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Information on clock-stops/restarts for processes implemented in IRIS

Industry Stakeholder Platform meeting
on the centralised procedure- 23/06/2025

Presented by Francisco Penaranda

Clock-stops/restarts background

- Legal text: Receipt of opinion/document triggers the start of a legal deadline

(e.g. "*Within 15 days after receipt of the opinion, the applicant or the marketing authorisation holder may notify the Agency in writing of his intention to request a re-examination of the opinion*")

- How is the "Receipt" defined?

Legal Context: Not a clear definition in pharmaceutical legal framework

Before IRIS: Inconsistent clock start times across EMA procedures

- Some cases: Clock starts when Eudralink packages are **sent**
- Others: Clock starts when Eudralink packages are **opened**

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IRIS implementation

➢ Opportunity for **harmonisation**:

- IRIS cannot track when a document is opened

➢ For the procedures that have been transitioned to IRIS:

- Clock starts when **notification emails are sent** (stating that a new document is available in IRIS)
- Practice since 2018 (e.g., Orphans) - No legal disputes

➢ Future implementation rule for processes in IRIS

Wherever 'receipt' starts a clock, the receipt date is the date on which the applicant/MAH receives a notification email from EMA stating that a new document is available in IRIS

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Transition

- Ongoing cases in OLD systems: Retain current practice (e.g., clock starts at opening where applicable) until completed

- All new IRIS processes: Clock starts when **notification emails are sent** (stating that a new document is available in IRIS)

- Documentation being updated to reflect this practice

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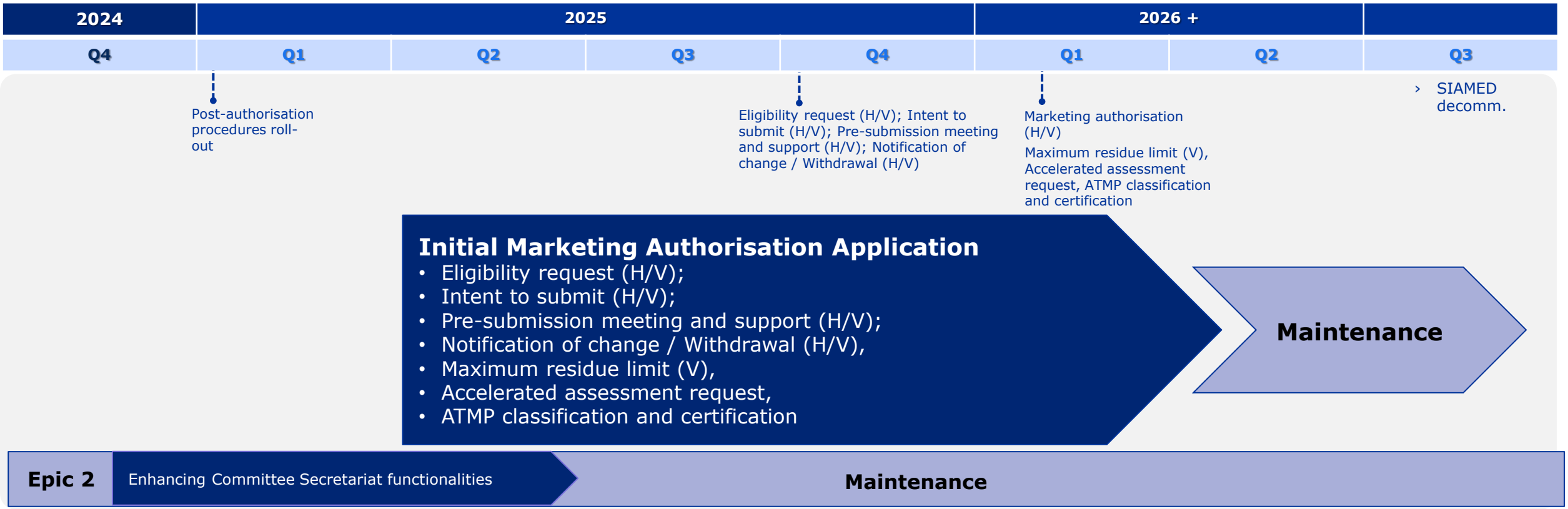
Regulatory Procedure Management in IRIS roadmap (epic 3)



Please note the ongoing development of Regulatory Procedure Management in IRIS will happen in stages, with incremental improvements across the entire regulatory procedure management landscape.

Legend

Development | **Maintenance**

Milestone

Acronyms

- **ATMP:** Advanced Therapy Medicinal Products

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