



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA SME Survey 2020

EMA roundtable with stakeholders – 15 years supporting SMEs



Presented by Clément Provansal on 27 November 2020
Scientific Officer, SME Office | Regulatory Science and Innovation Task Force (TRS)

An agency of the European Union





Introduction



Survey objectives and scope

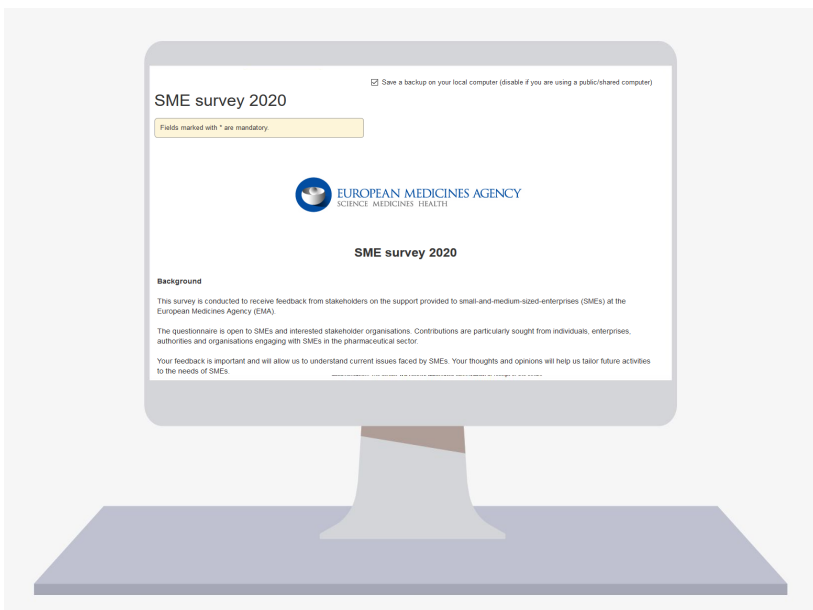
- Evaluate the **experience** from SMEs and stakeholder organisations on the operation of the SME Regulation.
- Receive **feedback** on the support provided to SMEs at the EMA.
- Better understand current **challenges** faced by SMEs.
- Tailor our **future activities** to better meet the needs of SMEs.

What do we aim to achieve?





Methodology



Period: 28 January – 17 March 2020 (7 weeks)

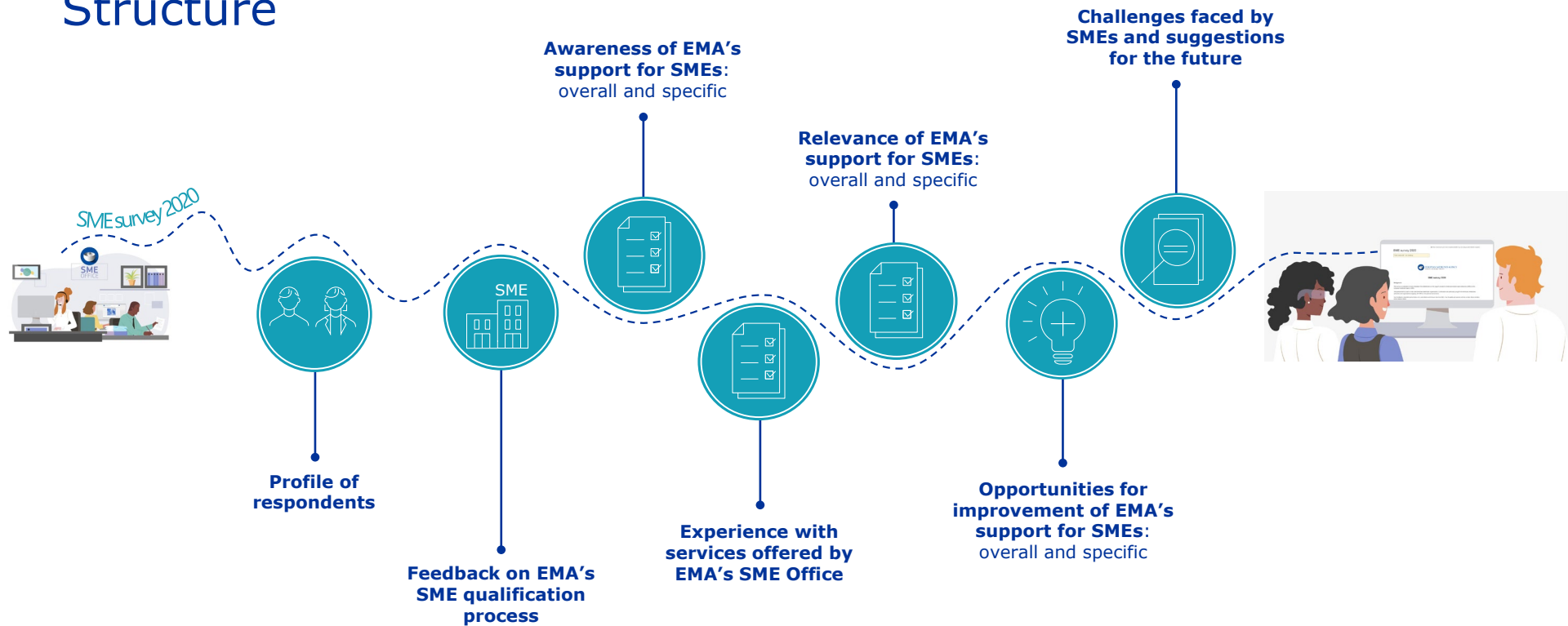
Response rate: 553 unique and valid responses

Methodology:

- Web-based survey (EU Survey)
- 18 questions
- Response format:
 - Dichotomous scale (e.g. 'Yes'/'No')
 - 4-point or 5-point rating scale (e.g. Very good – Good – Poor – Very poor – Not applicable)
 - Multiple choice and multiple response
 - Free text



Structure



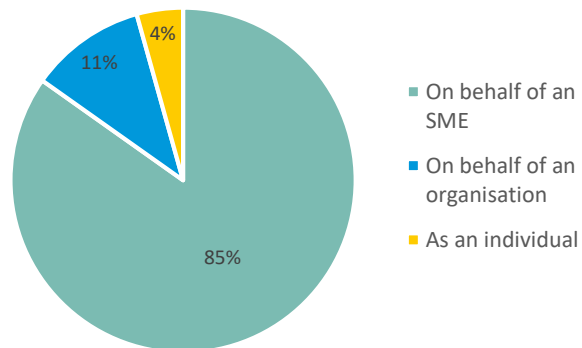


Findings from the survey

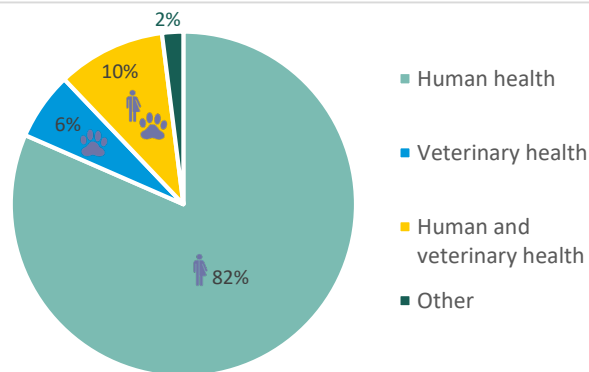


Profile of respondents

Are you completing this survey as:



Entity's field of activity:



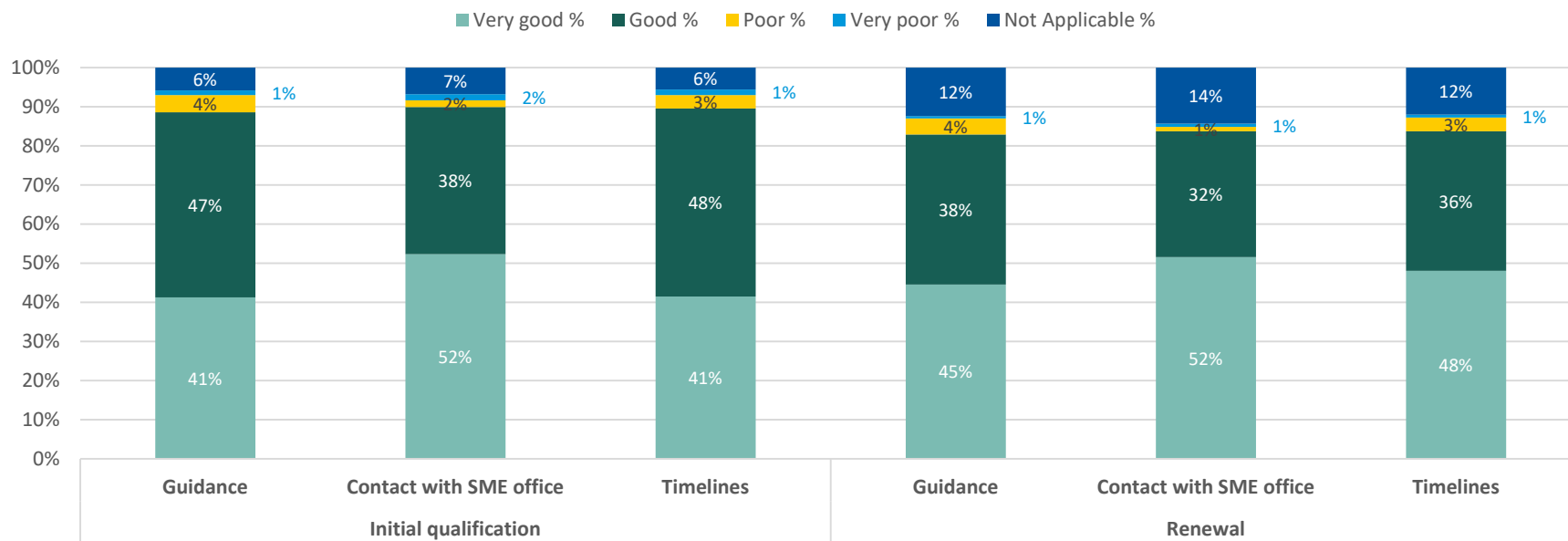
Top 3 business activity:

- Development, manufacturing or marketing of pharmaceuticals (65%)
- Service providers to the pharmaceutical industry (18%)
- Operating in the medical device and technology field (11%)

93% of all respondents have at some point held SME status with EMA.

EMA's SME qualification process

Please rate your experience with EMA's SME qualification process. (n=516)



Nine out of ten SMEs satisfied with the overall process of registration with the SME office. SME renewal process could benefit from improved guidance and timelines.



EMA's support for SMEs – Overview

Financial fee incentives (pre-authorisation)



Financial fee incentives (post-authorisation)



Regulatory assistance services



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 SME info days)



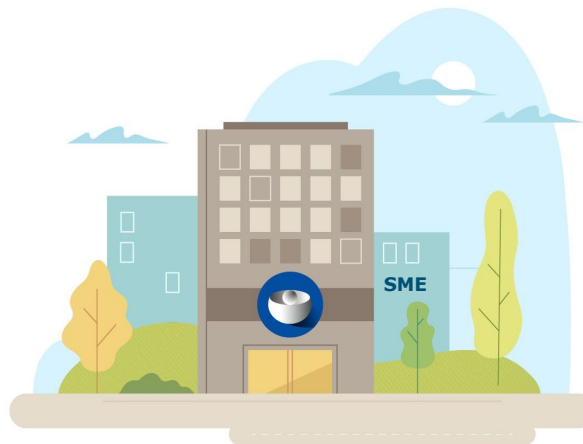
SME user guide



SME newsletter

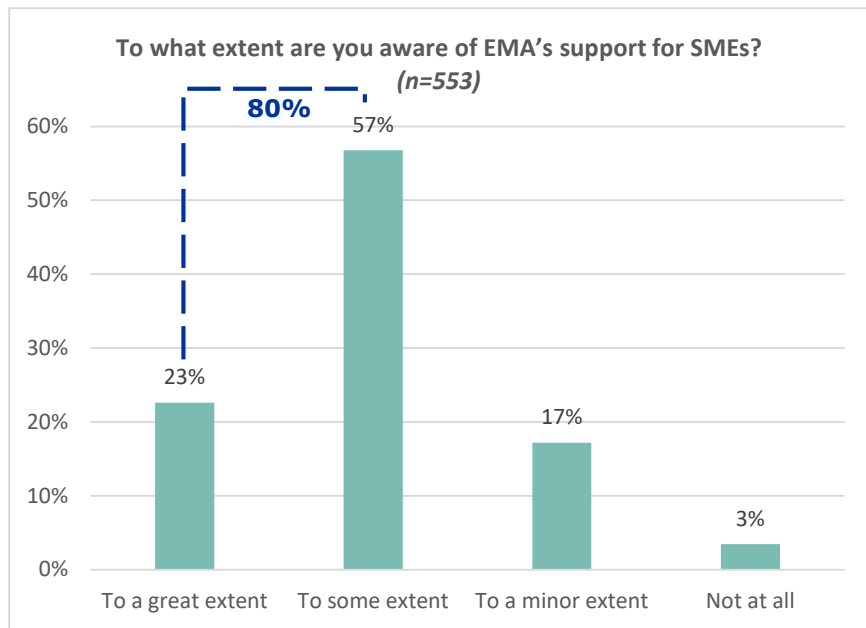


Support to Priority medicines scheme (PRIME)





Awareness of EMA's support for SMEs – Overall



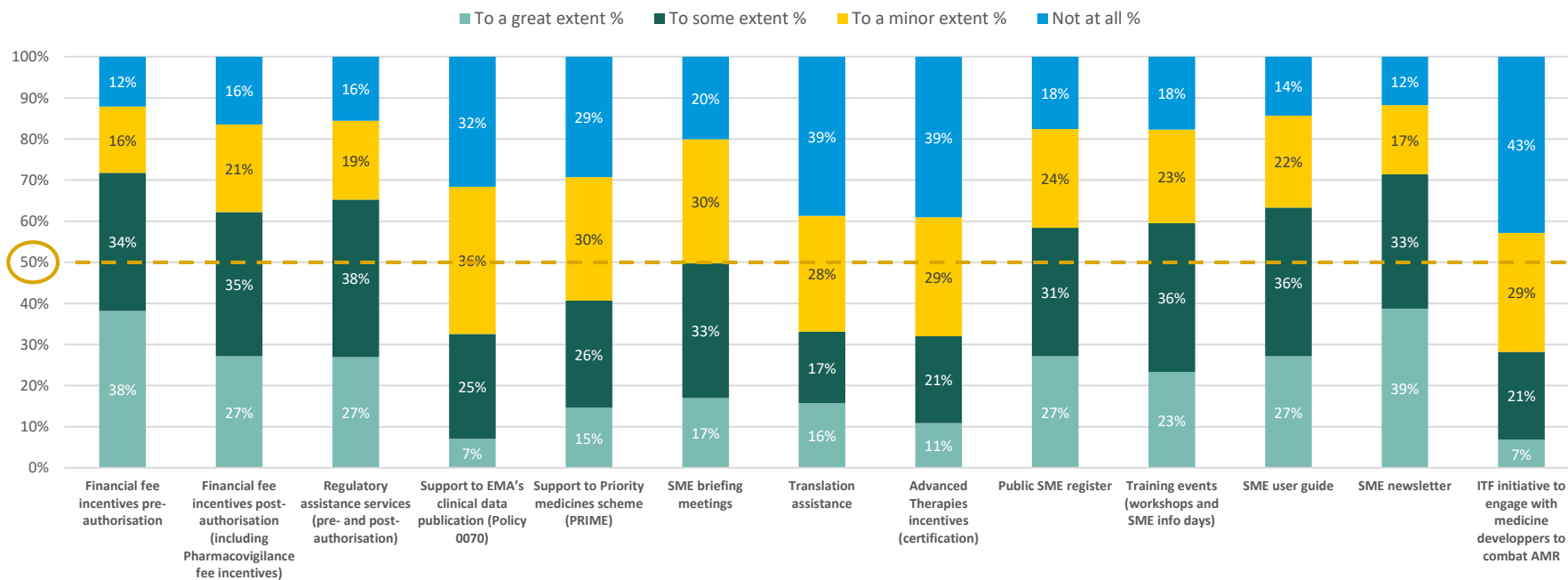
The majority of respondents (**80%**) indicated that they were **aware** of EMA's support for SMEs to **at least some extent**.

This a **9-point improvement** compared to the feedback received in the 2015 SME survey, which could be explained by actions put in place to raise awareness.



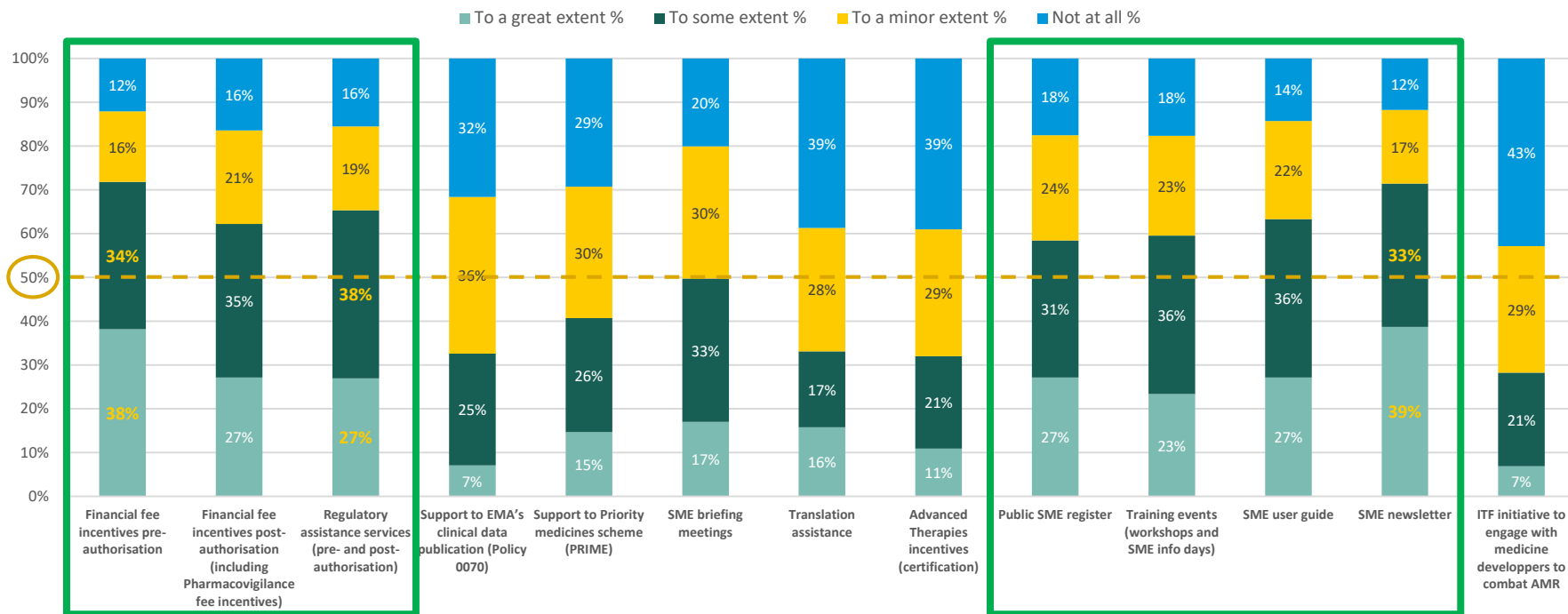
Awareness of EMA's support for SMEs – Specific services

To what extent are you aware of the following support activities provided for SMEs by EMA? (n=553)





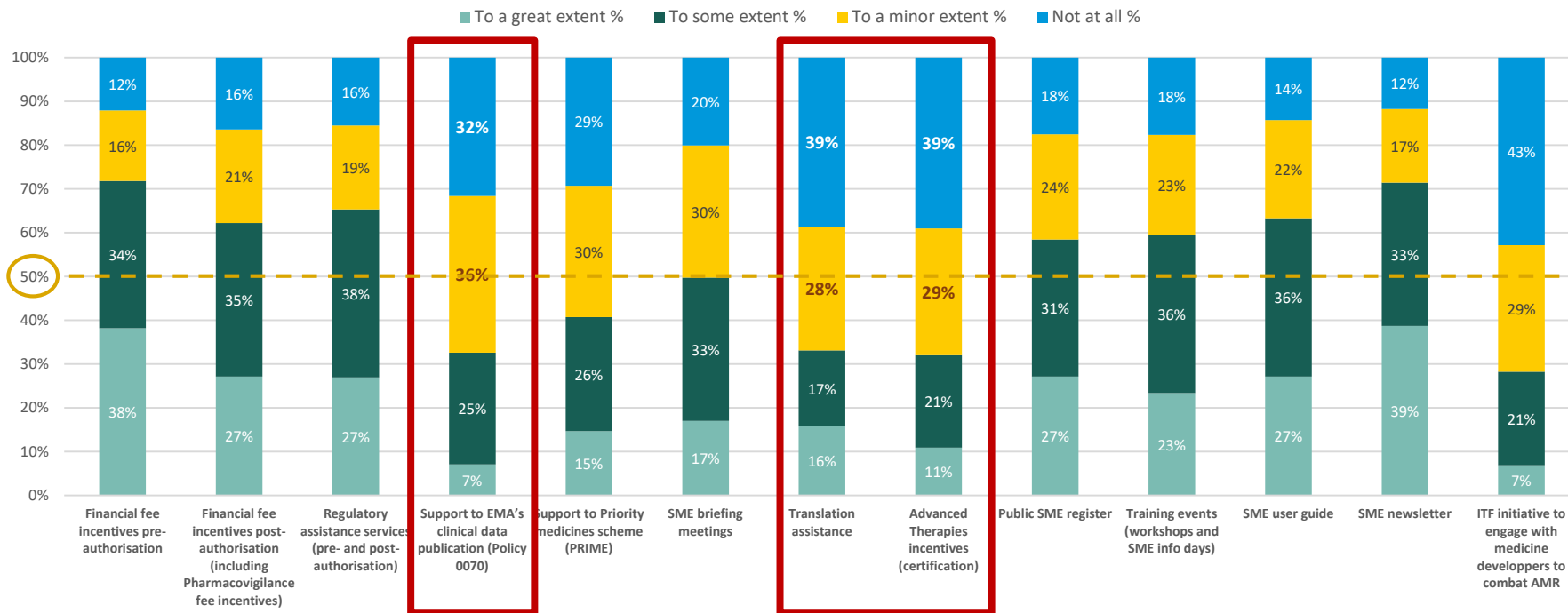
To what extent are you aware of the following support activities provided for SMEs by EMA? (n=553)



Of the twelve services surveyed, more than half of respondents indicated awareness of seven services to a great extent or to some extent.



To what extent are you aware of the following support activities provided for SMEs by EMA? (n=553)

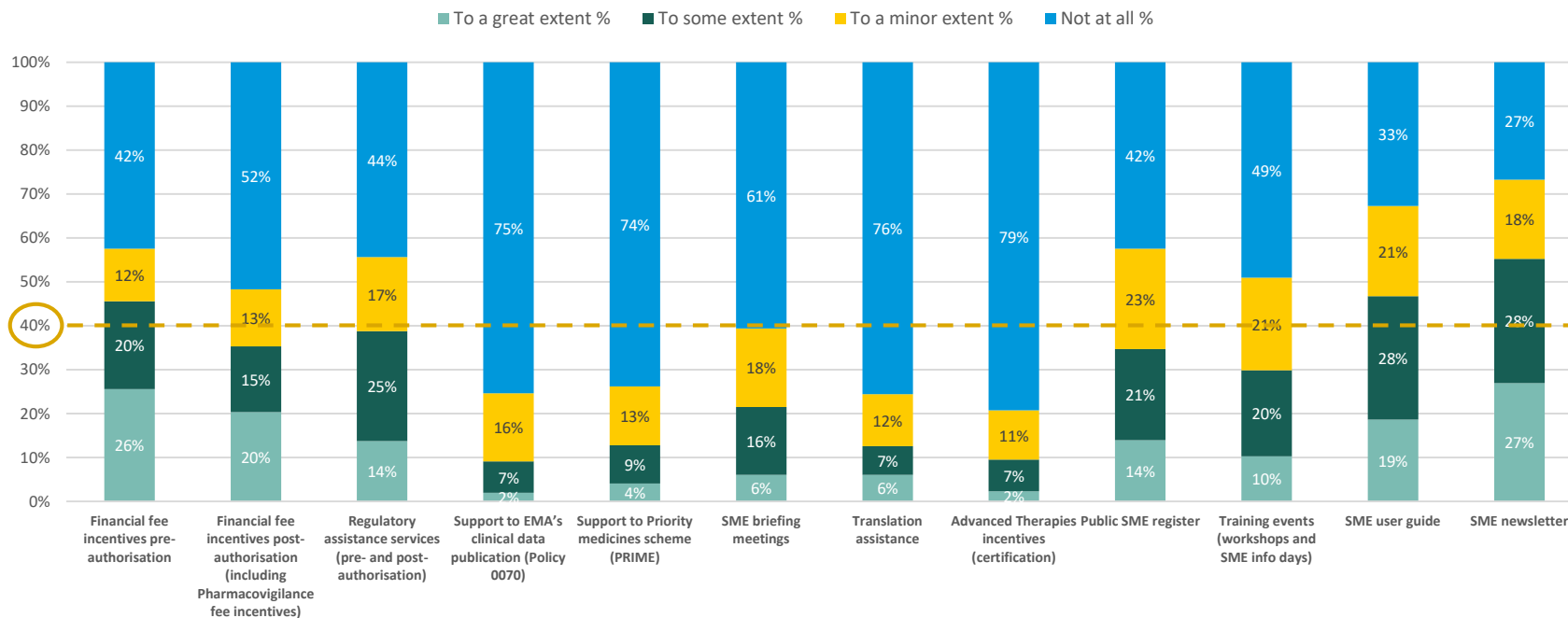


Three services ranked low in terms of awareness. Seven out of ten respondents indicated no or only minor awareness.



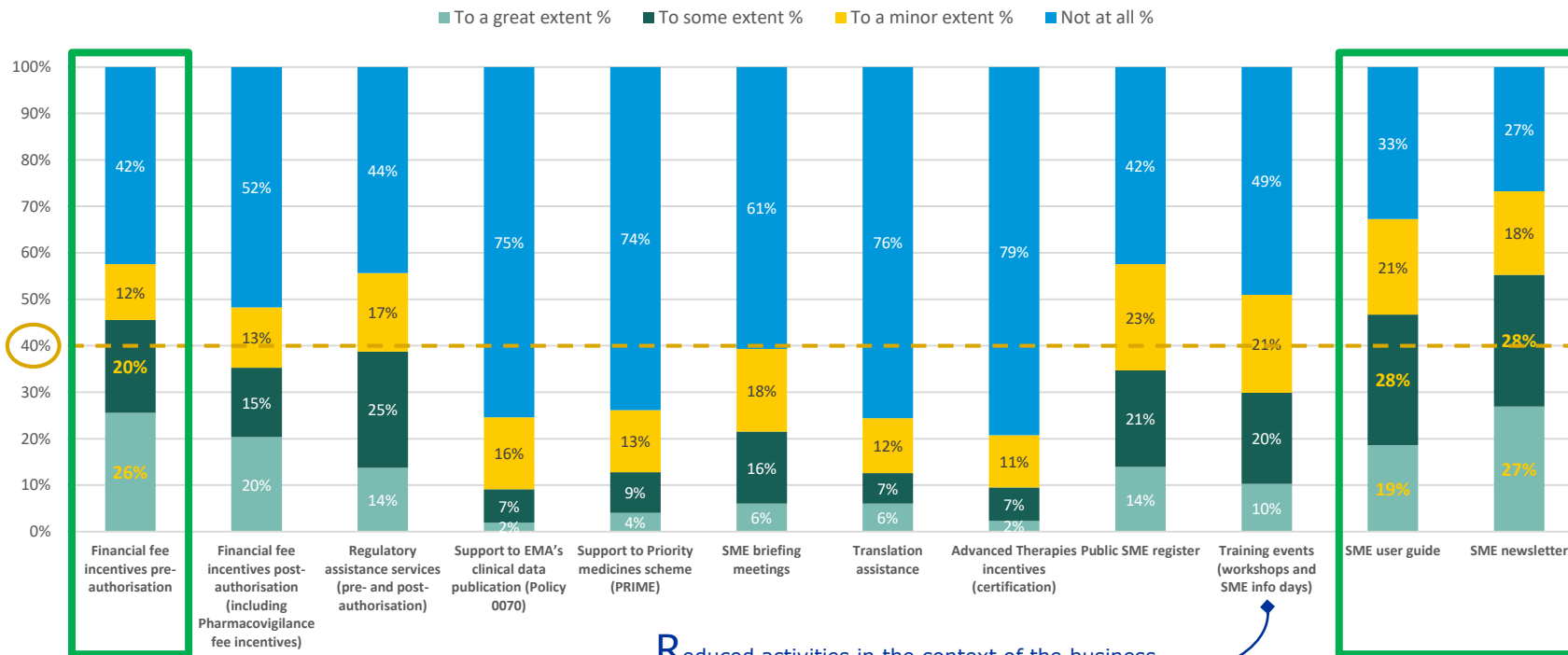
Experience with services offered by EMA's SME Office

To what extent did you use the following support activities provided for SMEs by EMA? (n=516)





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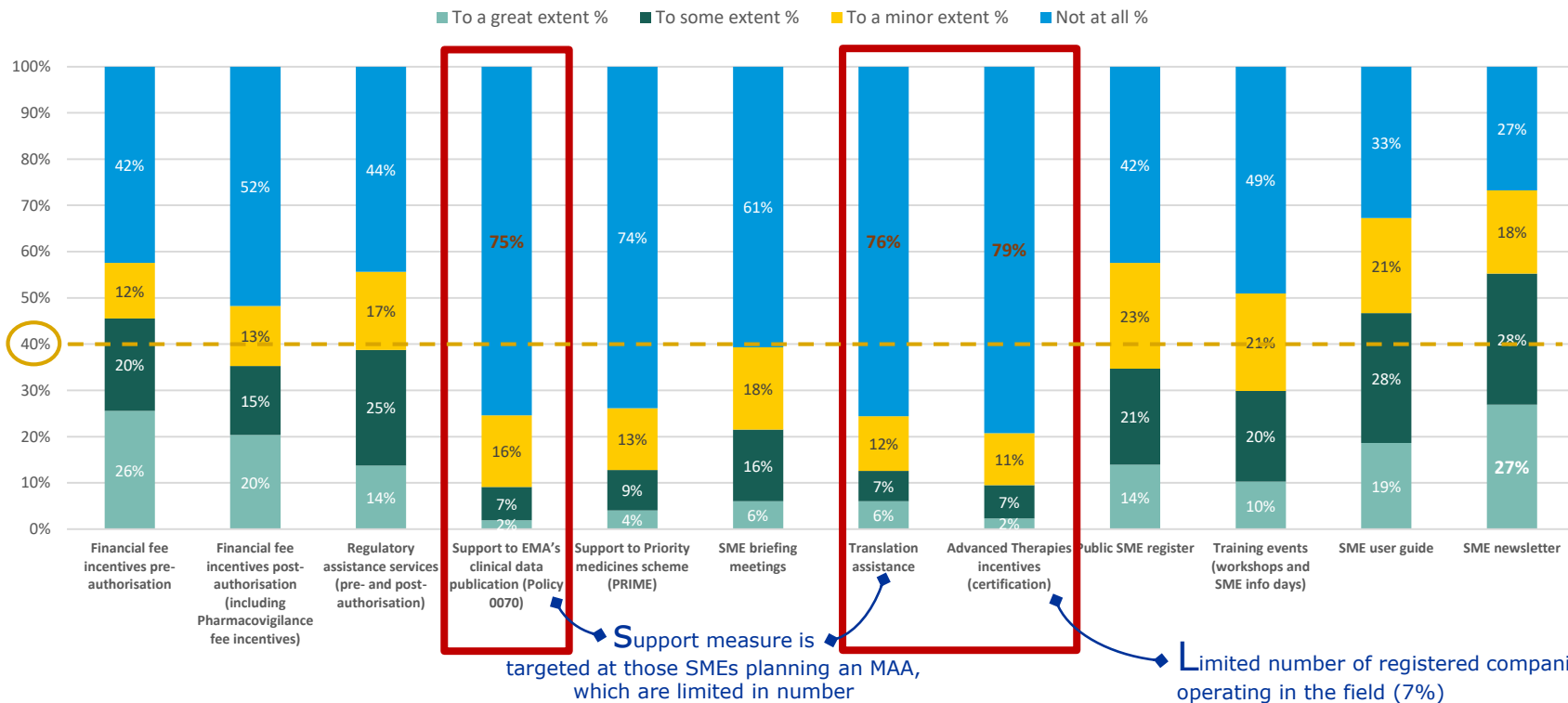


Reduced activities in the context of the business continuity planning and EMA's relocation

Two services that respondents were **most aware** of were also those that were **mostly used**.



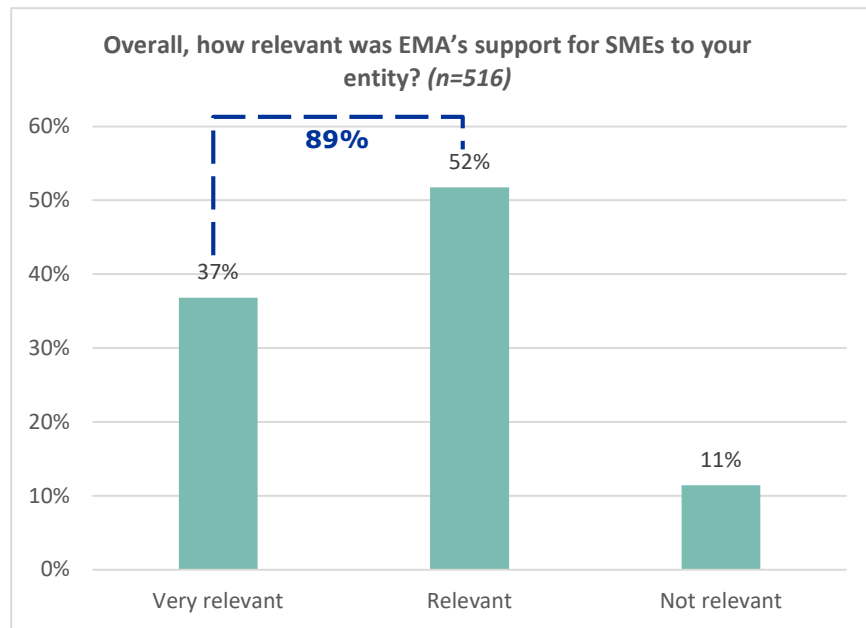
To what extent did you use the following support activities provided for SMEs by EMA? (n=516)



Those services that respondents were **least aware** of were also those that were **used the least**.



Relevance of EMA's support for SMEs – Overall



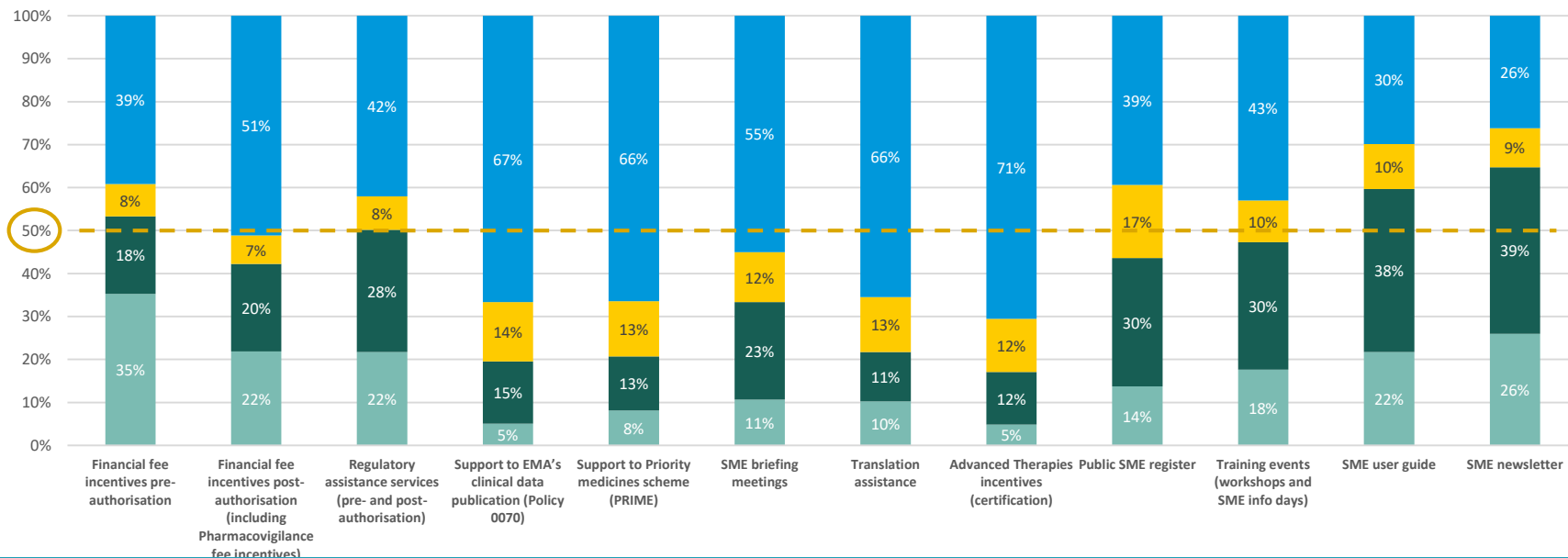
High proportion of respondents indicated that the SME initiative had been **relevant or very relevant (89%)**, with one in ten responded that support was not relevant.

This is showing an **11-point improvement** compared to the feedback received in the 2015 SME survey.

Relevance of EMA's support for SMEs – Specific services

How relevant was the following specific support received? (n=516)

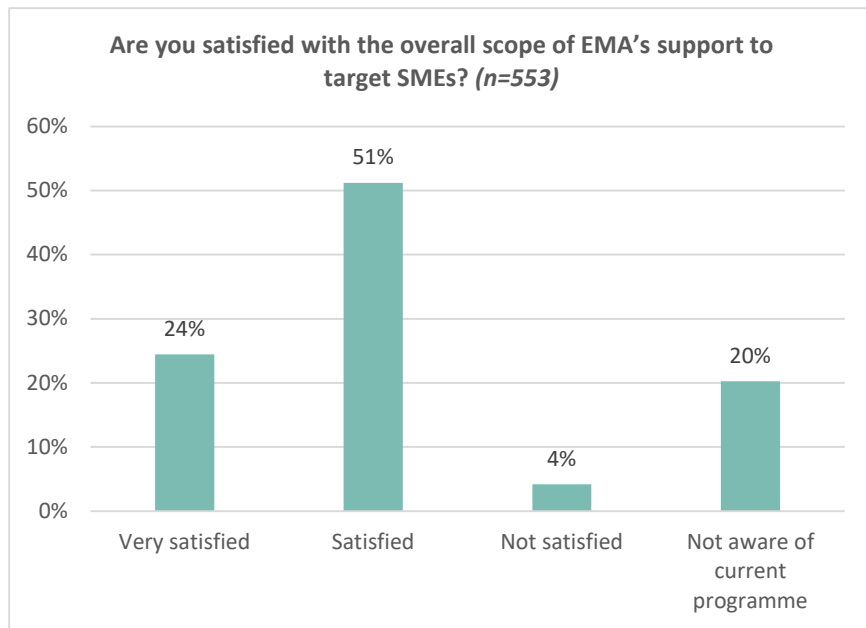
Very relevant % Relevant % Not relevant % Not applicable yet %



Breakdown for specific support activities in terms of their respective relevance rate is **in line** with previously reported scores for **awareness and use**.



Improvement of EMA's support for SMEs – Overall



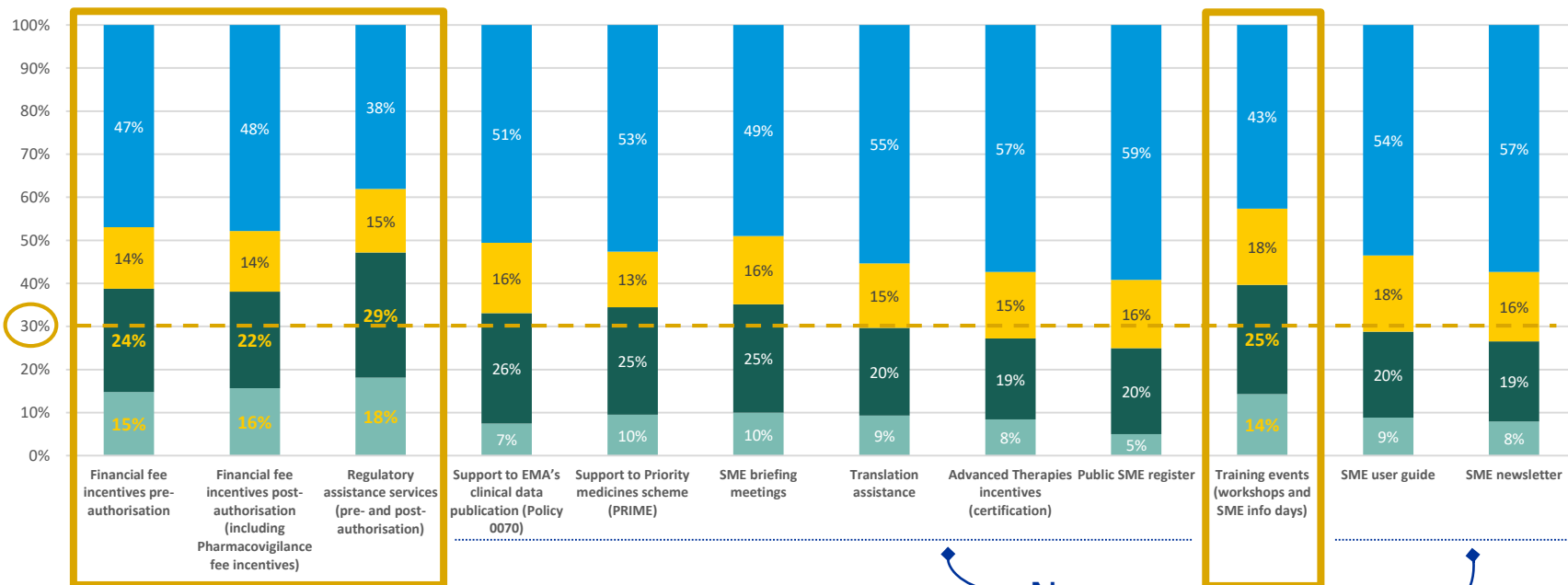
Overall, respondents were **satisfied** with the scope of EMA's support to target SMEs: 24% very satisfied, 51% satisfied and 4% not satisfied. Twenty percent (20%) declared not being aware of the current programme



Improvement of EMA's support for SMEs – Specific services

Does EMA need to revise or expand specific activities to support SMEs? (n=441)

Yes, to a great extent % Yes, to some extent % Yes, to a minor extent % No %



No need, or if any, to a minor extent, to revise or expand the following support services



Challenges faced by SMEs and suggestions for the future

Digitalisation

Regulatory fees

Competition

Access to finance

Globalisation

Finding partners and customers

Recruitment

Education, training, access to information

Administrative or regulatory burden

Market access

Cost of production or labour



8 themes based on EMA SME survey (2015) & 3 new identified in the EC SME performance review (2019)

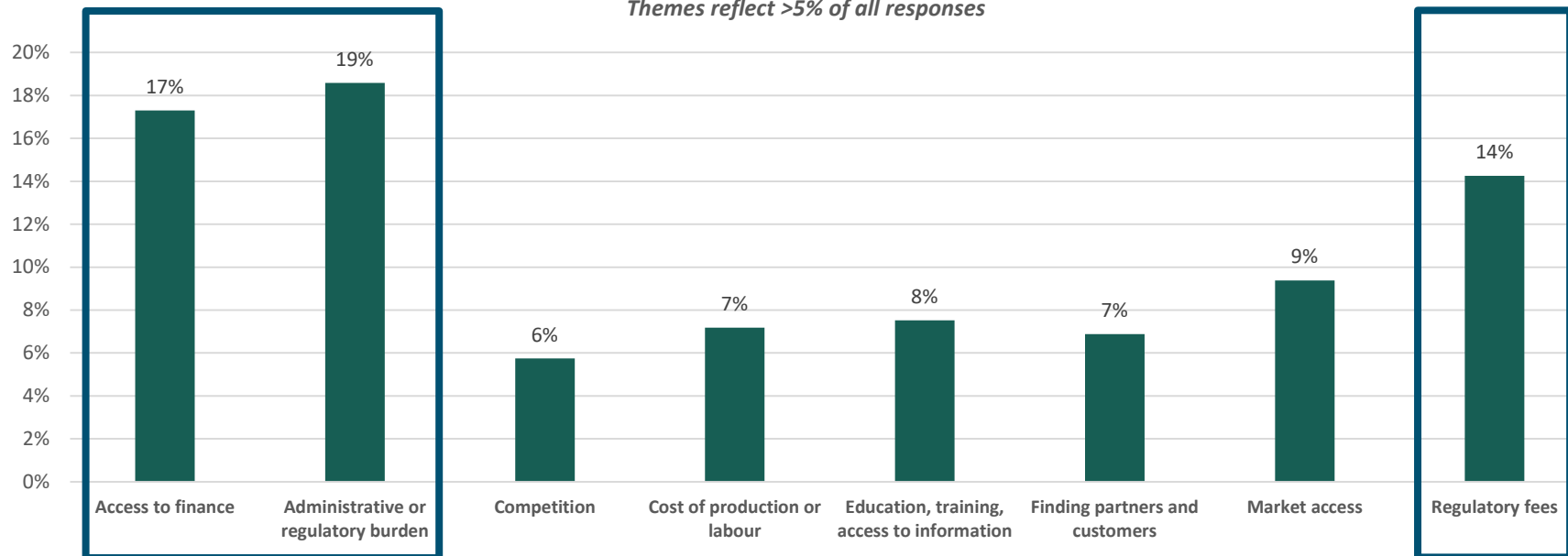




Challenges faced by SMEs and suggestions for the future

In your opinion which of the following topic(s) do you consider to be the main challenge(s) that SMEs are facing? (n=553)

Themes reflect >5% of all responses



Challenges faced by SMEs and suggestions for the future

Administrative and regulatory burden

Complexity of regulations.

Requirements for preparation of multiple regulatory files.

Lack of harmonisation of regulatory requirements between authorities.

Suggested measures by respondents:

- Simplify, reduce or harmonise regulatory requirements at EU level and globally;
- Introduce exemptions for regulatory procedures or requirements;
- Reduce and simplify the administrative burden;
- Enhance regulatory and scientific advice.





Challenges faced by SMEs and suggestions for the future

Access to finance


Suggested measures by respondents:

- Increase and facilitate access to finance and capital;
- Increase access to information on funding opportunities for SMEs at EU and national level;
- Facilitate networking, partnering, matchmaking between SMEs, academia and investors;
- Other suggested measure reported under access to finance related to introduction of tax credit.





Challenges faced by SMEs and suggestions for the future

Challenges	Suggested measures by respondents
Regulatory fees 	<ul style="list-style-type: none">▪ Enhance EMA and national fee incentives particularly for veterinary and micro-sized enterprises;▪ Introduce or enhance fee incentives for serialisation (falsified medicines legislation).
Market access	<ul style="list-style-type: none">▪ Offer guidance and support on market access, pricing and launch;▪ Align licensing and market access requirements.
Education, training, access to information	<ul style="list-style-type: none">▪ Increase training;▪ Provide financial support for training organised by third party organisations;▪ Enhance EMA website experience.



Challenges faced by SMEs and suggestions for the future

Challenges	Suggested measures by respondents
Cost of production or labour	<ul style="list-style-type: none">▪ Facilitate access to information on suppliers.
Finding partners and customers	<ul style="list-style-type: none">▪ Increase SME networking opportunities in the EU and internationally;▪ Facilitate access to information on validated and accredited service providers.
Digitalisation	<ul style="list-style-type: none">▪ Support the digital transformation of SMEs, particularly veterinary and micro-sized enterprises;▪ Enhance training on digital transformation.
Recruitment	<ul style="list-style-type: none">▪ See finding partners and customers.



Conclusion





- **Confirmation** that the SME Regulation continues to successfully deliver on its intended objectives.
- Minor differences between respondents in the human and veterinary fields were noted.
- SME initiative remains **relevant** to SMEs. Some **improvement** highlighted compared to the feedback received in the 2015 SME survey.
- Need to continue **raising awareness** and **expand** the programme particularly on regulatory assistance services by the SME office, training events and financial incentives, both for pre- and post-authorisation.
- **Challenges** faced by SMEs covered all phases of an enterprise or product life cycle. Top three for **future priorities** to focus on the administrative and regulatory burden, access to finance and regulatory fees.

Thank you for your attention

Any questions?



Further information

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