



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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

Regulation (EC) No 2049/2005 (hereafter referred to as the 'SME Regulation') aims to promote innovation and the development of new medicinal products by SMEs through the implementation of dedicated provisions for SMEs in the pharmaceutical sector.

The objective of the SME office survey, launched in August 2015, was to receive detailed feedback from SMEs and SME stakeholders on the SME initiative, 10 years following its implementation. It also aimed to identify current and future challenges faced by SMEs in the pharmaceutical sector and areas for further development of the Agency's SME programme.

2. Methodology

The consultation took place over a 6-week period in August 2015 through a web-based survey. The survey contained a maximum of 17 questions and was largely based on the initial SME survey, conducted in 2011 to mark the 5-year anniversary of the implementation of the SME initiative.

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

- Dichotomous Scale (Yes/ No)
- 4-point Rating Scale (Great extent– Some extent - Minor extent - No)
- 3-point Rating scale (Very relevant – Relevant – Not relevant)
- Multiple choice and multiple response
- Free text

The survey was published on the EMA website on 19 August 2015 and was additionally sent via e-mail to contacts from the SME database (2904 active and non-active records) as well as to SME stakeholders. Five hundred and thirty-seven (537) responses were received. Of those, 534 responses were considered valid (answering at least the first 4 questions of the questionnaire).



3. Profile of respondents

The majority of respondents were SMEs (81%), 12% completed the survey on behalf of organisations and 7% were individuals. The field of activity of the respondents was in human health (82%), veterinary health (9%) and both (8%). The business activity of the majority of companies was pharmaceuticals (62%), 15% were regulatory consultancies and 12% were in the medical device field. As survey responses were anonymised, more in depth data was not available on the respondents' profiles. However, as the majority of respondents indicated holding or having held SME status with the Agency at some point in time, it seems justified to use this population as a reference.

The typical profile of an SME that is or has been registered with the Agency is as follows:

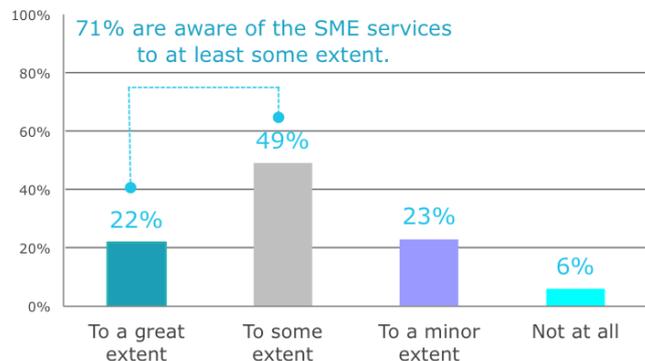
- Micro-sized
- Autonomous
- Based in the UK (19%), Germany (12%) or France (8%)
- Active in the human medicines field

4. Findings from the survey

- **Awareness of the Agency's SME programme**

The first question sought feedback on the general level of awareness of the SME regulation and its implementing measures. The majority of respondents (71%) indicated that they were aware of the Agency's SME programme with 49% quantifying their experience 'to some extent' and 22% 'to a great extent'. Feedback on the respondents' knowledge of specific support activities and services offered through the SME office was also requested.

To what extent are you aware of the Agency's programme for SMEs? (n=534)



The services that were surveyed were:

- Financial fee incentives (pre- and post-authorisation)
- Regulatory assistance
- SME briefing meetings
- Translation assistance
- Advanced therapies medicinal products incentives
- Public SME register
- Workshop and training events
- SME newsletter

For a detailed description of the above listed services, including usage statistics please refer to the 'Report on the 10th anniversary of the SME initiative' (EMA/155560/2016).

Seven out of the ten surveyed services ranked high in terms of awareness, with more than half of all respondents indicating awareness of the respective service to a great or some extent.

- 1

Financial fee incentives

Scoring highest in terms of awareness were **financial fee incentives** (pre-authorisation) with 66% awareness (to a great extent 35%, to some extent 31%).
- 2

Regulatory assistance

This was followed by **regulatory assistance** with 65% being aware of this service (to a great extent 29%, to some extent 36%).
- 3

SME newsletter

The **SME newsletter** ranked third with 63% awareness (to a great extent 28% to some extent 35%).

The following additional services also scored consistently high above the 50% mark: financial fee incentives (post-authorisation) (61%), SME user guide workshop & training events (59%) and the public SME register (58%). Limited awareness was reported for three of the ten surveyed services (see info box 1): SME briefing meetings, translation assistance and incentives relating to advanced therapies.

Info box 1

LIMITED AWARENESS

Limited awareness was reported for three of the ten surveyed services.

- **SME briefing meetings:**



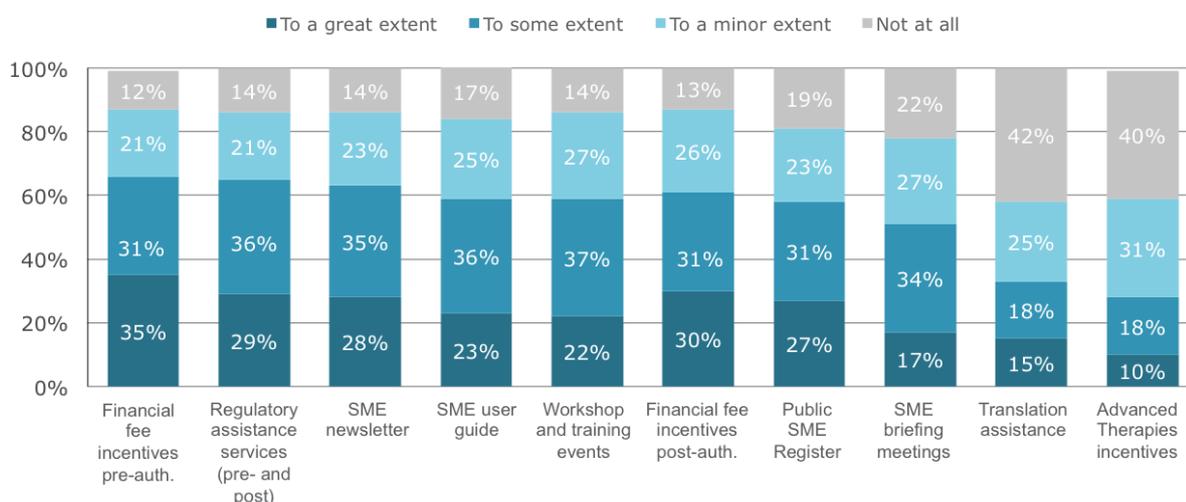
1 in 2
respondents were not aware of SME briefing meetings or only to a minor extent.
- **Translation assistance / Advanced therapies incentives**

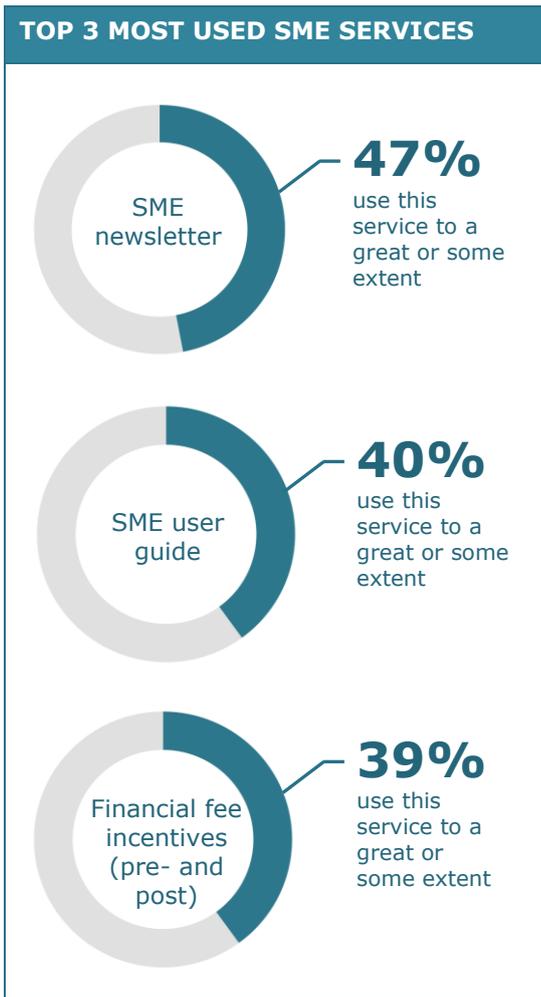


7 in 10
respondents indicated no or only minor awareness of the translation assistance (67%) and advanced therapies incentives (71%).

As outlined in the next section 'Experience with the programme', those services that respondents were least aware of were also those that were used least (info box 2). The table below gives a detailed overview of how aware respondents were of all ten SME services. Info box 1 provides details on the three services that ranked lowest in terms of awareness.

To what extent are you aware of the following support activities provided for SMEs by the Agency? (n=464)





• **Experience with the programme**

Survey results indicate a correlation between awareness of a respective service and how often this particular service is used. Accordingly, responses show that the services most widely used are those, which respondents were sufficiently aware of: the SME newsletter, the SME user guide and financial fee incentives (pre- and post-authorisation) (see info box 2).

Moderately used were the SME register (used by 36% to at least some extent), regulatory assistance (used by 35% to at least some extent) and workshops and training events (used by 31% to at least some extent).

The limited awareness of and experience with SME briefing meetings can be explained by the lack of related information on the SME office website.

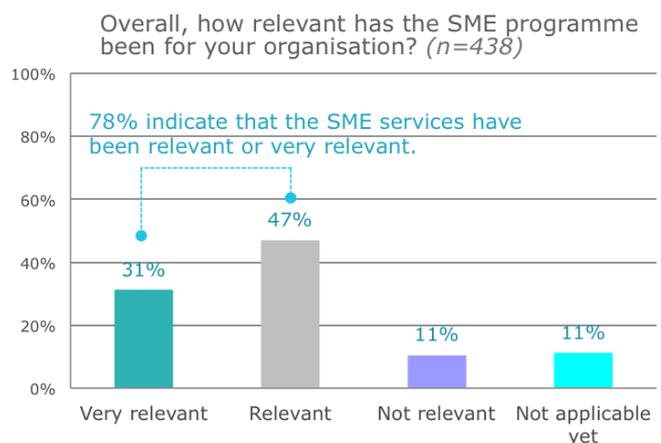
With regard to translation assistance, low scores are due to the fact that this support measure is targeted at those SMEs planning a marketing authorisation application, which are limited in number. Thus, focusing only on those companies for whom translation assistance was relevant, all but one have made use of this service to date.

Finally, low awareness and uptake of incentives relating to advanced therapies might be explained by the limited number of companies in the space overall and the lack of details on the advantages of the incentives on offer.

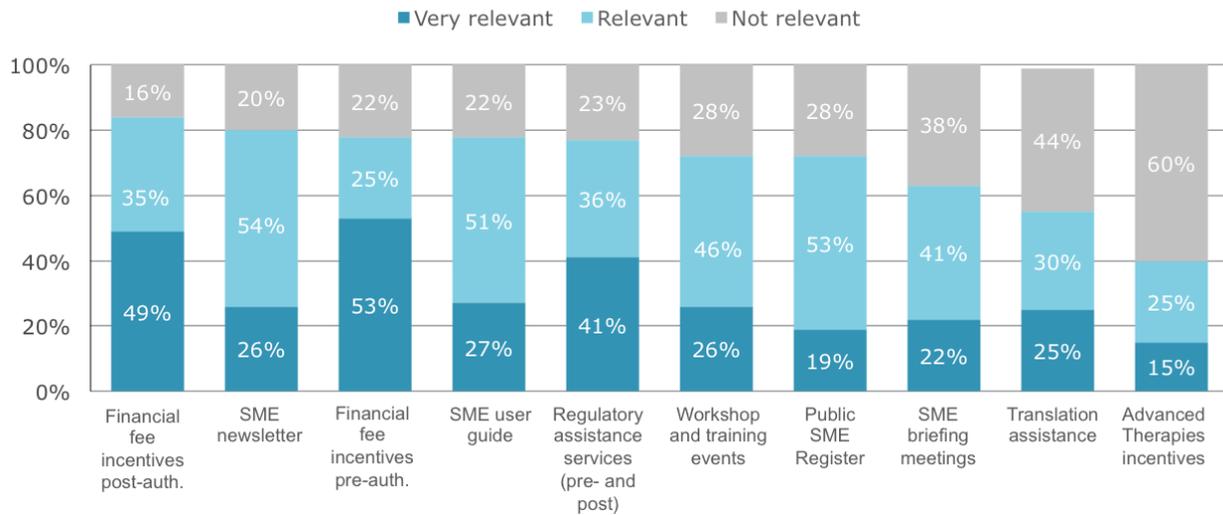
• **Relevance of the programme**

A high proportion of respondents indicated that the SME initiative had been relevant or very relevant to their company (78%), while for one in ten respondents the provided support services had not been applicable yet.

In terms of relevance, financial incentives (post-authorisation) were rated highest (very relevant 49%, relevant 35%) followed by the SME newsletter (very relevant 26%, relevant 54%). Financial fee incentives (pre-authorisation) and the SME user guide both scored third place in terms of relevance with nearly eight in ten rating them either very relevant or relevant. The complete breakdown for specific support activities in terms of their respective rated relevance is provided in the following chart.



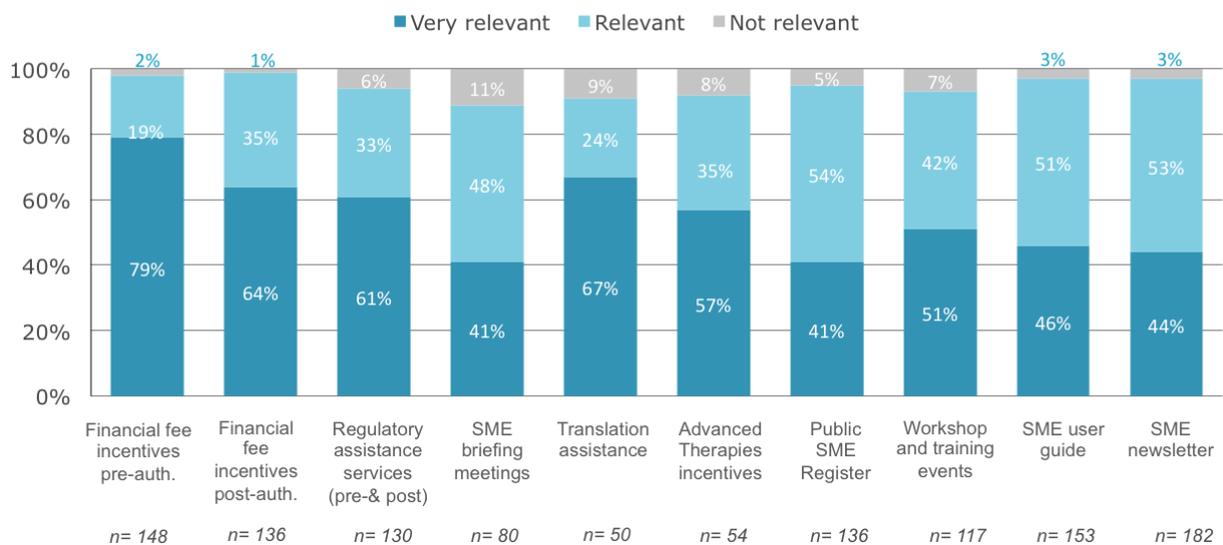
How relevant were the following specific activities? (n=422)



Incentives relating to advanced therapies and translation assistance scored lowest in terms of their perceived relevance with 60% and 44% of respondents respectively classifying them as 'not relevant'. The survey also found that both these support activities had not been applicable yet for around half of the surveyed population. This is in line with the previously reported low scores for awareness and usage.

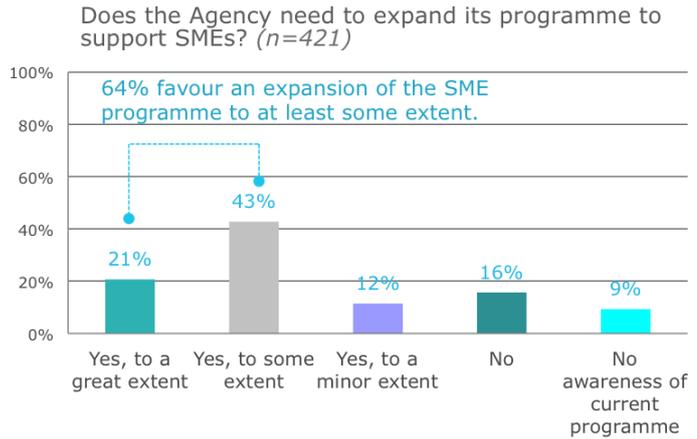
Interestingly filtering responses to include only those respondents who had benefitted from a specific incentive to at least some extent showed that all services were deemed relevant or very relevant (>89%) by those who had made use of it. For example, respondents who had benefitted from the advanced therapies incentives to at least some extent rated this service relevant (35%) or very relevant (57%).

Respondents who have made use of a particular service to at least some extent, consistently rate that respective service very highly (>89%) in terms of relevance.



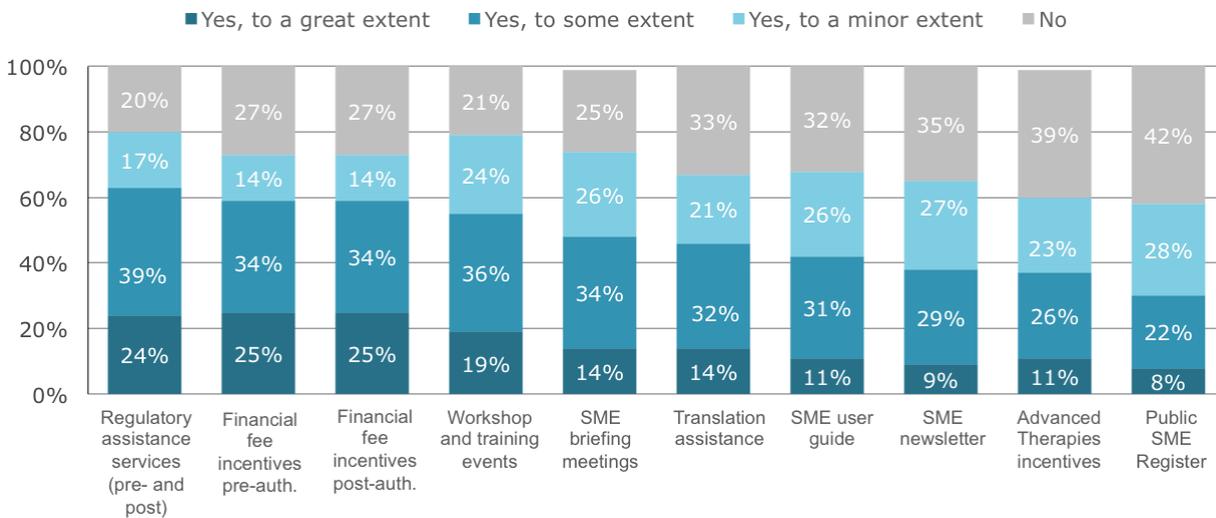
- **Scope of the programme**

Overall, respondents were satisfied with the scope of the Agency’s SME programme. Sixteen percent (16%) felt that the current programme was sufficient, 12% that minor changes were needed and 43% that it needed expanding ‘to some extent’. One in five respondents felt that the programme needed to be broadened ‘to a great extent’.



Looking at specific support measures, a majority of respondents considered that the Agency should further expand the regulatory assistance provided to SMEs (to a great extent 24%, to some extent 39%), closely followed by 59% expressing the wish for increased financial incentives, both pre- and post- authorisation (to a great extent 25%, to some extent 34%) and 55% who felt that more workshops and training events would be beneficial (to a great extent 19%, to some extent 36%). In terms of the remaining support services (SME briefing meetings, translation assistance, SME user guide, SME newsletter, advanced therapies incentives, public SME register), the majority of respondents indicated that expansion was only needed to a minor extent or not at all.

Does the Agency need to **expand specific activities** in the EMA programme to support SMEs? (n=414)

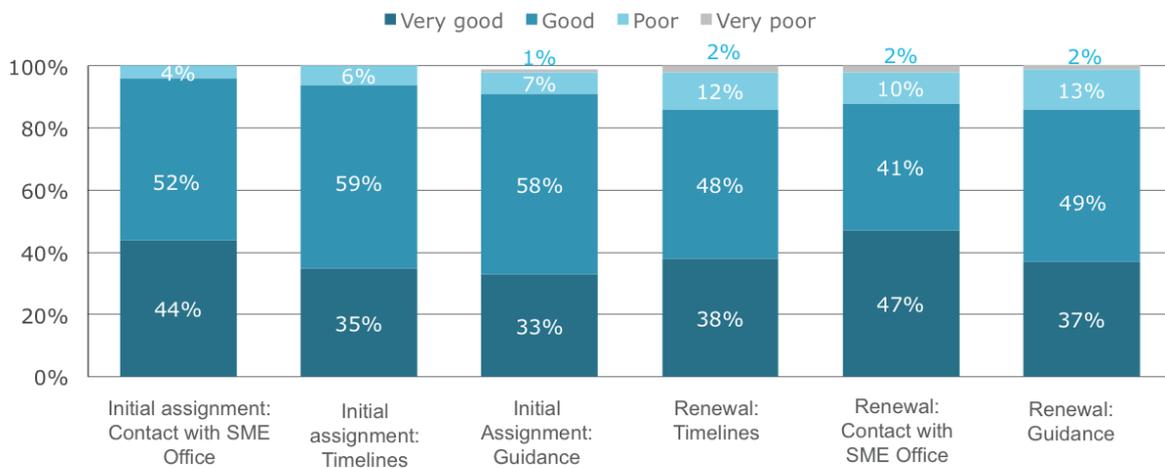


- **Feedback on the SME registration**

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

The level 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. A small number of respondents considered that the SME renewal process would benefit from improved guidance (15%) and timelines (12%). Details about the initial assignment and renewal process are provided in the following chart:

Please rate the Agency's SME registration process. (n=307)



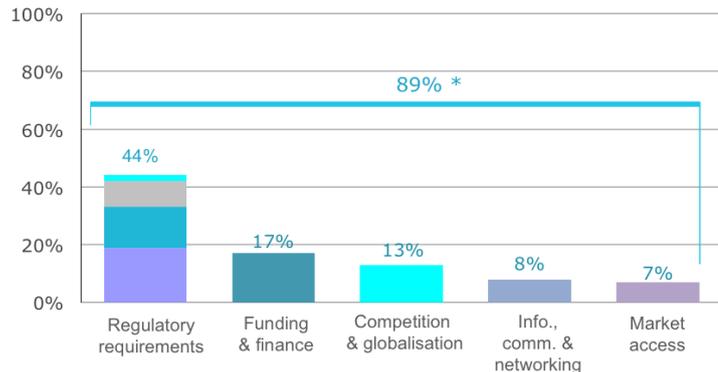
5. Challenges and suggestions for the future

The survey also took the opportunity to ask respondents to reflect on current as well as future challenges that SMEs may be facing and to provide input on suggested measures that may address these challenges. The breakdown of current and future challenges and suggested measures were similar, with market access and recruitment, education, training emerging as new future themes.

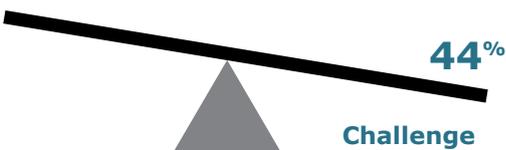
Three hundred seventy three (373) responses were received. Identified commonalities in the responses were

grouped into five themes: regulatory requirements, funding and finance, competition and globalisation, information, communication & networking and market access.

In your opinion, what challenges will SMEs be facing in the next 5 years?

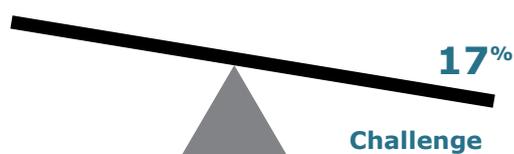


(*) Themes reflect >=5% of all responses)



REGULATORY REQUIREMENTS

The burden of regulations is cited as a top concern for more than 4 in 10 surveyed SMEs. Under the header of 'regulatory requirements', respondents reported challenges concerning the complexity of regulations (19%), the administrative burden (e.g. preparation of multiple regulatory dossiers, multiple procedures) (14%), regulatory costs, such as fees for regulatory procedures (9%) and lack of harmonisation of regulatory requirements between regulatory authorities (2%).



FUNDING & FINANCE

Access to finance and capital was a recurring concern expressed (17%). Amongst suggested measures to mitigate this challenge were more dedicated funding for SMEs as well as earlier access to funding.

Accordingly, feedback on suggested measures to address perceived challenges mainly focused on ways to mitigate concerns surrounding regulatory requirements (42%). Suggestions included an increase of regulatory support and assistance (17%) (e.g. specific contact points for SMEs during regulatory procedures at the EU and national level as well as more informal and early advice), a reduction of cost of EU and national regulatory procedures, in particular in the area of pharmacovigilance (9%), a reduction of the regulatory burden (9%) (e.g. fewer but clearer guidance in particular for pharmacovigilance, and ensuring guidance is changed less frequently). Other suggestions included the need for harmonisation of regulatory requirements in particular for veterinary products and at the national level (5%) and a reduction of the administrative burden (2%) (e.g. simplifying procedures, reducing the need for repeated submission of identical data for various regulatory procedures).

Other reported challenges and their related measures included:

IDENTIFIED CHALLENGES	SUGGESTED MEASURES BY RESPONDENTS
Competition & globalisation (13%)	<ul style="list-style-type: none"> • Support internationalisation of SMEs • Support entry of 'third countries' innovators in Europe
Information, communication & networking (8%)	<ul style="list-style-type: none"> • Improve access to information & communication, e.g. increase information available in EU languages • Increase training opportunities e.g. through workshops • Engage SMEs and stakeholders, e.g. through networking opportunities for SMEs, in particular with academia and research centres
Market access (7%)	<ul style="list-style-type: none"> • Increase interaction between regulatory authorities and HTA bodies
Recruitment, education, training (4%)	Same as those under ' Information, communication & networking '

6. Conclusions

The survey confirmed that, ten years after its introduction, the SME initiative has met its intended objective, which is to support pharmaceutical innovation in small and medium-sized enterprises.

Almost eighty per cent reported that the SME initiative had been relevant or very relevant to them. Overall, the benefits considered the most significant were financial incentives (pre- and post-authorisation), the SME newsletter, the SME user guide and regulatory assistance.

A third of respondents had no or only limited knowledge of the SME programme overall, highlighting the need for improved information and communication to raise awareness of the scheme, in particular for SME briefing meetings, translation assistance and incentives relating to advanced therapies.

In terms of scope of the SME programme, regulatory assistance and financial incentives were considered as areas, where increased support was most needed. This was equally highlighted in the most frequent challenges, which related to regulatory requirements, the administrative burden and cost of regulatory procedures and suggested support measures on how to address them. Market access and recruitment, education and training were new themes emerging as challenges identified by SMEs.

The Agency is committed to continuing to support SMEs in the pharmaceutical sector. An action plan setting out the Agency's activities to tackle effectively challenges of SMEs will be elaborated taking into account the 10 year report on the SME programme (EMA/155560/2016) and the EU Medicines Agencies Network Strategy to 2020.