EMA
EUROPEAN MEDICINES AGENCY

Update on digitalisation initiatives affecting CP submissions

16th meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines

15 June 2026

Madalina-Cristina Duta-Mare, Kristiina Puusaari, Simona Griniene, EMA

Key upcoming changes affecting CP submissions

Several **digitalisation initiatives** affecting **Centralised Procedure submissions** will be introduced **between June and September 2026**. Key milestones are outlined below:

Go-live dates:

15 June

Industry Contact Management

Contact management for centralised products will move to the **IRIS Industry Portal**, allowing **IRIS Industry Coordinators** to manage MAH contacts directly and without EMA intervention.

*Register **here** to join our webinar on **11 June** (11:00-12:15) and learn more about this change.*

18 August

Pre-submission activities

Selected pre-submission activities will transition to IRIS:

- **Human domain & Veterinary domain:** Eligibility, Letter of Intent, Accelerated assessment
- **Human domain** (only)**:** Pre-submission interactions

21 August

Pre-submission activities

Selected pre-submission activities will transition to IRIS:

- **Veterinary domain** (only)**:** Pre-submission interactions

1 September

iMAAs & eAF form

- **Initial marketing authorisation** applications will be managed through IRIS (H/V)
- Subject to a successful testing phase and NCA readiness, the **updated MAA eAF** will also become mandatory (H)

More details on the eAF in the following slides

Industry Contact Management – Key changes

From 15 June MAH contact management for centralised products will move to the **IRIS Industry Portal**, allowing **IRIS Industry Coordinators** to manage MAH contacts directly and without EMA intervention.

Purpose

To provide MAHs with **better visibility** on their **centralised product contacts** and with a **self-service tool** to maintain them in a timely manner

Changes

- **No more Service Now tickets** to be raised **to change** the centralised product contact
- For ongoing MAAs or other procedures in SIAMED, the **request to change MAH contact needs to be sent to procedure lead (H) or procedure coordinator (V) via email**. In addition, the MAH will be asked to update MAH contacts for its pending products via IRIS portal.
- **Change of MAH product contact does not automatically update contacts for ongoing cases in IRIS**. The MAHs need to change them separately.

Key message

Please ensure your MAH has IRIS Industry Coordinator role assigned to be able to manage centralised product contacts via IRIS!

Human MAA eAF v1.28.0.0 – Key changes

Version 1.28.0.0 of the interactive PDF electronic application form (eAF) for human Marketing Authorisation Application (MAA) is now available on the eAF website, together with the associated release notes.

Purpose

Address structural limitations in the current form and support **alignment with the ISO Identification of Medicinal Products (IDMP)** data model.

Outcome

More structured and interoperable representation of medicinal product information **across the EU regulatory network.**

No regulatory changes

The proposed **changes do not modify the regulatory intent** or the type of information collected in the form.

Benefits

More accurate representation of complex medicinal products and ensuring that **key product attributes** (such as product composition, packaging, manufacturing responsibilities and administration characteristics) can be described in a **consistent and machine-readable way**.

Human MAA eAF v1.28.0.0 – Testing and Rollout

Version 1.28.0.0 of the interactive PDF electronic application form (eAF) for human marketing authorisation application (MAA) is now available on the eAF website, together with the associated release notes.

Initial testing

Completion of **user acceptance testing (UAT)** led by **EMA** involving **selected NCA and MAH representatives**.

May 2026

Extended MAH testing

MAHs completed the PDF form testing, reporting their feedback during the first week of June 2026.

June 2026

Rollout

All MAAs starting after 1 September 2026 should use the updated eAF version 1.28.0.0.
Further details regarding the mandatory transition will be communicated in due course.

1 September 2026

Human variations – PLM web-based eAF
Mandatory use for CAPs
1st Sept 2026

The PLM Portal web-based variation application form (eAF) will be in **Mandatory use for all CAP variations from September 2026**.

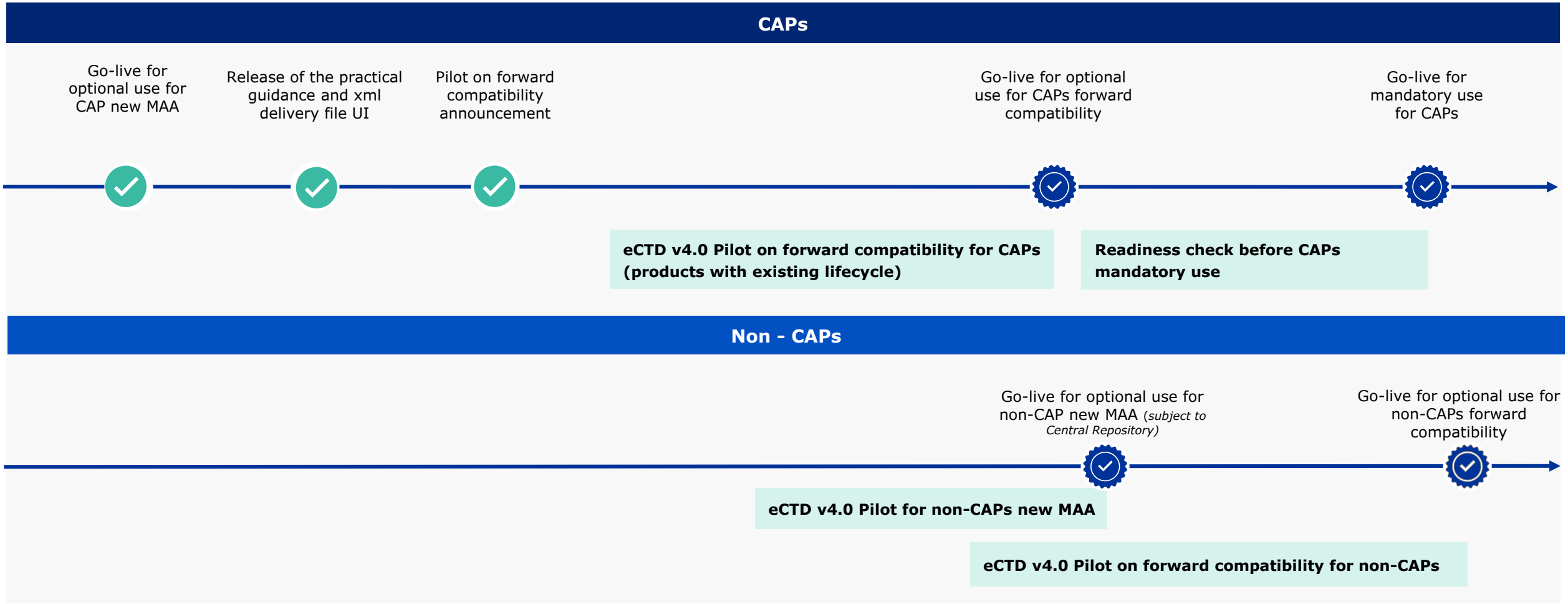
From 1 September 2026 onwards, any **new*** human CAP variation application sent to EMA using the **interactive PDF eAF will be rejected** unless it is accompanied by a valid and **justified technical reason preventing the use** of the PLM web-based eAF.

The possible technical issues preventing the use of PLM eAF are detailed here: Upcoming mandatory use of PLM web-based eAF for CAPs · PLM

Further details on how to **justify the exceptional use of the PDF eAF** will be communicated prior to the beginning of the Mandatory use for CAPs.

*This applies to new variation applications submitted to EMA on or after 1st September. The form version should not be changed for ongoing variations that have been submitted/started prior to 1st September 2026.

eCTD v4.0 implementation milestones - Industry



Acronyms

CAP: Centrally Authorised Product
Non-CAP: Non- Centrally Authorised Product
MAA: Marketing Authorisation Application
UI: User Interface

Legend

Go-live
Completed activity
Dev. activities

EMA

eCTD v4.0 implementation – Key points

Optional use of eCTD v4.0 for new CAP MAAs

- **Optional use** launched on 22 December 2025, while **eCTD v3.2.2 continues to be accepted** during transition period.
    - A new **end-to-end testing phase** is ongoing. MAHs are invited to **submit eCTD v4.0 test submissions** (if not yet ready to use the standard in production).
    - **Mandatory use** is **not expected before late 2027** (subject to testing outcomes and readiness checks).

Ongoing/ planned pilots

- A pilot on **forward compatibility for CAPs** has been ongoing since **March 2026**. The pilot has encountered technical challenges, which are being addressed.
- The technical pilot for **new MAA for non-CAPs** has been delayed to **Q3/Q4 2026** due to technical issues.

Central Repository feasibility study

- A **feasibility study** on the Central Repository is planned, with an **outcome** expected in **late 2026/early 2027**.
- The study results will inform the **go/no-go decision** for the next implementation steps.

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