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From: [redacted]
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To: EO-PresubmissionConsultation
Subject: Comments Ombudsman Inquiry on EMA pre-submission activities
Attachments: Ceva answers.docx

Follow Up Flag: ema18
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Dear Sir,

Please find attached Ceva Santé Animale comments on the Ombudsman Inquiry on EMA pre-submission activities.

Kind regards,

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Ceva answers

1. It may happen that EMA staff members and experts who participate in pre-submission activities will be involved in the subsequent *scientific evaluation and/or marketing authorisation* procedure for the same medicine. To what extent is this a matter of concern, if at all? Are there specific pre-submission activities of particular concern in this regard? How should EMA manage such situations?

This is not a concern, it may help for a better comprehension of the final dossier and give an early idea/access to the reviewer.
Pre-submission meetings are meanly administrative with EMA staff, so no direct link with the scientific assessors.

2. Should EMA allow experts from national authorities, who have previously provided scientific **advice** at national level on a particular medicine, to be involved in EMA's scientific **evaluation** of the same medicine?

Yes, it make sense that EMA use the best competencies to asses a dossier and particularly in this case if some national expert already work on the subject.

3. What precautionary measures should EMA take to ensure that information and views provided by its staff members and experts in the context of pre-submission activities are not, in practice, considered as a "binding" pre-evaluation of data used to support a subsequent application for authorisation?

Current EMA GL are clear and transparent and usually conclusion in minutes meeting are also clear.

4. Is the way in which EMA engages with medicine developers in pre-submission activities sufficiently transparent?

   If you believe that greater transparency in pre-submission activities is necessary, how might greater transparency affect: i. EMA's operations (for example the efficiency of its procedures, or its ability to engage with medicine developers) and ii. medicine developers?

Yes guidance are clear, pre-submission meeting are transparent for the applicant.
If the idea is to give transparency to general public (& competitors !) to the content of pre-submission meeting of an applicant, we will not use this tool anymore.

5. Is there a need, in particular, to enhance the transparency of scientific advice EMA provides to medicine developers? Would it, in your opinion, be useful or harmful, for example, if EMA:
   - disclosed the names of the officials and experts involved in the procedures;
   - disclosed the questions posed in scientific advice procedures; and/or
   - made public comprehensive information on the advice given.
   If you have other suggestions, for example regarding the timing of the publishing of information on scientific advice, please give details and the reasons for your suggestions.

Giving the name of the official and expert involve in a procedure is a possibility as far as the applicant and the product cannot be identified by a competitor. The current process publishing EPAR at the end of the procedure is sufficient.

6. What would the advantages and disadvantages be of making scientific advice, given to one medicine developer, available to all medicine developers?

It will be a strong disincentive for an applicant to use the SA procedure. The current EPAR after the marketing authorisation give sufficient indication to all interested developers.

7. Should EMA be limited to providing scientific advice only on questions not already addressed in its clinical efficacy and safety guidelines[4]?

No, guidelines are only guidance and if the applicant estimate that he needs clarification, it is important that he can do it, whatever the situation.

8. Any other suggestions on how EMA can improve its pre-submission activities? If so, please be as specific as possible.

- It can be interesting to have face to face meeting around the scientific advice, to clarify some points with the nominated experts and rapporteur, co-rapporteur.
- Sharing protocol maybe helpful to find agreements