



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

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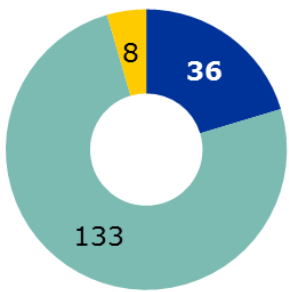




Report published on
[EMA website](#)

How criteria for eligibility have
been applied

What type of support
applicants have received so far

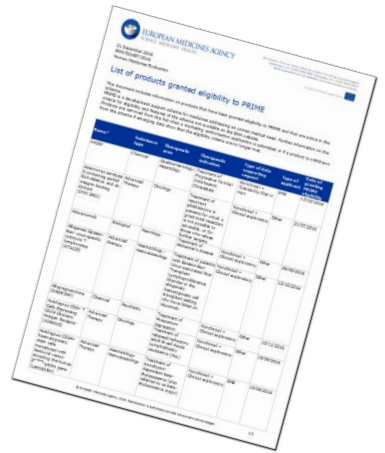


■ Granted ■ Denied ■ Out of scope*

177 requests received
> 50 % from SMEs
36 granted*

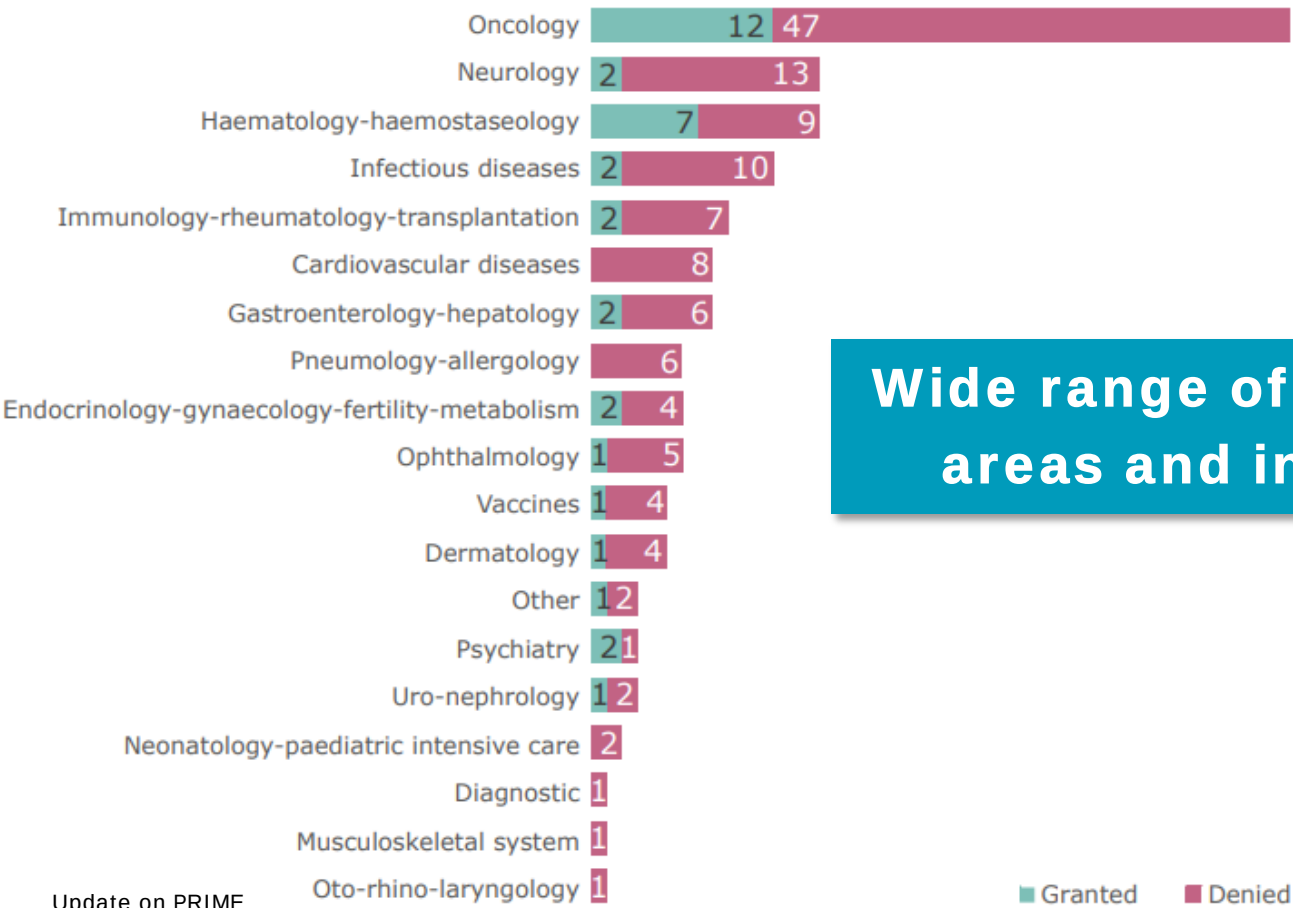


+
Publication of
report and list
of products on
EMA website

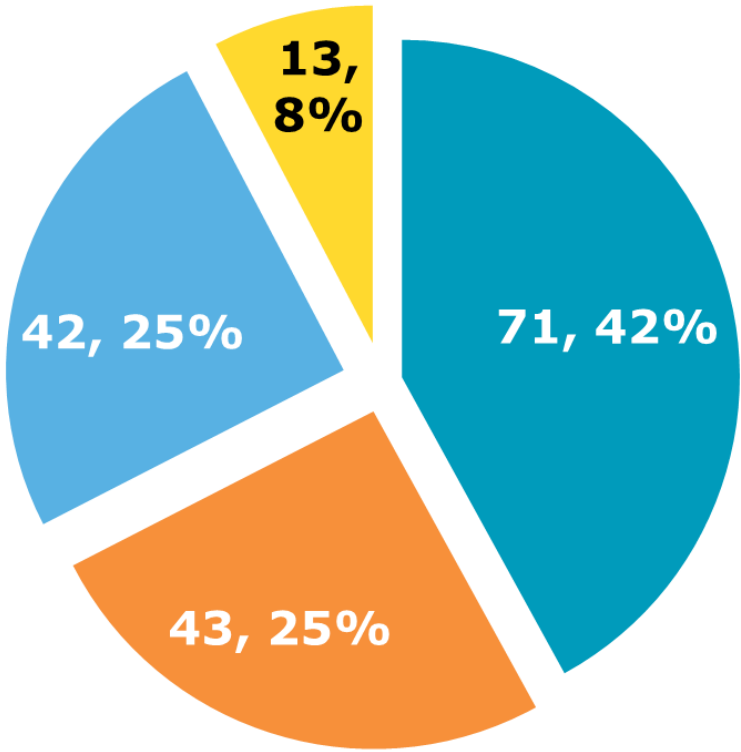


Product Name	Marketing Authorisation Holder	Therapeutic Area	Indication	Date of PRIME decision	PRIME status
...	...	...	...	...	...

21 % success rate



Wide range of therapeutic areas and indications



**High number of
advanced therapy medicines**

 Chemical  Biological  ATMP  Other

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



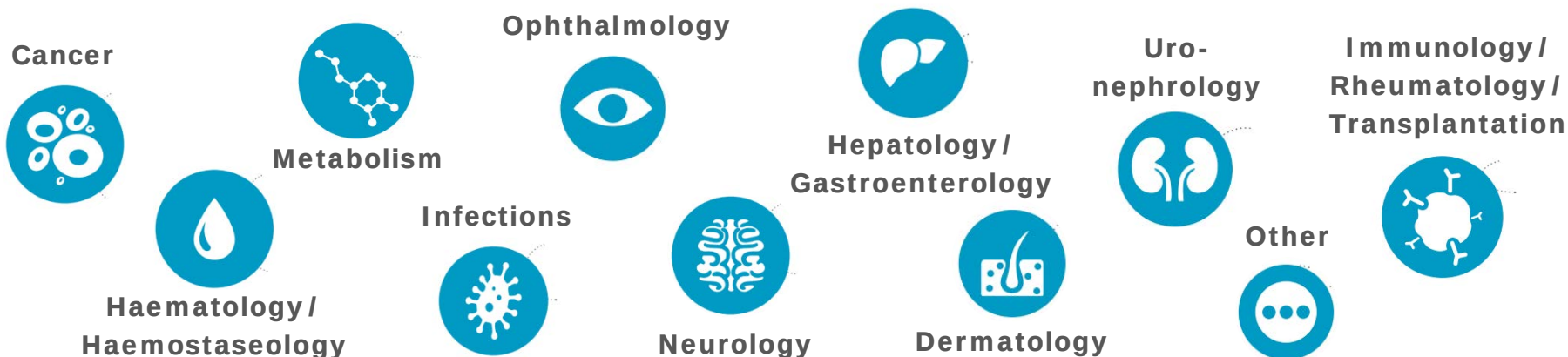
36 products eligible to PRIME since launch

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



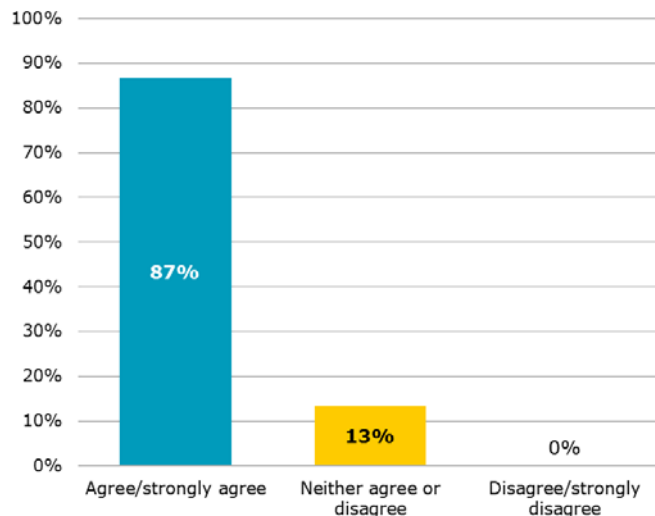
- Short anonymous questionnaire (10 questions)
- Sent to 20 applicants that had a kick-off meeting in the past 12 months.
- Focused on the preparation, objectives, conduct and follow-up of the kick-off meeting.

**Good response rate
75 % (15 responders)**

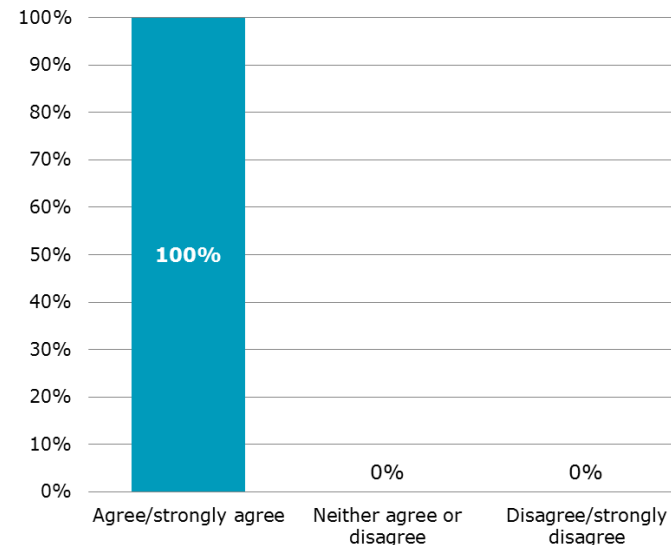


Preparation of kick-off meeting

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

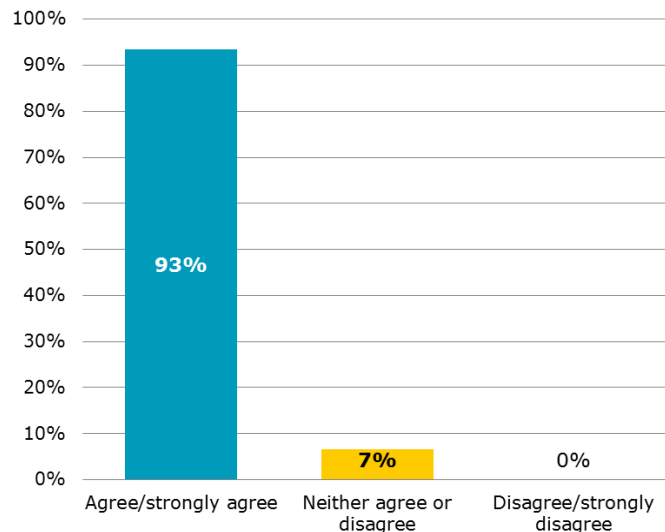


High satisfaction with preparatory steps and support before the meeting

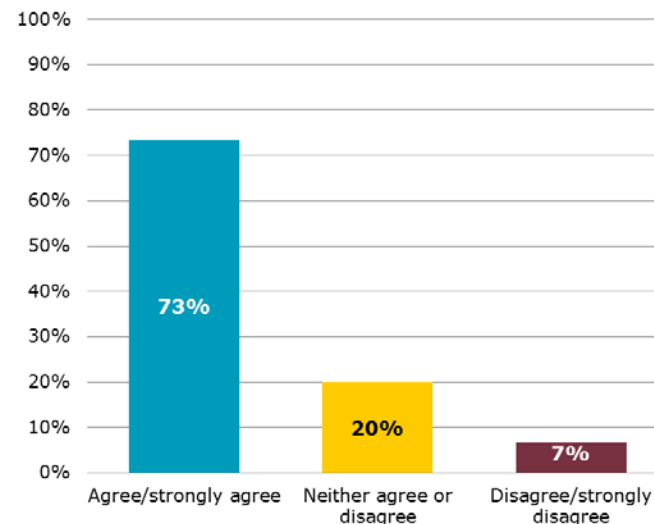


Objectives of the meeting

Q3. The meeting objectives were clear to the applicant



Q4. The meeting met your objectives and expectations

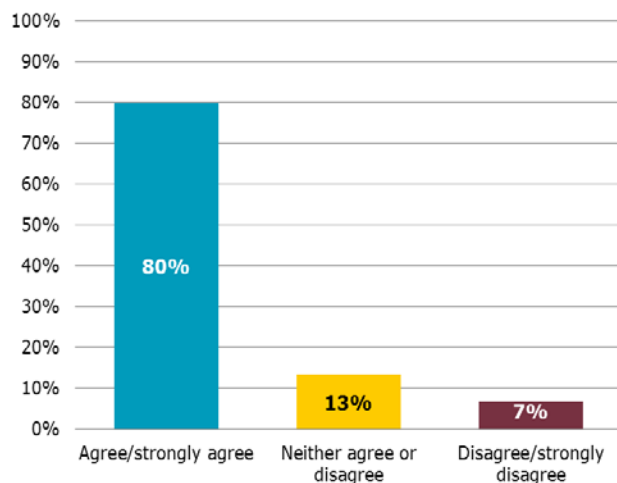


Good satisfaction with objectives of the meeting

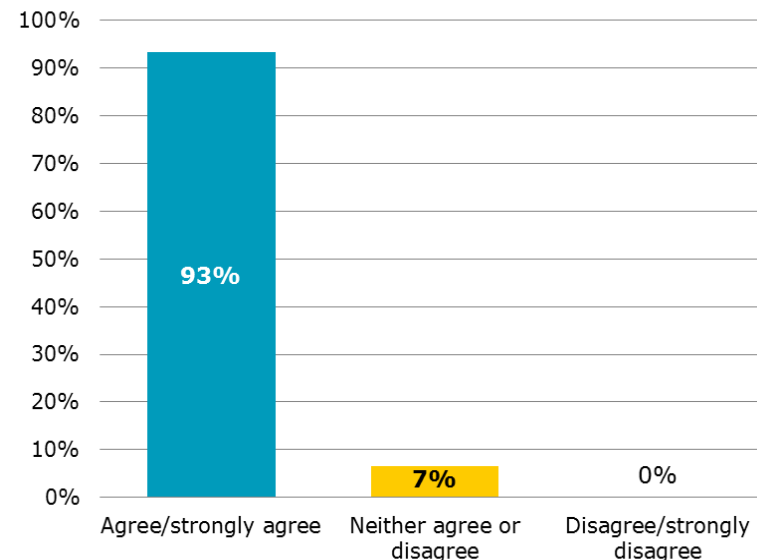


Outcomes of the meeting

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



Q7. The recommendations were realistic.

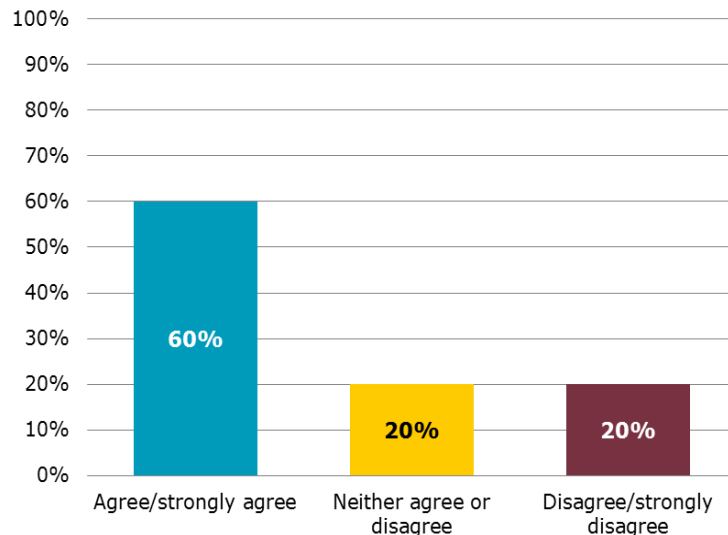


Good agreement on impact of the meeting on development plans



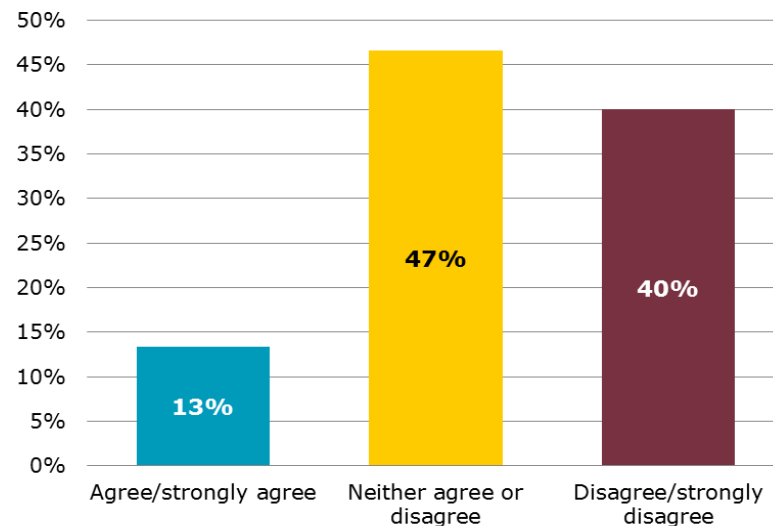
Outcomes of the meeting

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

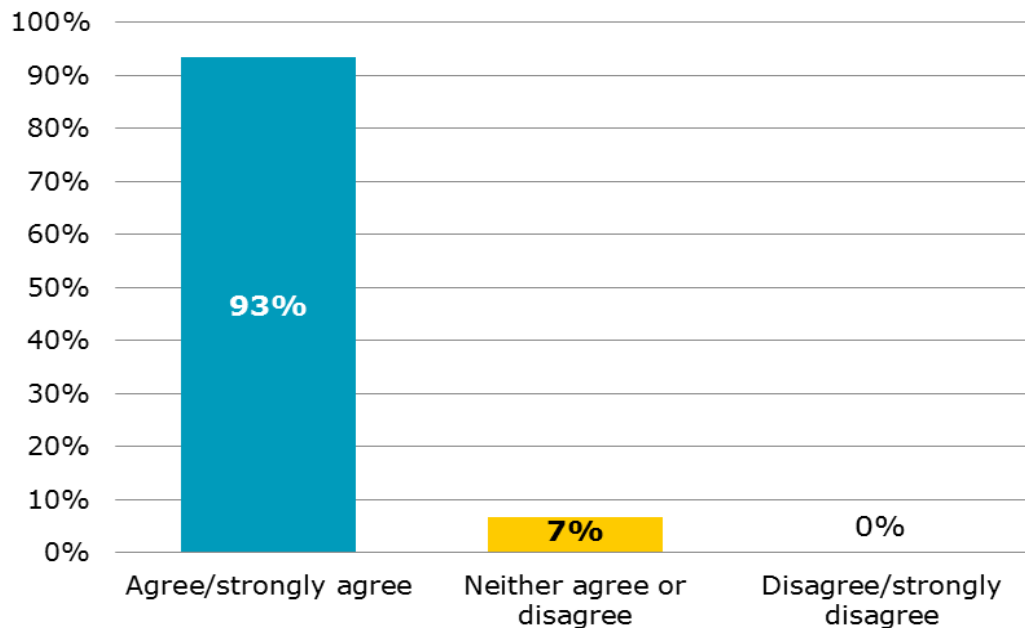


In contradictions with other responses – question not understood ?



Overall feedback

Q9. Overall, the meeting was useful

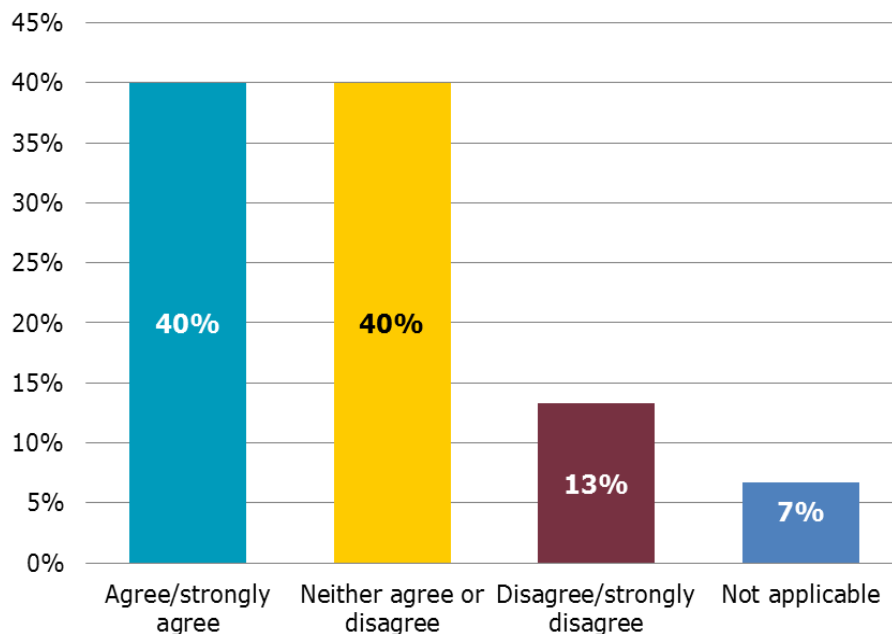


High satisfaction with the kick-off meeting



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



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PRIME - PRIORITY MEDICINES

PRIME is a scheme launched by the European Medicines Agency (EMA) to enhance support for the development of medicines that target an unmet medical need. This voluntary scheme is based on enhanced interaction and early dialogue with developers of promising medicines, to optimise development plans and speed up evaluation so these medicines can reach patients earlier.

Through PRIME, the Agency offers early and proactive support to medicine developers to optimise the generation of robust data on a medicine's benefits and risks and enable accelerated assessment of medicines applications.

This will help patients to benefit as early as possible from therapies that may significantly improve their quality of life.

Accelerated assessment

PRIME builds on the existing regulatory framework and tools already available such as scientific advice and accelerated assessment. This means that developers of a medicine that benefitted from PRIME can expect to be eligible for accelerated assessment at the time of application for a marketing authorisation.

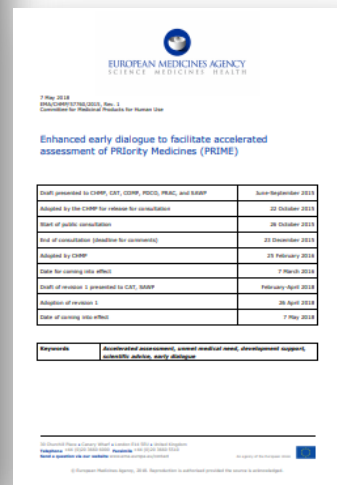
Related content

- ▶ Support for early access
- ▶ Two years of PRIME (7/5/2018)
- ▶ First anniversary of PRIME: experience so far (19/5/2017)
- ▶ Launch of PRIME – Paving the way for promising medicines for patients (07/03/2016)

Report: PRIME: a two-year overview

PRIME: a two-year overview

Updated Reflection paper, Q&A, template



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7 May 2018
EMA/000712/2018
Committee for Medicinal Products for Human Use

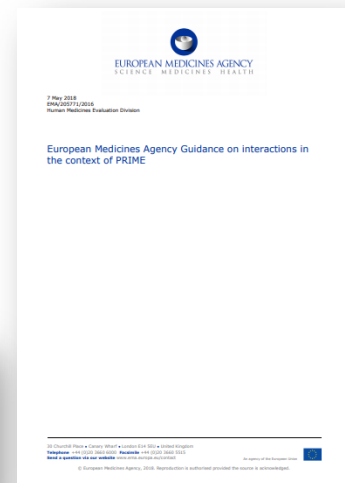
Enhanced early dialogue to facilitate accelerated assessment of Priority Medicines (PRIME)

Scout presented to CHMP, SAT, CORP, MRLC, and SAMP	June September 2016
Adopted by the CHMP for inclusion for consultation	30 October 2016
Start of public consultation	30 October 2016
End of consultation (deadline for comments)	31 December 2016
Adopted by CHMP	25 February 2017
Start of working into effect	17 March 2017
Scout of member 1 presented to CHMP, SAMP	February-April 2017
Adoption of member 1	30 April 2017
Date of working into effect	7 May 2018

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

EMA/000712/2018
7 May 2018
Committee for Medicinal Products for Human Use

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7 May 2018
EMA/000712/2018
Human Medicines Evaluation Division

European Medicines Agency Guidance on interactions in the context of PRIME

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New guidance on kick-off meetings and other interactions

EUROPEAN MEDICINES AGENCY
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7 May 2018
EMA/CMPH/07766/2015, Rev. 1
Convention for Medicinal Products for Human Use

Enhanced early dialogue to facilitate accelerated assessment of **PRIority Medicines (PRIME)**

Draft presented to CHMP, CAT, CMPH, PQOL, PRAC, and SBWP	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)	28 December 2015
Adopted by CHMP	23 February 2016
Date for coming into effect	7 March 2016
Draft of revision 1 presented to CAT, SBWP	February-April 2016
Adoption of revision 1	26 April 2016
Date of coming into effect	7 May 2016

Keywords	Accelerated assessment, unmet medical need, development support, scientific advice, early dialogue
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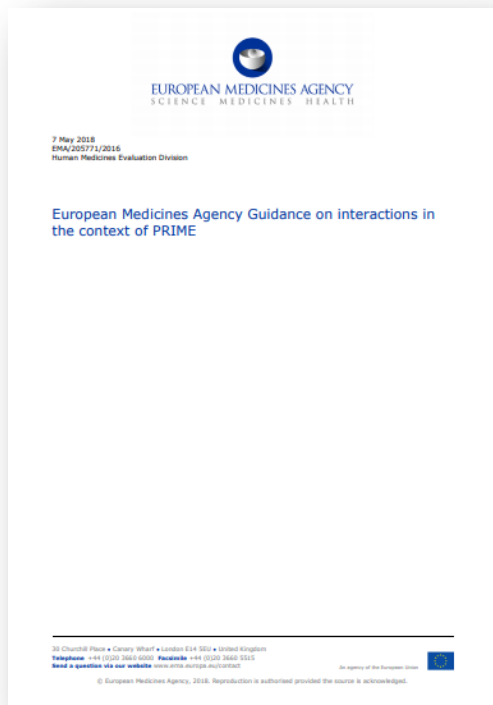
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- Improve guidance to support more robust application
- New section in the template:
'Overview of next steps in the development and expected benefits of PRIME'
- Q&A on collaboration with FDA



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



- 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

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