REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

Press release

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

EMA is implementing additional temporary measures to further streamline activities in the European medicines regulatory network to enable experts to deal with an increasing volume of COVID-19-related assessment procedures.

Due to the very active pipeline of upcoming COVID-19 vaccines and treatments, a number of ongoing procedures, and the roll-out of authorised vaccines to millions of people across the EU, the resources of EMA and the European medicines regulatory network are highly focused on the review of COVID-19 vaccines and therapeutics, and the rigorous safety monitoring of these medicines.

EMA has agreed a number of measures with its Management Board to ensure that the network can continue to dedicate resources to COVID-19 whilst always maintaining the robustness of its scientific evaluations. These 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. The new temporary measures include:

Pre-authorisation procedures

- All **initial marketing authorisation applications (MAAs) for COVID-19** vaccines and therapeutics will continue to be given first priority. There will continue to be two independent, simultaneous scientific assessments with separate initial reports for these procedures, with no change to the current responsibilities of the rapporteur and co-rapporteur at EMA's human medicines committee (CHMP).

- For **initial MAAs for non-COVID-19 products**, unless they are advanced therapy medicinal products (ATMPs) or other very complex medicines to be considered by the CHMP, the co-rapporteur will no longer provide a separate assessment report to the rapporteur in the first phase of the evaluation. Instead, he or she will review the submitted data and give a detailed critique of the rapporteur's assessment report. These measures will free up some of the co-rapporteur resources to focus on COVID-19 activities.
- For **all applications**, there will temporarily no longer be a separate, formally appointed peer reviewer, but the assessment will rely on the intrinsic peer review that is part of the CHMP'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 (COVID-ETF).

These measures will apply to initial MAAs starting in May 2021.

While the measures will affect the way the initial MAA reports are prepared, the responsibilities of the rapporteur and co-rapporteur will not change. Their role is to apply their scientific expertise throughout the MAA procedure, supported by their respective experts. In addition to drafting their first reports, they finalise the lists of questions, review the product information, assess the applicant's responses, finalise the list of outstanding issues and lead on all committee discussions including oral explanations.

Post-authorisation procedures

Currently, the involvement of co-rapporteurs in the assessment of post-authorisation procedures to extend indications and extension applications (so-called line extensions) depends on the complexity of the file. The approach to these procedures is being temporarily amended as follows:

- For **COVID-19 products,** the co-rapporteur will be systematically involved in all such procedures; however, the need for two separate

assessment reports, or for providing a detailed critique of the rapporteur's assessment report, will depend on the complexity of the application.

- For **non-COVID-19 products**, when the co-rapporteur is involved, the co-rapporteur will produce comments on the rapporteur's assessment report but will not draft a full separate report in the first phase of the evaluation.

These changes will take effect from May 2021.

EMA will also undertake additional activities, as needed, to facilitate the appointment or re-appointment of (co-)rapporteurs, such as even further facilitating the use of multinational assessment teams and the identification of experts that can support the assessment procedures. Where required, EMA will also expand the support from the EMA secretariat in the assessment process. EMA will regularly review these measures and amend them as necessary, in agreement with the CHMP and the Management Board.

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Ministry of Health
11 May 2021