.

Scoring highest in terms of awareness :

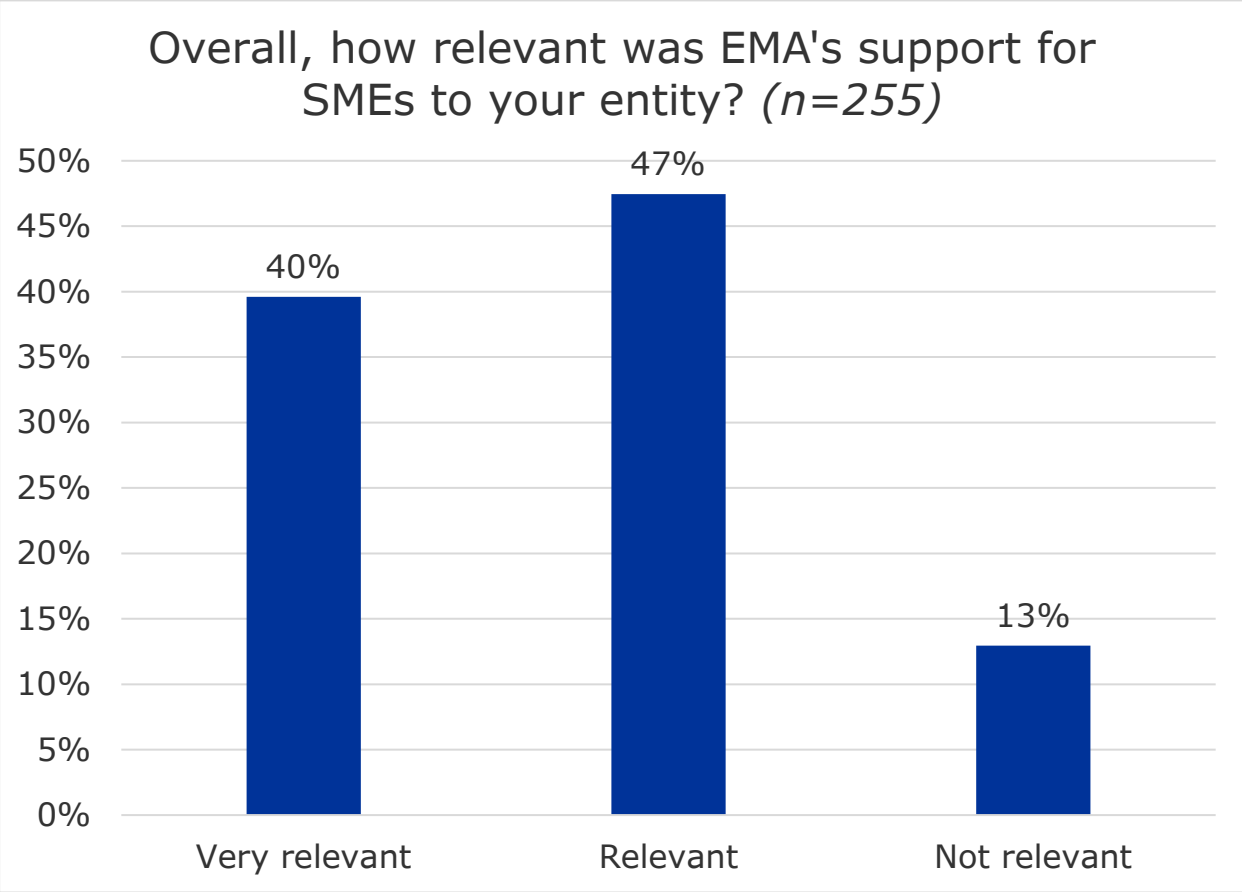
- SME newsletter
- SME user guide
- Financial fee incentives pre-authorisation
- Trainings and events

Limited awareness :

- Advanced Therapies incentives (certification)

Figures aligned with use of such support services

Relevance of EMA’s support for SMEs



High proportion of respondents indicated that the SME initiative had been **relevant or very relevant** (**87%**).

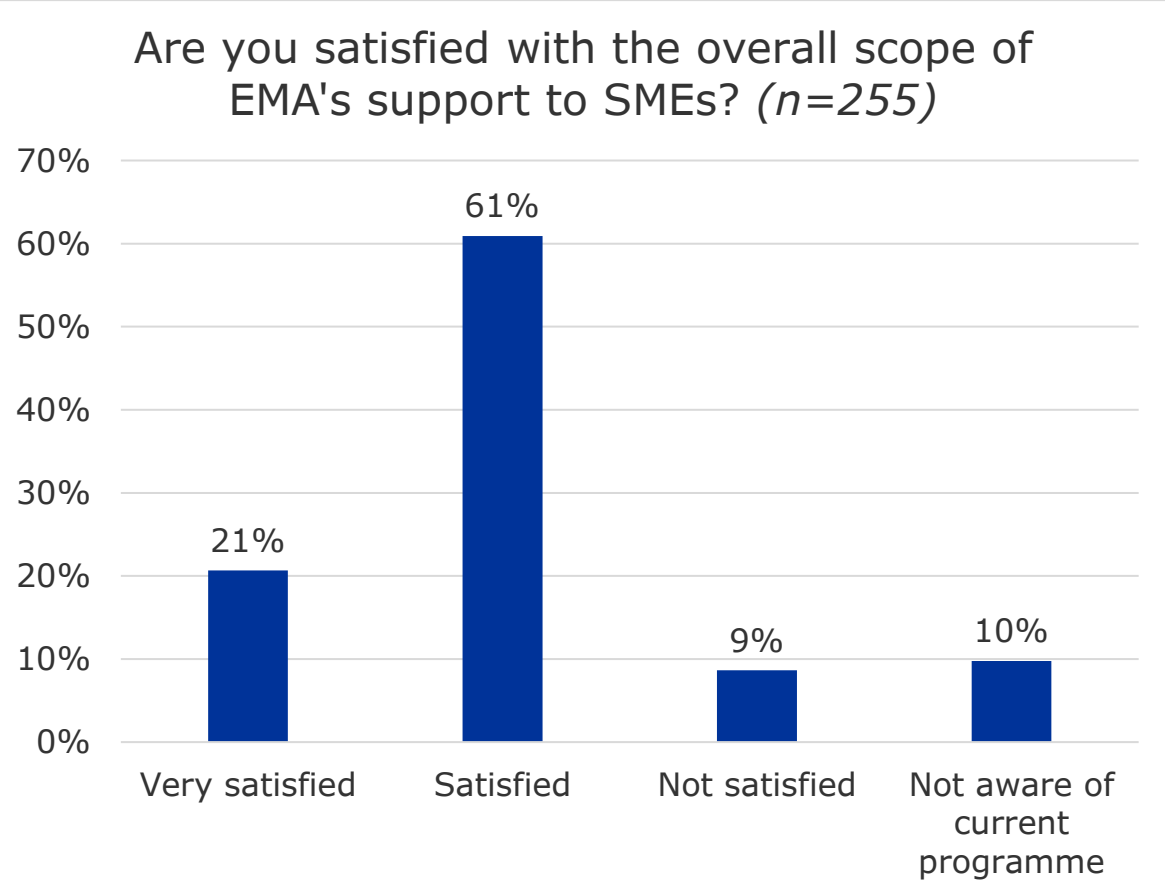
Scoring highest in terms of perceived relevance (>80%):

- SME newsletter
- SME user guide
- Training and events
- Regulatory assistance services

Scoring lowest in terms of perceived relevance (37%):

- Advanced Therapies incentives (certification)

EMA’s support for SMEs



Overall satisfaction with **82%** being satisfied with the overall scope of EMA’s support to SMEs.

Respondents suggested certain activities to be expanded:

- Regulatory assistance services
- Training events
- Financial fee incentives pre- and post-authorisation

Suggestions:

- Reviewing SME definition’s criteria, venture capital provisions
- Strengthening post-authorisation support
- Supporting DCP and MRP
- Reducing regulatory timelines

SMEs and shortages

Awareness and experience

- Most respondents (84%) reported **no medicine shortages** in the past two years.
- **Limited awareness** of guidance and reporting obligations.

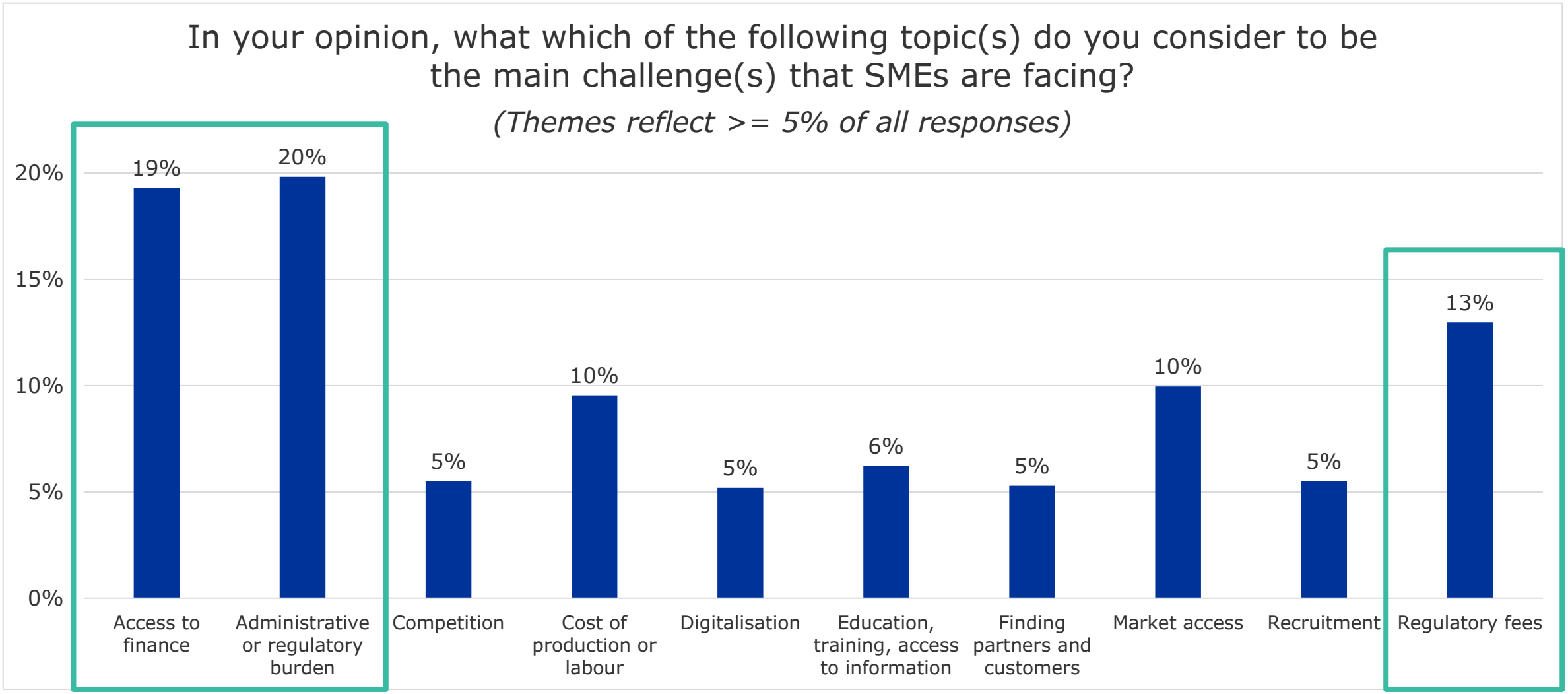
Reported challenges

- Reduced source materials availability and increased costs.
- CMOs capacity limits.
- Lengthy regulatory procedures (e.g. inspections, variations).

Suggested measures

- **Regulatory alignment:** Simplify and harmonise medicines shortage reporting.
- **SME support:** Assist in preparing shortage prevention and mitigation plans, fee incentives for shortage-related procedures (e.g. variations).
- **Security stock funding:** Establish an EU fund for SMEs to maintain post-approval stock.
- **Import & coordination:** Streamline non-EU import procedures and enhance authority dialogue.
- **Awareness & training:** Promote EU shortage initiatives via training events.

Challenges faced by SMEs and suggestions for the future



Challenges faced by SMEs and suggestions for the future

Administrative and regulatory burden

Complexity of regulations (MDR, CTR, IVDR).

Fast-evolving regulation driven by innovative technologies (e.g., targeted therapies, companion diagnostics).

Lack of harmonisation of regulatory requirements between authorities.

<u>Measures suggested by respondents</u>:

- **Simplifying and streamlining** regulatory frameworks in the EU.
- Introducing **flexibilities and exemptions** for regulatory procedures or requirements.
- Enhancing regulatory and scientific advice throughout the **product lifecycle**.
- Providing support for **decentralised procedures**.
- **Increasing awareness** of EMA's regulatory support.

Challenges faced by SMEs and suggestions for the future

Access to finance

Measures suggested by respondents:

- **Expanding and facilitating** access to EU funding programs (e.g., diversifying funding instruments, easing eligibility criteria, focusing on early-stage financing).
- Supporting **institutional investors' investment** in venture capital companies.
- Improving **access to information** on funding opportunities for SMEs through targeted communications and training.
- **Promoting networking**, partnerships and matchmaking between SMEs and investors (e.g., through dedicated fora).
- **Introducing tax credits**.

Challenges faced by SMEs and suggestions for the future

Regulatory fees

Easing regulatory fees for SMEs through EMA and National fee incentives in pre- and post-authorisation, flexible payment modalities (e.g., deferrals, instalments), and for specific activities such as serialisation (falsified medicines legislation).

Enhancing guidance on SME incentives of Regulation (EU) 2024/568 on fees and charges payable to EMA.

Market access

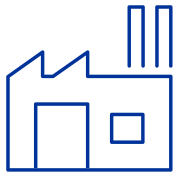
Providing support and guidance on HTA, market access, pricing & reimbursement and launch, through early dialogue with competent authorities.

Harmonising and simplifying pricing & reimbursement across Member States.

Finding partners and customers

Promoting partnering and networking with investors (e.g., dedicated fora, online platforms).

Challenges faced by SMEs and suggestions for the future



Cost of production or labour

Publishing a list of Contract Development and Manufacturing Organisations (**CDMOs**).

Education, training, access to Information

Expanding training and networking events (e.g., free of charge workshops, webinars, **e-learning including real case studies and lean training material**), specifically for new regulations and funding.

Providing information in EU languages.

Digitalisation

Offering financial support to implement digital tools (e.g. software for regulatory submissions, pharmacovigilance, dossier preparation).

Providing training on digital tools and digital transformation.

Recruitment

Supporting the use of **centralised recruitment** platforms and systems (e.g. EURES).

Conclusion

- **Continued relevance and effectiveness** of the regulation in supporting SMEs in the pharmaceutical sector.
- Highly valued incentives and tools with need to **continue raising awareness of services and scope of programme**.
- Top three challenges faced by SMEs are **administrative and regulatory burden, access to finance,** and **regulatory fees**.

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Thank you

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