EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

Presented by Veronika Jekerle
Head of Office Quality of Medicines, EMA

5th industry stakeholder platform for R&D support virtual meeting
16 November 2020

PRIority **ME**dicines scheme – Quality perspective

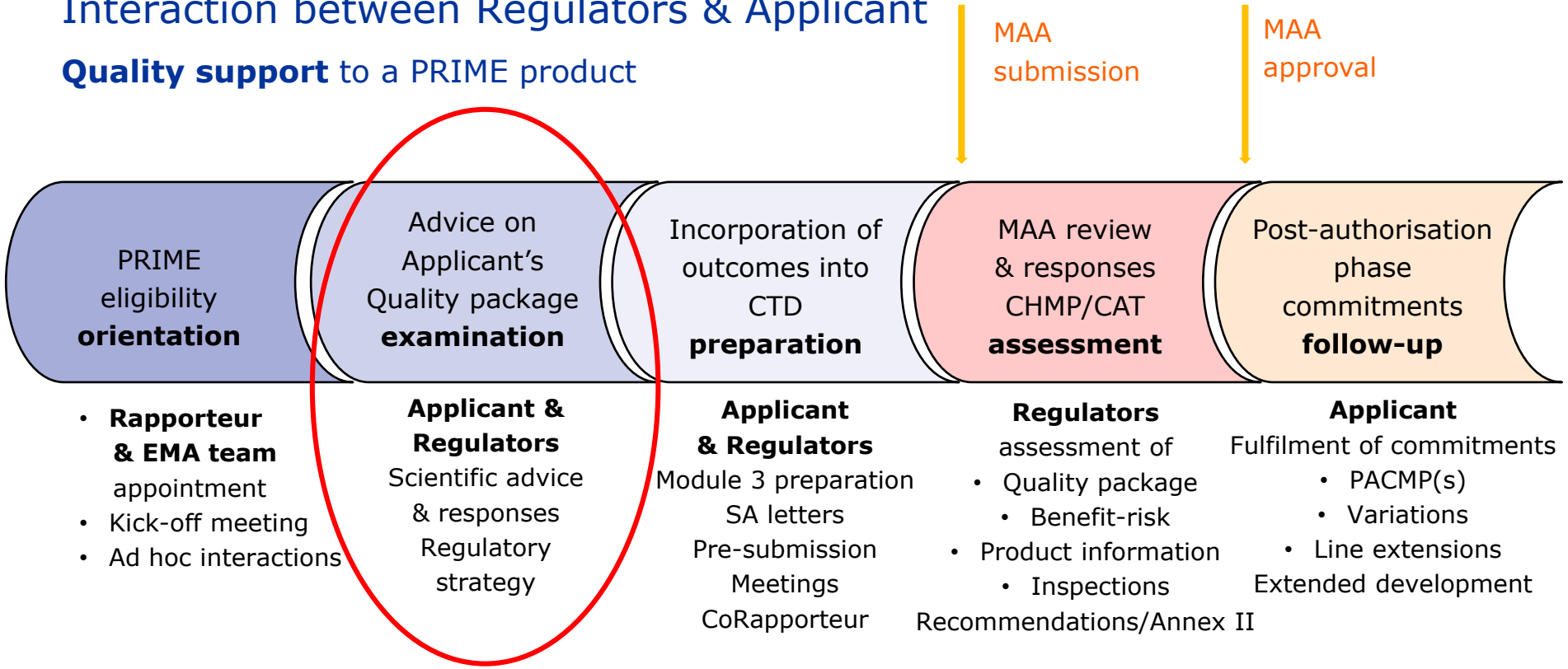
support the development of medicines with **major public health interest**

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



Example (ATMP)

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