EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10th Industry Stakeholder Platform Meeting

Topic 4: CHMP AR Revamp Project update

27 June 2023

Francesca Day

Project objectives

EUROPEAN MEDICINES AGENCY

CHMP
Workplan 2022

Activity areas

Improve/optimise the initial evaluations assessment report with the aim to simplify, avoid replication of work and meet/consider stakeholders' expectations. Examine the best use of available resources at CHMP and EMA to achieve this goal.

Key objectives

- Review ways to improve the efficiency, robustness, consistency and soundness of outputs throughout the initial MAA evaluation process.

Activities in 2022

CHMP activities to achieve the objectives set for this area:

- Optimise the related assessment report templates (e.g. benefit-risk section, efficacy section of overview template) to avoid duplication of information while facilitating inclusion of all relevant information (e.g. explanation of the therapeutic indication, efficacy and safety in subgroups and outcomes of SAG meetings and oral explanations).

CHMP topic leaders: Johann Lodewijk Hillege

Other contributors:

Member/alternate	Name	MS
Member	Kristina Dunder	SE
Member	Jayne Crowe	IE

Work to date

EUROPEAN MEDICINES AGENCY

- ✓ Up-front request for WORD version of key documents in eCTD *Working Documents* folder
- ✓ Deployed a generic template for Response to Questions
  - Currently only required for initial MAA responses to D120 LoQ and D180 LoOI
  - If successful, will extend to other procedures
  - Already possible to use it for any responses if the company chooses
- ✓ Extensive work on D80 non-clinical, clinical and quality templates
- ✓ Extensive work on 1 single CHMP AR which starts at D1 and evolves to the EPAR
- ✓ Close collaboration with Industry representatives throughout

Where are we?

EUROPEAN MEDICINES AGENCY

Step	Date
Teams to come back with Draft concept	By mid-May
Authoring of Draft 1	By 30 Jun 22
Steering Group review	By 31 Aug 22
PROM consultation	31 Oct 22 PROM
Authoring of Draft 2	18 Nov 22
Wider review (SG, industry, CHMP, EMA...)	By 06 Jan 23
Steering group decision on way forward	30 Jan 2023
Drafting groups to update templates	Mid-March 2023
Second review - Clinical	21 Apr 23
Second review - Non-clinical	05 May 23
Comment implementation	16 Jun 23
Final Draft endorsement by Steering Group	07 Jul 23
CHMP Endorsement	10 Jul 23 PROM

Completed

Pending

Implementation plan – overall proposal

EUROPEAN MEDICINES AGENCY

Step 1

- New D80 clinical and non-clinical reports used by Assessors
- No change to processes
- D95 Co-Rapp assessment remains

Step 2

- Pilot with industry
- Applicant completes D80 clinical and non-clinical reports
- No change to processes
- D95 Co-Rapp assessment remains

Step 3

- Complete D80 quality report template
- Include D80 quality template in pilot
- No change to processes
- D95 Co-Rapp assessment remains

Step 4

- Complete CHMP AR/Overview template
- Move to co-authoring on SharePoint between Rapp teams
- D95 Co-Rapp assessment replaced by D80 combined report

Parallel stream

- Creation of a dedicated D80 clinical template for Biosimilars

Implementation plan – Step 1 proposal

EUROPEAN MEDICINES AGENCY

Step	Date
Prepare training materials on new templates	By 31 July
Training materials agreed by Steering Group	By 08 September
Pin-point procedures starting Q4 2023 and associated assessors	By 30 August
Organise training sessions during September 2023	11 September – 06 October
New templates become effective on 01 October for 09 October 2023 submission deadline	09 October

Pilot with industry

EUROPEAN MEDICINES AGENCY

Proposal for pilot with industry

During the pilot, a small number of companies will be asked to pre-fill the D80 non-clinical and clinical report templates with factual information

Companies will be contacted by EMA at least 3 months ahead of submission

Participation in the pilot is voluntary

Expectations from companies

- Pre-fill the D80 non-clinical and clinical AR templates with factual information (clear instructions provided in the templates)
- Provide the completed AR templates (in Word format via Eudralink – not part of eCTD) by the start date of the procedure (i.e. ~ 1 month after submission)

Close collaboration

- Dedicated meeting with EMA/Rapps prior to submission
- Rapp teams to contact company for any clarifications once ARs received
- Possibility of meetings with Rapp teams during the procedure
- Aim to solve any concerns, reduce number and repetition of questions

Timelines for pilot

- If new templates implemented from October, target MAA submissions in Nov/Dec (submission date 6-Nov and 27-Nov) and then Q1 2024 for the pilot
- Need to give companies at least 3 or 4 months notice ahead of submission

Step	Date
Identify candidates (1 per sub deadline)	By 16 June
Confirm Rapporteurs on board	By 30 June
CHMP endorsement	10 July
Contact companies	By 20 July
Organise training session for PLs and Rapps	July-September
Pre-submission meeting with companies	Sept onwards

Any questions?

Further information

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

Follow us on **@EMA_News**