EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Additional measures to allow experts to focus on COVID-19 activities

Committee's workload and co-Rapporteur involvement

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EMA has agreed a number of measures with its Management Board to ensure that the European medicines regulatory network can continue to dedicate resources to increasing volume of COVID-19-related procedures whilst maintaining the robustness of its scientific evaluations for all products.

These temporary measures complement the arrangements prioritising COVID-19 procedures that are already in place under the current phase 2 of the business continuity plan for the European medicines regulatory network, such as maximum flexibility with timetables or temporary changes of rapporteurs for non-COVID-19 procedures.

These measures apply to initial MAAs, extension of indications and line extensions that started in May 2021.

Peer reviewer and peer review

1. Peer-Reviewer is abandoned to free up resources

2. Applicable for all products: COVID, non-COVID, and ATMP

3. The assessment will rely on the intrinsic peer review that is part of the CHMP/CAT's role in the evaluation process. In the case of COVID-19 products, there are additional reviews by the COVID-19 EMA pandemic Task Force.

4. Peer review TC is maintained to ensure Rapp+Co-Rapp+PRAC+EMA discuss all comments received.

New Co-Rapporteur critique for IMA from May 21

1. The co-rapporteur assessment will be incorporated in the rapporteur AR in the first phase of the evaluation.

Exceptions: COVID, ATMP, very complex applications and re-examinations.

2. Rapp AR and Co-rap critique will be shared with all committee members and applicant.

3. Committee members will be able to comment on both positions.

4. Time tables have been adjusted and published.

5. Exceptions will be decided by the CHMP always ahead of procedure start.
Applicant will be informed in the validation letter.

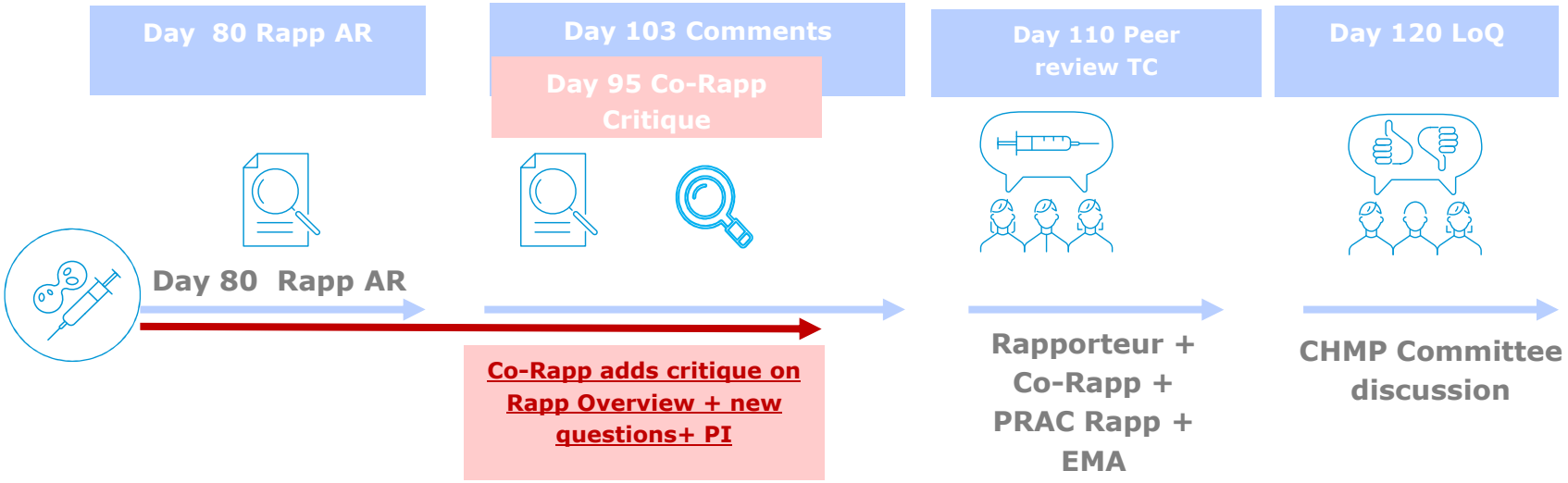
Co-Rapporteur involvement in extensions of indications and line extensions from May 21

1. **For Covid:** Co-Rapp will always be involved. Independent AR or critique will depend on the complexity and will be decided by Rapporteurs and EMA before the start of the procedure

4. **For non-Covid:** Co-Rapp mostly not involved Need for Co-Rapp involvement will be decided by the rapporteurs and EMA before the start of the procedure

5. **For non-Covid:** When involved assessment of Co-Rap will be a critique. Replacement of the Rapporteur by the Co-Rapporteur is also possible in line with previously agreed measures

Co-Rapporteur Critique in the first phase of the MAA



- Accelerated assessment/ATMP time table is adapted accordingly.
- No change to the 2nd and 3rd phase of evaluation

Take home message

These temporary measures relate to the first phase of the evaluation only and maintain the robustness of the scientific evaluation.

The final scientific conclusion on an application is taken after several stages of data review and sequential assessment reports are updated after Committee discussions, or after new information is received from the applicant in response to questions or oral explanations.

The Co-rapporteur responsibilities do not change and he/she will continue to lead the evaluation with the Rapporteur.