EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

How have eligible products benefited from PRIME so far?

First anniversary of PRIME: experience so far, 19 May 2017

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Features of the PRIME scheme

Early access tool, supporting patient access to innovative medicines.

- **Written confirmation of PRIME eligibility** and potential for accelerated assessment;
- **Early CHMP Rapporteur appointment** during development;
- **Kick off meeting** with multidisciplinary expertise from EU network;
- **Enhanced scientific advice** at key development milestones/decision points;
- **EMA dedicated contact point**;
- **Fee incentives** for SMEs and academics on Scientific Advice requests.

Kick-off meetings: experience on 15 products

Who

Applicant

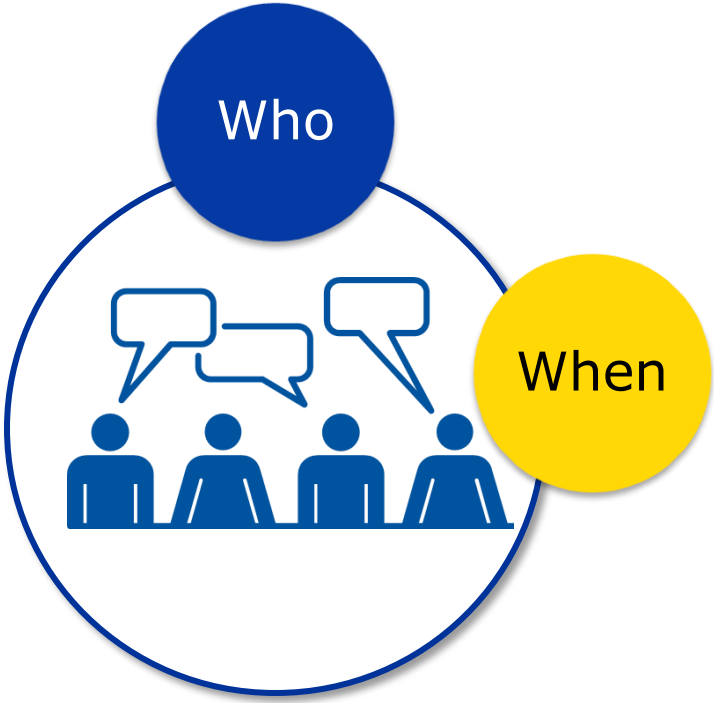
Rapporteur and assessors (all disciplines)

CAT/CHMP/SAWP chairs

Representatives from PDCO, COMP and PRAC

EMA

Kick-off meetings: experience on 15 products

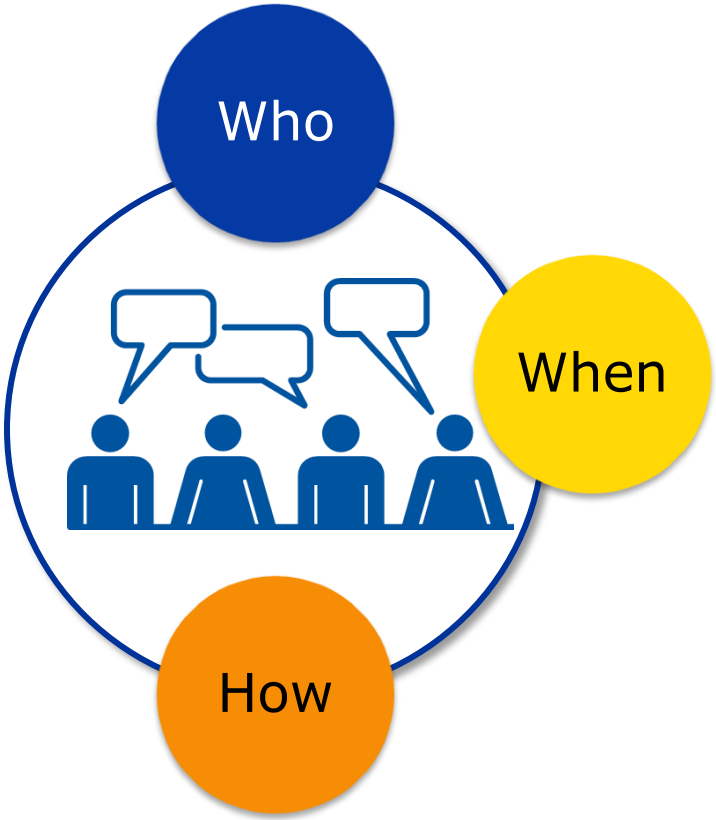


~ 4 months after eligibility
(range: 52-177 days)

In margins of CAT/CHMP meetings

Find optimal timing (particularly if ongoing scientific advice)

Kick-off meetings: experience on 15 products

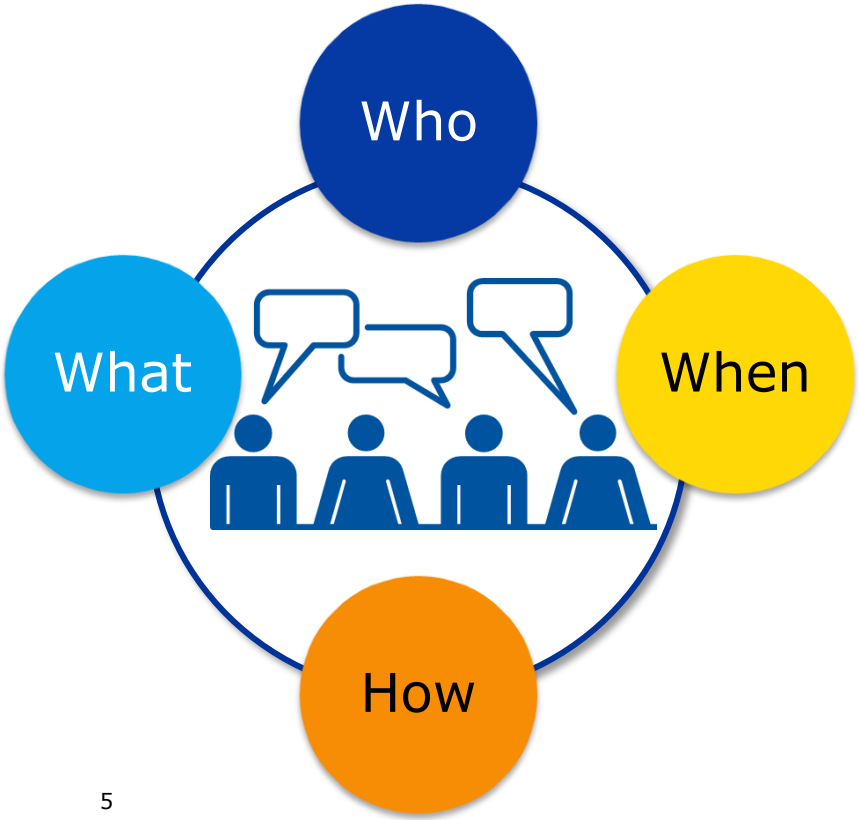


Briefing document
(~3-4 weeks in advance)
essential for fruitful
discussion

Internal preparatory
teleconference
(~2 weeks)

Tailored agenda

Kick-off meetings: experience on 15 products



Broad discussion on development and regulatory strategy

Many issues identified for future scientific advices

★ Raise awareness on planning of post-authorisation aspects and HTA interactions

★ Agree on future interactions

Early Rapporteur appointment

Opportunity for **knowledge gain** on the product

Identification of **relevant expertise** and build adequate team

Opportunity to **influence** development

Very positive views on the **kick-off meeting**

- ✓ Importance of preparation and tailored agenda
- ✓ Facilitate interactions across committees and with EMA

Timing of PRIME eligibility is critical for fruitful engagement

Involvement in follow-up **scientific advice** and workload

Need to **improve follow-up communications/updates**

Enhanced scientific advice

7 products
11 SA requests
following kick-off meetings

Multi-stakeholder
1 EMA/HTA parallel advice
2 with patients involved

Rapporteur involvement
through one of SAWP coordinator

All aspects covered
Quality,
nonclinical, clinical

Flexibility
Shorter pre-submission
3 adopted in 40 days

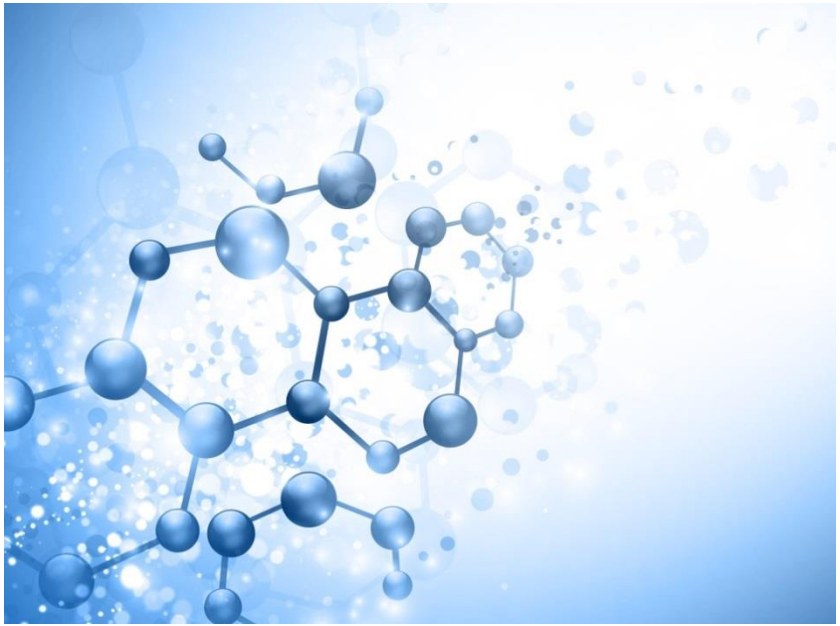
Other interactions with the applicant: EMA contact point

Address or direct queries

Ad hoc teleconference/meeting with Rapporteur and EMA

Area for improvement:
Applicant to provide regular updates on development progress and milestones

In summary,



Kick-off meeting: excellent opportunity to initiate interaction and flag issues
→ Guidance in drafting

Rapporteur appointment enables early identification of potential issues

Excellent **collaboration across committees**

Iterative **scientific advices** with opportunity for multi-stakeholders involvement

Scheme triggers **discussions across** product type / class

Thank you for your attention

Further information

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