

Reflections on iterative advice – concrete examples where and how this could work – Quality (CMC)

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PRIority **ME**dicines scheme – Quality perspective support the development of medicines with **major public health interest**

Scientific & regulatory advice	Robust data generation	Accelerated access
early interaction	focus the development	discuss filing strategies early on
raise awareness on regulatory & scientific requirements as early as possible	promote robust & high quality data	generate and leverage high quality + prior knowledge data for MAA dossier

https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines



Interaction between Regulators & Applicant **Quality support** to a PRIME product

MAA submission MAA approval

PRIME eligibility orientation

Advice on Applicant's Quality package examination

Incorporation of outcomes into CTD preparation

MAA review & responses CHMP/CAT assessment Post-authorisation phase commitments follow-up

- Rapporteur & EMA team appointment
- Kick-off meeting
- Ad hoc interactions

Applicant & Regulators

Scientific advice & responses

Regulatory strategy

Applicant & Regulators

Module 3 preparation SA letters

> Pre-submission Meetings CoRapporteur

Regulators

assessment of

- Quality package Benefit-risk
- Product information
- Inspections

Recommendations/Annex II

Applicant

Fulfilment of commitments

- PACMP(s)
- Variations
- Line extensions

Extended development

5th Industry Stakeholder Platform on R&D support - Jekerle



Example (ATMP)

support to PRIME product during pre-authorisation & MAA (on Quality)

