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From: [redacted]
Sent: 30 January 2019 15:19
To: EO-PresubmissionConsultation
Cc: [redacted]
Subject: Comments Ombudsman Inquiry on EMA pre-submission activities
Attachments: European Ombudsman presubmission activities_HVB_VPM_2019.pdf

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Dear European Ombudsman,
Many thanks for the opportunity to comment on EMA pre-submission activities.
Please find enclosed comments from the Department for Pharmaceuticals Affairs (Main Association of Austrian Social Security Institutions).
With kind regards,
Anna Nachtnebel

Main Association of Austrian
Social Security Institutions

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Vienna, 30th January 2019

Comments from the Department for Pharmaceutical Affairs, Main Association of Austrian Social Security Institutions, on the Ombudsman Inquiry OI/7/2017/KR on EMA pre-submission activities

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?*

   Yes, this is of concern. A strict separation of experts involved in pre-submission activities and scientific evaluation and/or market authorization procedures has to be ensured to avoid any conflict of interest. Foremost scientific advice activities with subsequent market authorization are concerned.

   Strategies for managing such situations may include:

- Strict conflict of interest rules
- Transparency on advice given including publication of any divergent opinions.
- Change the current fee-for-service model to guarantee the independence of the institution
- Further develop and publish more “Generic guidelines” by incorporating learnings from scientific advice to allow all applicants to profit

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?*

   No. For the same reasons stated above.

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?*

   - Clearly separate pre-submission from authorisation actitivies
   - A clear statement that advice within pre-submission activities does not guarantee a positive decision on market authorisation
   - A summary of the advice given and of the communication/exchange between applicant and experts should be made public
   - Conflict of interest statements

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?

   Currently, transparency concerning pre-submission activities is not sufficient, since hardly any information is available. Greater transparency does not automatically influence EMA's operations. One could argue that transparency of pre-submission activities is of public interest, and that the work-load (e.g. for EMA personal, payers, authorisation agencies) is actually reduced since relevant answers derived from previous consultations might be found in the public domain. Thus, questions from market developers might already be tackled due to previous pre-submission activities.

   To avoid any drawbacks for developers it has to be ensured that truly commercially sensitive information is not published.

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.

   If names of experts are published the possibility exists that they are influenced by external parties or that specific experts are selected.

   Publication of the questions posed and information on the advice given at the time of market authorization would allow public scrutiny whether pre-submission participation was actually worthwhile, i.e. were relevant questions satisfactorily answered.

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

   Advantages:
   - Reduce work-load of EMA/national experts since answers might also be relevant for other developers
   - Further refinement of existing guidelines by incorporating key learnings
   - Development of new guidelines on repeatedly asked questions
   - Public debate allowing a broader input on drug development guidance in general

   Disadvantages:
   - Checking documents prior to publication for commercially confident information might lead to increasing work-load
   - Publication of advice given early during product development might keep developers from seeking advice in the first place

- Divergent opinions on e.g. relevant study design, comparator, outcomes of those providing scientific advice and those deciding on marketing authorisation will be very difficult to explain – increased pressure to grant market authorisation after scientific advice

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

   Yes; otherwise scarce resources are used inappropriately for only one applicant.

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

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