EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 September 2020
EMA/MB/505166/2020
Management Board meeting of 1 October 2020

Agenda point 6.b, for endorsement

Additional safeguards (to be) put in place for securing the robustness and independence of the scientific review process for Marketing Authorisation Applications for COVID-19 treatments

Issues for consideration

Taking into account an increasing public scrutiny of how the scientific assessment of COVID-19 treatments (therapeutics and vaccines) will be performed, it is crucial that the robustness and independence of the scientific review process for Marketing Authorisation Applications (MAAs) for these treatments is secured and that measures are in place to not only address the risk of bias but also to avoid the perception of bias.

The measures announced in the letters sent on 21 August and 2 September 2020 to the European Medicines Regulatory Network (EMRN) were taken because of the need to ensure that the MAA process for COVID-19 treatments and the EU vaccine purchasing procedure under the Advance Purchasing Agreements (APAs) are two separate processes as otherwise the credibility of the scientific assessment in the context of the licensing process is negatively affected. The Agency had to proceed with the implementation of these measures without delay as for instance the process for appointment of (Co)-Rapporteurs was starting. The Management Board (MB), therefore, is asked to note these additional safeguards put in place.

In addition, another recently identified aspect needs to be considered as well. It relates to the consequences for the scientific review process for a MAA for a COVID-19 treatment in case of funding (directly and/or indirectly) by a State/Government of a pharmaceutical company developing such a COVID-19 treatment. In particular, the situation whereby a CHMP member, coming from a national governmental organisation concerned by the matter, takes the lead of the scientific assessment by acting as (Co)–Rapporteur needs to be carefully considered.

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Action requested of the Board

NOTE the presented cover note	5.1.2f
NOTE the additional arrangements put in place as described in and attached to the Executive Director's email sent to the Management Board on 27 August 2020	5.1.2f
NOTE the follow-up letter sent on 2 September 2020 to the European Medicines Regulatory Network (EMRN) in relation to the need to secure (1) the necessary expertise from the EMRN during the COVID-19 pandemic and (2) the robustness and independence of the scientific review process for the licensing of COVID-19 treatments	5.1.2f
ENDORSE the additional safeguards to be put in place to address the specific case of the consequences of State/Government funding for COVID-19 treatments with respect to the scientific review process of MAAs for these treatments	5.1.2f

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