EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

Management Board meeting 1 October 2020
Agenda item 6.b, for endorsement

EMA 25 years

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Actions already taken by EMA (1/2)

- Letters sent to the EMRN on 21 August and 2 September 2020, highlighting the need to ensure that the robustness and independence of the scientific review process for MAAs for COVID-19 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:
  - Therefore, the need was identified to ensure that the MAA process for COVID-19 treatments and the **EU** vaccine purchasing procedure under the APAs are 2 separate processes
  - Consequently, restrictions have been introduced for CHMP-PRAC-SAWP-ETF Chairs, and all members in case of involvement in the EU purchasing process for a particular vaccine or any other vaccine which is subject to the EU purchasing procedure

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Actions already taken by EMA (2/2)

- The new arrangements, which come on top of the existing arrangements on CoIs described in EMA Policy 0044, already have been put in place for the concerned Committees/ other scientific fora
- The MSs are responsible for ensuring that these measures are adequately implemented at national level
- The MB, who was informed on 27 August 2020, is invited to **note** these additional safeguards put in place
- First feedback from concerned Committee/ other scientific fora members has indicated that so far only in few instances there is a need to introduce participation restrictions; the MB will be kept informed on any further developments

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Specific case of the consequences of State/ Government funding for the MAA process for COVID-19 treatments (1/4)

- The EMA recently became aware through published information on funding by a State/ Government of a pharmaceutical company developing a COVID-19 treatment:
  - In terms of direct funding through direct investment in such pharmaceutical company (direct equity financing/ capital increase)
  - In terms of indirect funding by providing financial support to the conduct of development programs and/ or an increase in production capacity
- The issue does **not** relate to the State/ Government funding as such, but **only to the consequences** that such funding may have on the public perception of the independence of EMA's scientific review of a MAA, **in particular** if a CHMP member, coming from a national governmental organization concerned by the matter, takes the lead of the scientific assessment by acting as CHMP (Co)-Rapporteur

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Specific case of the consequences of State/ Government funding for the MAA process for COVID-19 treatments (2/4)

- This type of situation is currently not addressed in any of EMA's policies, and since EMA was confronted with an urgent situation, and in order not to unnecessarily delay the start of the rolling review for a COVID-19 vaccine, an *ad hoc* decision was taken as follows:
  - EMA, as a precautionary measure, awaiting a wider reflection at the October MB meeting, recommended to the CHMP member who already had submitted a (Co)-Rapporteur bid, that such bidding was reconsidered
  - Following discussions between EMA and the concerned NCA, the CHMP member subsequently withdrew the bid; EMA is grateful for the action taken
- However, it should be acknowledged that similar situations are very likely to arise over the next weeks and months; therefore, specific arrangements to be applied proactively and in a transparent way, are needed

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Specific case of the consequences of State/ Government funding for the MAA process for COVID-19 treatments (3/4)

- The following approach is proposed, acknowledging that the most appropriate balance in the interests of public health is needed between avoiding as much as possible the perception of bias versus securing the necessary high-quality scientific expertise and avoiding unnecessarily delaying the start of the scientific review process:
  - Direct State/ Government funding: CHMP/ PRAC member can not act as (Co)-Rapporteur; even if a bid is received, such bid will not be considered
  - Indirect State/ Government funding: it is strongly recommended that a CHMP/ PRAC member does not act as (Co)-Rapporteur; in case following 2 rounds of bidding no (Co)-Rapporteur can be found, as an exception the CHMP member can be appointed Co-Rapporteur; the submitted bid, therefore, will only be considered in the 3rd bidding round
  - EMA will only act on the basis of publicly available information, known to EMA at the moment of the decision-making on (Co)-Rapporteur appointment; if the information becomes publicly available afterwards there will be no retroactive decision to change the (Co)-Rapporteur appointment, but full transparency will apply

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Specific case of the consequences of State/ Government funding for the MAA process for COVID-19 treatments (4/4)

- It is important to note that this proposed approach:
  - Should not be seen as introducing an additional element, i.e. the notion of a "national conflict of interest", in the selection of (Co)-Rapporteurs
  - Is only addressing a very specific situation in the context of a pandemic where there will be even more scrutiny of the scientific review process for MAAs
  - Is, therefore, not setting a precedent for the scientific review for MAAs for non-COVID-19 treatments
- The MB is invited to **endorse** the proposed approach; the MB will be kept informed on any further developments