EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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 – specific case of the consequences of State/ Government funding for COVID-19 treatments

1. Introduction

Reference is made to the letters sent on 21 August and 2 September 2020 to the European Medicines Regulatory Network (EMRN) elaborating on the need to secure the robustness and independence of the scientific review process for marketing authorisation applications (MAAs) for COVID-19 treatments (both therapeutics and vaccines), and the introduction of additional safeguards to address this need. As specified in these letters, such need was identified to ensure that the MAA process for COVID-19 treatments and the EU vaccine purchasing procedure under the Advance Purchasing Agreements (APAs) are 2 separate processes and that even the perception of bias is avoided.

Recently, EMA has become aware of another situation which bears the risk of at least perceived conflict of interest or perception of bias. This situation relates to State/ Government funding (directly or indirectly) of a pharmaceutical company developing a COVID-19 treatment and the possible consequences such funding may have on the scientific review process for a MAA for this treatment.

2. Problem statement

The problem recently identified by EMA relates to both direct funding by a State/ Government of a pharmaceutical company developing a COVID-19 treatment through direct investment in such pharmaceutical company (direct equity financing/ capital increase) or through more indirect funding by providing financial support to the conduct of development programs and/ or an increase in production capacity. Such information was put in the public domain by the Government concerned.

First, it needs to be emphasised that the government funding as such is **not** questioned at all by EMA. What is being considered are only the **consequences** that such funding may have on the public perception of the independence of EMA's scientific review process, and how to best address such perception, including the impact of the mitigating actions. More specifically, it needs to be carefully considered if it is appropriate in such a situation that a CHMP member, coming from a national governmental organisation concerned by the matter, takes the lead of the scientific assessment by

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acting as (Co)-Rapporteur. This is a specific situation the Agency has never been confronted with before. EMA, after careful consideration, is of the view that in the light of the increased scrutiny that will be applied in terms of how MAAs for COVID-19 treatments will be dealt with by the Agency, accepting such an approach may be perceived as inappropriate. In addition, if this is not adequately addressed and in a timely manner, it could undermine the trust of stakeholders and the general public in the scientific review process and in the medicinal product itself, and could ultimately even question the credibility of EMA/ the CHMP and all Regulatory Authorities involved in the process.

Consequently, since the Agency was recently confronted with such a situation and the concerned CHMP delegation had already submitted a bid for (Co)-Rapporteurship for a COVID-19 vaccine MAA, EMA, as a **precautionary measure**, took the decision to **recommend** that the bidding for (Co)-Rapporteurship was reconsidered. The Agency also announced that it would initiate a wider reflection on this topic at the October Management Board meeting as similar cases were likely to arise in the future. The CHMP delegation subsequently withdrew its bid and the Agency is grateful for the action taken.

3. Proposed way forward

In trying to find a way forward for this unprecedented situation, several aspects need to be considered:

- Is there a need to differentiate between direct and indirect funding (for description of the terms, see above)?
- Level of public awareness?
- Publication source of the information on the funding?
- Timing of the public awareness?
- Impact on the available expertise and on the start of the rolling review/ review of the MAA?

Whilst the ultimate aim should be that the robustness and the independence of the scientific review process should not be perceived as being jeopardised, it is important to find the **most appropriate balance** in the interests of public health between avoiding the perception of bias versus not affecting the availability of the required high-quality scientific expertise and avoiding unnecessarily delaying the start of the procedure. Furthermore, it is equally important not to be seen as including an additional element for the selection of (Co)-Rapporteurs by introducing the notion of a "national conflict of interest". The proposed approach should, therefore, be understood as addressing a very specific situation in the context of a pandemic where there will be utmost scrutiny of the way Regulatory Authorities have handled the scientific review for MAAs for COVID-19 treatments. Consequently, this proposed approach is **not** setting a precedent for the scientific review for non-COVID-19 MAAs. It is about managing the public perception of a potential conflict of interest in these special circumstances of heightened scrutiny and in an environment where vaccine hesitancy is already an established concern.

The following approach is proposed:

- In the context of the scientific review of MAAs for COVID-19 treatments (therapeutics and vaccines) the perception of bias should as much as possible be **avoided**.
- In the case of **direct** State/ Government funding as described above, a CHMP member coming from a national governmental organisation concerned by the matter **cannot** take the lead of the scientific assessment by acting as (Co)-Rapporteur. **Neither** can a PRAC member coming from a national governmental organisation concerned by the matter act as PRAC (Co)-Rapporteur. In practice this means that even if a bid is submitted, such bid will not be considered during the decision-making on the appointment of (Co)-Rapporteur.
- In the case of **indirect** State/ Government funding as described above, it is **strongly recommended** that a CHMP member coming from a national governmental organisation concerned by the matter **does not** take the lead of the scientific assessment by acting as (Co)-Rapporteur. Likewise, it is **strongly recommended** that a PRAC member coming from a national governmental organisation concerned by the matter **does not** act as PRAC (Co)-Rapporteur. In case **difficulties** are experienced in terms of finding the required expertise to act as (Co)-Rapporteur following **2 rounds** of the bidding process, as an **exception** the CHMP member coming from a national governmental organisation concerned by the matter **can** be appointed Co-Rapporteur (on condition that the criteria for appointment have been fulfilled). Since the PRAC (Co)-Rapporteur appointment process only allows for the PRAC member coming from the same Member State as the CHMP Rapporteur to act as PRAC Co-Rapporteur, there will be **no** involvement of the PRAC member coming from the national organisation concerned by the matter. The aforementioned exception needs to be duly justified and recorded. In practice this means that when a bid is submitted, such bid is noted during the first 2 rounds of bidding; only in a 3rd round the aforementioned exception will be applied.
- EMA will only act on the basis of **publicly available information** confirming such direct or indirect funding, either information which is available from an authoritative source (provided by the State/ Government) or information which has been published by the applicant for the MA. In addition, EMA will only take into account the public information available at the moment of the decision-making on the (Co)-Rapporteurship appointment. If the information becomes available at a later stage, there will be **no** retroactive decision taken to change the (Co)-Rapporteur appointment, neither for the CHMP nor for the PRAC. However, EMA will ensure that there is full transparency at the level of the CHMP and the PRAC. This will be minuted and the published minutes will include such information.