[redacted]

From: [redacted] on behalf of GD-adm

Sent: 28 January 2019 10:21
To: EO-PresubmissionConsultation
Subject: VB: Comments Ombudsman Inquiry on EMA pre-submission activities´
Attachments: Comments Obudsman Inquiry on EMA pre-submission activities.pdf

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Dear Sir/Ms,
Please find the response concerning the Comments Ombudsman Inquiry on EMA pre-submission activities´.
Yours sincerely,

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LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Date: 28 January 2019 Dnr: 3.4.1-2019-007549

EU ombudsman
Email: [redacted]

Comments Ombudsman Inquiry on EMA pre-submission activities' Response from the Swedish Medical Products Agency to the Public Consultation

Thank you for the opportunity to comment on this important issue. Please see attached the response to the questions of the Public Consultation by the Swedish Medical Products Agency.

[redacted]

Catarina Andersson Forsman
Director General

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Below are the responses to the questions by the Swedish Medical Products Agency to the public consultation by the EU Ombudsman on EMA pre-submission activities

Question 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?

MPA response:

This is a matter of course rather than a matter of concern. The pre-submission activities relate to communicating the formal scientific and/or regulatory requirements for the future application. Why the same staff/experts who evaluate the documentation being part of a subsequent marketing authorization application, could not do this is unclear. There are great advantages in terms of the quality of regulation that there is a continuity of understanding of particular procedures.

Question 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?

MPA response:

The aim of the scientific advice meeting at national level is to discuss the company's development plan, to clarify relevant EMA guidelines (if needed) and to give advice on preclinical and clinical study design. This could for example include advice on appropriate endpoints and the statistical analysis plan. The goal is to ensure good quality of the studies performed and of the submitted dossier; thus enhancing the chances to obtain robust evaluable data, which is crucial for a successful outcome of an MAA. It is always clearly communicated to the company that the advices given are not legally binding.

This taken into account, we see no reason for not allowing experts who participated in national advice to be involved in the scientific evaluation at the time of submission. To refuse them to participate could even hamper the quality of the evaluation since available expertise within the regulatory system is limited in most therapeutic areas. It is unclear what would be gained by duplicating the system with no communication between the national and EU level.

Question 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?

MPA response:

The fact that the views expressed in pre-submission activities are non-binding is clearly communicated. Furthermore, the structure of the EU evaluation process itself, where different teams in different member states work independently to provide their respective assessment reports, and member state scrutiny of rapporteur/co-rapporteur evaluations through the CHMP, PRAC and other committees takes place ensure that views expressed within pre-authorisation activities are not a binding pre-evaluation. Views expressed by EMA during the pre-submission phase also are reviewed by multiple parties, ensuring that views expressed within pre-authorisation activities are not a binding pre-evaluation. Finally, data from key studies are generally only evaluated during the marketing approval phase, while pre-authorisation activities generally focus on the planning of studies.

Question 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?

MPA response:

There is full transparency within the regulatory system, while legal provisions for data confidentiality must be respected with regards to other parties.

Question 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.

MPA response:

The particular assessors are not personally responsible for EMA advice and decisions which are made by committees; therefore, it is not considered relevant to disclose the names of the officials and experts involved in the procedures. Individual assessor views might in fact be contrary to the decisions made It is essential as mentioned before that legal provisions for confidentiality can be guaranteed with regards to other parties.

See also previous responses above

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

MPA response:

It is unclear how this could be done while maintaining data confidentiality. However, general scientific guidelines for drug development are produced by the scientific committees, which summarize previously provided advice but also provide a reference point for future advice.

Furthermore, EMA's position on the interpretation of regulatory guidelines and rules on specific topics typically addressed in discussions or meetings with developers and MAHs, throughout the whole life-cycle of a product, are made publically available through Questions & Answers sections on EMA website.

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

MPA response:

No. The application of the general principles in the particular case may be a subject in need of clarification.

Furthermore, scientific advice is part of the public health mission of the EMA, insofar as unnecessary or in-optimally designed clinical or preclinical experiments may be avoided.