15 December 2020
EMA/277477/2020
Regulatory Science and Innovation Task Force

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

1. Background, objectives and scope of the survey

The adoption of Commission Regulation (EC) No 2049/2005 (hereafter referred to as the 'SME Regulation'[1]) on 15 December 2005 included implementing provisions relating to SMEs in the pharmaceutical sector with the aim of promoting innovation and the development of new medicinal products by SMEs.

The objective of the survey, launched in January 2020, was to receive feedback and experience from SMEs and stakeholder organisations on the operation of the SME Regulation. It also aimed to understand the challenges currently faced by SMEs and to help EMA in tailoring future activities to their needs.

2. Methodology

The consultation took place over a 7-week period through a web-based survey. The questionnaire included a maximum of 18 questions and was largely based on the previous SME survey[2], conducted in 2015 to mark the 10-year anniversary of the implementation of the SME initiative. All but two – (*i.e.* respondent details and open text comments) – questions required a reply in order to submit the report.

The survey combined the following response formats, depending on the nature of the 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

[1] Commission Regulation (EC) No 2049/2005
[2] SME Survey Report 2015

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The survey was published on the EMA website and on social media on 28 January 2020, and was sent via email to contact points from the SME register (including 2852 active and non-active records) as well as to industry organisations representing SMEs. Five hundred and fifty-eight (558) responses were received. Of those, 553 responses were considered valid (5 responses were duplicates, for which the most complete feedback of the two was taken into account).

3. Profile of respondents

Most of the respondents were SMEs (85%), 11% completed the survey on behalf of an organisation and 4% were individuals (Figure 1). The fields of activity of the respondents were in human health (82%), veterinary health (6%) and both (10%) (Figure 2). The business activities of the majority of companies were in the development, manufacturing or marketing of pharmaceuticals (65%), 18% were service providers to the pharmaceutical industry and 11% were operating in the medical device and technology field. As survey responses were anonymised, more in-depth data was not available on the respondents' profiles. The majority of respondents (93%) indicated holding or having held SME status with the Agency at some point in time.

Figure 1

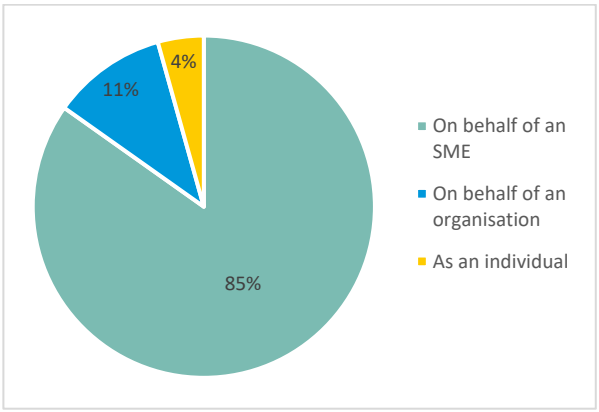
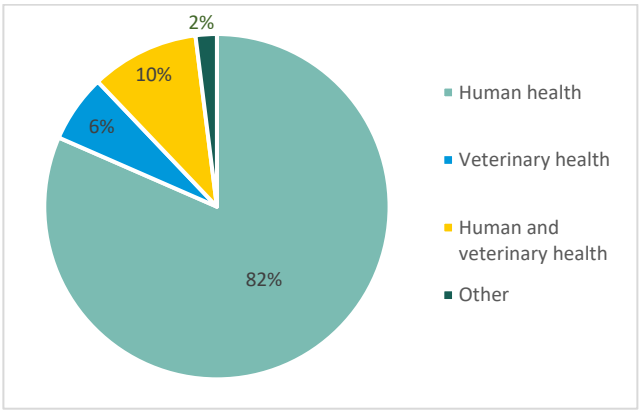


Figure 2



4. Findings from the survey

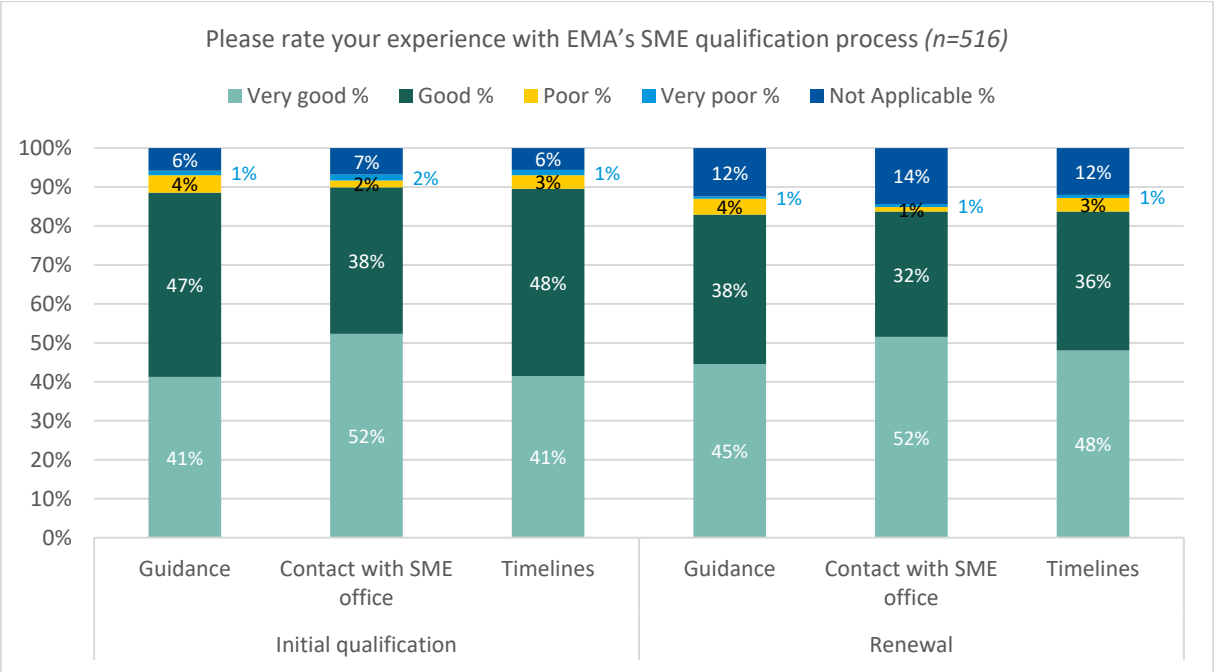
The survey was divided into sections including feedback on EMA's SME qualification process, awareness of EMA's support to SMEs, review of EMA's current SME incentives and opportunities for improvement.

Feedback on EMA's SME qualification process

Respondents were asked to provide comments on the qualification process, which companies must undergo before being able to benefit from the SME incentives.

The degree of satisfaction with the SME assignment process was very high, with nine out of ten SMEs satisfied with the overall process of registration with the SME office (Figure 3). Of those respondents who effectively made use of this process, a very small number considered that the SME renewal process would benefit from improved guidance (6%) and timelines (5%). An improvement is noted on those specific aspects of the renewal process, as compared to the feedback received in the previous SME survey (9 and 7-point for guidance and timelines respectively).

Figure 3

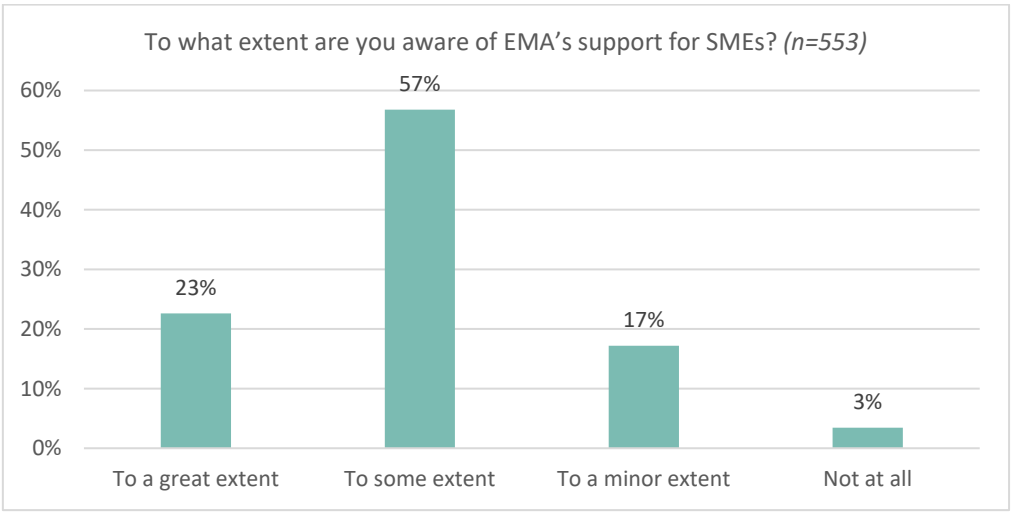


Services offered by EMA's SME Office

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

The first question sought feedback on the general level of awareness of the SME regulation and its implementing measures. The majority of respondents (80%) indicated that they were aware of EMA's support for SMEs, with 57% quantifying their knowledge 'to some extent' and 23% 'to a great extent'. This is a 9-point improvement compared to the feedback received in the previous SME survey, which could be explained by actions put in place to raise awareness[3] (Figure 4).

Figure 4



[3] EMA action plan for small and medium-sized enterprises (SMEs)

Feedback on the respondents' knowledge of specific support activities and services provided for SMEs by EMA was also requested.

The following SME services were surveyed:

- Financial fee incentives (pre- and 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

For a detailed description of the above listed services, please refer to the Annex.

Of the twelve services surveyed, over half of respondents indicated awareness of seven services to a great extent, or to some extent (Figure 5).

Scoring highest in terms of awareness at 72% were the SME newsletter (to a great extent 39%, to some extent 33%) and financial fee incentives (pre-authorisation) (to a great extent 38%, to some extent 34%).

Regulatory assistance services rated third with 65% (to a great extent 27%, to some extent 38%).

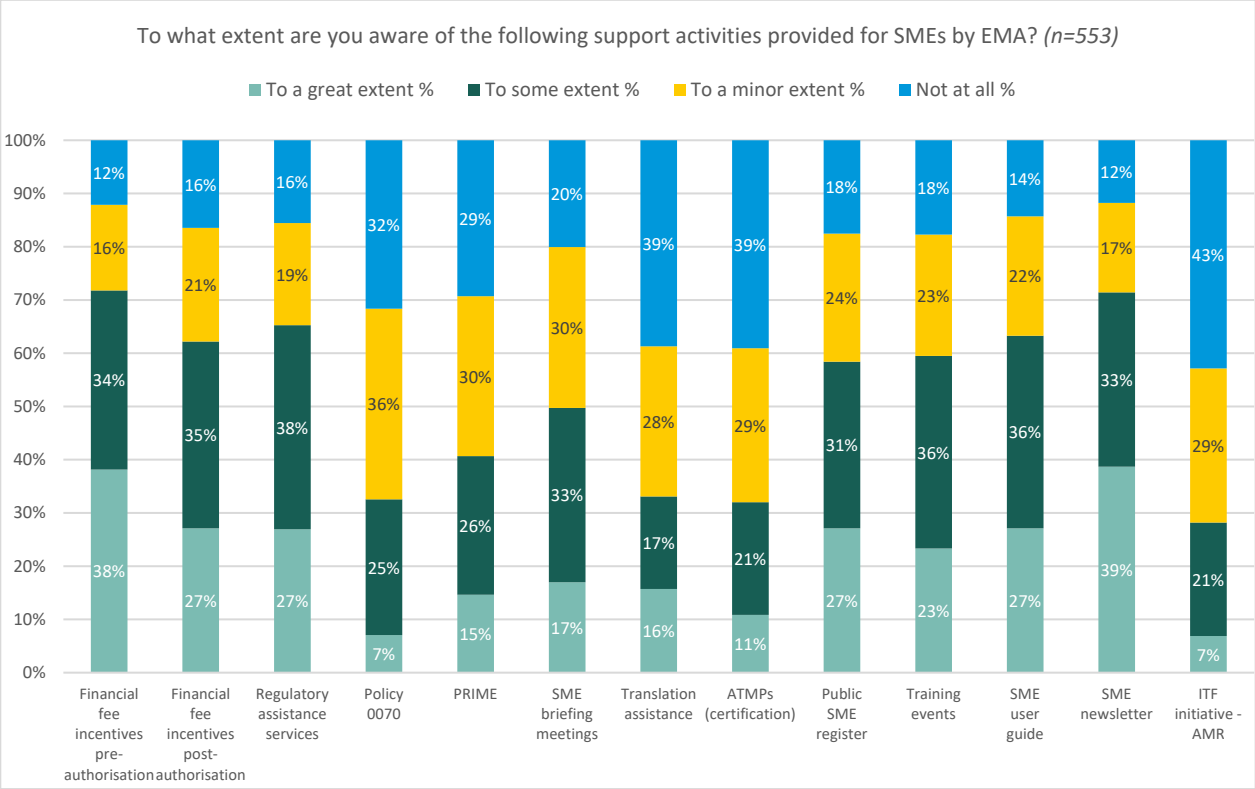
The following services also scored well above the 50% mark: SME User Guide (63%), financial fee incentives (post-authorisation) (62%), training events (workshops and SME info days) (59%) and the public SME Register (58%).

Lower scores were reported for SME briefing meetings (50%) and support to Priority medicines scheme (PRIME) (41%).

Three services ranked low in terms of awareness. Seven out of ten respondents indicated no or only minor awareness of translation assistance with 33% (to a great extent 16%, to some extent 17%), advanced therapies incentives with 32% (to a great extent 11%, to some extent 21%) and the support to EMA's clinical data publication (Policy 0070) with 32% (to a great extent 7%, to some extent 25%). As outlined in the next section 'Experience with services offered by EMA's SME Office, those services which respondents were least aware of were also those which were least used.

In addition, the questionnaire sought specific feedback on the awareness of the Innovation Task Force (ITF) initiative to engage with medicine developers to combat antimicrobial resistance (AMR), for which the majority of respondents (72%) indicated no (43%) or only minor (29%) awareness.

Figure 5



- **Experience with services offered by EMA's SME Office**

The most widely used services were: the SME newsletter (used by 55% to a great extent or to some extent), the SME User Guide (used by 47% to a great extent or to some extent) and financial fee incentives (pre-authorisation) (used by 46% to a great extent or to some extent) (Figure 6). Two services that respondents were most aware of were also those that were mostly used.

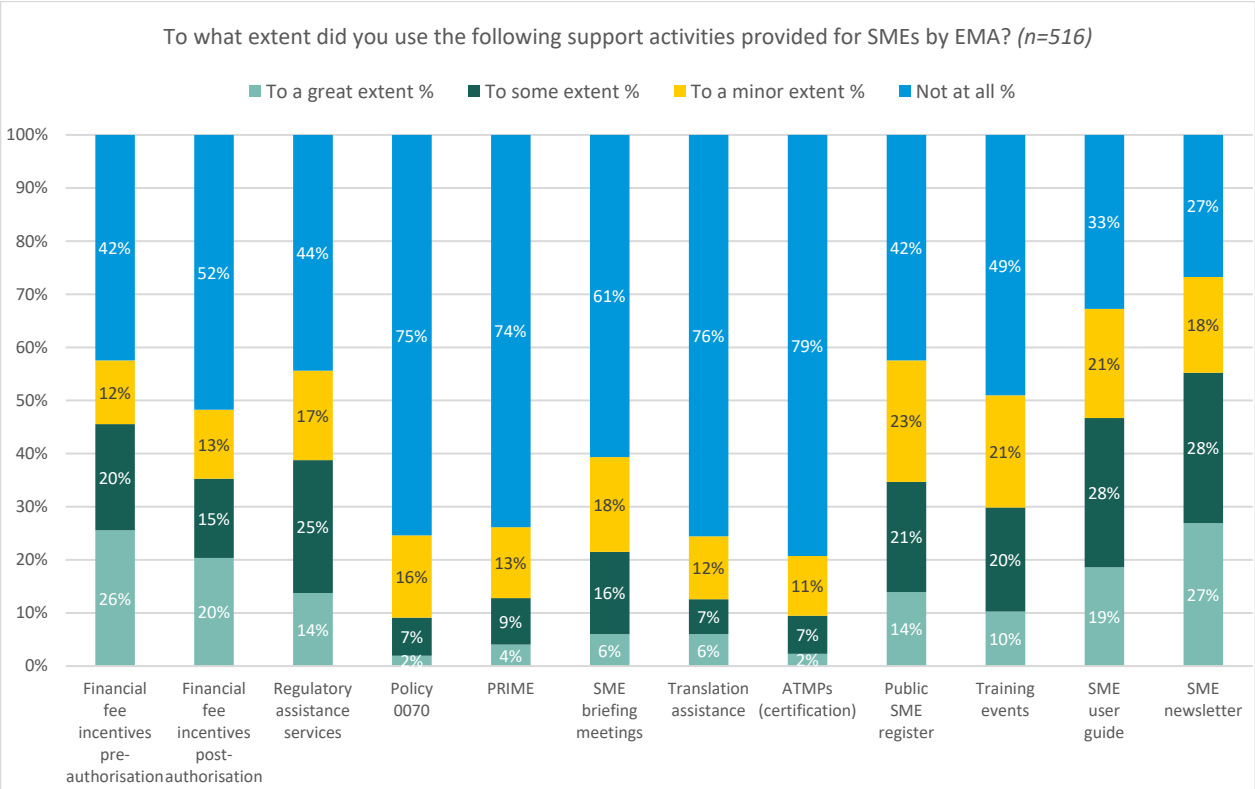
Moderately used were the regulatory assistance services (used by 39% to a great extent or to some extent), the financial fee incentives (post-authorisation) (used by 35% to a great extent or to some extent), the Public SME Register (used by 35% to a great extent or to some extent), training events (workshops and SME info days) (used by 30% to a great extent or to some extent), the SME briefing meetings (used by 22% to a great extent or to some extent) and support to Priority medicines scheme (PRIME) (used by 13% to a great extent or to some extent). Lower scores for training events might be related to limited activity for this support measure in the context of the business continuity planning and EMA's relocation.

Limited experience was reported on incentives relating to advanced therapies (79% did not use it at all), translation assistance (76% did not use it at all) and the support to EMA's clinical data publication (Policy 0070) (75% did not use it at all).

Low scores for incentives relating to advanced therapies might be explained by the limited number of registered companies operating in the field (7%).

With regards to translation assistance and support to EMA's clinical data publication (Policy 0070), low scores might be related to the fact that this support measure is targeted at those SMEs planning a marketing authorisation application, which are limited in number.

Figure 6



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

A high proportion of respondents indicated that the SME initiative had been relevant or very relevant (89%) (Figure 7). An 11-point improvement compared to the feedback received in the previous SME survey was noted.

In terms of relevance, the SME newsletter was rated the highest (65% – very relevant 26%, relevant 39%) followed by the SME User Guide (60% – very relevant 22%, relevant 38%) and financial fee incentives (pre-authorisation) (53% – very relevant 35%, relevant 18%).

Lower scores were reported for the following services: regulatory assistance services (50% – very relevant 22%, relevant 28%), training events (workshops and SME info days) (48% – very relevant 18%, relevant 30%), Public SME Register (44% – very relevant 14%, relevant 30%), financial fee incentives (post-authorisation) (42% – very relevant 22%, relevant 20%), SME briefing meetings (34% – very relevant 11%, relevant 23%), support to Priority medicines scheme (PRIME) (21% – very relevant 8%, relevant 13%) and translation assistance (21% – very relevant 10%, relevant 11%).

Incentives relating to advanced therapies and EMA's clinical data publication (Policy 0070) scored the lowest in terms of relevance with 17% and 20% of respondents respectively. The scores are in line with previously reported low scores for awareness and use.

The breakdown for relevance of specific support measures is provided in Figure 8.

Figure 7

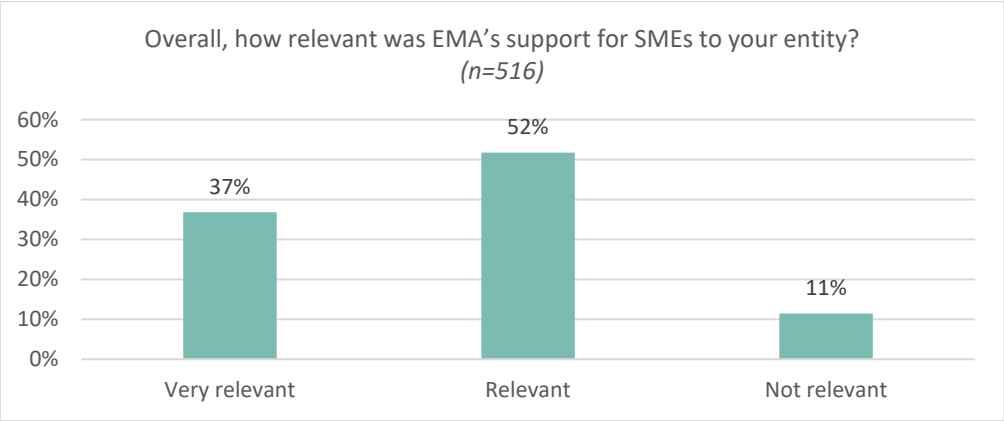
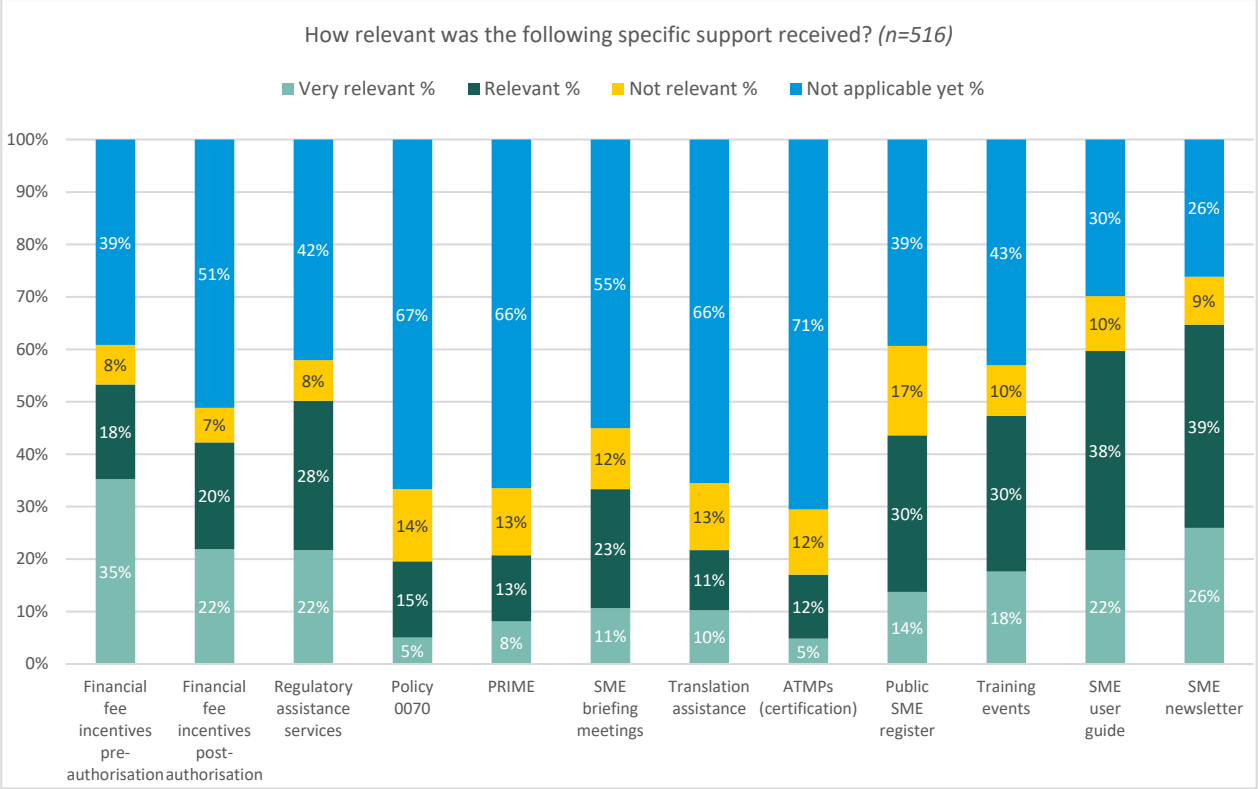


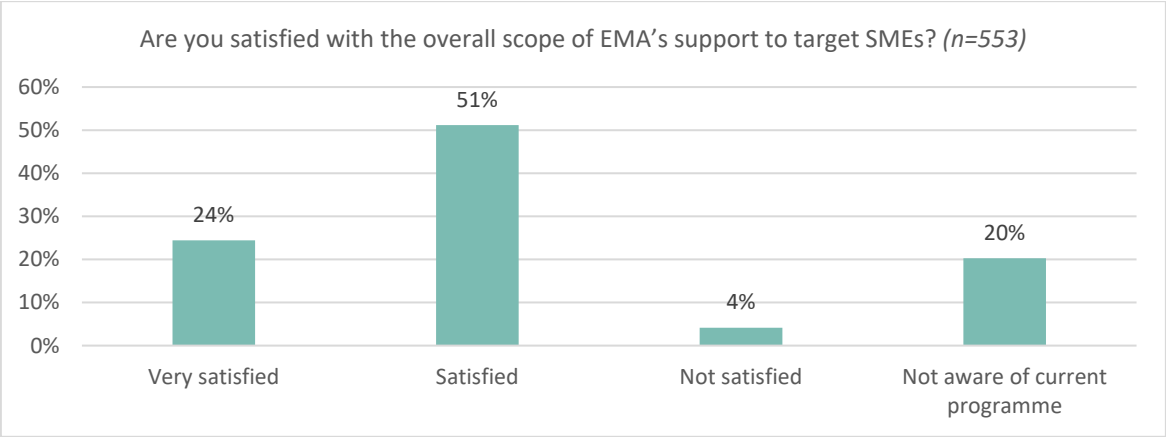
Figure 8



- **Opportunities for improvement of EMA's support for SMEs**

Overall, respondents were satisfied with the scope of EMA's support to target SMEs: 24% very satisfied, 51% satisfied and 4% not satisfied. Twenty percent (20%) declared not being aware of the current programme (Figure 9).

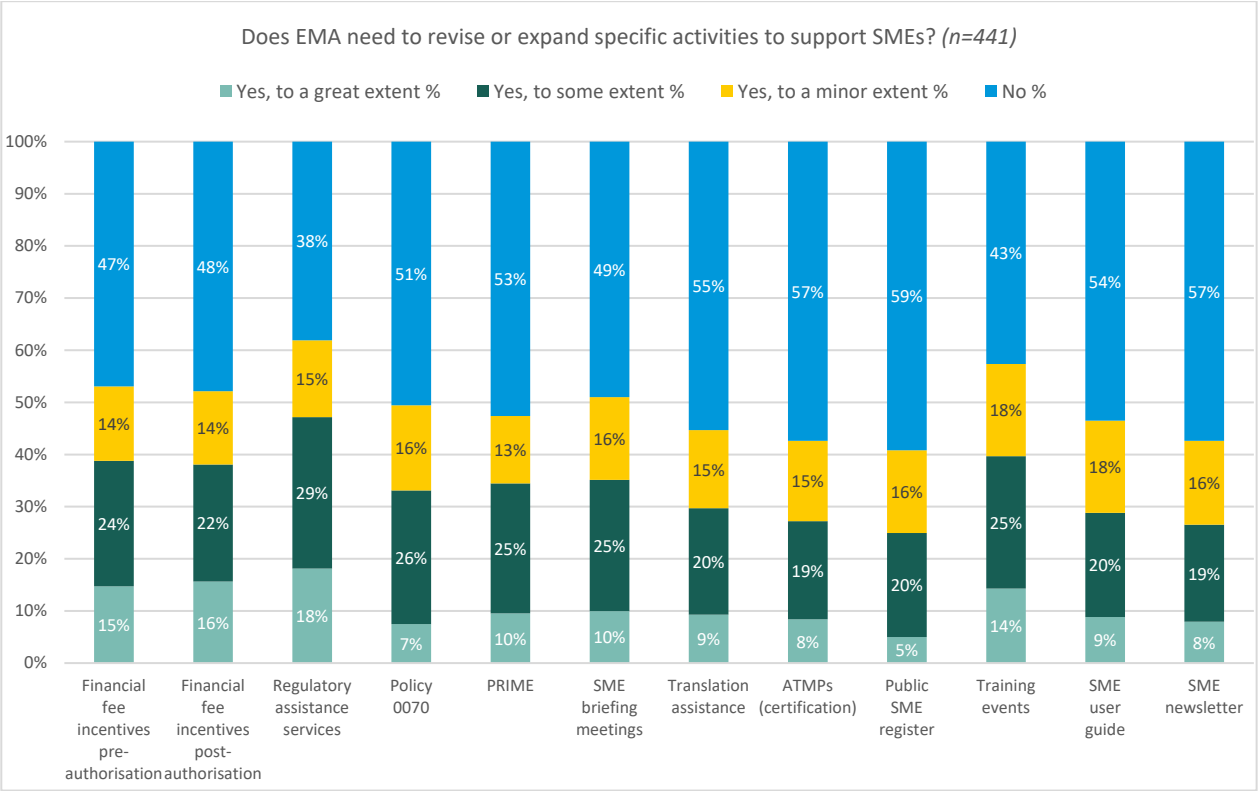
Figure 9



Looking at specific activities to support SMEs, respondents considered that the Agency should further revise or expand regulatory assistance services provided to SMEs with 47% (to a great extent 18%, to some extent 29%). This was followed by training events with 39% (to a great extent 14%, to some extent 25%) and financial incentives, both pre- (39%) and post-authorisation (38%) (Figure 10).

Respondents indicated that there was no need, or if any, to a minor extent, to revise or expand the following support services: SME briefing meetings, translation assistance, SME User Guide, SME newsletter, advanced therapies incentives, the public SME Register, support to EMA's clinical data publication (Policy 0070) and support to Priority medicines scheme (PRIME).

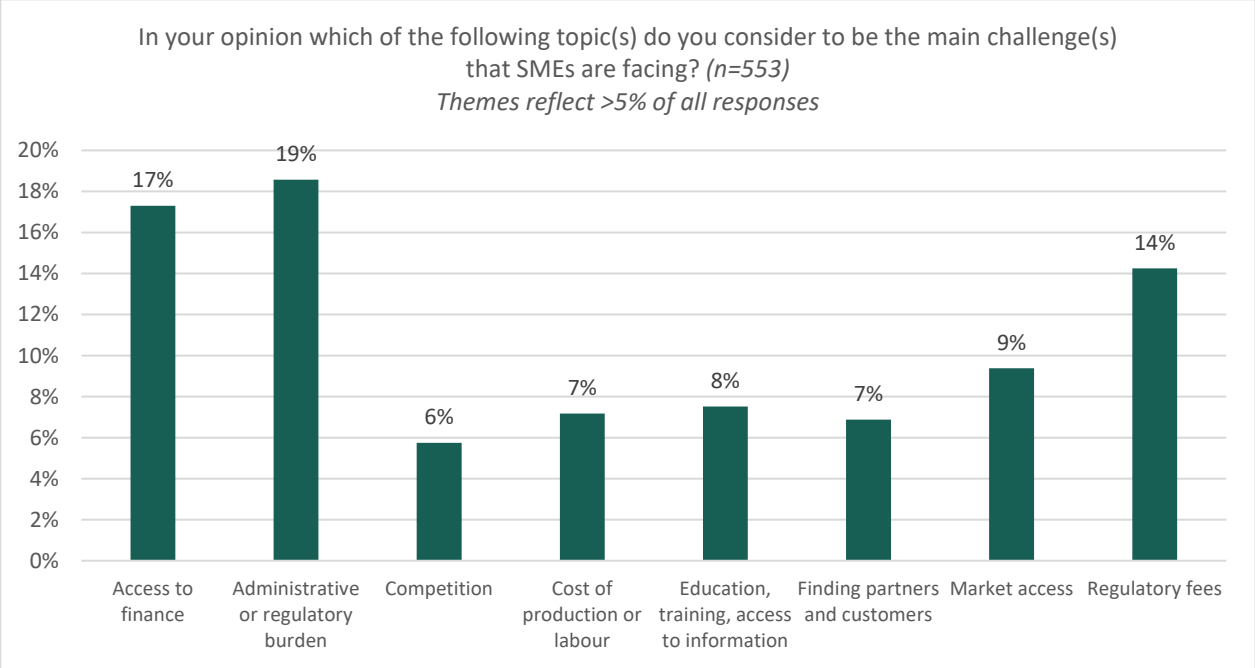
Figure 10



5. Challenges faced by SMEs and suggestions for the future

The survey aimed to receive feedback from respondents on challenges that SMEs are facing and elicited measures to address them. Eight themes were identified based on the previous EMA SME survey: Administrative or regulatory burden; Access to finance; Competition; Globalisation; Education, training, access to information; Market access; Recruitment; Regulatory fees. In addition, three new topics identified in the 2019 SME performance review[4] conducted by the European Commission were added to the previously listed themes: Cost of production or labour; Digitalisation; Finding partners and customers (Figure 11).

Figure 11



ADMINISTRATIVE OR REGULATORY BURDEN

Administrative and regulatory burden was reported as a challenge faced by 19% of respondents. Challenges were related to complexity of regulations, requirements for the preparation of multiple regulatory files and lack of harmonisation of regulatory requirements between authorities.

Suggested measures to address these challenges are summarised as follows:

- Simplify, reduce and harmonise regulatory requirements at EU level and globally (*e.g.* for clinical trials and marketing authorisation applications, engagement with SMEs during guidance development).
- Introduce exemptions for regulatory procedures or requirements (*e.g.* paediatric investigation plan (PIP), pharmacovigilance).
- Reduce and simplify the administrative burden (*e.g.* SME registration, cooperation with EU and national authorities supporting SMEs).
- Enhance regulatory and scientific advice (*e.g.* informal and early advice, align evidence needs with HTA stakeholders).

[4] SME Performance review 2019

ACCESS TO FINANCE

Access to finance was reported as a challenge by 17% of respondents. Suggested measures are summarised as follows:

- Increase and facilitate access to finance and capital (*e.g.* diversify types of funding (grants, loans, equity), ease eligibility criteria), develop targeted instruments for start-ups and in specific fields such as anti-infectives, regenerative medicines, orphan medicines, repurposing medicines developments).
- Increase access to information on funding opportunities for SMEs at EU and national level.
- Facilitate networking, partnering and matchmaking between SMEs, academia and investors (*e.g.* platforms for demand and supply of venture capital).
- Other suggested measures reported under access to finance related to introducing tax credits.

Other challenges and suggested measures are highlighted in the following table. Additional challenges identified by respondents were related to Brexit.

CHALLENGES	**SUGGESTED MEASURES BY RESPONDENTS**
Regulatory fees (14%)	Enhance EMA and national fee incentives (pre- and post-authorisation), particularly for veterinary and micro-sized enterprises. Introduce or enhance fee incentives for serialisation (falsified medicines legislation).
Market access (9%)	Offer guidance and support on market access, pricing and launch. Align licensing and market access requirements.
Education, training, access to information (8%)	Increase training (*e.g.* workshops, webinars, e-learning). Provide financial support for training organised by third party organisations. Enhance EMA website experience (*e.g.* clarity on regulatory updates).
Cost of production or labour (7%)	Facilitate access to information on suppliers.
Finding partners and customers (7%)	Increase SME networking opportunities in the EU and internationally (*e.g.* for funding, partnering, identifying vendors, suppliers or expertise). Facilitate access to information on accredited service providers.
Digitalisation (5%)	Support digital transformation of SMEs, particularly veterinary and micro-sized enterprises (*e.g.* reduce electronic systems requirements, provide incentives or free access to software, in particular for pharmacovigilance and serialisation). Enhance training on digital transformation (*e.g.* IRIS).
Recruitment (3%)	See finding partners and customers (*e.g.* digital platform for recruitment).

6. Conclusions

The survey confirmed that the SME Regulation continues to successfully deliver on its intended objectives, which are to promote innovation and the development of new medicines for human and veterinary use by SMEs.

Almost ninety per cent of respondents reported that overall, the SME initiative had been relevant or very relevant to them, which is an improvement compared to feedback received in the previous survey. Specific incentives considered the most significant were the pre-authorisation financial fee incentives, the SME User Guide and the SME newsletter.

About twenty percent of respondents had no knowledge or only limited knowledge of EMA's support for SMEs, highlighting the need to continue raising awareness of the programme.

In terms of scope of EMA's support, regulatory assistance services provided by the SME office, training events and financial incentives, both for pre- and post-authorisation, were considered as areas which could be further expanded by EMA.

Overall, minor differences between respondents in the human and veterinary fields were noted.

Challenges faced by SMEs covered all phases of an enterprise or product life cycle, with the top three relating to the administrative and regulatory burden, access to finance and regulatory fees.

Suggested measures on how to address these challenges were highlighted. They included easing the burden of regulation, reducing its complexity, facilitating access to finance with a wider range of funding tools targeted at start-ups and their pipelines, and enhancing fee incentives over the product life-cycle.

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 ATMPs 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[5]**

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.

[5] EMA SME register

- **Training events (workshops and SME info days)[6]**

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

- **SME User Guide[7]**

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

- **SME newsletter[8]**

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

[6] Info days and trainings
[7] User guide for micro, small and medium-sized enterprises
[8] SME newsletters