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From: [redacted]
Sent: 20 December 2018 14:55
To: EO-PresubmissionConsultation
Subject: Comments Ombudsman Inquiry on EMA pre-submission activities

Dear European Ombudsman Office,

I would like to comment on the questions raised regarding interaction with pharmaceutical companies before MAA, in particular due to Scientific Advise Procedures.

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?

The main content of the answers to applicant is developed by independent experts, mainly from academia. Later national representatives discuss and combine the answers to a final response letter. EMA staff mainly provided administrative roles in the process.

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. However, one might considerer to make this process more transparent in a way, that applicants would know if the answer to their national and EU scientific advise procedure involved the same persons.

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?

It is clear that scientific advise (SA) is not pre-assessment of data. We state this whenever the applicant intents to have pre-assessment (which of course happens). Theoretically a pre-evaluation of questions could exclude such questions from SA process, however, this would require detailed and highly competent review of questions before experts work on them.

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?

I think it is transparent

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.

It would be harmful if applicants know their experts before there is a final answer. They would make pressure. I think it also would be better not to disclose the experts at all. The coordinators are disclosed anyway.

It would be a no-go to make questions and answers available for public. The data belong to the companies and this would severely hamper the quality of SA given since relevant data would not be presented to experts. Many companies might not go for SA at all in this case.

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

See above. Drug development is competitive and no one can expect that this from companies.

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

Definitely not. The guidelines give only broad guidance and every drug development program is different. We strictly avoid to repeat answers that are given in the guidelines but provide individual advise.

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

More joint procedures that involve EMA and FDA or involve scientific advice and re-imbursement issues should be encouraged.

Kind regards,
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