EMA
EUROPEAN MEDICINES AGENCY

Continuous evolution of the PRIME scheme – EMA update

16th Industry stakeholder platform on research and development support

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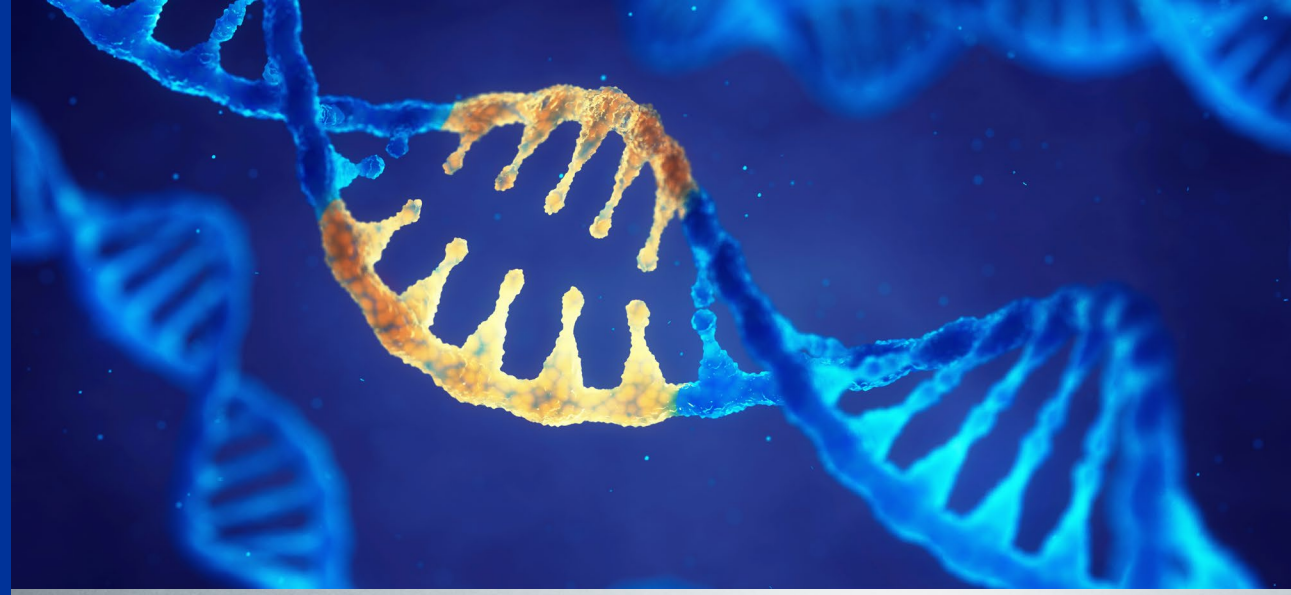
02 July 2026



Presentation Outline

- Update on the PRIME Product Development Coordinator (PDC) Pilot
- Update for implementation of the PRIME pilot report recommendations
- Update on analysis of the scheme at 10 years

PRIME: Experience, analysis, evolution

2022

EMA publishes analysis of first 5 years' experience

2023

Launch of new pilot features addressing 5YA findings

2025

March: Pilots conclude

Analysis and survey of pilot experience

July Product Development Coordinator **launch**

2026

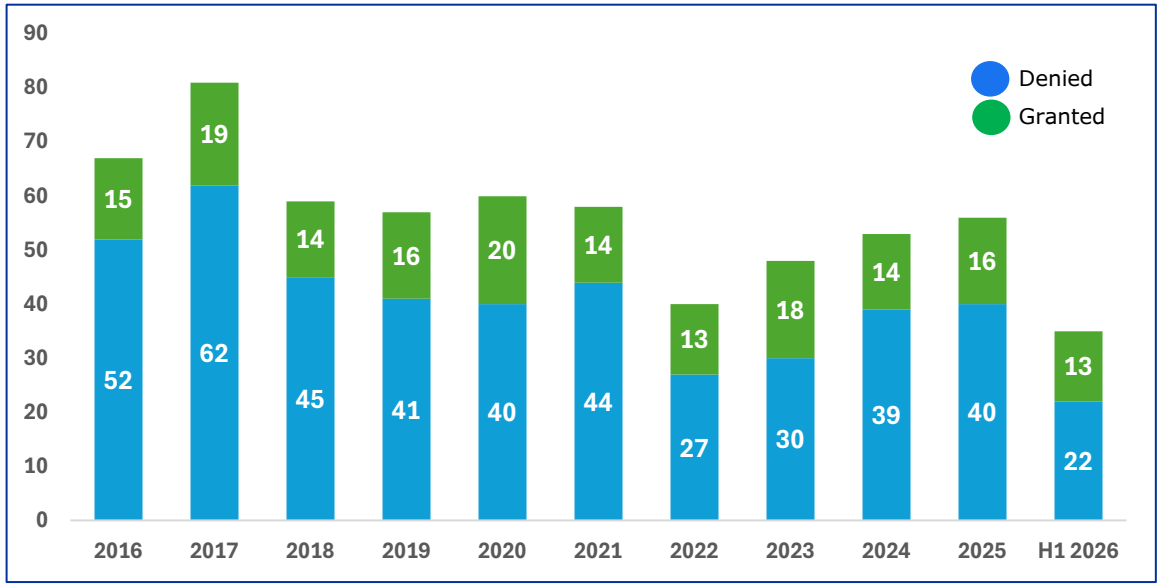
March: **Pilot Feature Report Published**

July: PDC Pilot **expansion**

Analysis of 10 years experience

Preparation for future operation under NPL

Continued increase in **applications** since 2022



Update on PRIME Product Coordinator Pilot

July 2025:

- SA scientific officers nominated as PDC
- **21 PRIME development products** included; scope for inclusion of new PRIME products
- Role and pilot launched; contact points notified July 2025
- Products cover Oncology, Haematology, Endocrinology/metabolism, Ophthalmology, Congenital/genetic disorders, Dermatology, Cardiovascular

July 2026:

- **Pilot expansion:** up to 20 additional PRIME designated products to be included
- Focus on products designated since July 2025 to build experience in early PRIME activities
- Onboarding additional PDCs covering additional therapeutic areas to broaden products in the pilot
- 12-month view of Pilot experience

Update on PRIME Product Coordinator Pilot: KPIs

Operational: Timely, efficient product development support

- Number of formal interactions and ad hoc queries of PRIME designation holders per PDC/product (PRIME assistant log)
- Time spent by PDCs on PRIME product-specific support activities captured through EMA's working time management system
- Time spent by PRIME scientific coordinator PRIME Coordination activities vs PRIME Product-specific support activities captured through EMA's working time management system

Value: Experience and perceived value of the role

- Satisfaction of PRIME designation holders with the PDC in terms of:
  - timeliness/proactivity in dealing with PRIME-related matters (formal interactions or ad hoc queries)
  - perceived added value in providing input on regulatory and scientific evidence matters (industry and network)

Impact:

- Number of issues/topics raised to PRIME Rapporteur by PDC stemming from development tracker or other formal and informal interactions; outcome and time to resolution

Planning for Implementation of PRIME pilot recommendations

Considerations for implementation of recommendations:

Actions broadly fall into 4 categories:

- updates to guidance
- process improvement/SOP revision
- document revision (tracker)
- IT tool/solution

Dependencies between recommendations and external dependencies (technical solution, agile scientific advice pilot, preSIG initiatives)

Based on complexity and dependencies, recommendations are categorised as short term (2H 2026), medium term (2027) or long term

Continued consultation required with Industry group in H2 2026 for relevant topics

Update on Implementation of PRIME recommendations

Product Development Tracker

Recommendation	Category	TImeline	Stakeholders/experts required
Refine the structure and formatting of the product development tracker (**improve user-friendliness, ease of review)**	Document revision	Medium term	Industry (sounding board in consultation with trade associations)
Update the published guidance and development tracker template	Guidance	Medium term	Industry (sounding board in consultation with trade associations), network assessors Dependency on previous action
Enhance the process for regular EMA/rapporteur feedback on periodic product development tracker following submission	Guidance/sop	Under implementation	EMA product team Rapporteur teams
Further promote the development tracker as a core support tool for iterative scientific advice, facilitate submission readiness, and obtaining accelerated assessment	Process review Guidance	Short term	EMA PRIME coordination
Consider future opportunities for enhanced use (also considering IT and knowledge management tools)	Technical solution implementation	Medium term Long term	Agreement on a document structure to be implemented Dependency on agency IT tools and broader knowledge management approach

Update on Implementation of PRIME recommendations

Expedited Scientific Advice

Recommendation	Category	TImeline	Stakeholders required
Provide additional guidance on the specific questions/topics where expedited scientific advice can be sought	Guidance	Short term	EMA
Broaden the specific scenarios in which expedited advice can be sought, including KOM/SRM topics	Guidance	Short term	Industry (sounding board, in consultation with trade associations), network assessors
Clarify **timelines for submission of documentation and receipt of written advice**	Guidance	Short term	EMA
Further decrease procedure duration, increase the agility of advice outside of the established timelines	Process	Medium term	Dependency: EMA agile SA pilot to ensure aligned processes

Submission Readiness Meeting

Recommendation	Category	TImeline	Stakeholders required
Further focus meeting core objectives (implementation of SA, MAA data maturity, AA)	Guidance	Short term	EMA, industry (sounding board), network assessors
Strengthened EMA product team involvement in submission readiness	Process	Under implementation	EMA product team
Establish clear routes for timely **follow-up of outstanding risks**	Process Guidance	Short Medium term	EMA, industry (sounding board), network assessors
Consider possibility for **more flexible timing of the SRM**	Process Guidance	Medium term	EMA, industry (sounding board), network assessors

PRIME 10-year planned analyses

5-year analyses mapped and assessed (priority and impact)
Analyses directly related to pilot features not within scope for the 10YA

Topic	Metric
II. PRIME Eligibility	
Overview of requests and outcomes	Submissions, therapeutic area, type of product, orphan, SME
Stage of development (early entry)	Early entry applications, outcome, level of clinical evidence submitted (safety only, preliminary efficacy)
II. Impact of PRIME on MAA:	
Overview of all PRIME MAA status	Development ongoing/withdrawn from scheme/under MAA evaluation/MAA opinion
Accelerated assessment	AA Requested/Obtained/Maintained vs non-PRIME products in the same period, per product type
Assessment duration analysis	Active time/clock-stop vs non-PRIME products in the same period
MA basis – CMA/EC/Full	CHMP opinion
III. PRIME activities:	
KOMs/SRMs/pre-submission	Number/scope of meetings

August 2026: Analysis Continues

September 2026: PRIME oversight group, EMA working party/committee presentation

Sounding board input through touchpoints in August/September

EMA internal/network consultation October ahead of finalisation

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Thank you

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