EMA
EUROPEAN MEDICINES AGENCY

Update on eAF and eCTD v4.0 in the CP

Fifteenth meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines

28 October 2025

PLM Portal web-based variation eAF

- Working together with the PMS team to solve remaining product data issues, while also implementing solutions on the eAF side that allow use of products in the eAF while there are some back-end data issues
  - Not so easy to 'list' products that cannot be used in PLM eAF
- Currently the use of eAF is 'flexible' i.e. products without package data can be selected on the medicinal product level
- Various different requests relating to user access have been received and are being reviewed
  - Different MAHs have very different operating models making it hard to adapt the access system to ensure confidentiality vs allow enough access
  - We are looking how to facilitate those users who need only partial access to certain portfolio – currently only possible on full portfolio vs individual form
  - Concurrent co-authoring is not currently supported – priority to be defined
- Performance improvements
  - Performance improvements, especially to support large applications, are being explored

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PLM Portal web-based forms roadmap

- The PLM VS Roadmap was presented at the QSPR earlier this week with updated timelines for the MAA eAF – currently foreseen for 2028
- Variations form will continue to be supported
  - Looking at opportunities to mandate use for CAPs where possible

- The eAF team is continuing the work on the ‘structured changes’ implementation for variations
  - First areas to be implemented related to manufacturing business operations
  - Further extended based on areas where ‘PUI write capabilities’ are available to benefit from the synergies, for example ‘add package’ scenario
  - Next steps to define the business process and how this data can be ingested in PMS

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eCTD v4.0 EU regional implementation

- Pilot has been conducted using ‘agile’ approach, starting first from very simple technical interoperability test and proceeding to further complexity as quickly as possible and this led to the fact that the validation criteria was not ready in the tool when we started Phase 2 of the pilot
- Phase 2 pilot analysis and validation aspects are still ongoing, and further stages of testing will also have the validation tool as a part of the test flow
- EMA has implemented the latest version from tool vendor in production and testing is currently ongoing for the ‘**end to end**’ process first with EMA, and expanding to NCAs and eventually to include MAHs so that the further test submissions can be sent directly to the test environment speeding up the pilot analysis
    - The difficulties in sending the submissions will be mitigated when end to end submission flow is in place for the next pilot stages
    - More focus on Change management, including regular feedback to pilot participants in the next phases, including a pilot follow-up meetings

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eCTD v4.0 EU regional implementation

- **EMA staff** and **NCAs (assessment teams)** are being trained.
- Latest training for the network took place on Thursday 27th November and further sessions based on various, different types of needs from the different stakeholders are being planned and organised
- **Optional use** initially for **CAPs new MAA applications** – announcement will be made in December, expecting first submissions in Q1 2026 (subject to MAH readiness)
- Pilot for forward compatibility (products with existing v3.2.2 lifecycle) will be launched in early 2026 (testing already ongoing with current pilot participants)
    - Starting with very simple forward compatibility cases for 'ongoing MAAs' and the proceeding to more complex scenarios with grouped submissions
- Subject to successful outcome of the pilot on products with existing eCTD v3.2.2 lifecycle, EMA planning to go-live with **optional use** for **forward compatibility submissions** in mid 2026

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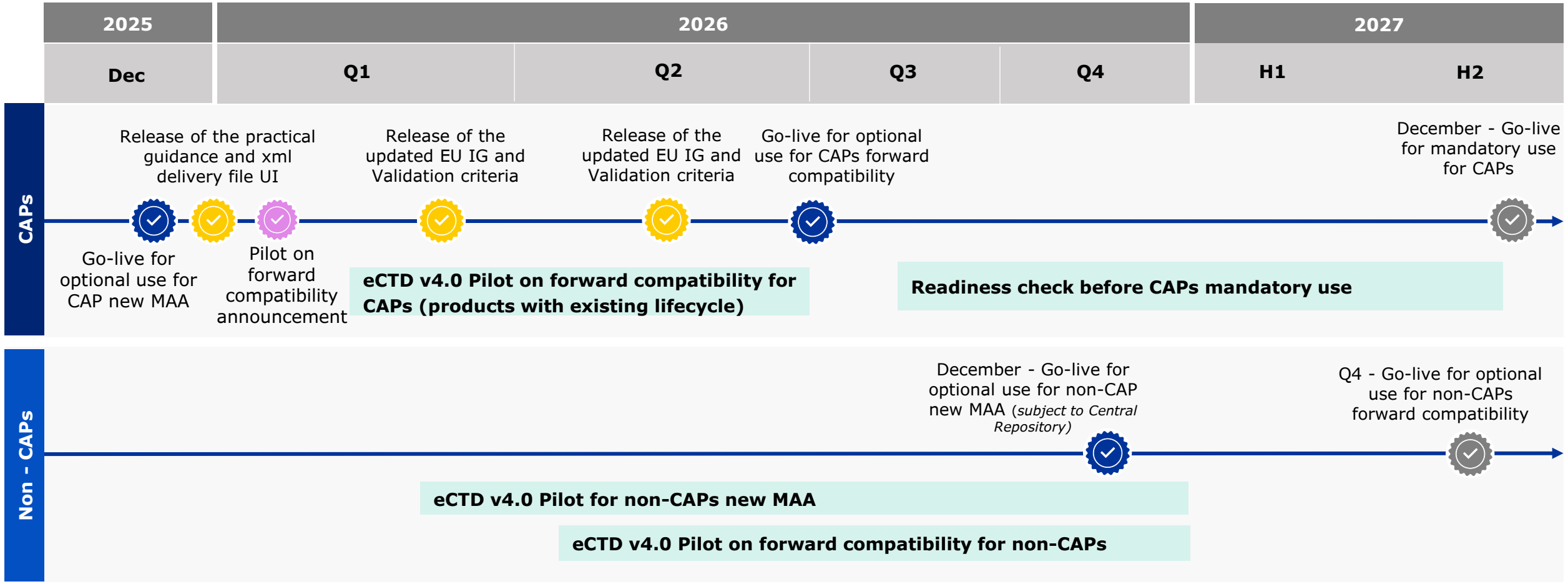
eCTD v4.0 implementation roadmap - Industry



Acronyms

CAP: Centrally Authorised Product

Non-CAP: Non- Centrally Authorised Product

IG: Implementation Guide

TBC: To be confirmed (more precise information will be communicated in due time)

Legend

Go-live | Milestone | Announcements | Dev. activities | TBC Go-live

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Thank you

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