EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Implementation of PRIME: update from the first experience

PCWP, 14 June 2016

Presented by Jordi Llinares
Product development scientific support

An agency of the European Union

Aligned with Vision of the EU Network

EU Medicines Agencies Network Strategy to 2020

- *Ensure timely access to new beneficial and safe medicines for patients*
  - *Better understanding of existing tools (conditional MA, accelerated assessment…) and prospective planning of their use*
- *Support for patient focused innovation and contribute to a vibrant life science sector in Europe*
  - *Facilitate innovation to ensure patient access to new medicines*
  - *Greater collaboration across network to support innovation*
  - *Consider further regulatory incentives for innovation, particularly in certain areas of public health need*

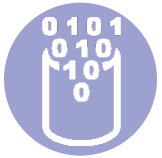
1 PRIority MEdicines (PRIME)

PRIME: Goal & Scope

To foster the development of ***medicines with high public health potential.***

Reinforce scientific and regulatory advice

- *Foster and facilitate early interaction*
- *Raise awareness of requirements earlier in development*



Optimise development for robust data generation

- *Focus efficient development*
- *Promote robust data generation*

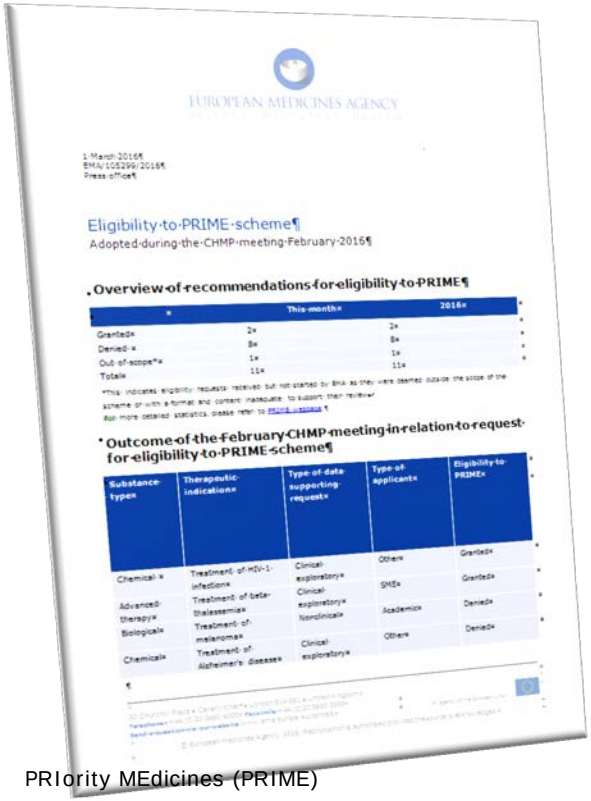
Enable accelerated assessment

- *Promote generation of high quality data*
- *Facilitated by knowledge gained throughout development*

Building on existing framework;

Eligibility according to existing ***Accelerated Assessment criteria****.*

Transparency



EUROPEAN MEDICINES AGENCY

1 March 2016
EMA/105299/2016
Press office

Eligibility to PRIME scheme
Adopted during the CHMP meeting February 2016

Overview of recommendations for eligibility to PRIME

	This month	2016
Granted	2	2
Denied	8	8
Out-of-scope*	1	1
Total	11	11

*This indicates eligibility requests received but not started by EMA as they were deemed outside the scope of the scheme or with a format and content inadequate to support their review.

For more detailed statistics, please refer to PRIME publication

Outcome of the February CHMP meeting in relation to request for eligibility to PRIME scheme

Substance type	Therapeutic indication	Type of data supporting request	Type of applicant	Eligibility to PRIME
Chemical	Treatment of HIV-1 infection	Clinical exploratory	Other	Granted
Advanced therapy Biologicals	Treatment of beta-thalassemia	Clinical exploratory	SME	Granted
	Treatment of melanoma	Nonclinical	Academic	Denied
Chemicals	Treatment of Alzheimer's disease	Clinical exploratory	Other	Denied

- Monthly report in CHMP highlights
- Active substance/INN for eligible products
- High-level statistics regularly updated on EMA public website
- Sharing information with relevant partners and stakeholders (EU Innovation Network, HTAs, PCWP, HCPWP)
- Industry workshop 12 months experience

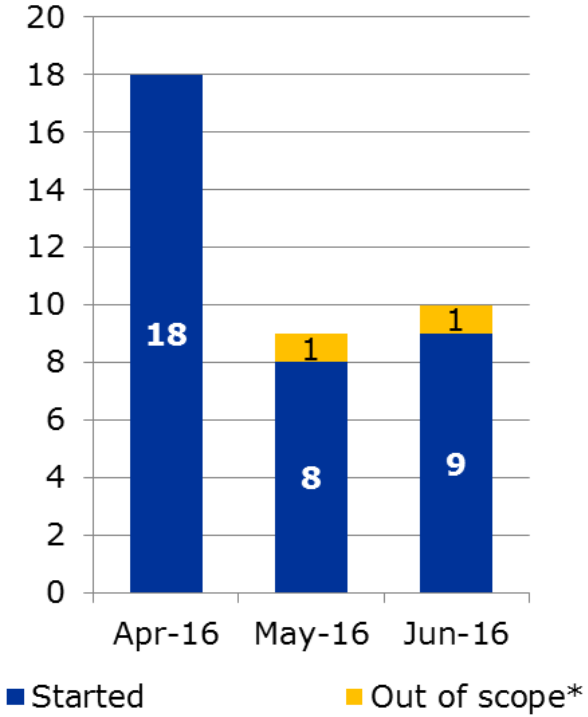
Impact on patients and public health

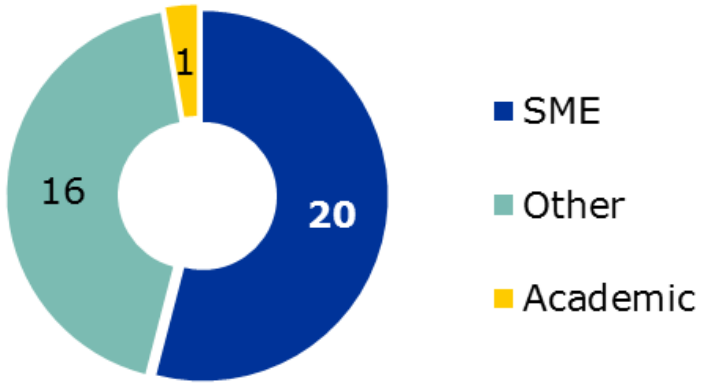
What positive impact do we hope to achieve?

- Support products that have early evidence on potential to address to a significant extent **an unmet medical need**
- Support less experienced drug developers with promising products
- Support efficient development and assessment
- Support speedy decision-making post-licensing

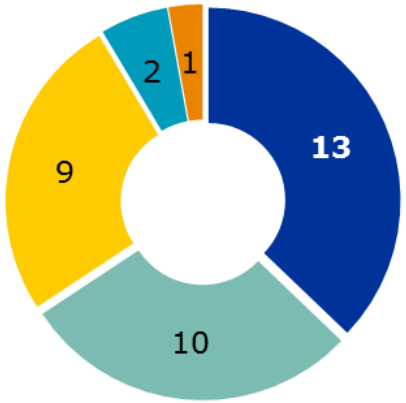
Ensure timely access for patients

37 applications received since launch on 7 March 2016

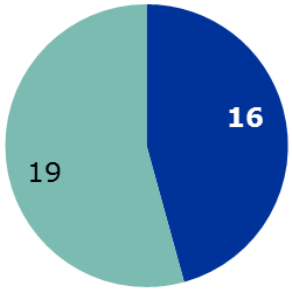




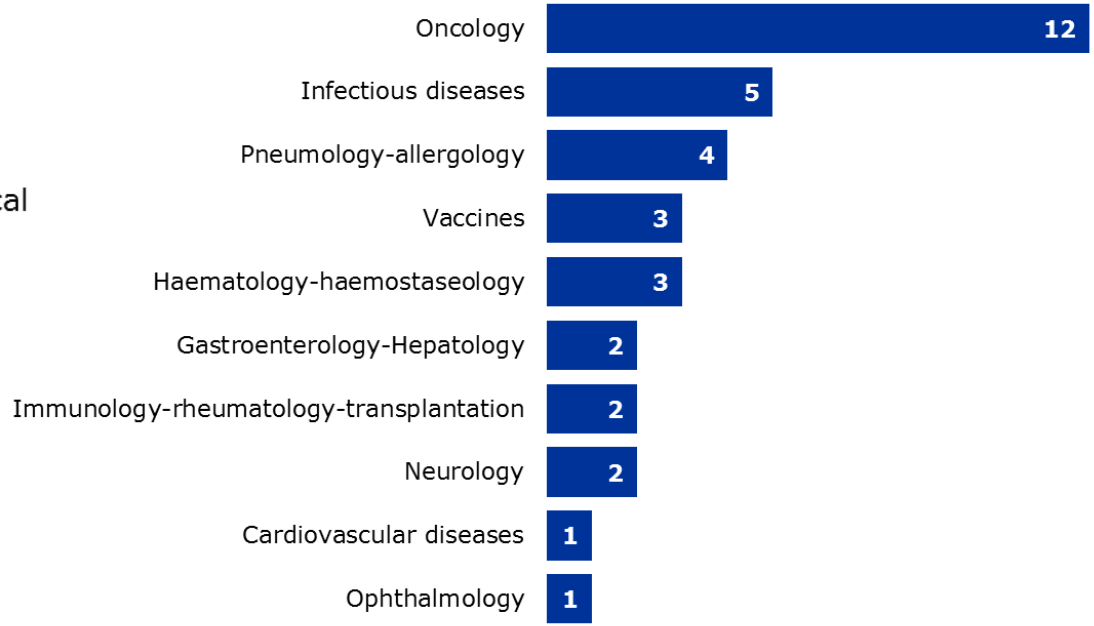
* Out of scope: 1 academic (no FIM data) and 1 large pharmaceutical with proof of principle data only



- Biological
- Chemical
- ATMP
- Immunological
- Herbal



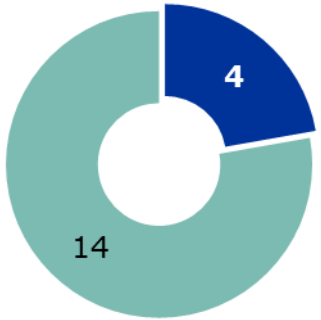
- Orphan
- Non-Orphan

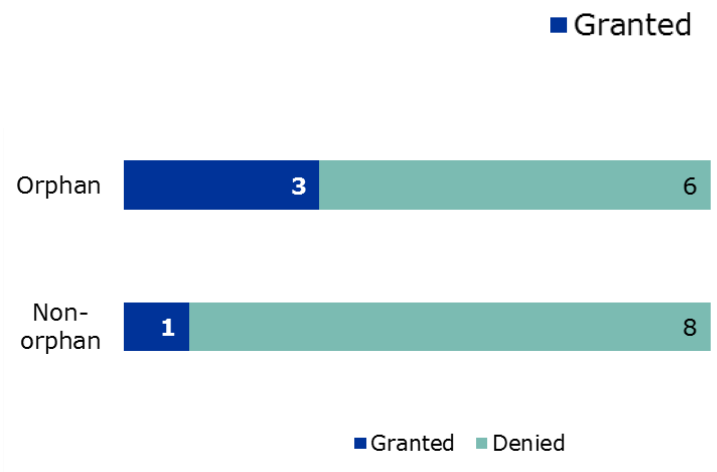


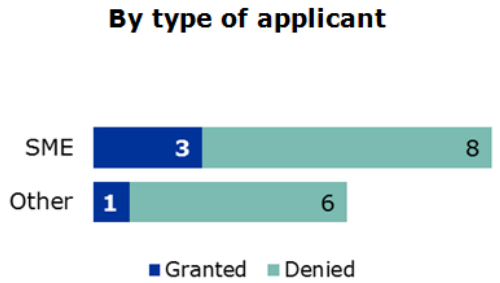
Data excluding out of scope applications

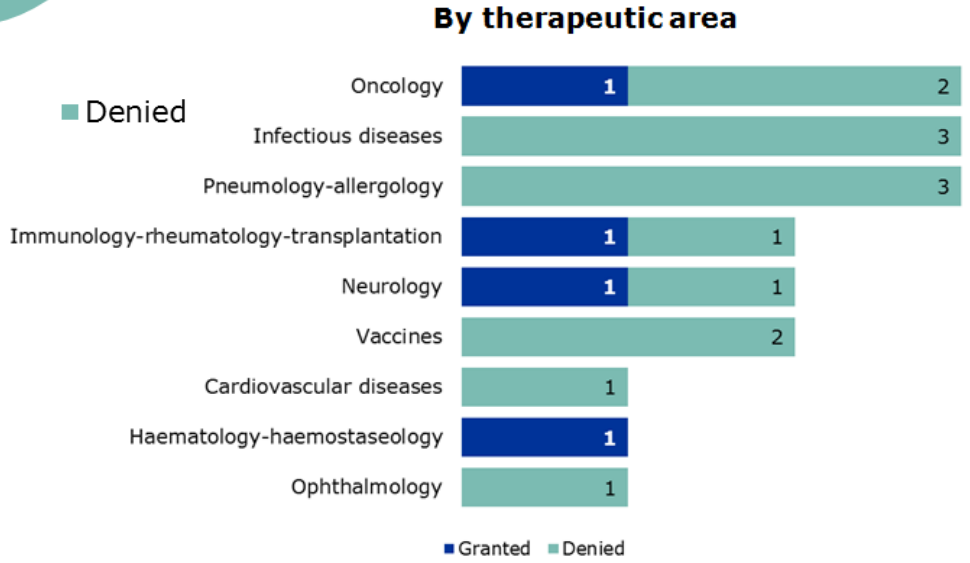
Outcome of first submission deadline

Adopted in May 2016









First 4 products granted eligibility

CCX-168
Treatment of patients with active ANCA-associated vasculitis (GPA and MPA)
Orphan

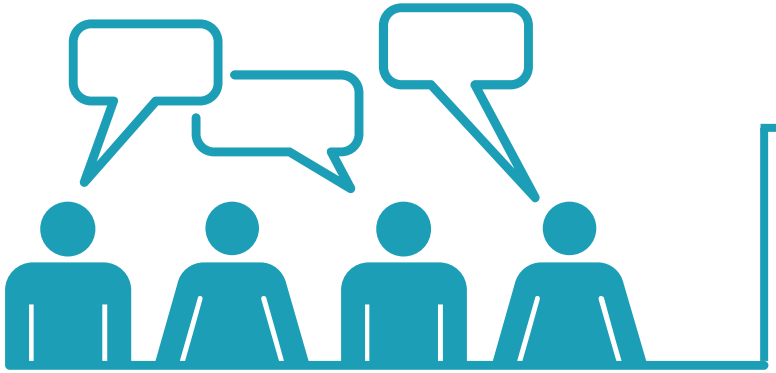
KTE-C19
Treatment of DLBCL, PMBCL, TFL
Orphan

Emapalumab
Treatment of primary haemophagocytic lymphohistiocytosis (HLH)
Orphan

Aducanumab
Alzheimer's disease

Cross-committee collaboration

- SAWP-CAT-CHMP in eligibility process
- Participation of all chairs in Oversight group
- Reports to all committees on outcome of eligibility
- Upcoming first kick-off meetings



Kick-off meeting

- **Multi disciplinary meeting with Rapporteur and experts from relevant committees**;

Patient experts , engagement with HCP

- Introduction of product and development status by applicant;
- Facilitate initial interaction between applicant and EU regulatory network;
- Discuss the overall development plan and regulatory strategy;
- Discuss involvement of other stakeholders (HTA, patients);
- Provide recommendation on milestones and topics for SA.

Thank you for your attention

Further information

Jordi.Llinares@ema.europa.eu
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
Send a question via our website www.ema.europa.eu/contact

Follow us on **@EMA_News**