EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Regulatory Science and Innovation Task Force

Outcome of SME Office survey on the implementation of the SME regulation - Commission Regulation (EC) No 2049/2005

Executive Summary

The SME Survey by the European Medicines Agency (EMA) reviewed the implementation of Regulation (EC) No 2049/2005, which supports SMEs in the pharmaceutical sector. Responses from SMEs in the human and veterinary medicines sectors confirmed strong satisfaction with EMA's support — especially regulatory assistance services, fee incentives, the SME qualification process and training. Tools like the SME User Guide and newsletters were widely valued, though limited awareness of some services suggests a need for stronger outreach. Respondents also highlighted challenges such as the regulatory burden, access to finance and regulatory fees, calling for regulatory simplification and streamlining, access to funding and enhanced advice and support.

1. Background, objectives and scope of the survey

Commission Regulation (EC) No 2049/2005 (hereafter referred to as the 'SME Regulation'), adopted on 15 December 2005, introduced specific provisions to support small and medium-sized enterprises (SMEs) in the pharmaceutical sector. Its aim was to foster innovation and facilitate the development of new medicinal products by SMEs.

EMA launched a survey in 2024, which sought to gather insights and feedback from SMEs and stakeholder organisations on the functioning and impact of the SME Regulation. The survey also aimed to identify current challenges faced by SMEs, ensuring that support measures remain relevant and effectively tailored to the evolving needs of SMEs in the biopharmaceutical sector.

2. Methodology

The consultation was conducted over a six-month period through a web-based survey. The questionnaire consisted of twenty questions, largely based on those used in the previous SME survey. Except for two questions – respondent details and open text comments – all items required a response in order to submit the survey.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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The survey used various response formats, depending on the nature of each question:

- Dichotomous Scale (e.g. Yes / No)
- 5-point Rating Scale (e.g. Very good – Good – Poor – Very poor – Not applicable)
- 4-point Rating Scale (e.g. To a great extent – To some extent – To a minor extent – Not at all)
- Multiple choice and multiple response
- Free-text input

The survey was published on the EMA website and promoted on social media. It was also distributed by email to contact points listed in the EMA SME register (comprising about 1800 entities holding or having held SME status), as well as to industry organisations representing SMEs, the EU Regulatory Network and the European Commission. A total of 266 unique and valid responses were received.

3. Profile of respondents

The majority of respondents (87%) were SMEs while 10% completed the survey on behalf of an organisation and 3% participated as individuals (Figure 1). In terms of activity areas, 83% were involved in human health, 8% in veterinary health, and 6% in both sectors (Figure 2). Most companies (67%) were engaged in the development, manufacturing, or marketing of pharmaceuticals. Moreover, 16% were service providers to the pharmaceutical industry, and 7% operated within the medical device and technology sector. As the survey was anonymised, more detailed respondent profiles were not available (10% of responded were classified as "others". Notably, 96% of respondents reported holding or having previously held SME status with EMA.

There were no notable differences in the survey findings between respondents in the human and veterinary health sectors.

Figure 1. Profile of entity

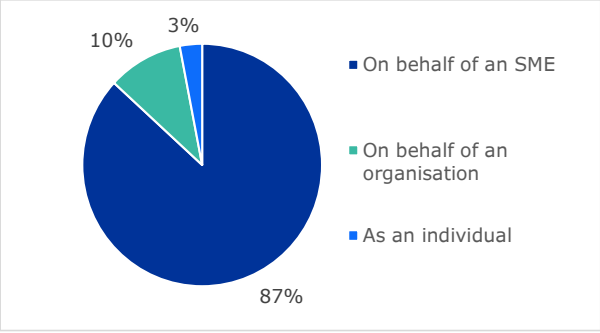
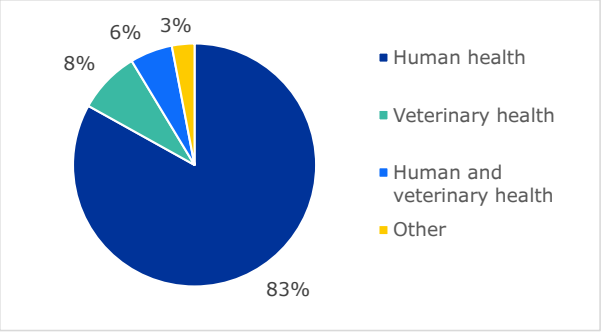


Figure 2. Activity area



4. Findings from the survey

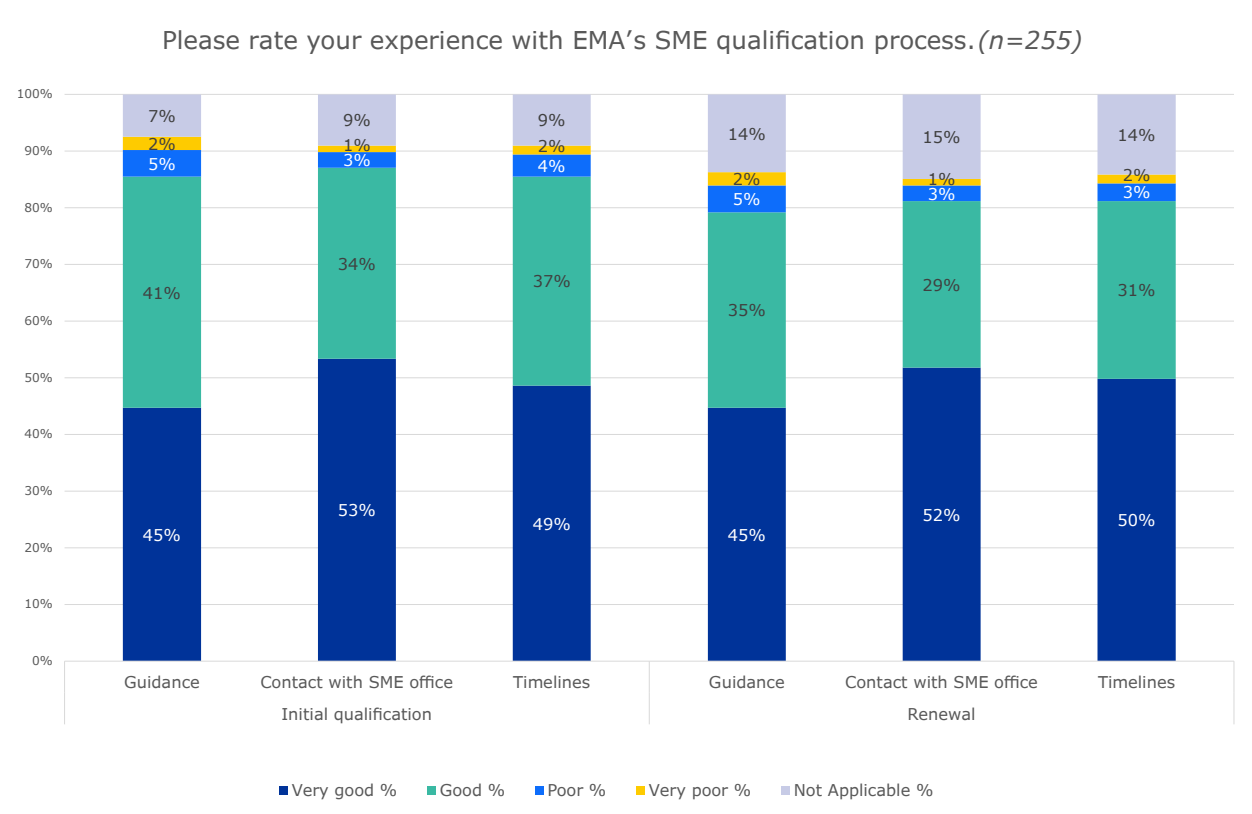
The survey was structured into five sections. Four of these — feedback on EMA's SME qualification process, awareness of EMA's support to SMEs, a review of EMA's current SME incentives and opportunities for improvement — were included in the previous survey. A new section focusing on SMEs and medicines shortages was added.

Feedback on EMA's SME qualification process

Respondents were invited to provide feedback on the SME qualification process, which companies must complete in order to access EMA's SME incentives.

A very high level of satisfaction was reported, with nine out of ten SMEs expressing satisfaction with the overall process of registration with the SME office (Figure 3). Compared to results from the previous SME survey, improvements were observed in the renewal process.

Figure 3. Experience with EMA's SME qualification process

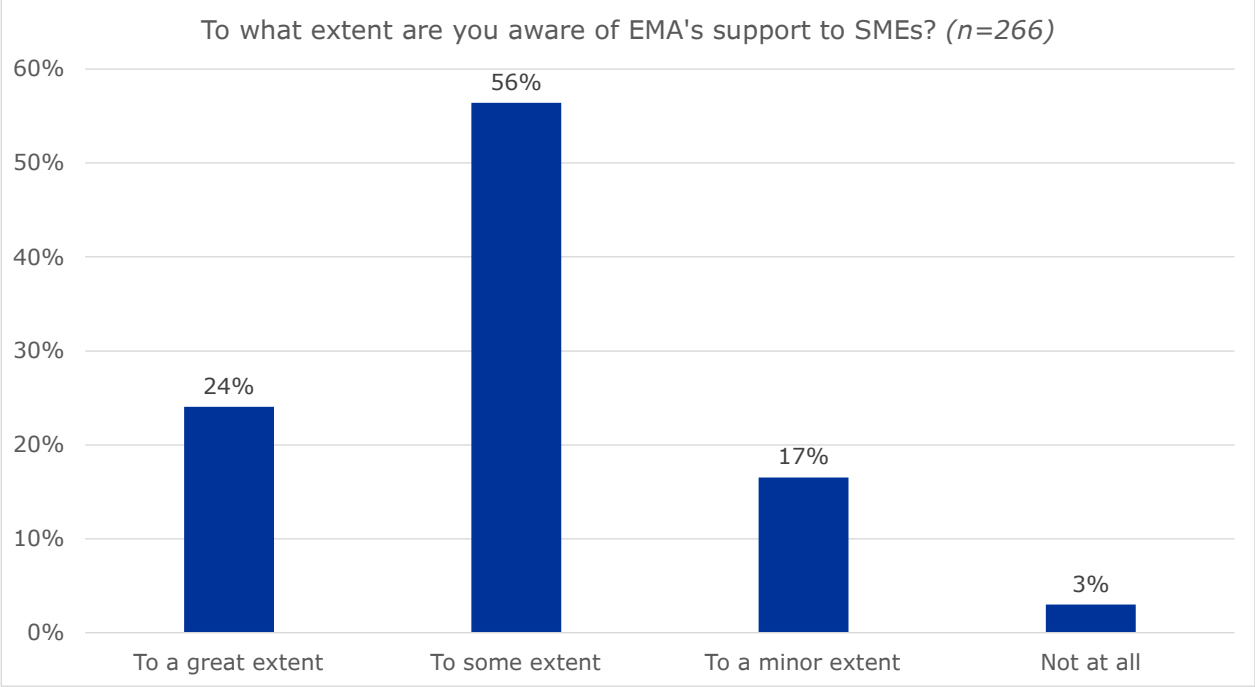


Services offered by EMA

- **Awareness of EMA's support for SMEs**

The first question assessed the general level of awareness of the SME regulation and its implementing measures. A majority of respondents (80%) indicated that they were aware of EMA's support for SMEs, with 56% stating they were aware 'to some extent' and 24% 'to a great extent'.

Figure 4. Awareness of EMA's support to SMEs



Feedback was also gathered regarding respondents' awareness of specific support activities and services provided by EMA for SMEs.

The survey covered the following SME-targeted services (see Annex for details of services):

- Financial fee incentives (pre-authorisation)
- Financial fee incentives (post-authorisation)
- Regulatory assistance services
- Support to EMA's clinical data publication (Policy 0070)
- Support to Priority medicines scheme (PRIME)
- SME briefing meetings
- Translation assistance
- Advanced therapies incentives (certification)
- Public SME Register
- Training events (workshops and SME info days)
- SME User Guide
- SME newsletter

Respondents reported a very high level of awareness for specific EMA services. Of the twelve services surveyed, over half of respondents reported being aware of eight of them either to 'a great extent' or to 'some extent' (Figure 5).

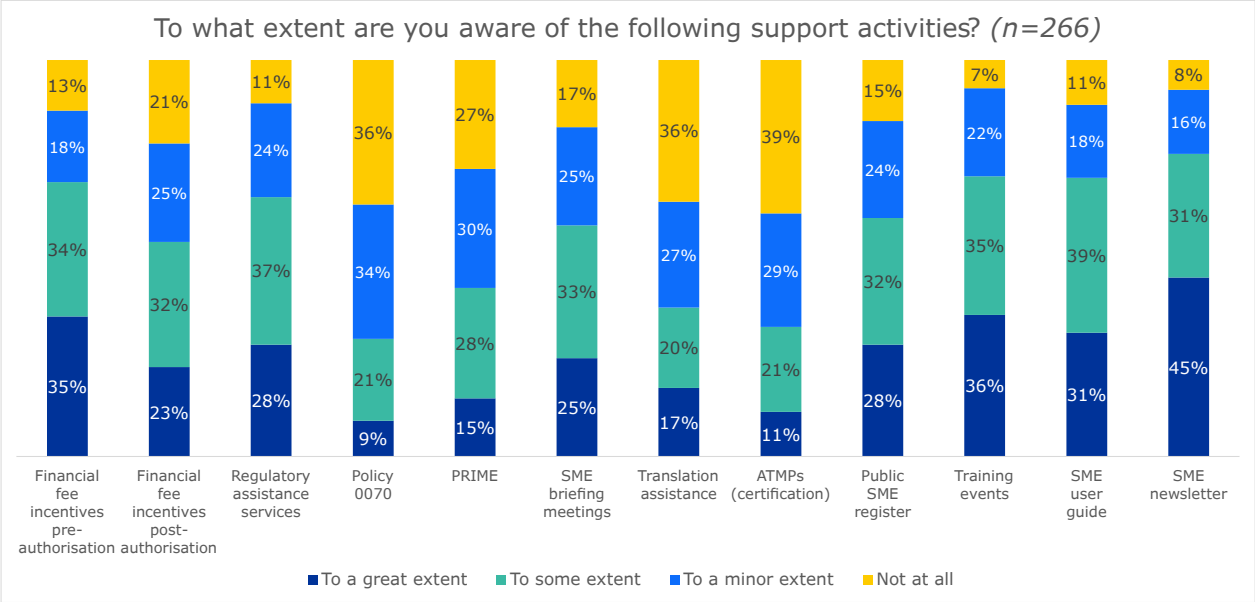
The SME newsletter ranked highest in terms of awareness, with 76% of respondents indicating familiarity (45% to a great extent, 31% to some extent). This was followed by training events — such as workshops and SME Info Days (71%), the SME User Guide (70%), and pre-authorisation fee incentives (69%).

Other services with awareness levels exceeding 50% included regulatory assistance (65%), the public SME Register (60%), SME briefing meetings (58%) and financial fee incentives (post-authorisation) (55%).

The survey also highlighted the need to improve awareness of certain services. For example, support related to the Priority medicines (PRIME) scheme was recognised by only 41% of respondents.

Among services ranked lowest in terms of awareness, respondents indicated no or only minor awareness of advanced therapies incentives (32%).

Figure 5. Awareness of EMA's support activities



- **Experience with support offered by EMA**

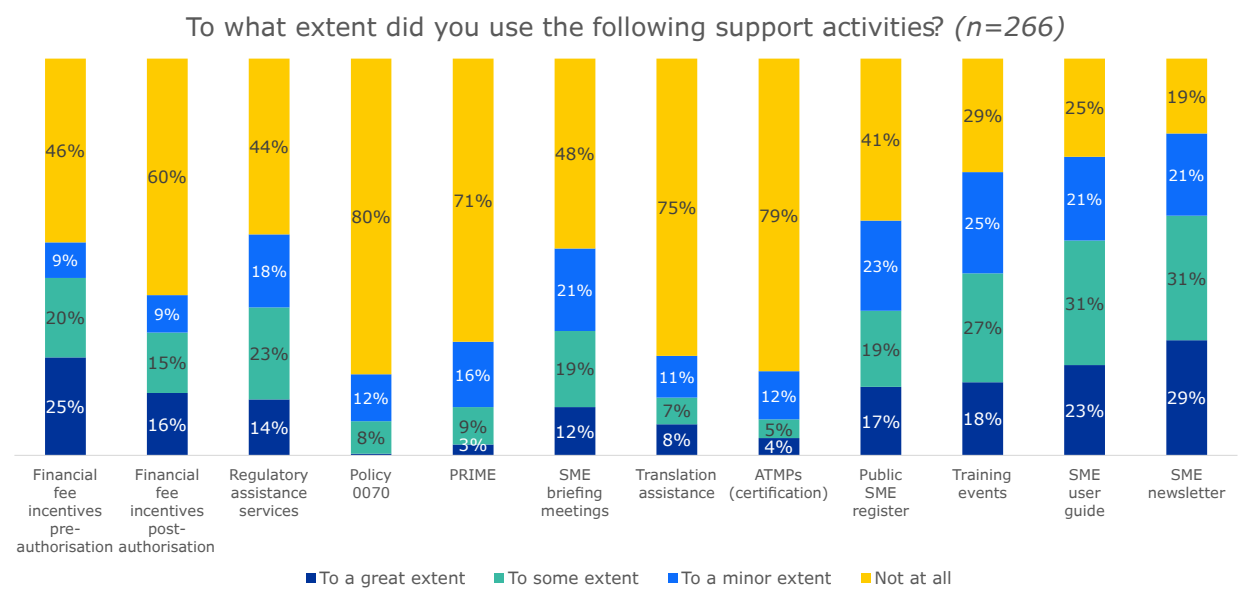
The most widely used services were: the SME newsletter (60% to a great or some extent), the SME User Guide (54% to a great or some extent), financial fee incentives (pre-authorisation) and training events (both at 45% to a great or some extent) (Figure 6).

Moderately used services included: regulatory assistance services (37% to a great or some extent), financial fee incentives (post-authorisation) (31% to a great or some extent), the Public SME Register (36% to a great or some extent), SME briefing meetings (31% to a great or some extent) and support to Priority medicines scheme (PRIME) (12% to a great or some extent).

Limited experience was reported for: incentives relating to advanced therapies (79% reported no use), translation assistance (75% no use) and support to EMA's clinical data publication (Policy 0070) (80% no use).

The low scores for translation assistance and support to EMA's clinical data publication (Policy 0070) are likely due to the targeted nature of these services, which are primarily intended for SMEs preparing a marketing authorisation application — a relatively small subset of registered SMEs.

Figure 6. Use of EMA's support activities



- **Relevance of EMA's support for SMEs**

A large majority of respondents (87%) indicated that the SME initiative was either relevant or very relevant (Figure 7), aligning with feedback from the previous SME survey.

To ensure the most meaningful results in assessing the individual relevance of services, the analysis included only responses from participants who had used the services, excluding those marked 'not applicable yet'.

Amongst individual support measures, financial incentives (pre- and post-authorisation), the SME newsletter, the SME user guide, training events and regulatory assistance services were rated most relevant by over 80% of respondents. Services like SME briefing meetings (77%) and the SME register (76%) also received strong support. Moderately rated services included translation assistance (67%) and PRIME (60%), while Policy 0070 (54%) and ATMPs certification (37%) were perceived as the least relevant. A detailed breakdown of the relevance ratings for each support measure is presented in Figure 8.

Figure 7. Relevance of overall EMA's support to SMEs

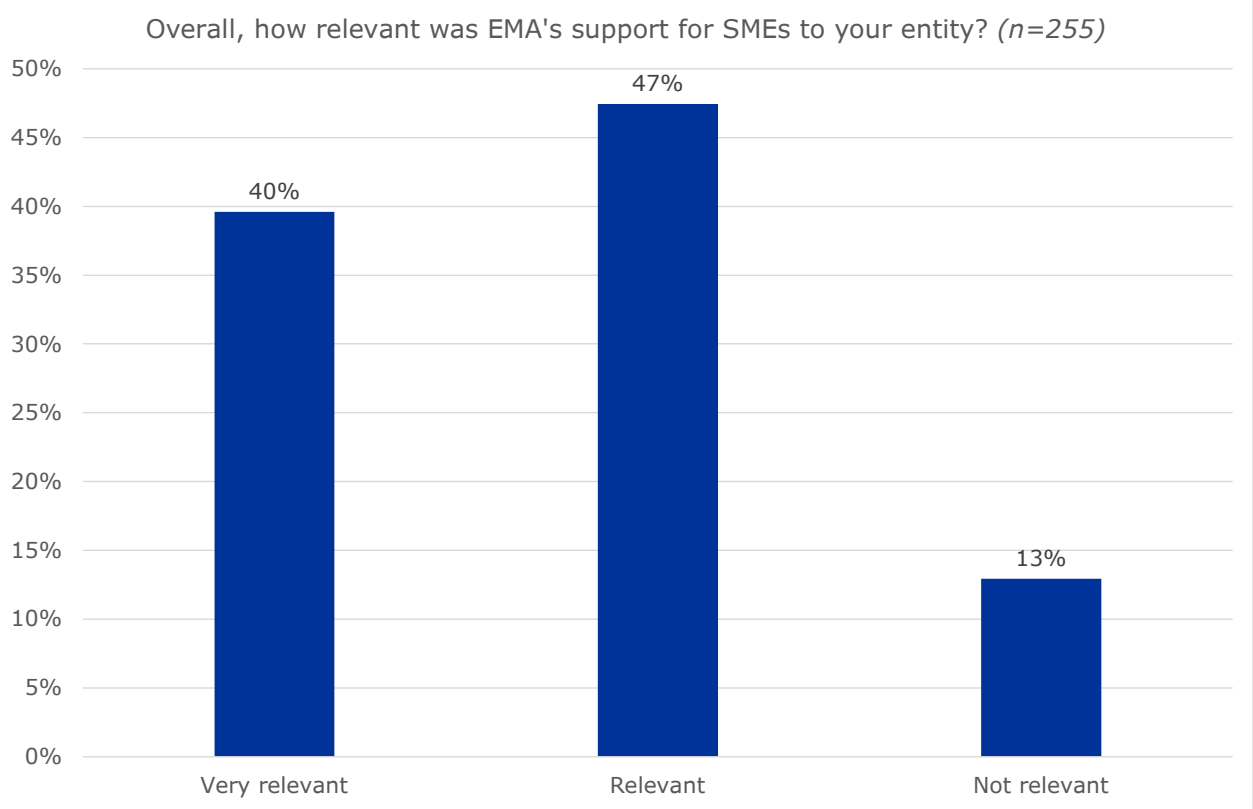
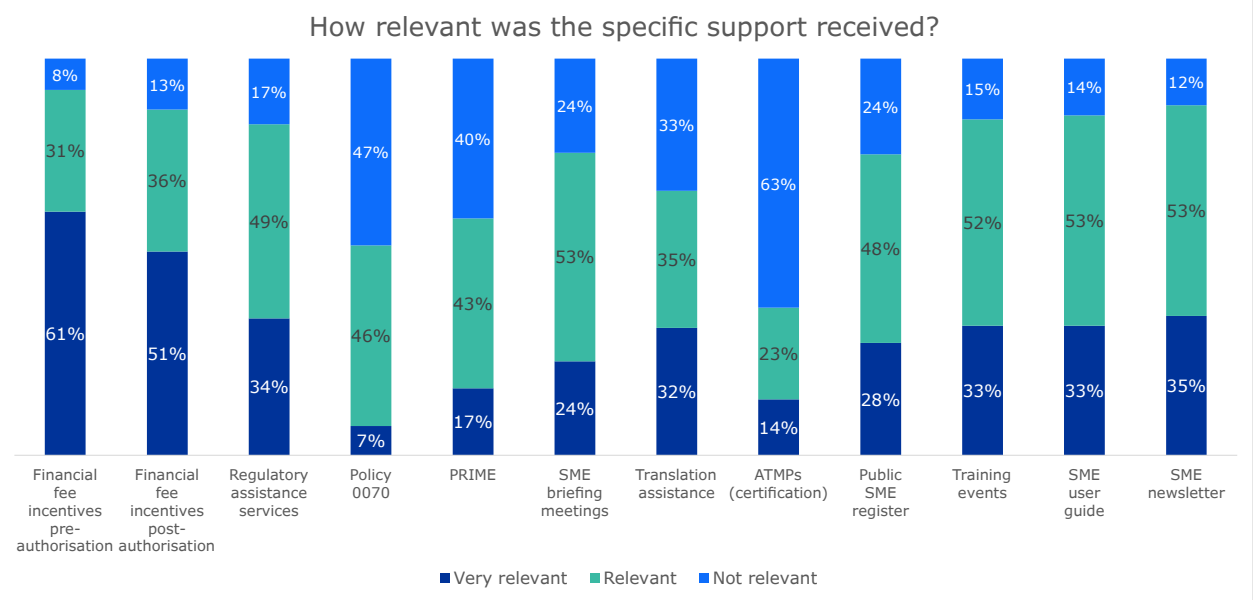


Figure 8. Relevance of specific EMA's support activities

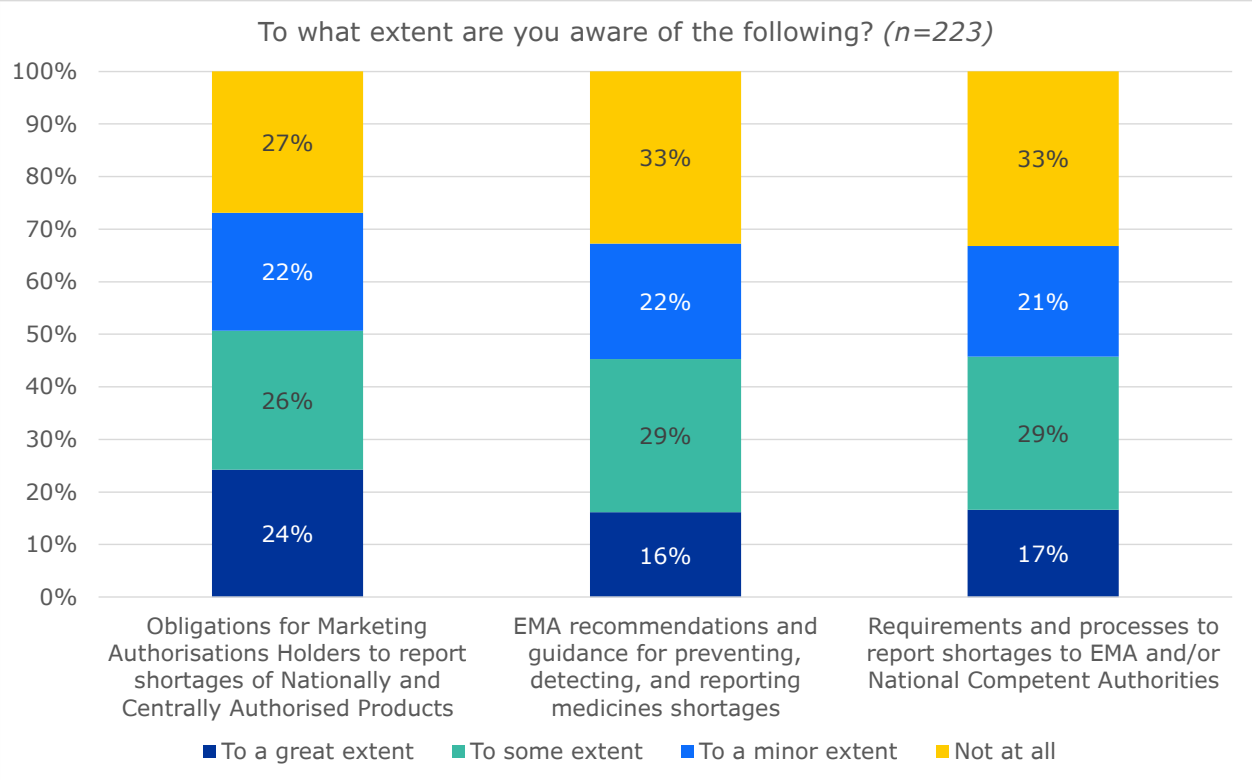


- **SMEs and medicines shortages**

Most respondents (84%) reported not having experienced a medicine shortage in the past two years while 16% indicated they had. Some respondents clarified that their organisations are at the development stage and do not yet have products on the market.

Awareness of obligations and reporting requirements related to medicines shortages was limited. About 50% of respondents indicated they had either no awareness or only limited awareness of these obligations and processes (Figure 9).

Figure 9. Awareness of obligations and requirements related to medicines shortages



Reported challenges included: delays from active substance and finished product manufacturers, reduced availability and increased costs of starting materials, capacity constraints at contract manufacturing organisations (CMOs) and lengthy regulatory procedures and approvals (e.g. marketing authorisations, inspections of manufacturing sites, variation applications for manufacturing changes).

Suggested measures to address these challenges include:

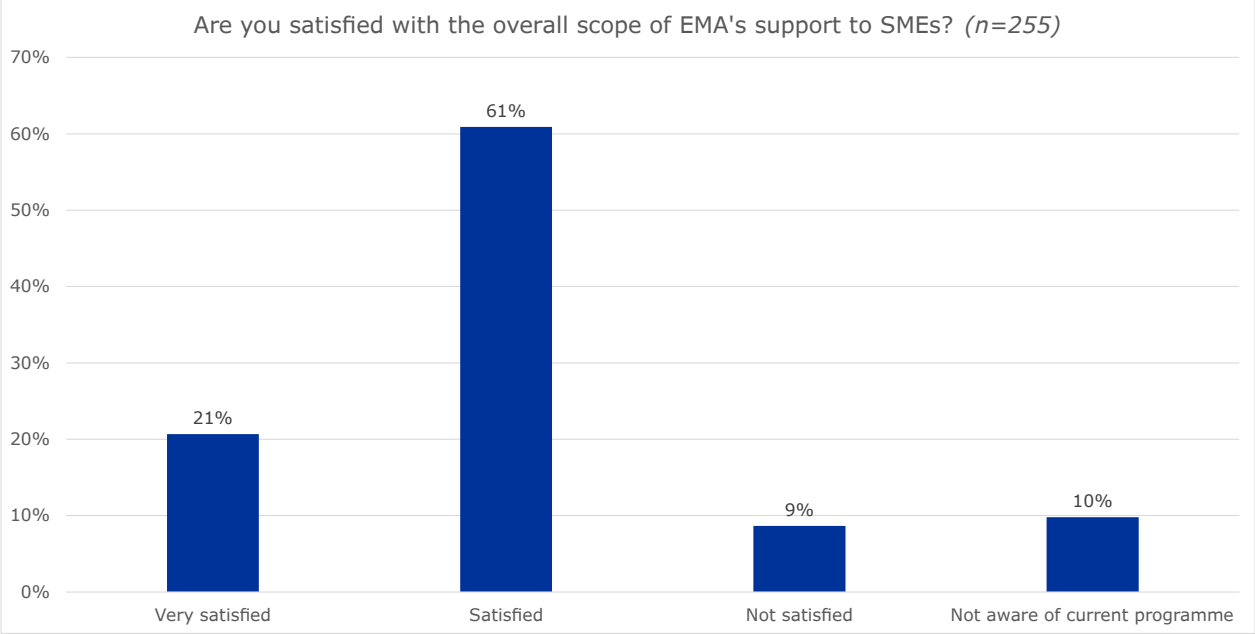
- Simplifying regulatory frameworks and align shortages' reporting requirements across the EU.
- Providing targeted support for SMEs (e.g. assistance with preparing shortage prevention and mitigation plans).
- Introducing targeted fee incentives for SMEs to support regulatory procedures aimed at preventing and managing medicines shortages.
- Establishing an SME-specific European fund to support the maintenance of a security stock following initial product approval.

- Simplifying import procedures for finished products from non-EU countries.
- Enhancing dialogue between regulatory authorities to improve the management of shortages (e.g. improving transparency on national stocks levels).
- Raising awareness of EU initiatives on medicines shortages through training & education, guidance and targeted communications.

- **Opportunities to improve EMA's support for SMEs**

Overall, respondents expressed a positive level of satisfaction with the scope of EMA's SME support programme: 21% were very satisfied, 61% were satisfied, 9% not satisfied and 10% reported not being aware of the current programme (Figure 10).

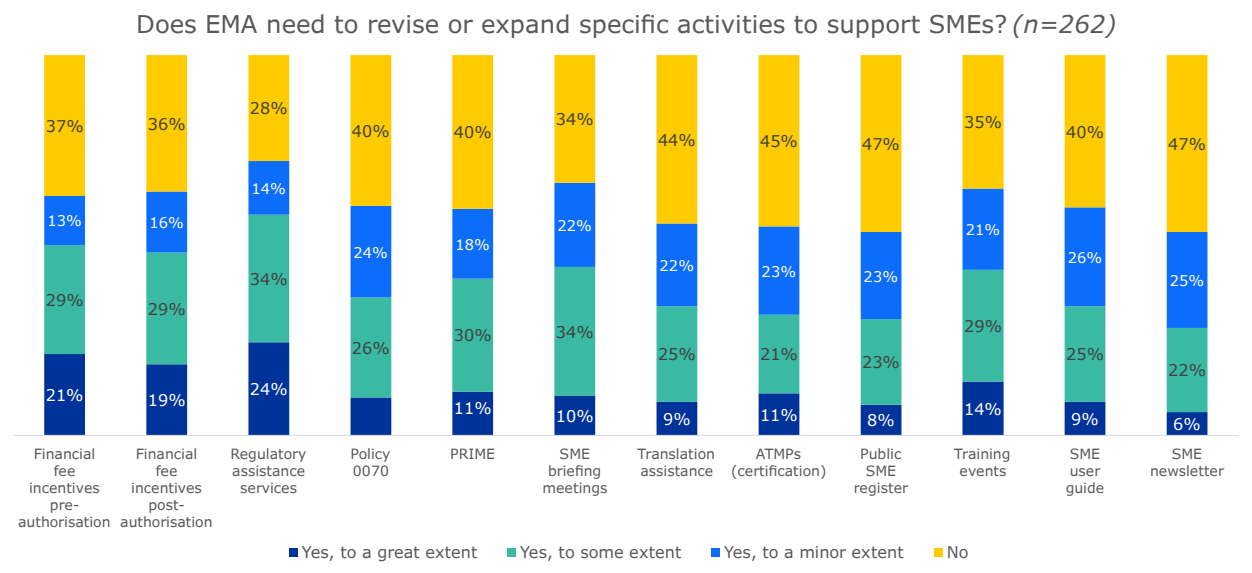
Figure 10. Satisfaction with EMA's support to SMEs



When asked about specific areas of support, respondents indicated that regulatory assistance services should be further revised or expanded, with 58% supporting this view (to a great extent: 24%; to some extent 34%). This was followed by financial incentives pre-authorisation (50%), post-authorisation (48%) and training events (43%) (Figure 11). Conversely respondents felt that no revision or only minor changes were needed for the following support services: the SME newsletter, advanced therapies incentives, the public SME Register and translation assistance.

Additional suggestions for enhancing SME support included: providing support for decentralised procedures (MRP – Mutual Recognition Procedure, DCP – Decentralised Procedure), reviewing the SME definition and its criteria, particularly regarding exemptions and thresholds for venture capital companies, reducing the timelines of regulatory processes and procedures, and strengthening support in post-authorisation. Some of these suggestions extend beyond the scope of EMA's mandate.

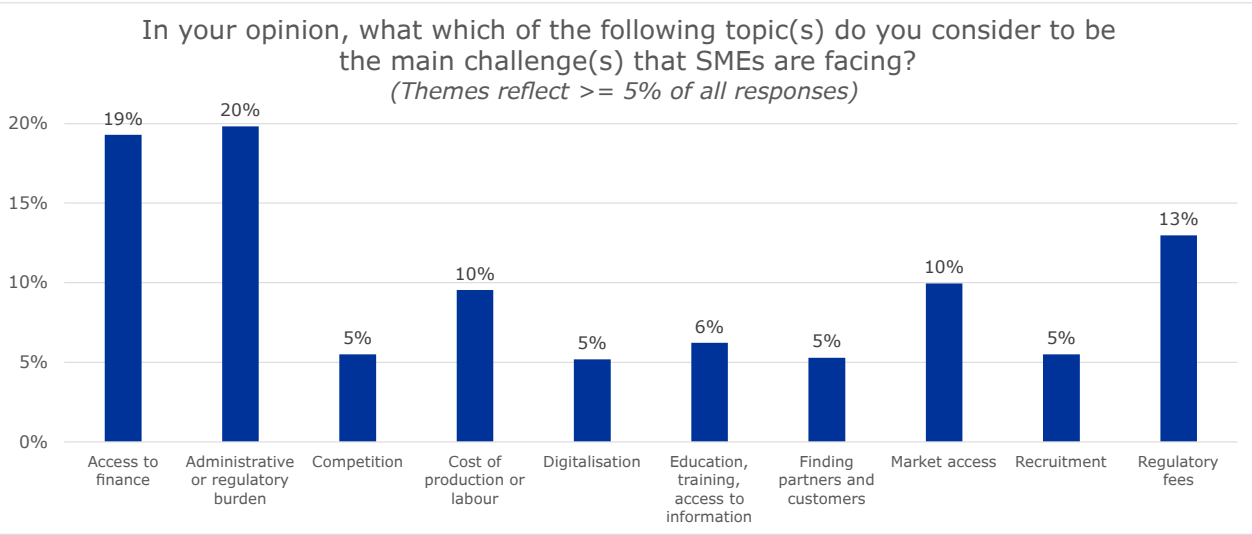
Figure 11. Assessing the need to revise or expand EMA's support activities



5. Challenges faced by SMEs and suggestions for the future

The survey sought to gather feedback from respondents on the key challenges faced by SMEs and to identify potential measures to address them. Based on the previous EMA SME survey, eleven thematic areas were explored: Administrative or regulatory burden, Access to finance, Competition, Cost of production or labour, Digitalisation, Finding partners and customers, Globalisation, Education & training and Access to information, Market access, Recruitment, Regulatory fees (Figure 12).

Figure 12. Challenges reported by SMEs



ADMINISTRATIVE OR REGULATORY BURDEN

Administrative and regulatory burden was identified as a challenge faced by 20% of respondents. Key issues included: the complexity of regulations, particularly related to the Medical Devices Regulation (MDR), the Clinical Trials Regulation (CTR), and the In Vitro Diagnostic Regulation (IVDR), the lack of harmonisation of regulatory requirements across regulatory authorities, and the evolving regulatory demands driven by innovative medicines and technologies (e.g. targeted therapies, companion diagnostics).

Suggested measures to address these challenges include:

- Simplifying and streamlining regulatory frameworks for the development and approval of medicines and technologies 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.

ACCESS TO FINANCE

Access to finance was reported as a challenge by 19% of respondents. Suggested measures to address this issue include:

- 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.

Other challenges and suggested measures are summarised in the following table:

CHALLENGES	**SUGGESTED MEASURES BY RESPONDENTS**
Regulatory fees (13%)	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 (10%)	Providing support and guidance on Health Technology Assessment (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 (9%)	Promoting partnering and networking with investors (e.g. dedicated fora, online platforms).
Cost of production or labour (7%)	Publishing and maintaining a list of Contract Development and Manufacturing Organisations (CDMOs) accessible to SMEs.
Education, training, access to information (6%)	Expanding training and networking events (e.g. free of charge workshops, webinars, e-learning including real case studies and lean training material), in particular for new regulations and funding. Providing information in EU languages.
Digitalisation (5%)	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 (5%)	Support the use of centralised recruitment platforms and systems (e.g. EURES).

6. Conclusions

The 2024 survey confirmed the continued relevance and effectiveness of the SME Regulation in achieving its core objectives — supporting innovation and the development of new medicines by small and medium-sized enterprises in the pharmaceutical sector.

The findings reflect a high level of satisfaction with EMA's SME support framework, with nearly 90% of respondents rating the initiative as relevant or very relevant. The most valued services included the SME newsletter, the SME User Guide, training events, and pre-authorisation fee incentives. Training events in particular were seen as both highly relevant and widely used, underscoring their importance in equipping SMEs with regulatory knowledge and skills. At the same time, the need for expanded and diversified training with leaner formats was articulated.

While general awareness of EMA's SME services remains strong, a notable minority of respondents reported limited knowledge of specific support tools — particularly the support to the Priority medicines (PRIME) scheme, advanced therapies incentives, and translation assistance. This highlights the importance of enhancing outreach efforts to ensure SMEs across all stages of development can benefit from available support.

Respondents called for improvements and enhancements in several areas, notably regulatory assistance services, financial fee incentives, and training. There was also support for initiatives tailored to the challenge of medicines shortages, including better guidance, streamlined reporting and dedicated support. Additional suggestions to improve SME support included: supporting decentralised and mutual recognition procedures, reviewing the SME definition, in particular venture capital provisions, reducing regulatory timelines, and enhancing post-authorisation support.

The challenges SMEs face extend across the product and business lifecycle. Foremost among these were the regulatory burden, access to finance, and regulatory fees. Other notable challenges included market access and training & education. Respondents suggested a range of solutions, including

regulatory simplification and streamlining, expanded access to EU funding, and enhanced advice and support.

Annex

Services surveyed:

- **Financial fee incentives (pre- and post-authorisation)**

Fee exemptions and reductions for pre- and post-authorisation regulatory procedures (e.g. scientific advice, inspections, post-authorisation procedures for centrally authorised products (such as variations) and pharmacovigilance activities.

- **Regulatory assistance services**

Direct assistance to SMEs by phone, email, teleconference on regulatory, administrative and procedural topics.

- **Support to EMA's clinical data publication (Policy 0070)**

Guidance on clinical data publication and free redaction tool license.

- **SME briefing meetings**

Early dialogue platform to discuss the regulatory strategy of a human or veterinary medicinal product development and navigate the range of procedures and incentives available.

- **Support to Priority medicines scheme (PRIME)**

Pre-submission support on the PRIME scheme.

- **Translation assistance**

Free of charge translations of the product information in the EU official languages required to grant an initial EU marketing authorisation.

- **Advanced therapies incentives (certification)**

Enables early review of quality and non-clinical data of advanced therapies and allows a developer to confirm the extent to which the available data comply with the standards that apply for evaluating a dossier.

- **Public SME Register**[1]

A public source of information on EU/European Economic Area-based SMEs involved in the manufacturing, development and/or marketing of human and veterinary products.

[1] EMA SME Register

- **Training events (workshops and SME info days)[2]**

Free of charge regulatory training courses dedicated to addressing the particular needs of SMEs.

- **SME User Guide[3]**

Provides an overview of procedures to support research and development activities and improves understanding of what is needed to obtain marketing authorisation.

- **SME newsletter[4]**

Circulated regularly and published on the EMA website to provide highlights, news, documents, and activities information on the EU regulatory environment for medicines.

[2] Info days and training
[3] User guide for micro, small and medium-sized enterprises
[4] SME newsletters