



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 years of SME support

SME survey 2015 – Taking stock of the experience gained with the Agency's SME initiative 10 years after its launch

Presented by Angela-Christina Schmidt on 29 November 2015; Industry Roundtable meeting
Corporate Stakeholders Department - Stakeholders & Communication Division

An agency of the European Union





Agenda

A. Introduction

- i. Survey objectives
- ii. Scope & methodology
- iii. Survey structure
- iv. Respondents' profile

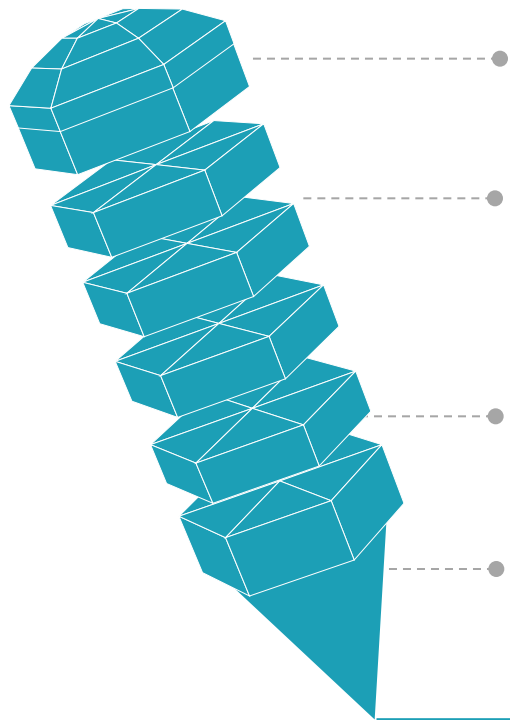
B. Summary of feedback



EMA SME Survey 2015

INTRODUCTION

Survey objectives



Evaluate the experience gained from the SME programme at the EMA since it was set up 10 years ago;

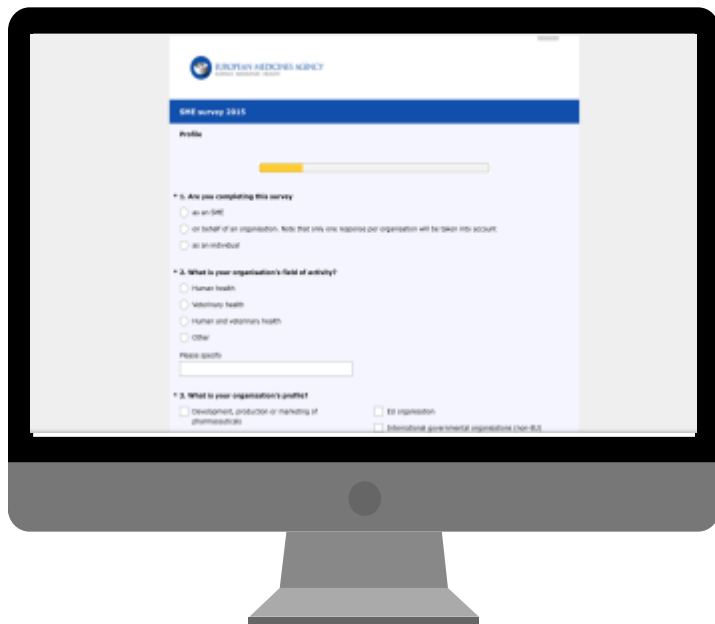
Elicit direct feedback from SMEs and Stakeholders to better understand current and future challenges faced by SMEs.

Identify areas for further development of the Agency's SME programme that could support innovation in the SME pharmaceutical sector;

Tailor our future activities to better meet the needs of SMEs.

What do we aim to achieve?

Scope & methodology



Scope: Services offered by the SME office, current and future challenges faced by SMEs, SME assignment process.

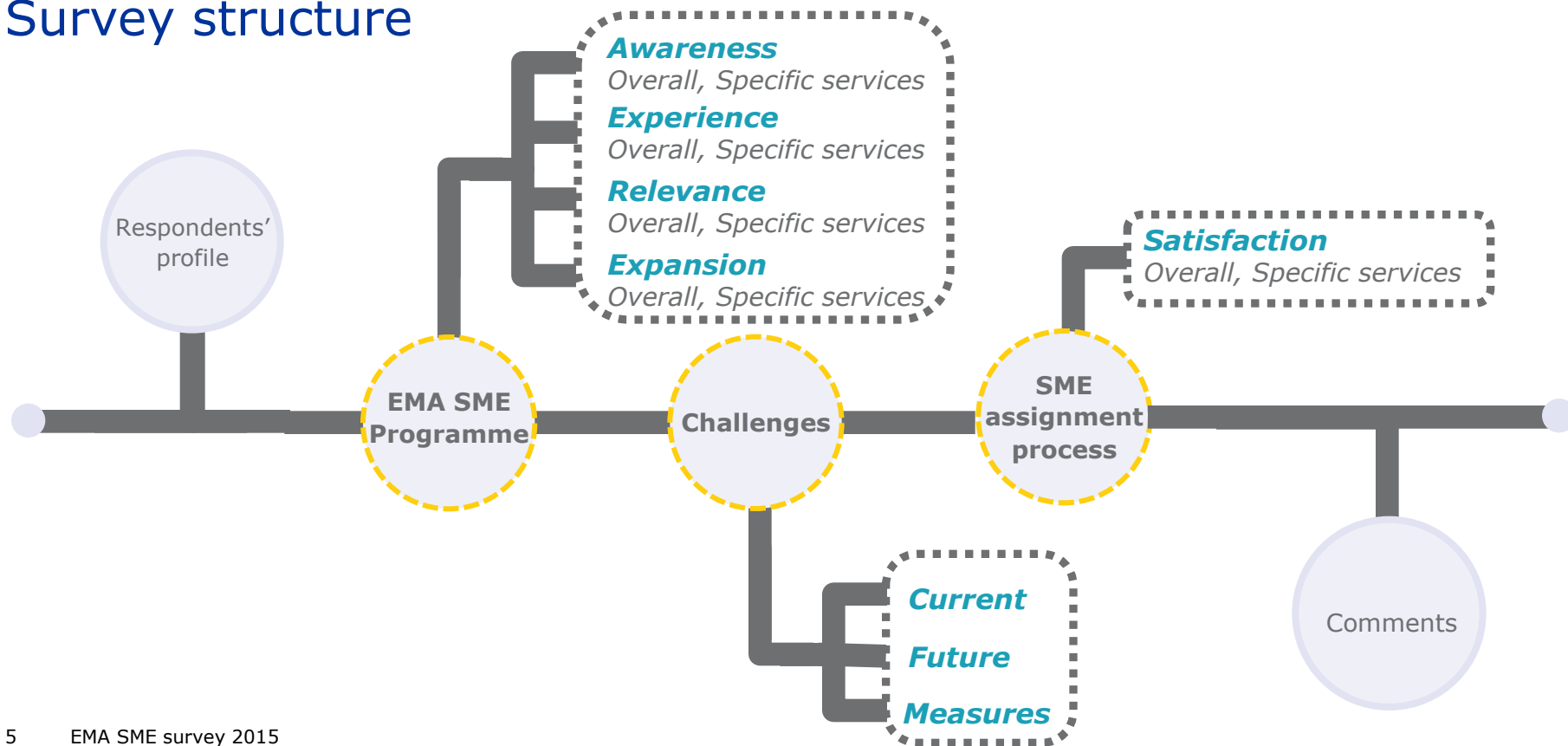
Period: 18 August – 30 Sept 2015

Response rate: 534 unique and valid responses

Methodology

- Web based survey
- 16-17 questions;
- Response formats:
 - 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.

Survey structure

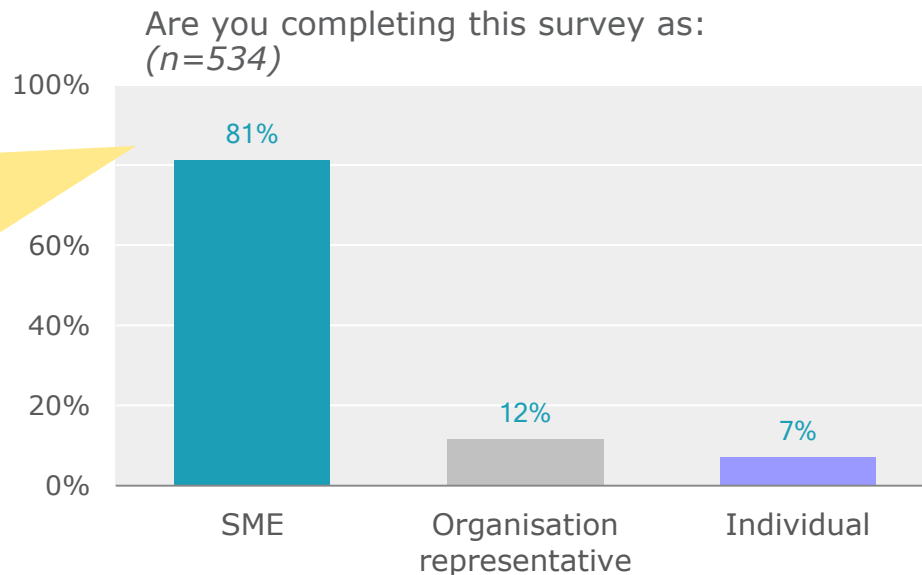


The sample population - Respondents' profile

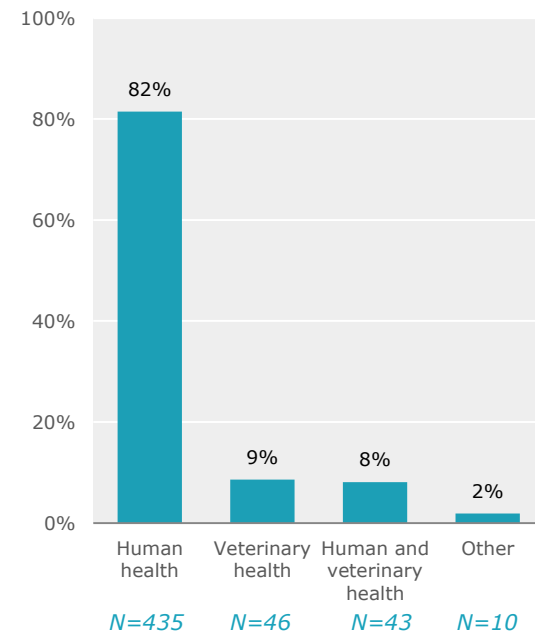
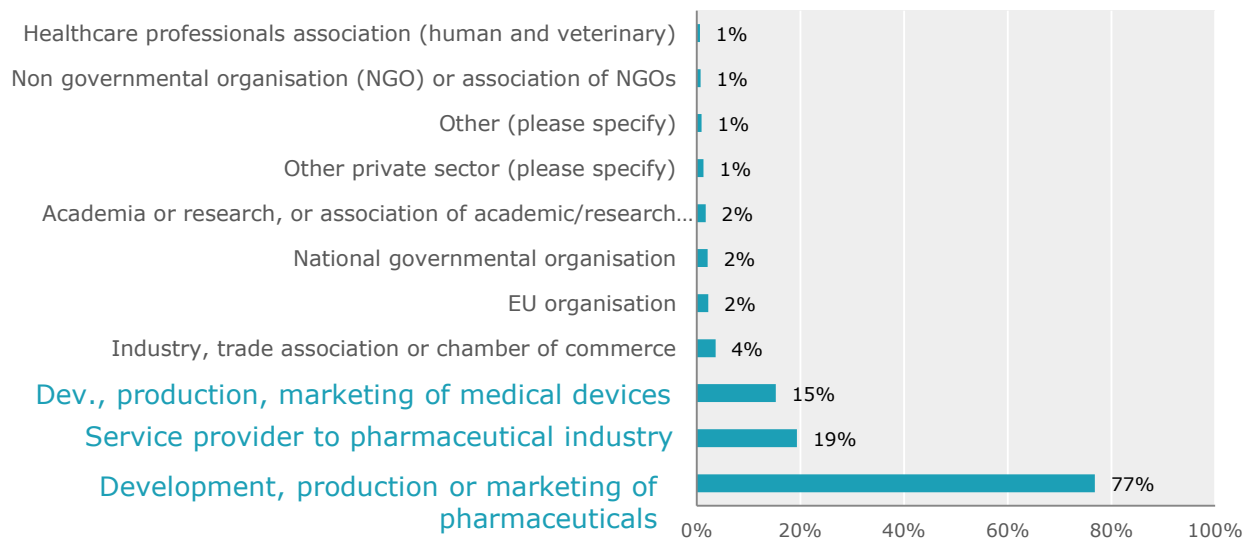
At least 65% of all respondents have at some point held SME status with the Agency.

The typical profile of this population:

- Micro sized;
- Autonomous;
- From the UK (19%), Germany (12%), France (8%);
- Active in the human field;



The sample population (n=534)



The majority of respondents were SMEs operating in the pharmaceutical field, developing products for human use.



EMA SME Survey 2015

SUMMARY OF FEEDBACK



SME PROGRAMME

SERVICES OFFERED BY THE SME OFFICE

Services offered by the SME Office - Overview

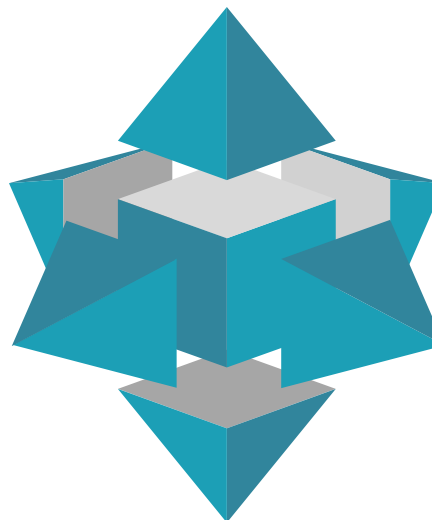
*Financial fee incentives
(pre-authorisation)*

*Financial fee incentives
(post-authorisation)*

*Regulatory assistance
(pre- and post
authorisation)*

SME briefing meetings

Translation assistance



*Advanced Therapies
incentives*

Public SME register

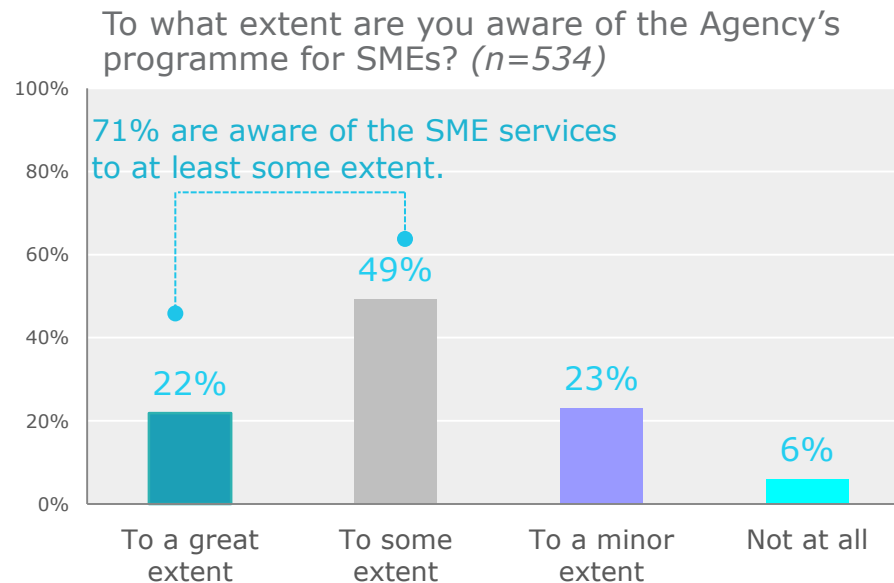
*Workshop and training
events*

SME user guide

SME newsletter

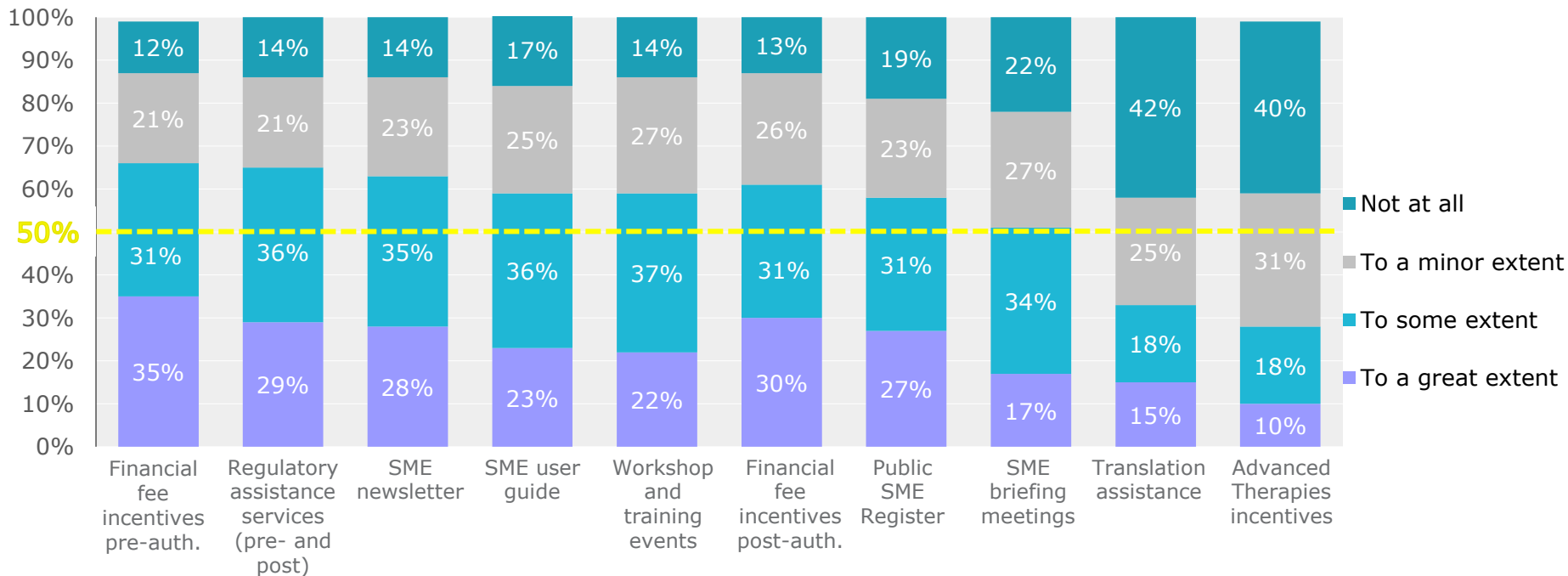
SME programme

Awareness overall

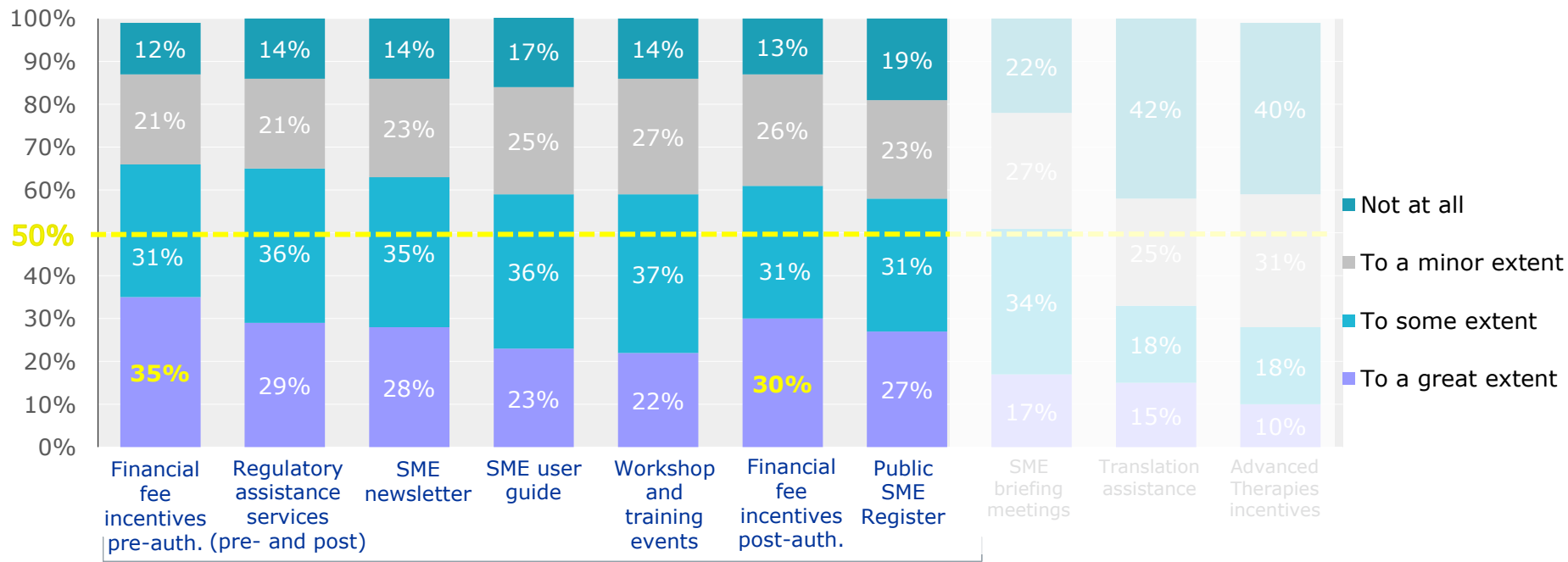


SME programme – *Awareness of specific services*

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



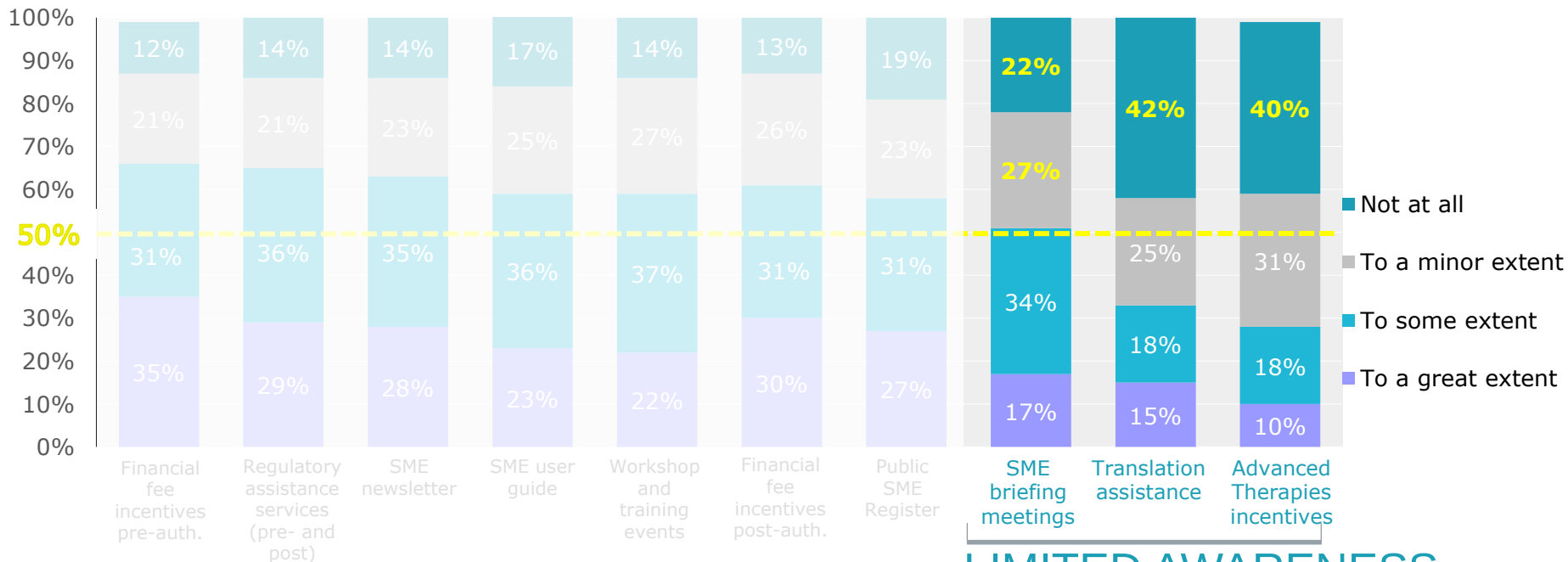
SME programme – *Awareness of specific services*



HIGH AWARENESS FOR 7 / 10 SERVICES

More than 50% all respondents are aware to a great or some extent.

SME programme – *Awareness of specific services*

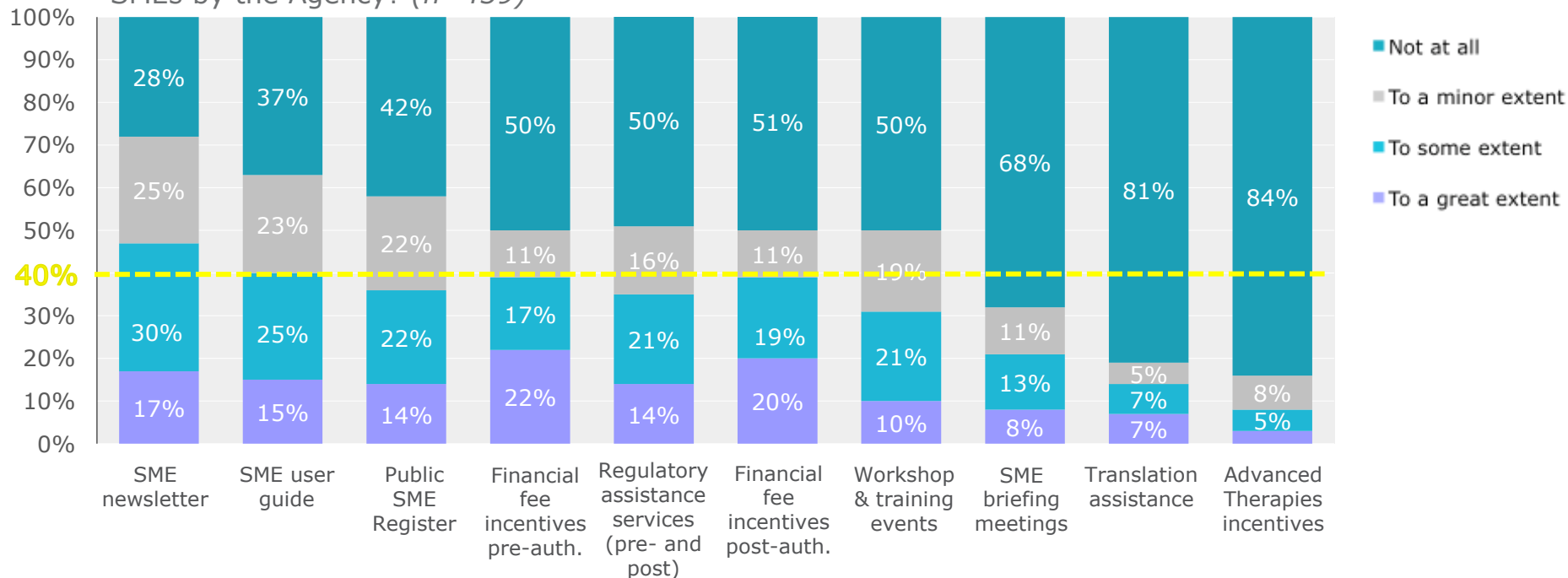


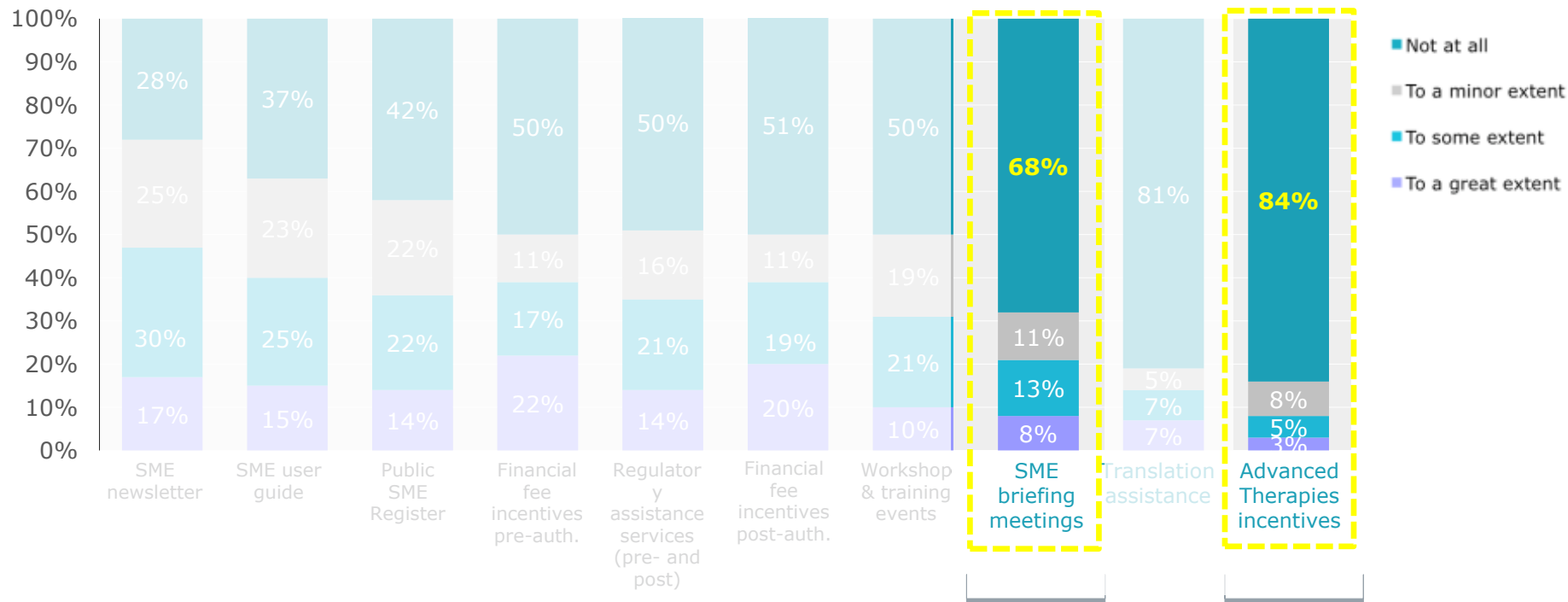
LIMITED AWARENESS

Almost 50% of all respondents are not at all aware of these services or only to a minor extent.

SME programme – *Experience with specific services*

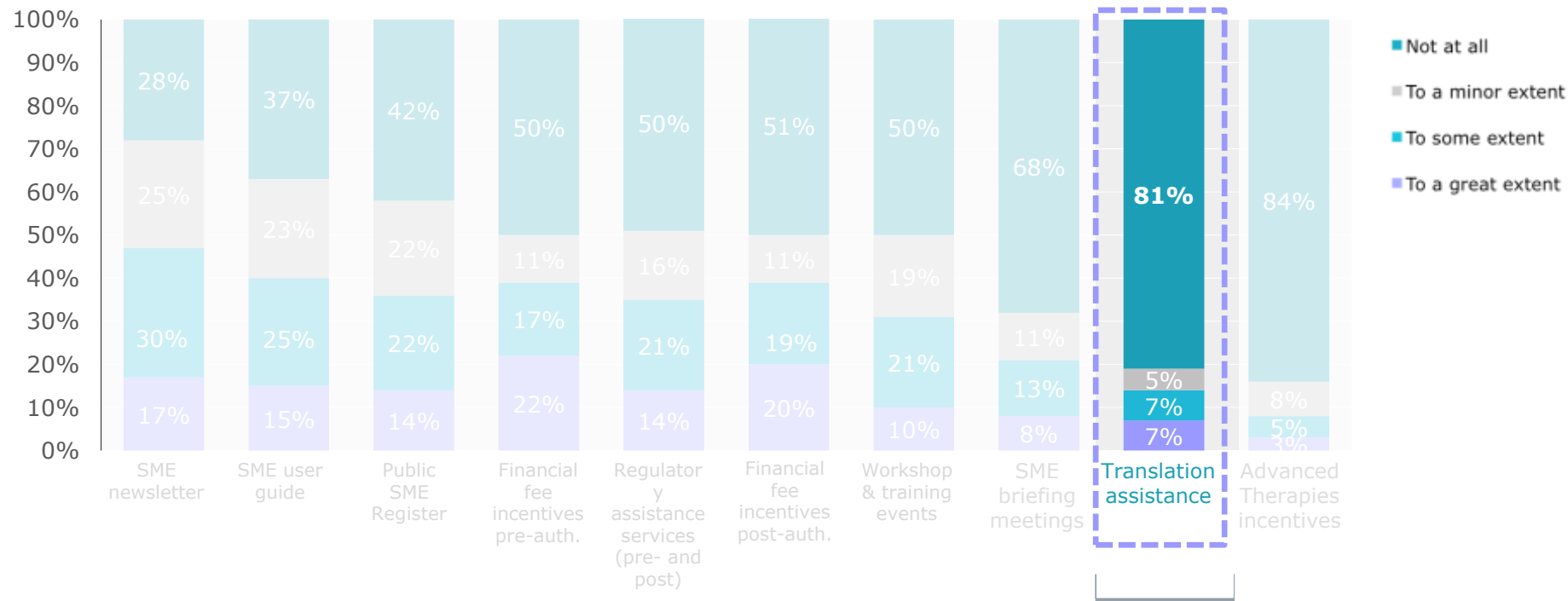
To what extent **have you made use** of the following support activities provided for SMEs by the Agency? (*n*=439)





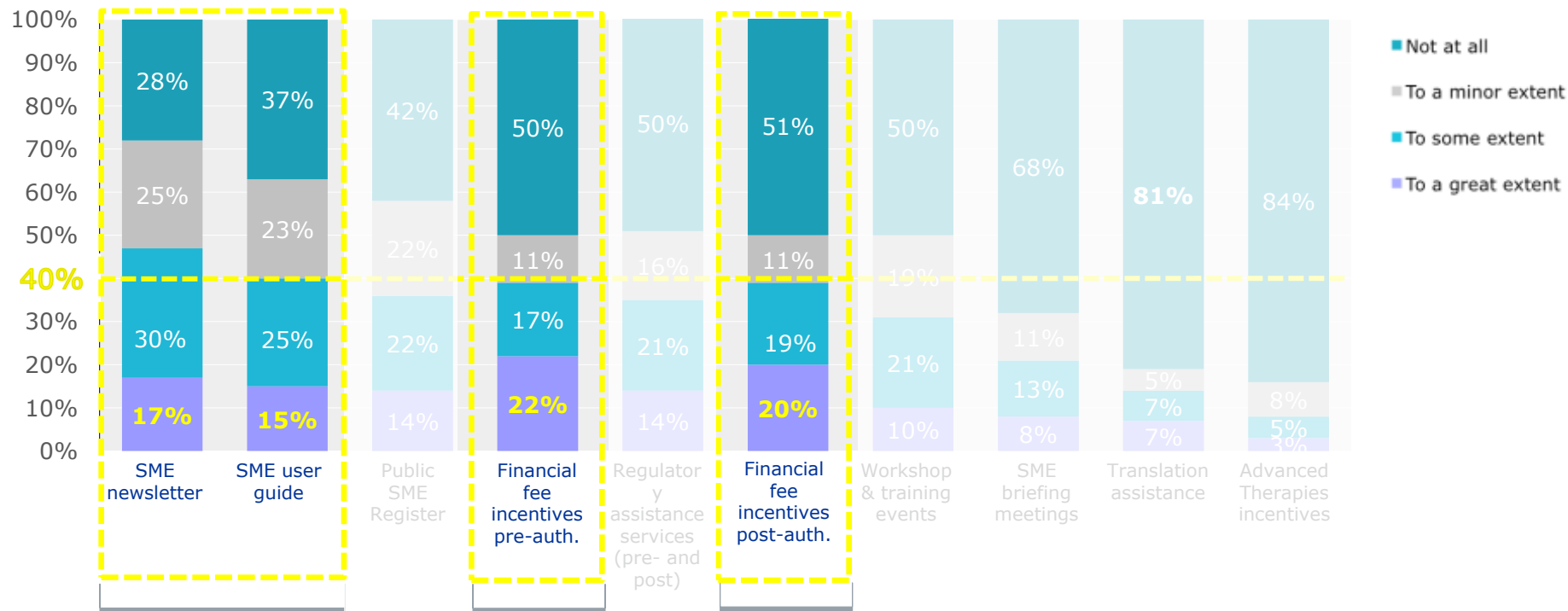
LIMITED USE

SMEs registered with the Agency use these services rarely. The same services ranked very lowly in terms of awareness as well.



USED BY ~100%...

... of those companies to whom
the translation service is
applicable!



USED MOST

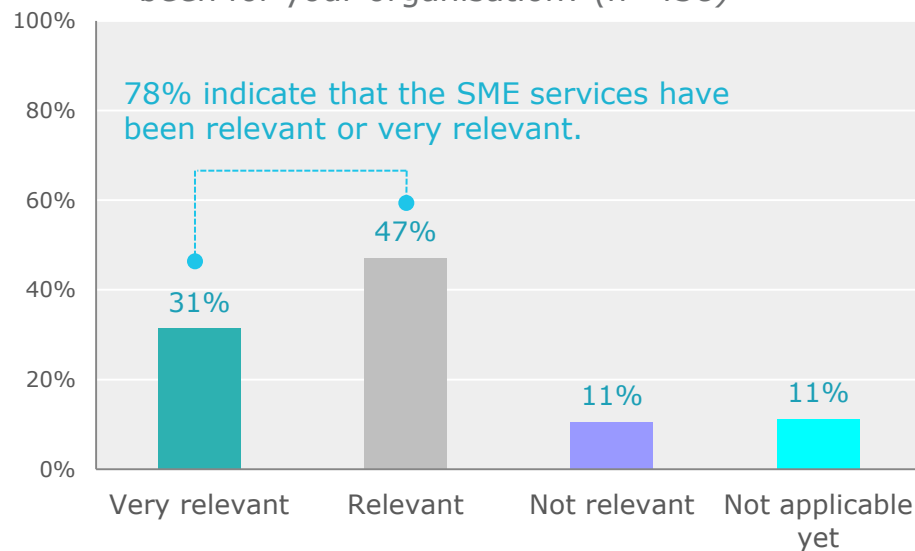
SMEs registered with the Agency use these services the most. The same services ranked quite high in terms of awareness as well.



SME programme

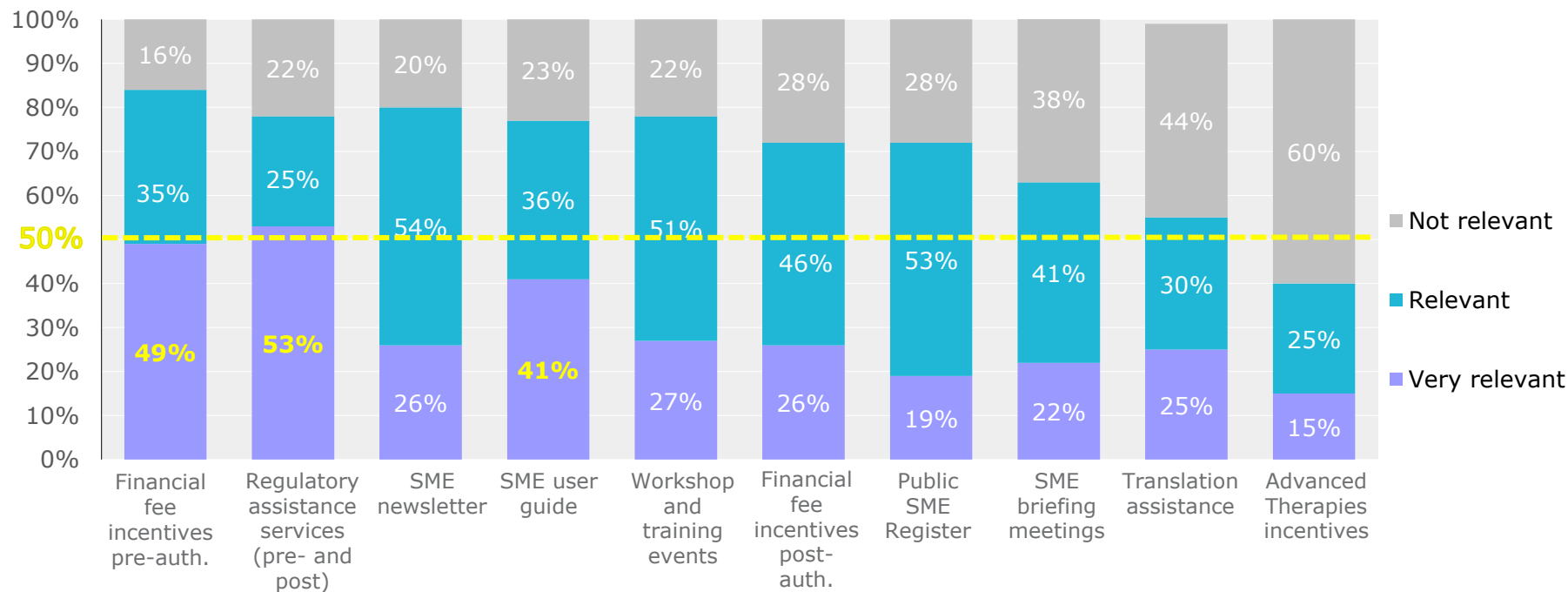
Relevance overall

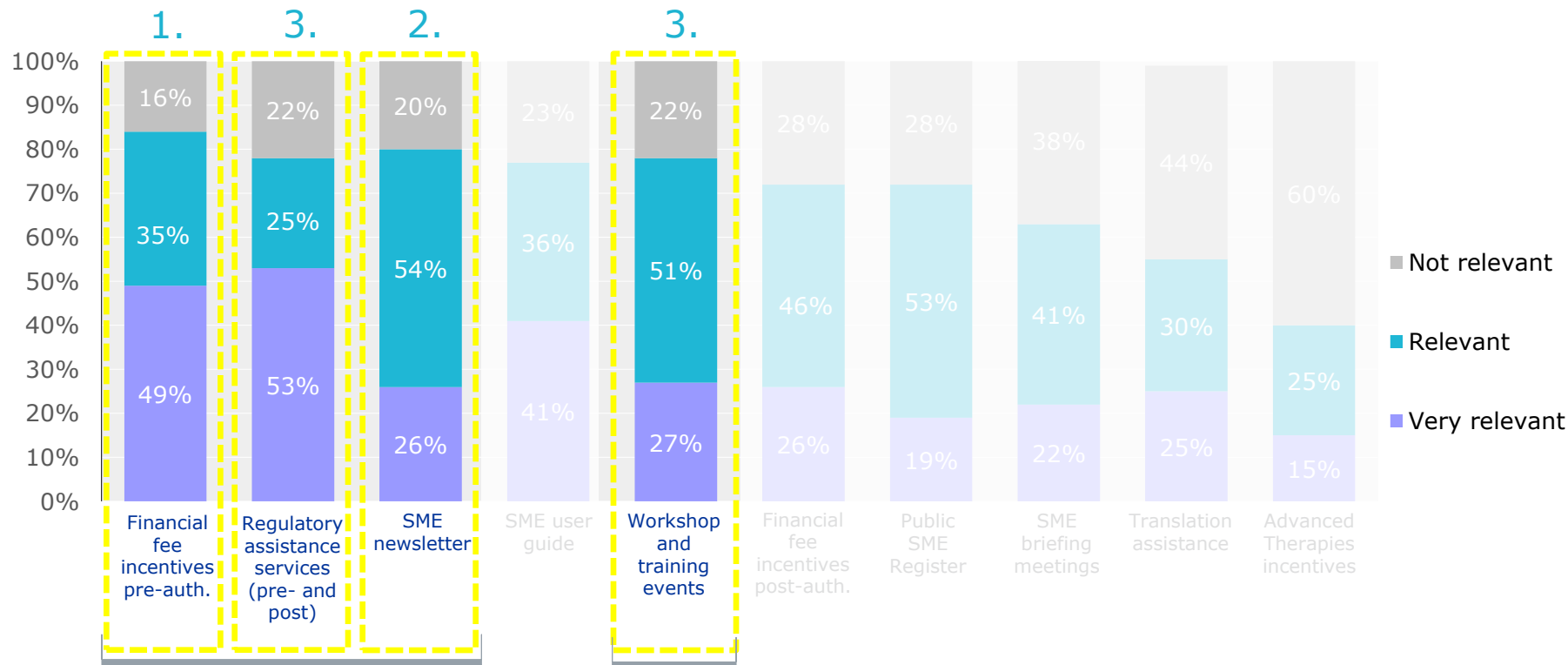
Overall, how relevant has the SME programme been for your organisation? ($n=438$)



SME programme – *Relevance of specific services*

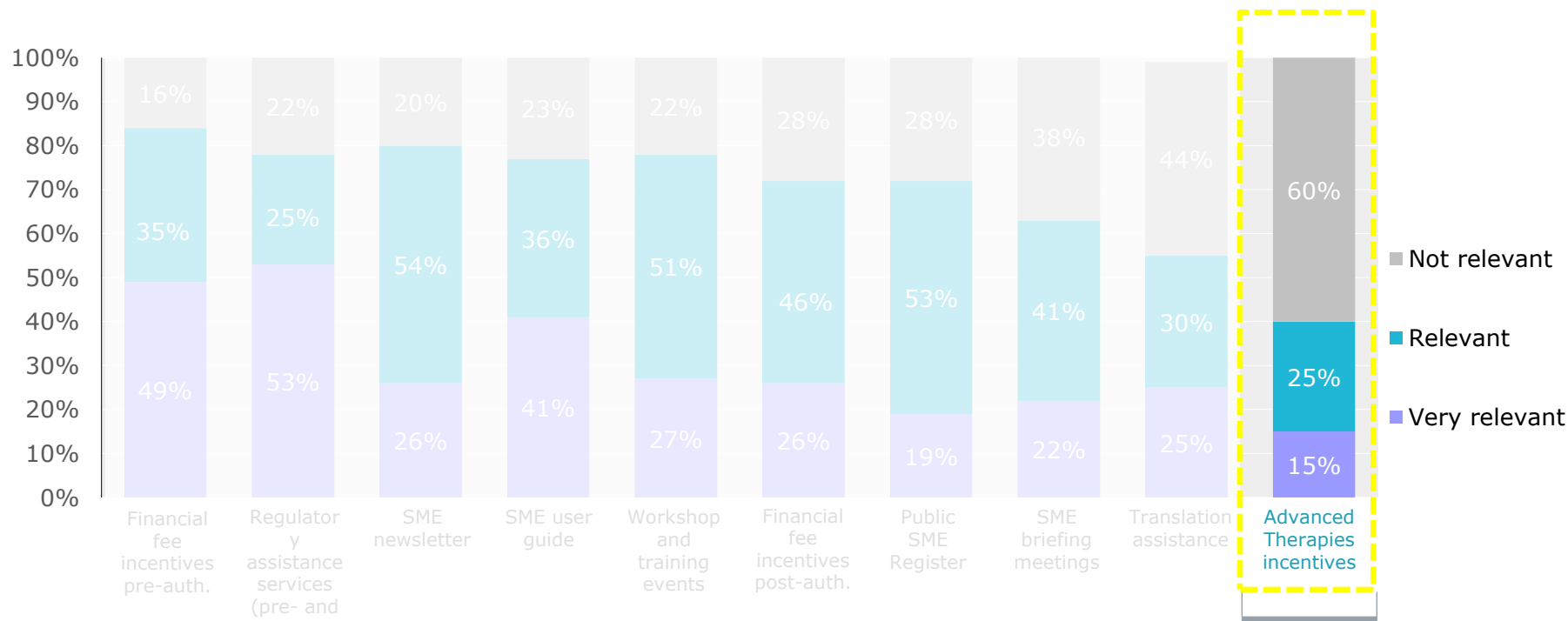
How **relevant** were the following specific activities? (n=422)





MOST RELEVANT

Respondents find these services the most relevant.
Awareness for these services was high.

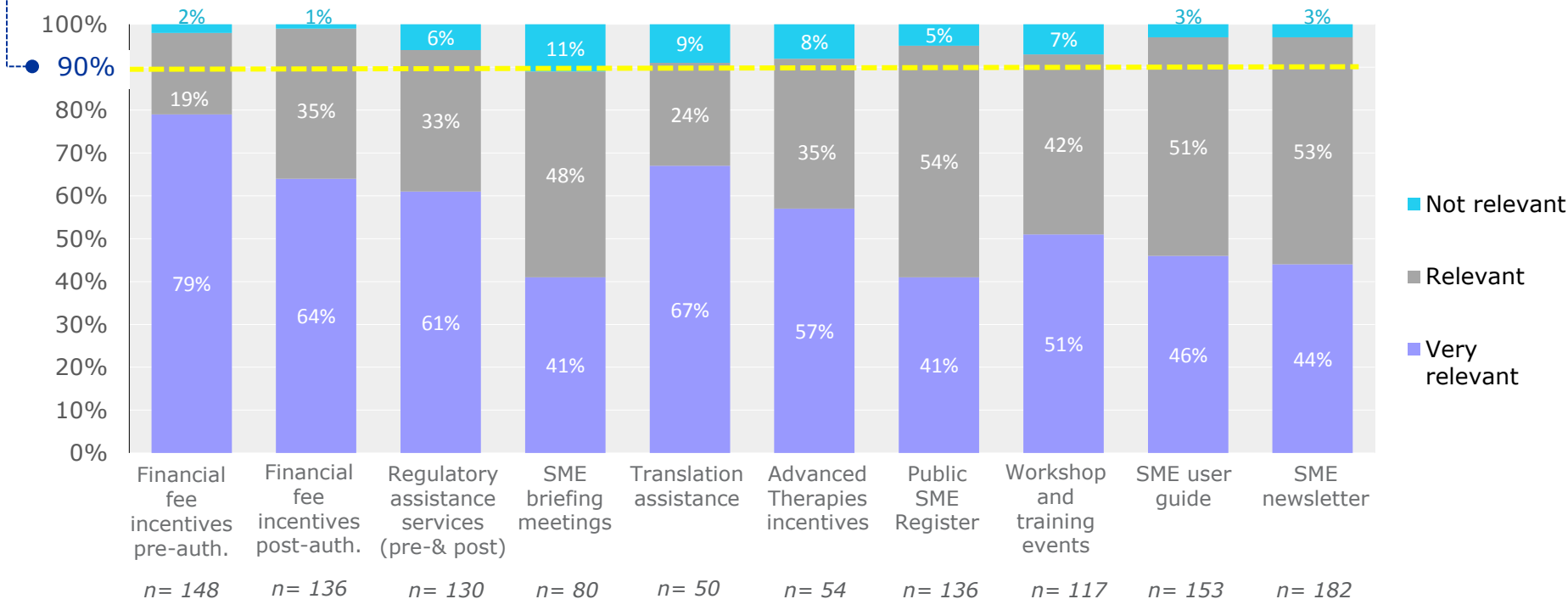


LEAST RELEVANT

... **however** respondents were least aware of this service and have consequently almost never used it.
91% of all respondents who have made use of this service to at least some extent, rated it relevant (35%) or very relevant (57%).

SME programme – *Relevance of specific services*

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.





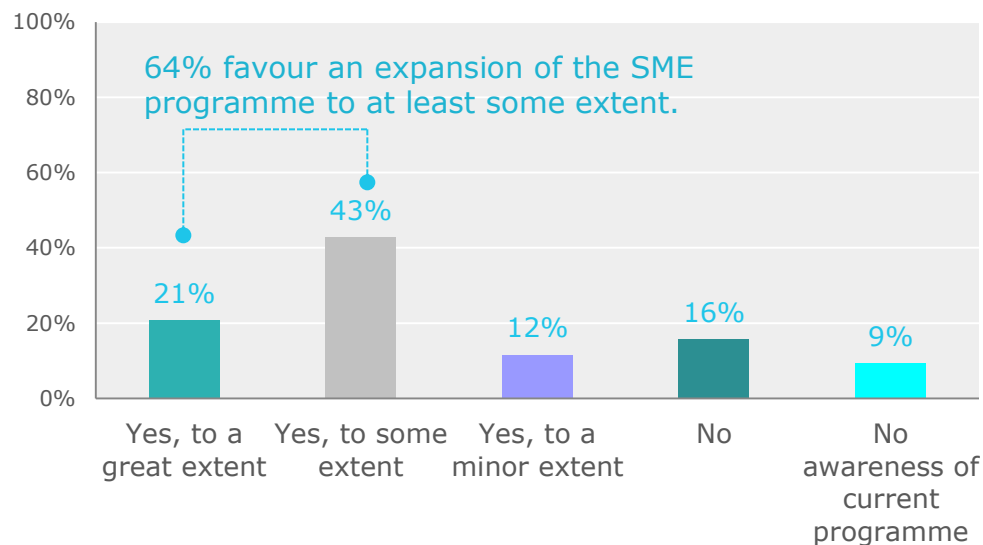
SME PROGRAMME

FUTURE SERVICES

SME programme

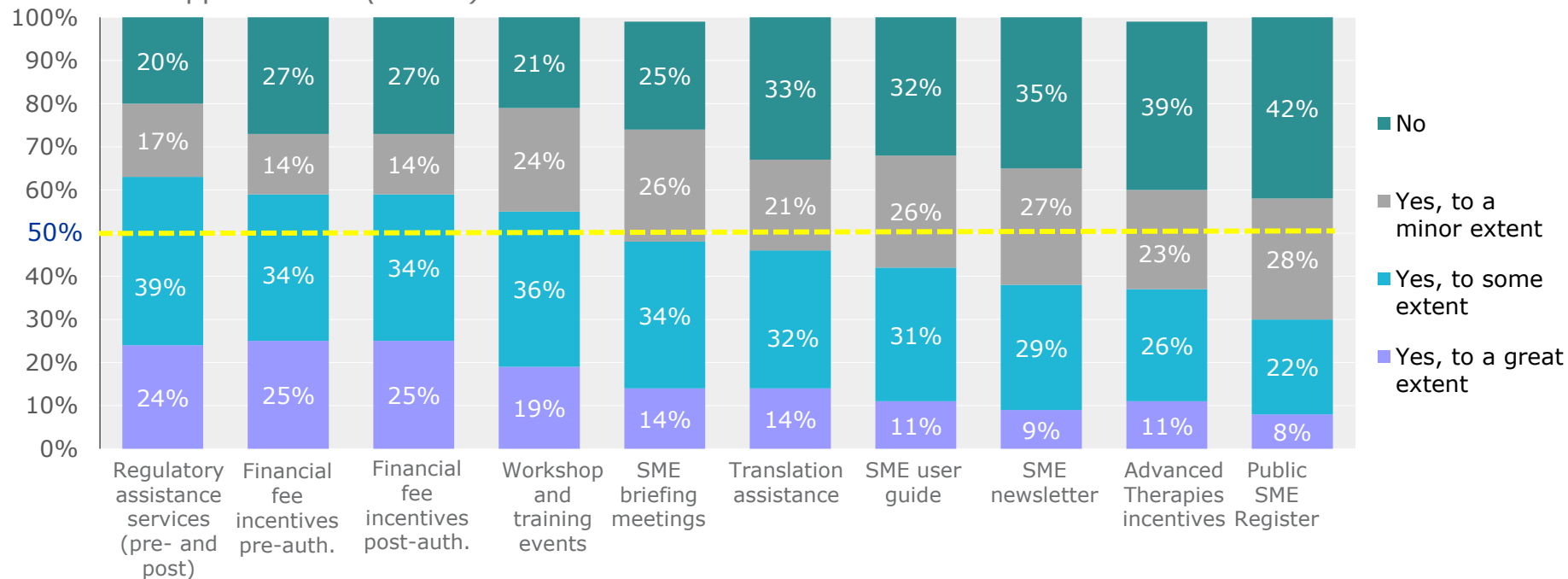
Expansion overall

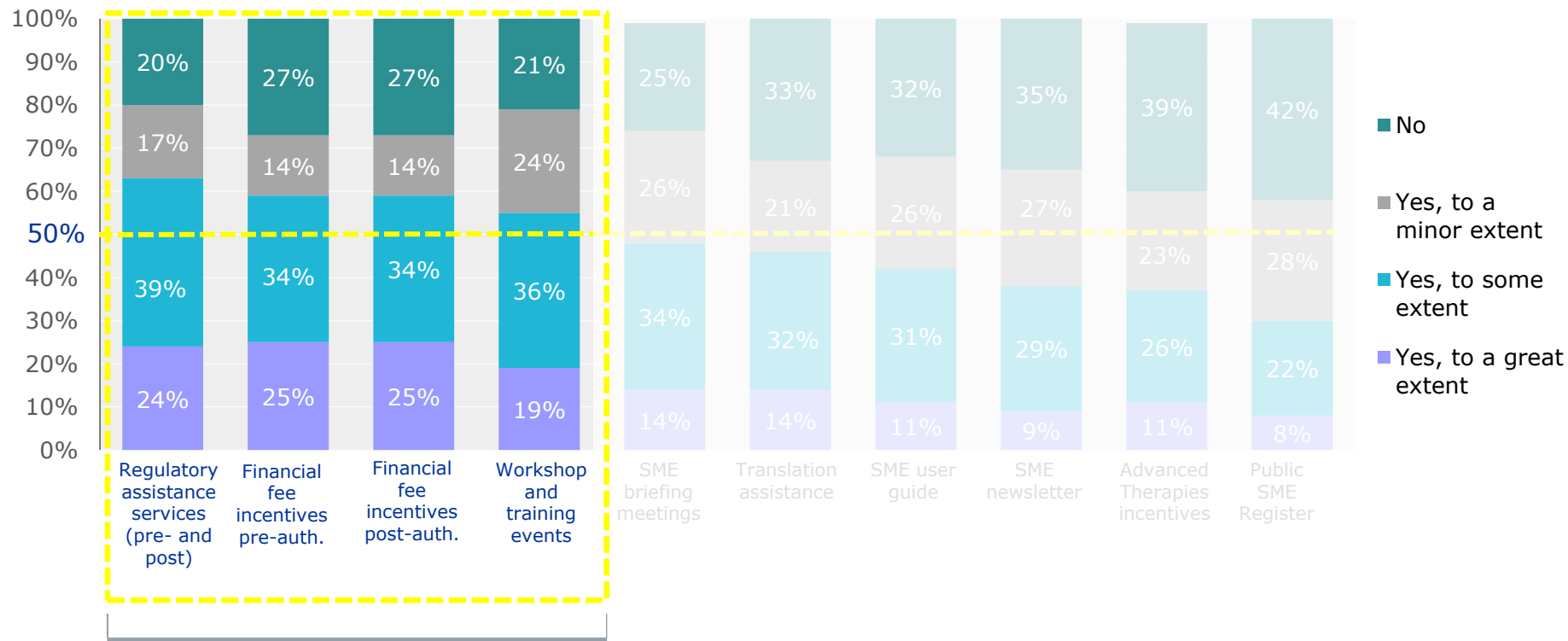
Does the Agency need to expand its programme to support SMEs? ($n=421$)



SME programme – *Expansion of specific services*

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





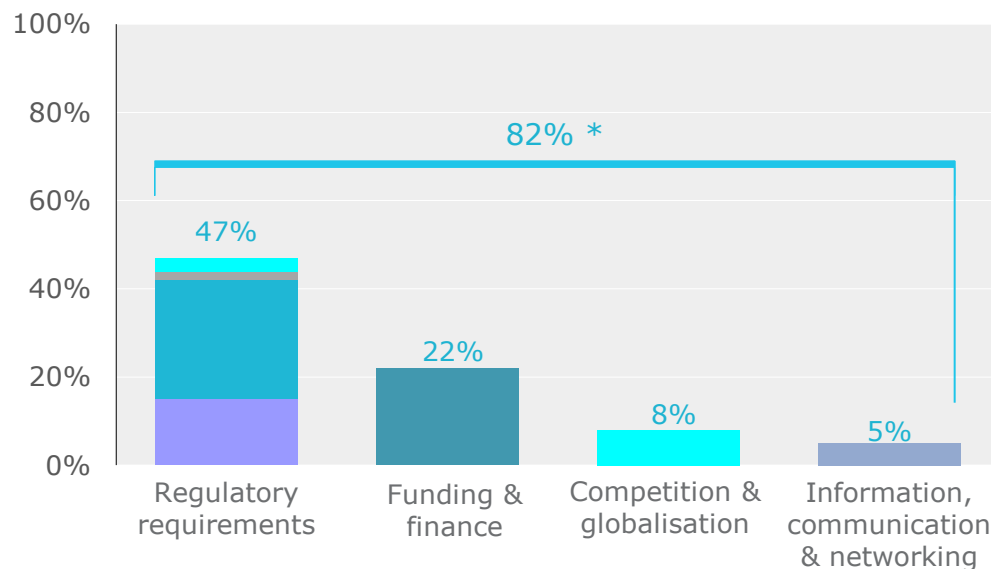
EXPANSION SUGGESTED

More than 50% of all respondents indicate that existing services should be expanded to at least some extent.



Current & future challenges

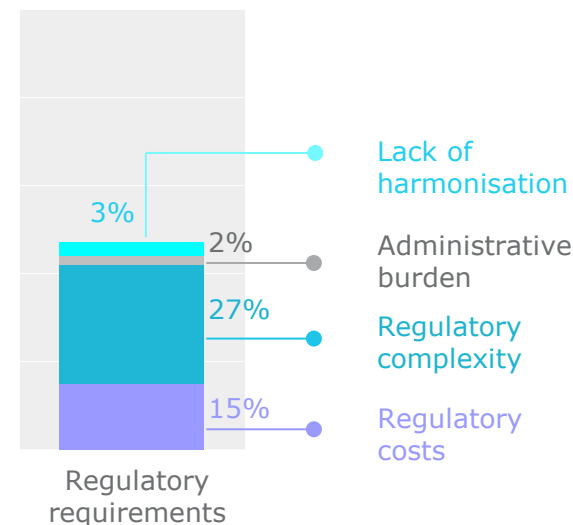
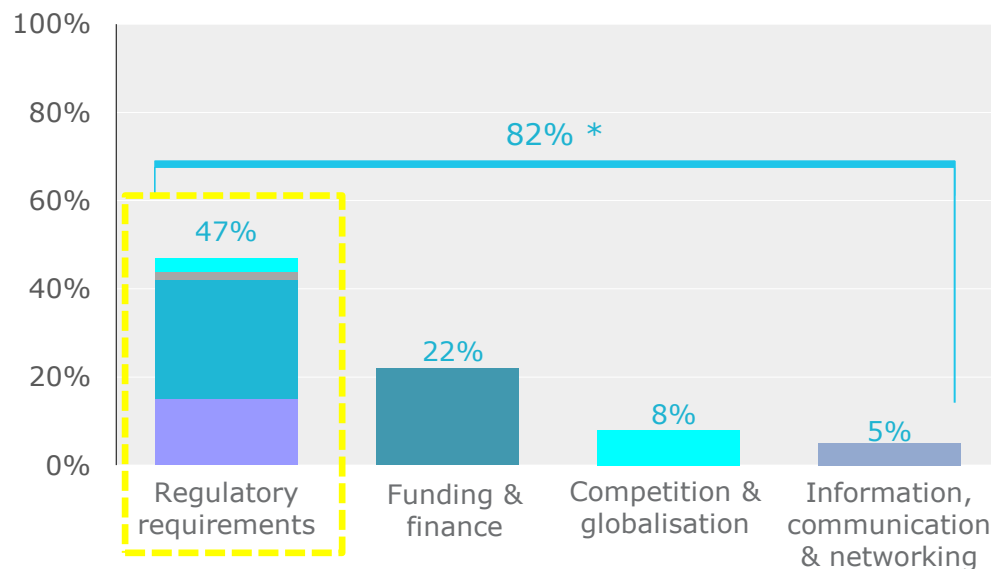
Challenges faced by SMEs – *Current* (n=373)



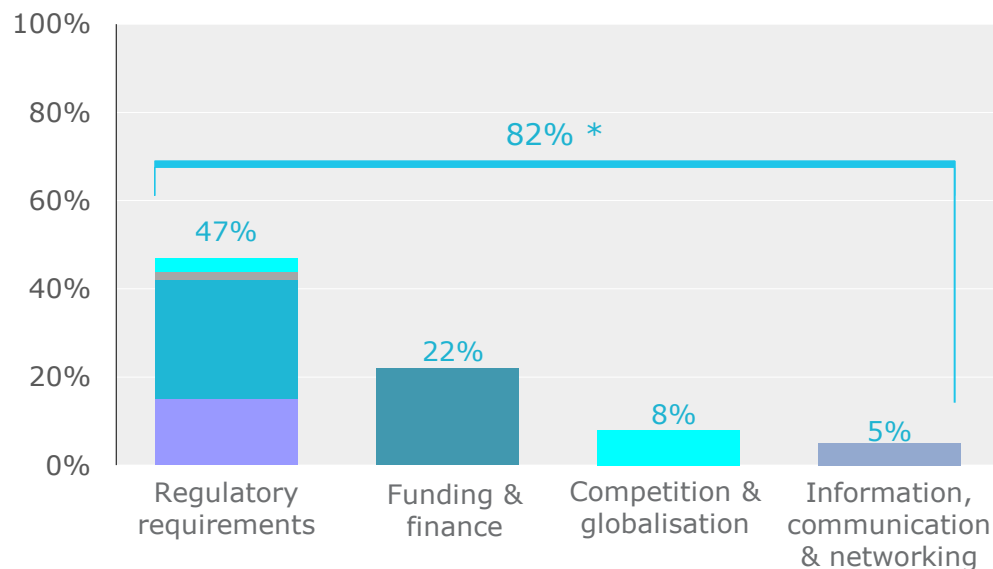
SAMPLE COMMENTS

- *Finding funding and the relevant expertise needed to move things forward.*
- *The cost of compliance with the current regulations is too high.*
- *Lack of funds to develop quickly products pipeline, slow approval route, bureaucratic drawbacks.*
- *The main challenges for SMEs are the difficulties to be competitive in front of the bigger companies.*
- *Different national interpretations of regulation. To be more European we have to be more 1 Europe.*
- *Too much paperwork in every direction.*

Challenges faced by SMEs – *Current* (n=373)



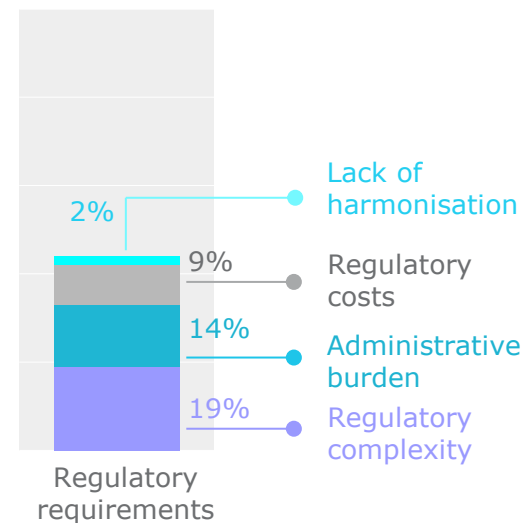
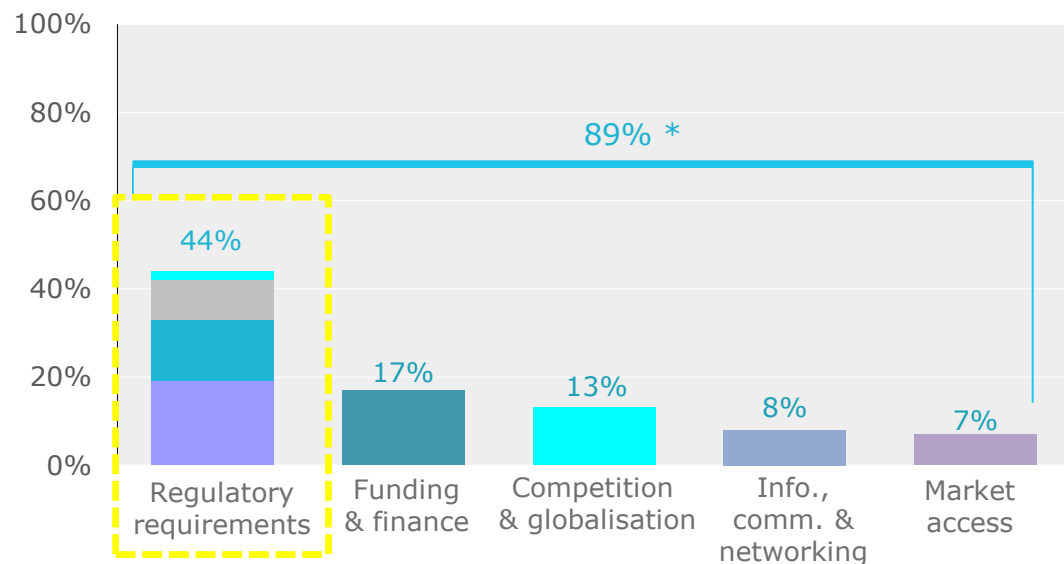
Challenges faced by SMEs – *Current*



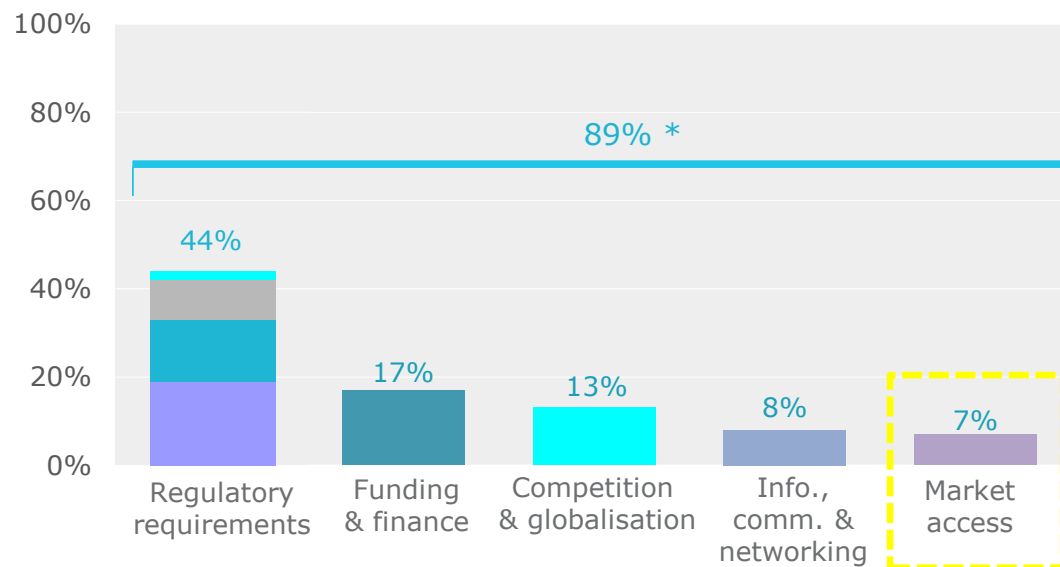
Emerging themes:

1. Market access (4%)
2. *Recruitment, education, training* (2%)

Challenges faced by SMEs – 5 years (*n=373*)



Challenges faced by SMEs – 5 years

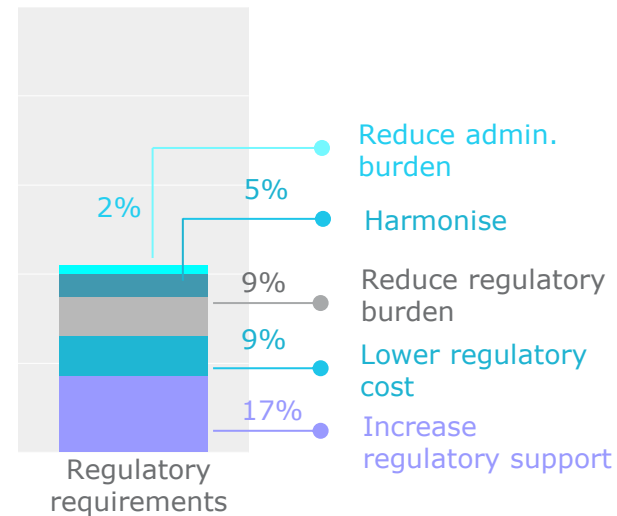
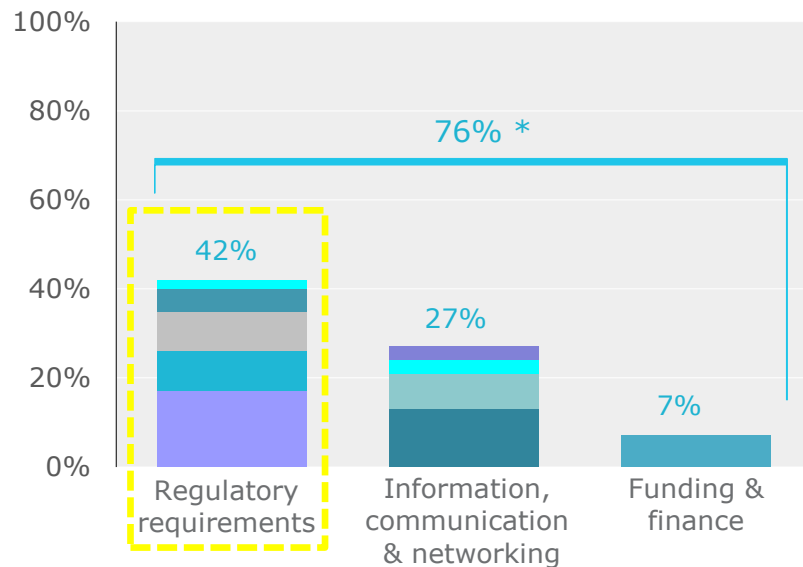


Emerging themes:

1. Market access (7%)
2. Recruitment, education, training (4%)

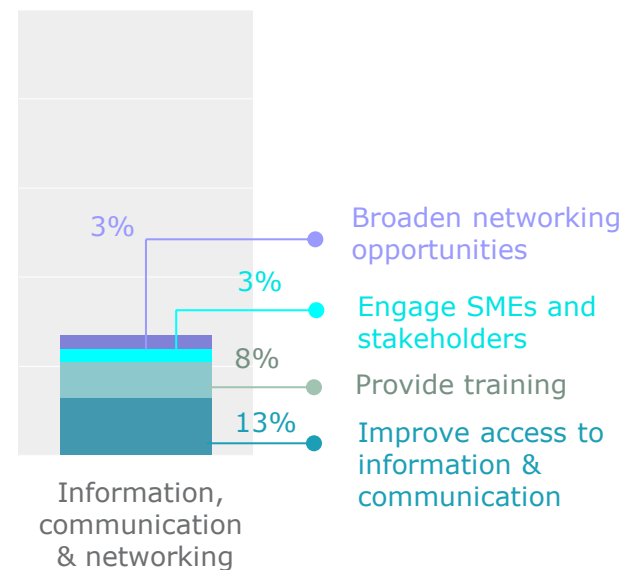
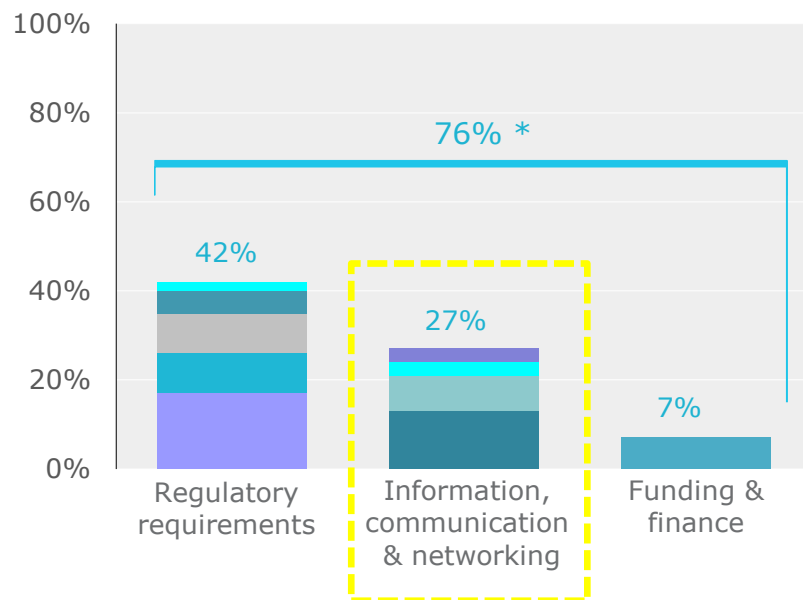
Measures

In your opinion, what measures could the Agency introduce to address these challenges? (*n*=373)



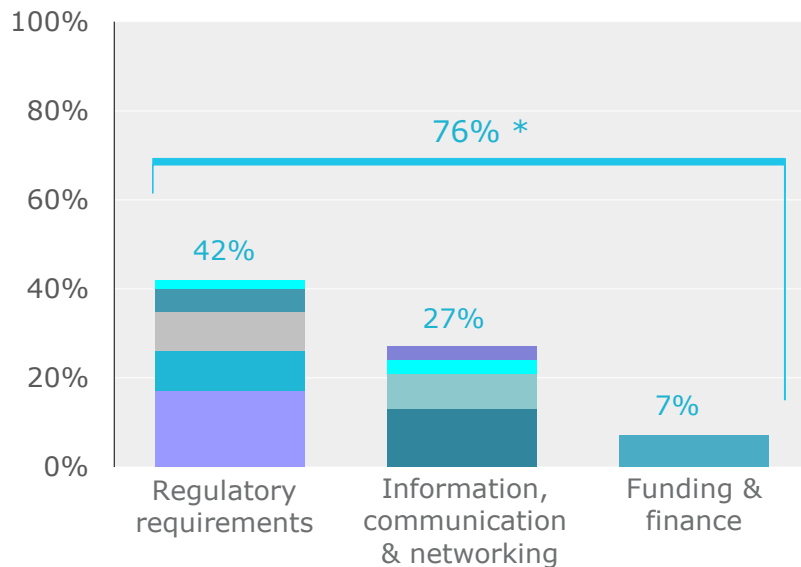
Measures

In your opinion, what measures could the Agency introduce to address these challenges?? ($n=373$)



Measures

In your opinion, what measures could the Agency introduce to address these challenges?? ($n=373$)



Emerging themes:

1. Market access:

- Early dialogue with HTA: Parallel SA/EMA HTA.

2. Recruitment, education, training

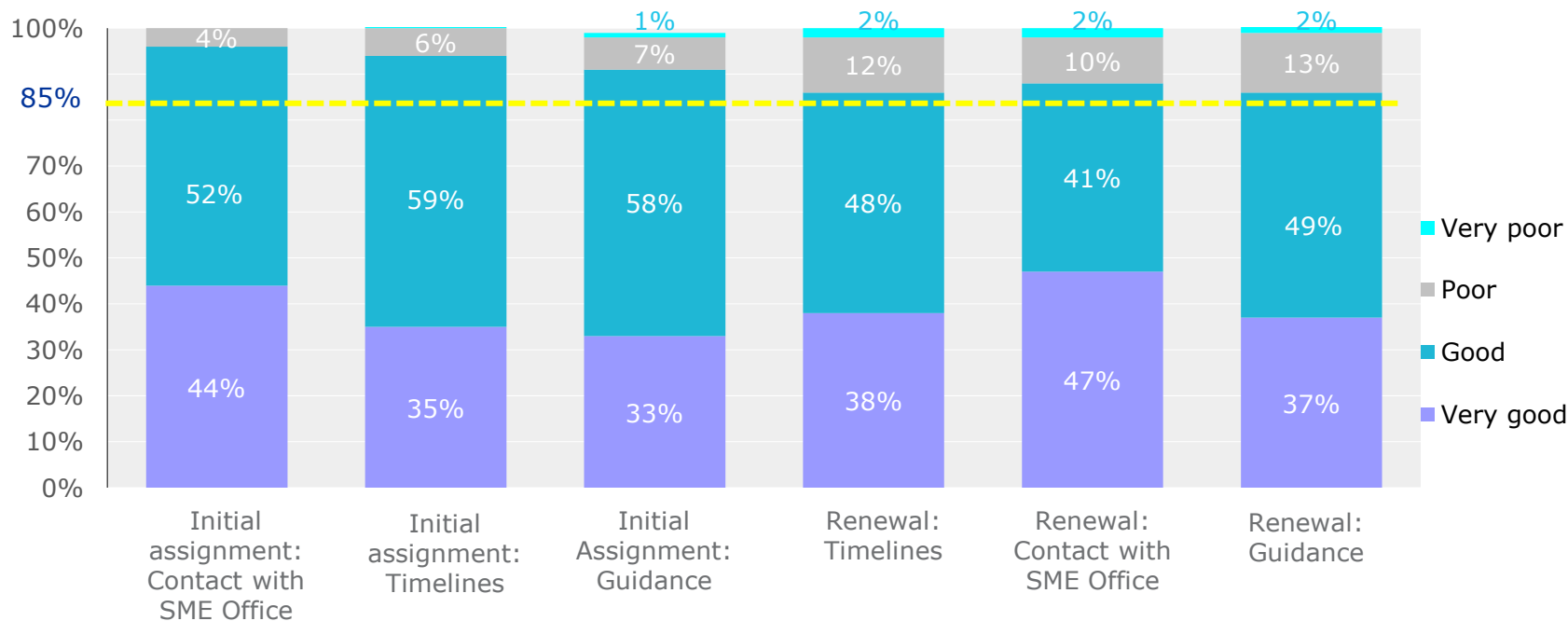
- Improve access to information;
- Offer more training and workshops.

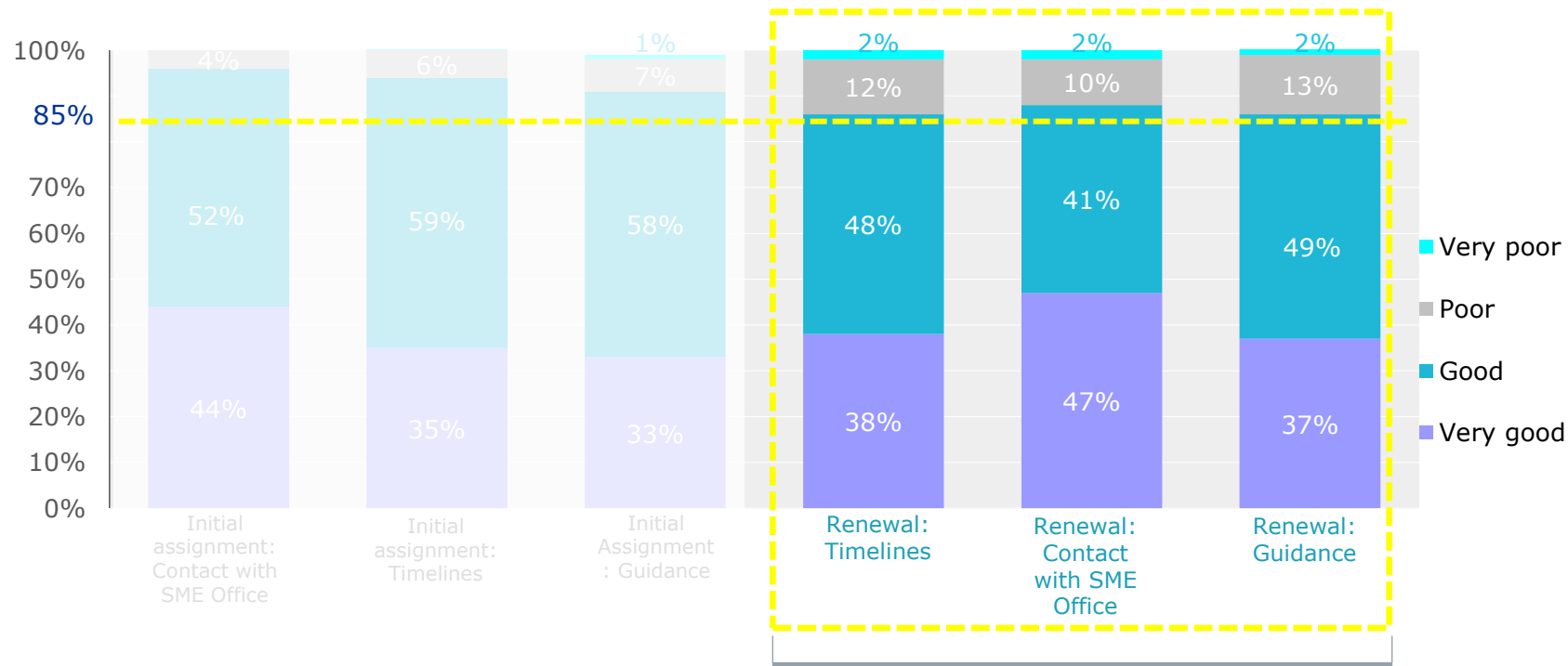


SME assignment process and incentives

SME assignment – *Satisfaction with initial assignments and renewals*

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





RENEWALS

While still being ranked as good or very good by more than 85% of all respondents, overall renewals have received lower satisfaction scores than initial assignments.

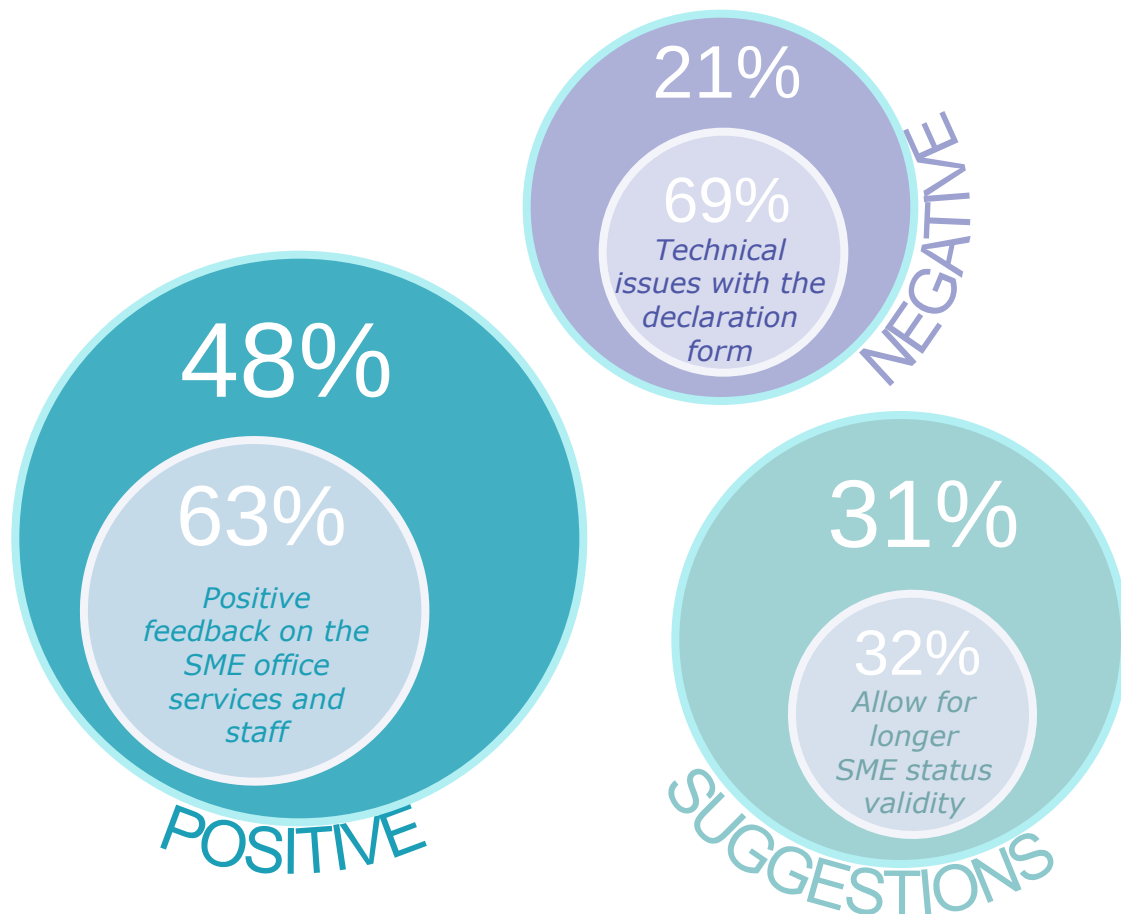
SME Survey 2015 **COMMENTS**





SAMPLE COMMENTS

- Thank you for your very appreciated support to SMEs .
- Personnel at EMA's SME Office and Innovation Task Force have done an excellent job at helping us and addressing our questions.
- Keep doing this !!!
- A very worthwhile service which is very much appreciated by those with whom I have worked.
- SME status needs to be renewed annually, it would be good if this could be done less frequently.
- Completing the renewal form takes ages. It could be made quicker if we could just update the previous years information rather than insert it all from scratch.
- The template for SME application and renewal is not working well when it comes to Electronic submission.



(n= 114)

Thank you for your attention

Further information

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