EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

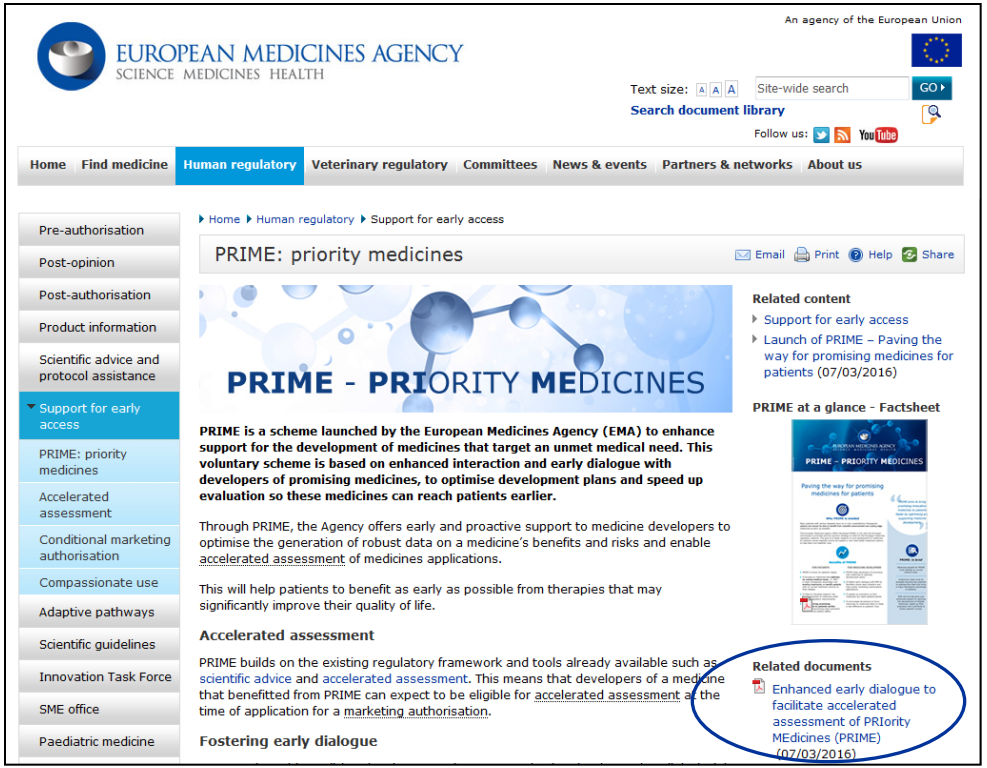
PRIME: Observations post-launch

3rd Industry stakeholder platform - Operation of the centralised procedure for human medicinal products, 21 April 2016

Presented by Jordi Llinares and Zahra Hanaizi
Product Development Scientific Support Department

An agency of the European Union

PRIME webpage and supporting documents



Factsheet in lay language

Q&A, templates, application form for applicants

prime@ema.europa.eu

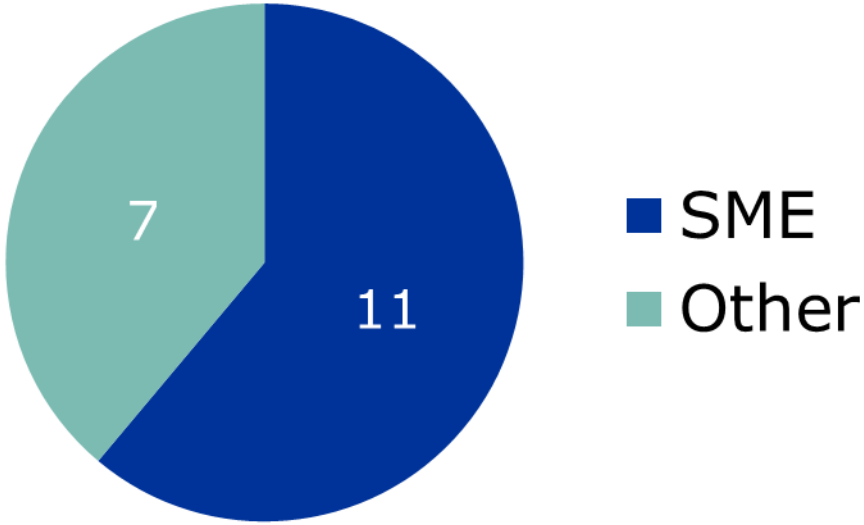
Queries received (1)

Request for multiple indication?	• One request to be submitted per indication
Literature references, IB, protocol	• Literature references: yes • Other documents: ok but should not be required
Submission of request and stage of development	• Reference to Q&A • Case-by case basis for other aspects
Form, UPI number? EMA number?	• Technical issues resolved • UPI assigned at start if first submission to EMA

Queries received (2)

Publication of the outcome: intellectual property rights, indication wording	• Email at start to prompt applicants to raise concern • Outcome letter will include proposed wording
Development of new indication for existing product of other MAH	• Acceptable
Applicant established outside of EEA	• EEA establishment not a requirement for PRIME eligibility • But requirement for other incentives (e.g. SME/academics early entry…)

1st submission deadline: 18 eligibility requests received



- Wide range of therapeutic indications including Alzheimer's disease and antimicrobial resistance
- Mostly proof of concept

A few observations…

- ✓ All applications in scope
- ✓ All of Adequate quality to allow assessment
- ⚠ Most requests received on the day of the deadline or the day before
- ⚠ No need to submit separate form for eligibility to centralised procedure
- ⚠ PIP or waiver not submitted in 12/18

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

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