EMA
EUROPEAN MEDICINES AGENCY

Update on ongoing initiatives in the centralised procedure

Stakeholders Platform Meeting
Topic #3

Fran Day

28-11-2025

Reminder – projects

Assuring the Network's Sustainability

H2 2022	H1 2023	H2 2023	H1 2024	H2 2024	H1 2025	H2 2025
Network Capacity Monitoring						
Network capacity project						
EMA/HMA Strategic Resource oversight group						
EMA/NCA Operational resource planning group						
Templates and processes						
CHMP AR Revamp Project						
Focus group on submission predictability						
GIREX						
Pre-SIG - Pre-submission interaction revamp project						
Training						
Benefit/Risk Project						
Focus group on streamlining LoQ → FG on str. LoQ						

Focus group on submission predictability

- Intensive monitoring of submission delays during 2023 (report published Q2 2024)
- Annex to Letter of Intent
- Multistakeholder workshop in Sept 2024
- Intensive monitoring 2 – H2 2025 **(ongoing)**
- DIA info day on 03 December 2025

Outcomes

Assuring the Network's Sustainability

- The workshop was well attended and received a good level of media attention
- Key messages:
  - Enhanced communication
  - Maturity of dossier
  - Submission readiness
- The DIA Info Day on 03 Dec aims to reproduce some of those key messages

Revamp achievements

Assuring the Network's Sustainability

Throughout, collaboration with CHMP, CAT, PRAC, industry & internal EMA stakeholders

end 2022

- WORD versions of key documents in eCTD *Working Documents* folder
- Response template

Oct 2023

- New D80 clinical and non-clinical reports used by Assessors

end 2024

- Completed CHMP AR/Overview template
- Completed D80 quality report templates

Nov 2023

- Pilot with industry
- Applicant completes D80 clinical and non-clinical reports
- 11 pilots now completed

Jan 2025

- Move to co-authoring on SharePoint between Rapp teams
- Include quality templates in pilot

Mar 2025

- Line Extension template updated in line with iMAA Overview

Ongoing

- EoI template update
- Generic/hybrid template
- Update to Overview template
- Draft report on pilot

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New templates

Line Extension template completed – differs from overview only in the administrative sections.

Indication Extension template ongoing – will be also based on the overview

Biosimilars template – on pause (included in main overview)

Generic/hybrid template – ongoing, targeting transition to IRIS

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Initial feedback on overview process

Assuring the Network's Sustainability

- The advantages of co-authoring are clear
- Some concerns regarding the SharePoint settings and many many versions created
- Some initial teething problems
  - Access issues
  - NCAs don't have as many permissions in SP as EMA staff (some work-arounds needed)
  - Revamp launch overlapped with IRIS launch – some confusion as the processes for Type IIs and LEs are not exactly the same for initial MAAs + use of different templates
  - Some confusion related to generic/hybrids being in SP, but the template is not geared up for co-authoring and the PRAC D94 stand-alone report still needs to be created (if there is an RMP)

EoI template being revamped, overview under review, then concentrate on generic/hybrids

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Update on Revamp Pilot

Assuring the Network's Sustainability

Product	Kick-off meeting	Actual submission dat	D80	Post-D80 meeting	D120	D210
1	05-Oct-23	23-Nov-23	18-Mar-24	10-Apr-24	25-Apr-24	12-Dec-24
2	13-Nov-23	21-Dec-23	22-Apr-24	13-May-24	30-May-24	14-Nov-24
3	08-May-24	23-May-24	09-Sep-24	25-Sep-24	17-Oct-24	25-Apr-25
4	12-Jun-24	22-Jul-24	04-Nov-24	04-Dec-24	12-Dec-24	24-Jul-25
5	10-Oct-24	11-Oct-24	20-Jan-25	04-Mar-25	27-Feb-25	18-Sep-25
6	12-Sep-24	11-Nov-24	17-Feb-25	15-Apr-25	27-Mar-25	exp 11-Dec-25
7	05-Sep-24	25-Nov-24	17-Mar-25	03-Jun-25	25-Apr-25	exp 11-Dec-25
8	10-Jan-25	04-Mar-25	16-Jun-25	25-Sep-25	24-Jul-25	exp 29-Jan-26
9	29-Apr-25	05-May-25	11-Aug-25	02-Oct-25	12-Sep-25	exp 23-Apr-26
10	09-Apr-25	05-May-25	11-Aug-25	12-Sep-25	18-Sep-25	exp 23-Apr-26
11	08-May-25	02-Jun-25	08-Sep-25	28-Oct-25	16-Oct-25	exp 21-May-26

Include quality templates

- All pilots have now completed
- Preliminary feedback: a lot of work for applicants and not much value for assessors
- Report in preparation – draft will be shared with participants by end 2025

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Pre-SIG

(pre-submission interactions group)

Jan 2025: focus group kick-off

Representatives from EMA, network and industry

Held a number of meetings during the course of 2025

The group agreed on a moving Rapp appointment before LoI and reinforcing pre-submission interactions

Oct 2025: Presentation to wider CAT/CHMP – Lots of feedback received, requiring follow-up

Dec 2025/Jan 2026: Will re-convene the group to discuss any possible amendments to the proposal

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Issues with translations

In recent months, we have noticed a gradual worsening of the quality of SmPC/PIL translations, including inconsistencies between clean and TC versions

Leads to corrections of opinion packages (pre EC decision) or corrigenda (post EC decision)

Protracted exchanges during the translation review phase (Day +5 to Day +25)

In some cases, delays to EC decisions

This is a call to all applicants – translation accuracy is key to the correct and safe use of the medicine – please take it seriously

EPAR process

(Problem statement and ongoing considerations)

We have noticed a gradual increase in the number of interactions regarding the CCI/PPD checks pre EPAR publication

It is not unusual to have 4 or even 5 rounds of consultation

Reminder: the consultation process should be only to remove CCI/PPD and (exceptionally) to correct any factual mistakes

Factual mistakes refers to data errors (e.g. 10.5 incorrectly reported as 1.05)

EMA in the process of clarifying the scope in the communications that are sent to applicants (target Q1 2026)

Timing for clock-stop extension requests

There has been some confusion regarding the timing for applicants to submit requests for clock-stop extensions

For request at the time of adoption of LoQ/LoOI/RSI:

→ Applicant knows already they will need more time

→ Request must be submitted by the Wed of CHMP week

For additional requests when already in clock stop:

→ Applicant is in clock stop and realizes they will need more time than originally thought

→ Request must be submitted by the Monday of the week before CHMP, prior to the already agreed restart

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Thank you

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