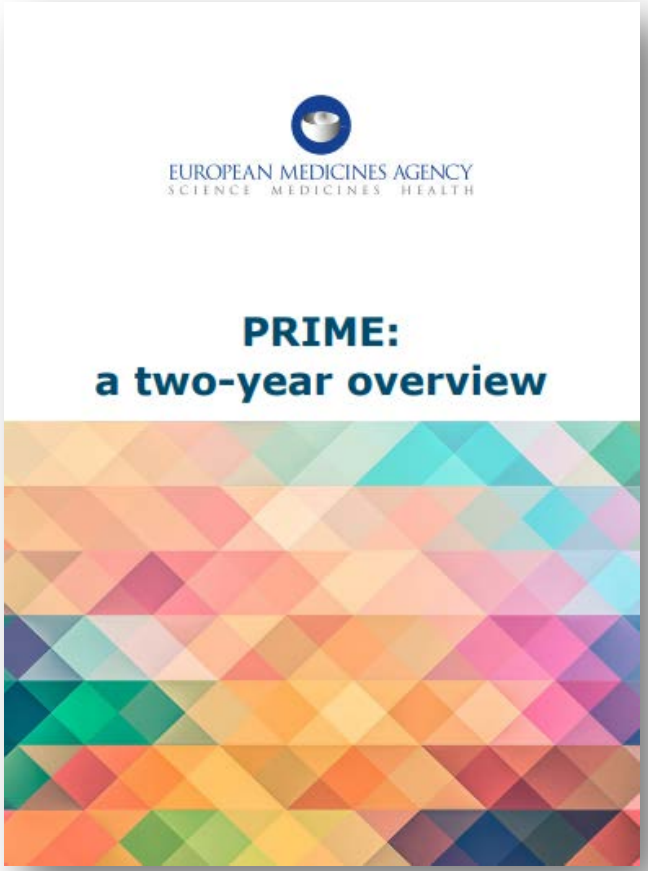
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on PRIME

Overview of updated guidance based on experience and learnings after 2 years of operation of the scheme

3rd Industry Stakeholder Platform on R&D support, 18 May 2018

Presented by Jordi Llinares and Zahra Hanaizi
Scientific and Regulatory Management Department

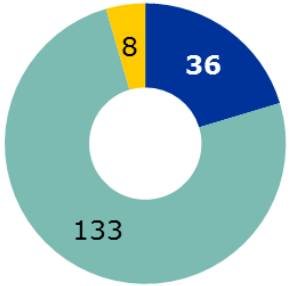


Report published on
EMA website

How criteria for eligibility have been applied

What type of support applicants have received so far

Two years of PRIME



■ Granted ■ Denied ■ Out of scope*

21% success rate

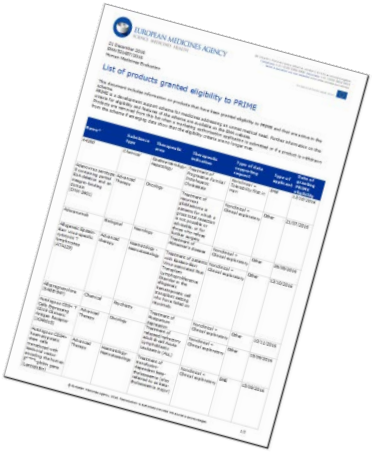
177 requests received

> 50% from SMEs

36 granted*

+

Publication of report and list of products on EMA website



Overview of therapeutic areas

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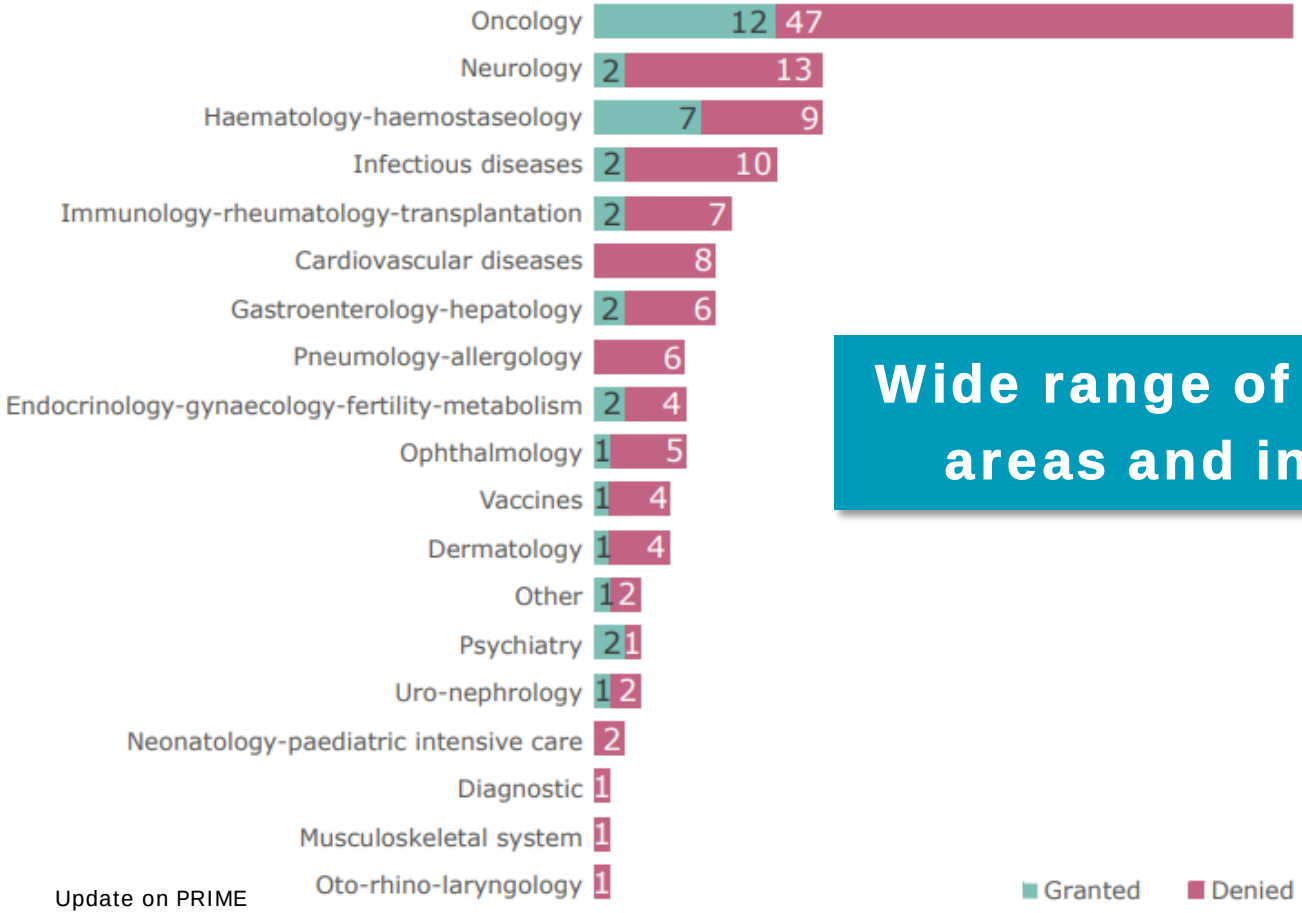
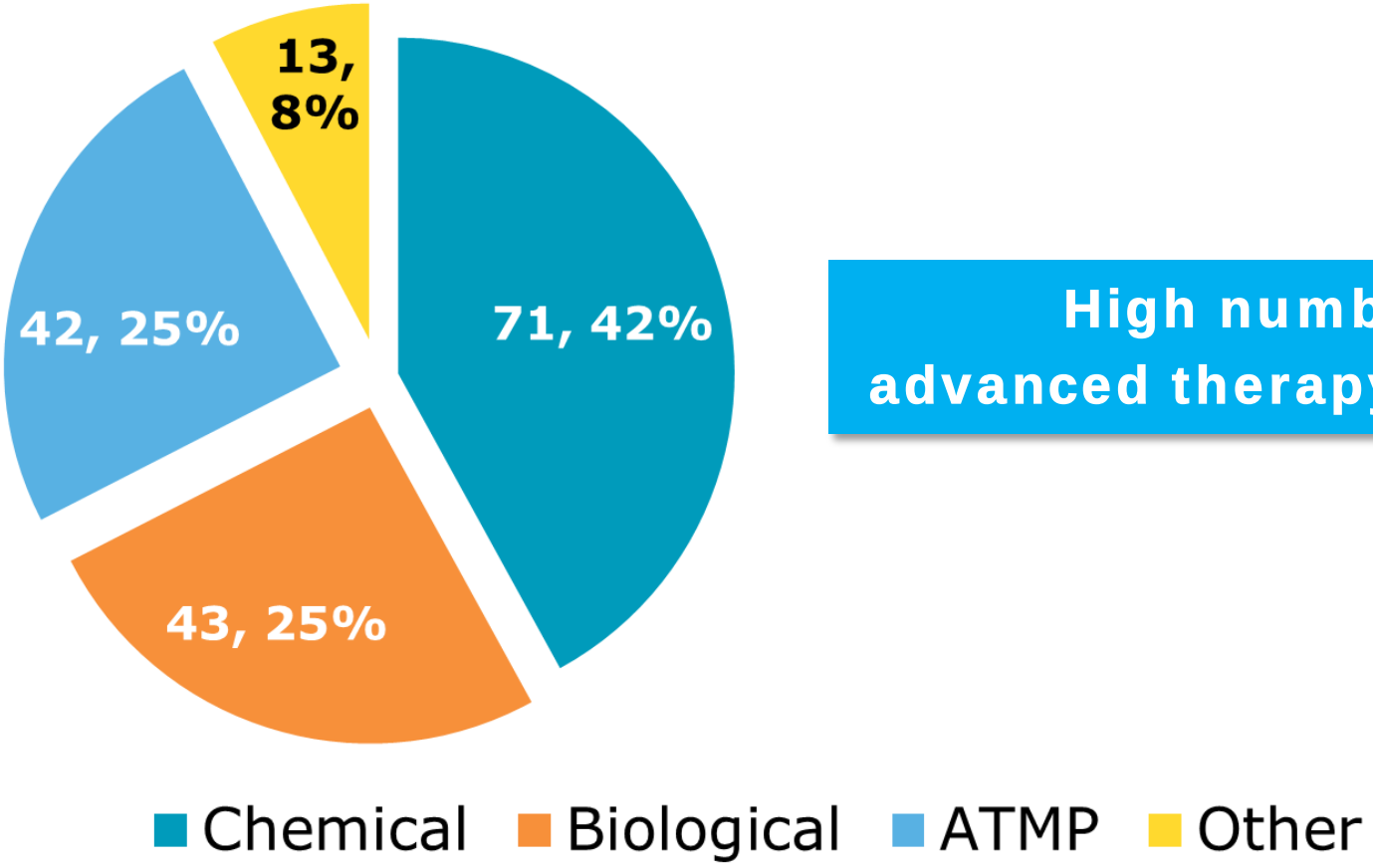


Wide range of therapeutic areas and indications

Overview of type of products



High number of advanced therapy medicines

2 year of PRIME eligibility assessments: 177 requests

- Good understanding of scope and good quality of applications
- Proof of principle: 8 received, 3 granted, 1 progress to proof of concept
- Proof of concept: 129/161 requests denied
  - 87% because of issues with robustness of presented data and/or inconclusive or insufficient effect

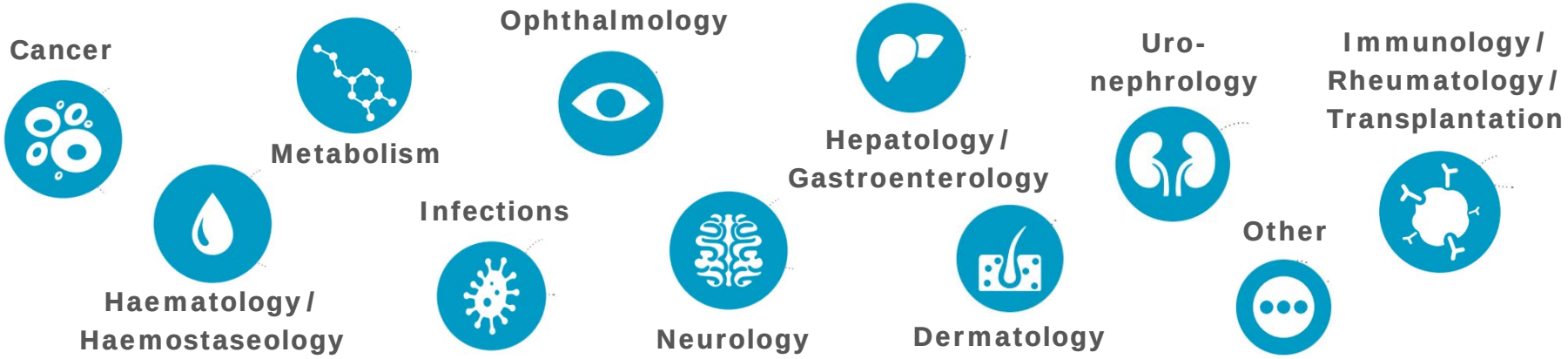
36 products eligible to PRIME since launch

30 in rare diseases

16 for paediatric patients

15 advanced therapy

Areas of unmet medical need and therapeutic indications covered



Our experience so far: 31 kick-off meetings

- Excellent tool to initiate dialogue and provide recommendation on the next steps
- Tailored to individual product
- Opportunity to raise awareness on importance of early dialogue with HTAs

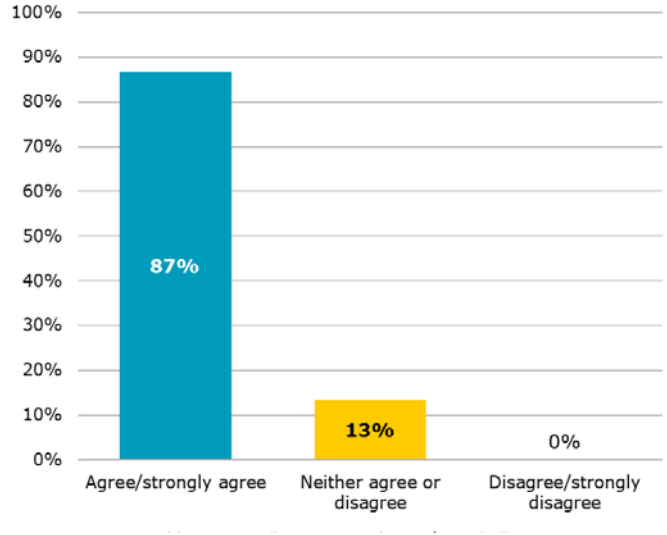
Kick off survey – April 2018

- Short anonymous questionnaire (10 questions)
- Sent to 20 applicants that had a kick-off meeting in the past 12 months.
- Focused on the preparation, objectives, conduct and follow-up of the kick-off meeting.

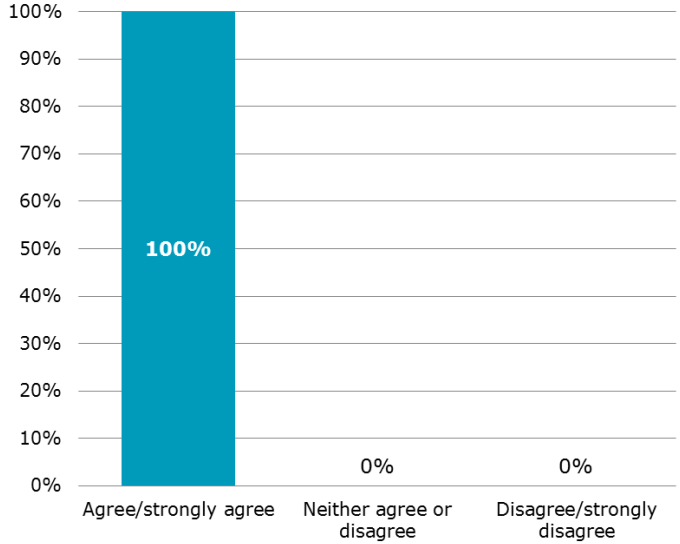
Good response rate
75% (15 responders)

Preparation of kick-off meeting

Q1. The written guidance provided was helpful to prepare the briefing document



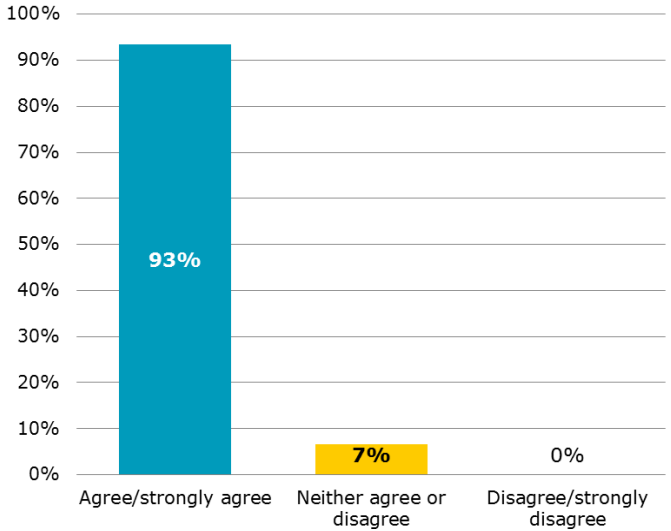
Q2. The support provided by EMA was helpful to prepare for the meeting



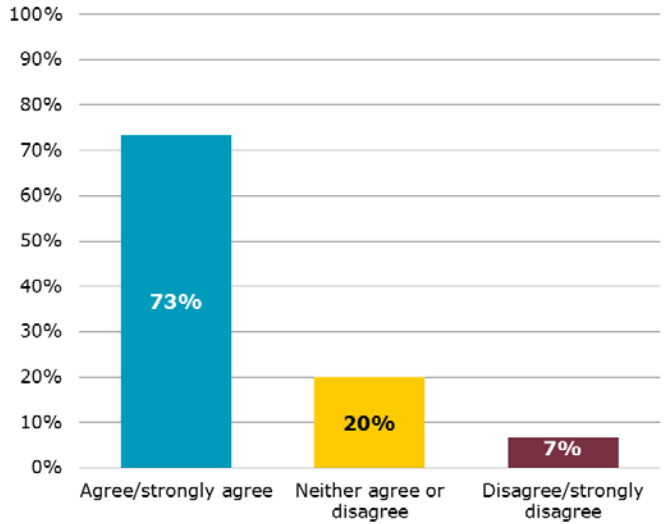
High satisfaction with preparatory steps and support before the meeting

Objectives of the meeting

Q3. The meeting objectives were clear to the applicant



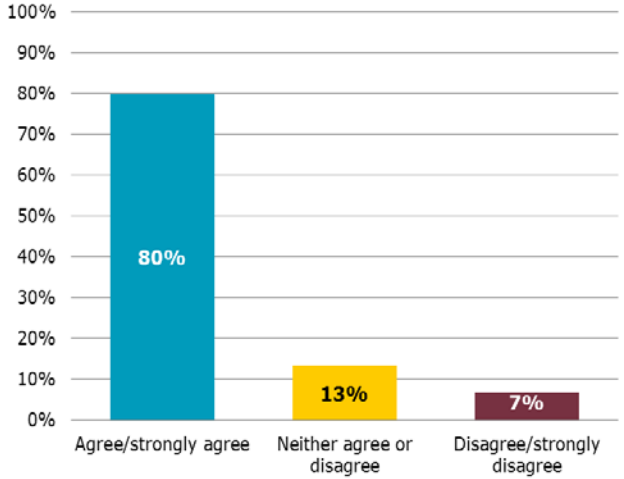
Q4. The meeting met your objectives and expectations



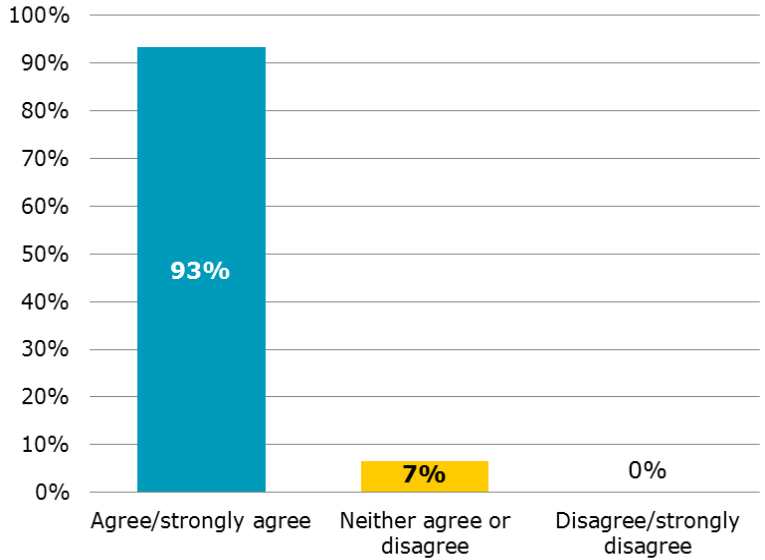
Good satisfaction with objectives of the meeting

Outcomes of the meeting

Q6. The meeting had an impact on your next development steps or planned interactions with regulators



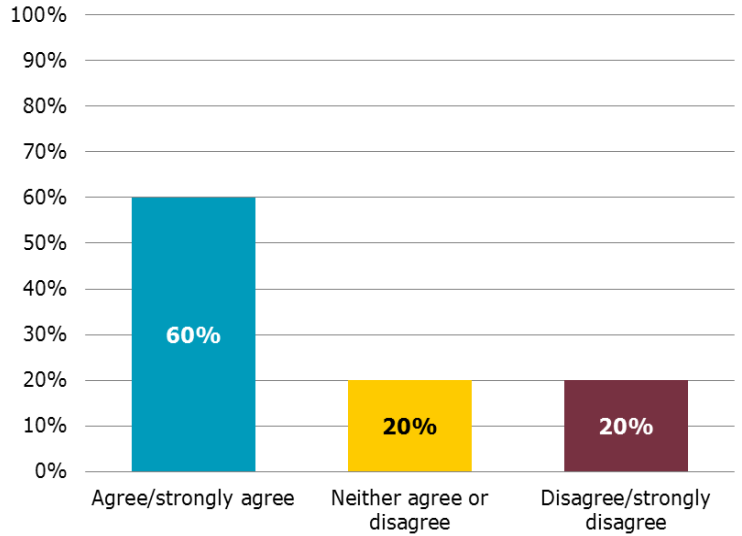
Q7. The recommendations were realistic.



Good agreement on impact of the meeting on development plans

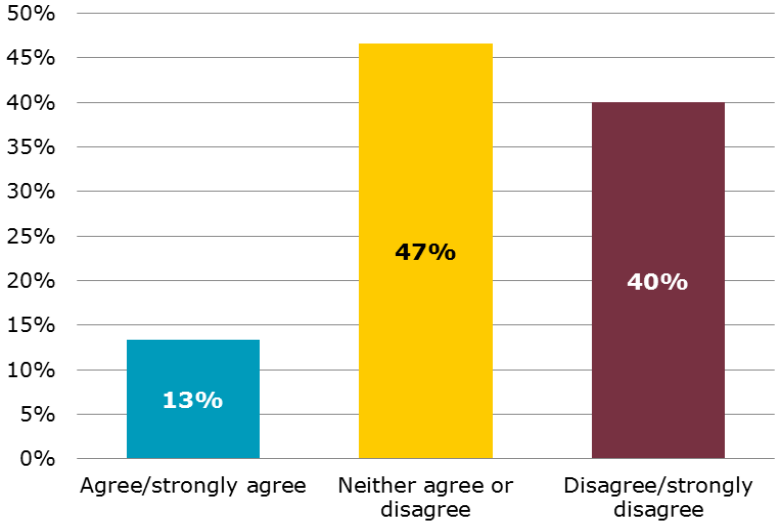
Outcomes of the meeting

Q5. The meeting helped you to understand how to interact with different committees



Area for improvement to support future interactions with multiple committees

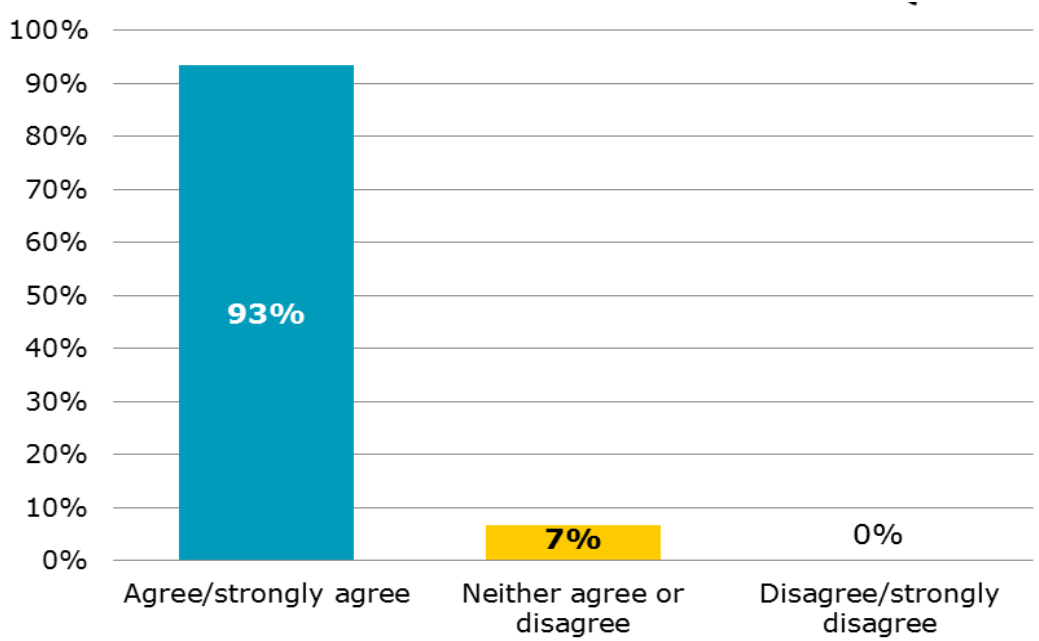
Q8. There were issues raised or guidance received at the meeting that the applicant were not aware of



In contradictions with other responses – question not understood ?

Overall feedback

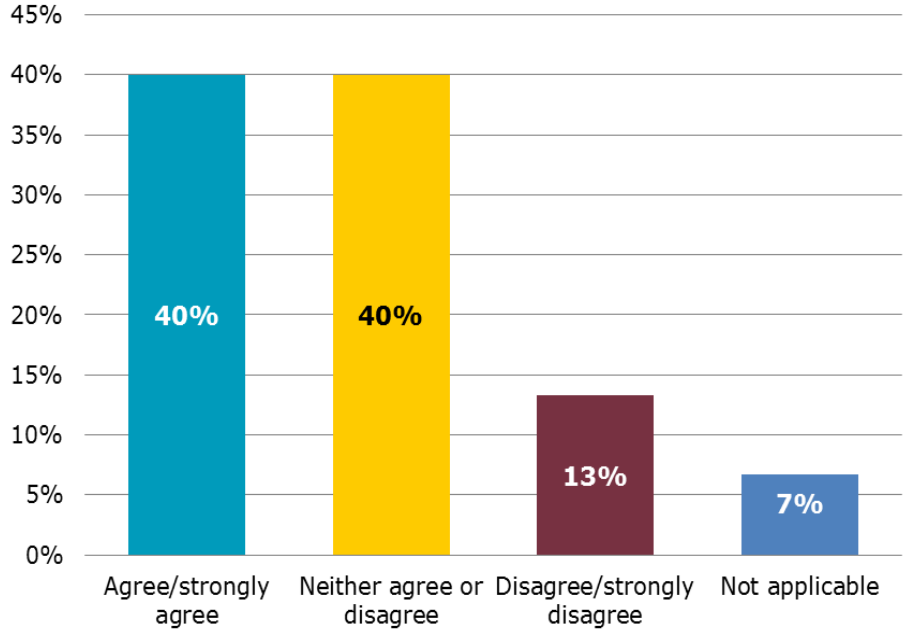
Q9. Overall, the meeting was useful



High satisfaction with the kick-off meeting

Follow-up after the meeting

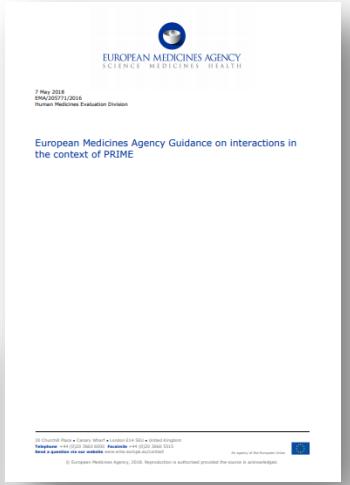
Q.10 The follow-up after the kick-off meeting is adequate



Area for improvement in follow-up interactions

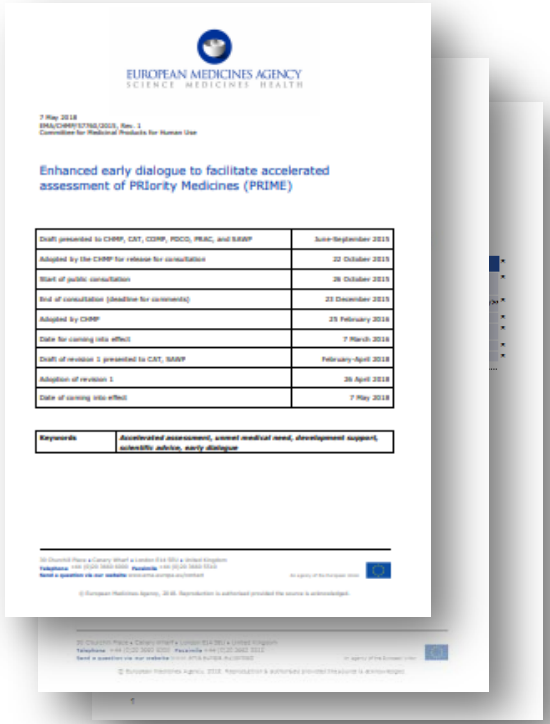
New and updated guidance to reflect 2 years of experience

Updated
Reflection paper, Q&A, template



***New* guidance on kick-off meetings and other interactions**

What's new: updated Reflection paper, Q&A, template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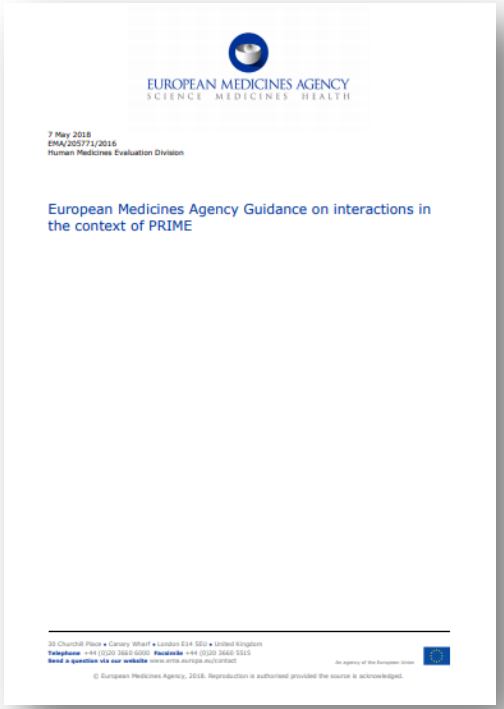
Enhanced early dialogue to facilitate accelerated assessment of PRIority Medicines (PRIME)

Draft presented to CHMP, CAT, COMP, PDCO, PRAC, and SAWP	June-September 2015
Adopted by the CHMP for release for consultation	22 October 2015
Start of public consultation	26 October 2015
End of consultation (deadline for comments)	23 December 2015
Adopted by CHMP	25 February 2016
Date for coming into effect	7 March 2016
Draft of revision 1 presented to CAT, SAWP	February-April 2018
Adoption of revision 1	26 April 2018
Date of coming into effect	7 May 2018

Keywords	*Accelerated assessment, unmet medical need, development support, scientific advice, early dialogue*

- Improve guidance to support more robust application
- New section in the template: 'Overview of next steps in the development and expected benefits of PRIME'
- Q&A on collaboration with FDA

What's new: Guidance on interactions in the context of PRIME



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7 May 2018
EMA/205771/2016
Human Medicines Evaluation Division

European Medicines Agency Guidance on interactions in the context of PRIME

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 Facsimile +44 (0)20 3660 5515
Send a question via our website www.ema.europa.eu/contact

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- Guidance for preparation and conduct of the kick-off meeting
- Expectations for regular updates
- Opportunities for ad hoc interactions

Follow-up on 2017 industry stakeholders' suggestions

Eligibility

- Scope (proof of principle, new indications)
- Optional pre-submission interactions
- Teleconference on rejections

PRIME support

- Kick-off meeting
- Regular/follow-up dialogue

Thank you for your attention

Further information

Zahra.hanaizi@ema.europa.eu

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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