

[REDACTED]

From: [REDACTED]
Sent: 31 January 2019 18:44
To: EO-PresubmissionConsultation
Subject: Comments to Obudsman inquiry OI/7/2017/KR
Attachments: EMA Pre-submission Consultation.docx

Follow Up Flag: ema16
Flag Status: Flagged

Please find our comments attached.

Freundliche Grüße/Best regards

Christine Piasek
Director Development | Corporate Regulatory Affairs

Biotest AG | Landsteinerstraße 5 | 63303 Dreieich | GERMANY
Phone: +49 6103 801-2000 | Mobile: +49 [REDACTED] | Fax: +49 6103 801-180
E-Mail: [REDACTED] | <http://www.biotest.de>

Biotest AG

Landsteinerstr. 5, D-63303 Dreieich

Telefon +49 (0) 6103 801-0, Telefax +49 (0) 6103 801-150

Vorstand/Board of Management: Dr. Bernhard Ehmer (*Vors./Chairman*), Dr. Michael Ramroth, Dr. Georg Floss

Vorsitzender des Aufsichtsrates/Chairman of the Supervisory Board:

Rolf Hoffmann

Handelsregister/Commercial Register: Offenbach HRB 42396

USt.-IdNr./VAT-Ref. No.: DE 114 127 423

Bitte beachten Sie unsere Datenschutzhinweise unter [Datenschutzerklärung](#)

For detailed information on data protection, please refer to [Data Privacy](#)

How the European Medicines Agency engages with medicine producers before they apply for authorisations to market their medicines in the EU - Invitation to comment within the European Ombudsman's inquiry OI/7/2017/KR

PUBLIC CONSULTATION - DATE Monday | 08 October 2018

The Ombudsman invites all interested parties, be it individuals or organisations from the public, private or voluntary sectors, to put forward their views on this issue by replying to the questions below.

Background

In 2017, the European Ombudsman opened^[1] an [inquiry](#) (OI/7/2017/KR) into the arrangements that the European Medicines Agency (EMA) has in place for engaging with individual medicine developers before they submit applications for authorisations to market their medicines in the EU (so-called 'pre-submission activities' or 'pre-authorisation activities'). Essentially, these 'activities' involve EMA providing advice, opportunities for dialogue and consultation, and regulatory and scientific support for medicine developers on different aspects of the authorisation process^[2].

EMA's [reply](#) to the letter opening the inquiry^[3], and a follow-up meeting, have given the Ombudsman a better understanding of the different types of pre-submission activities that exist. In so far as these activities facilitate the development and availability of high-quality, effective and safe medicines, they benefit patients and serve the public interest. Nonetheless, such meetings and preliminary discussions may pose some risks, including to the objectivity of how authorisation applications are subsequently assessed, particularly where the process is not sufficiently transparent.

Questions

Please give reasons for your 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?**

From a pharmaceutical industry view it is highly encouraged to have the possibility to get into contact with EMA staff members/experts during the pre-submission activities who may participate in the subsequent Evaluation or Marketing Procedure(s). Development is often very complex and not always straight forward. Thus, explaining the course of development to an EMA expert may facilitate the submission. Nevertheless this should not influence the contents-related assessment/evaluation. On the other hand applicants are well informed that the outcome of scientific evaluations/advices are non-binding.

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, for the same reasons as above. They can support the EMA internal discussions among the experts, explain their view and recommendations to the other assessors and so facilitate the evaluation in a contents-wise and timely manner (e.g. hints on formal aspects of submissions may help to shorten the validation period of the applications (win/win situation)).

2. 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?

Usually this is an information which is already stated on the EMA Homepage, other Authorities add a statement to their Evaluation /Assessment or announce it in addition in their Response letter.

3. 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?

In general the transparency is sufficient.

Counterquestion: What is meant by transparency? Publicity?

- i. EMA's operations:
- ii. medicine developers:

4. 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;
Could be useful, if the Applicant would get the possibility to get into direct contact with the respective EMA Assessor to e.g. ask for a 2nd/follow-up advice with the same people.
On the other hand an EMA response is interpreted as a consolidated answer of all member states, irrespectively of who is providing the answer.
 - disclosed the questions posed in scientific advice procedures;

Harmful: part of data protection.

and/or

- made public comprehensive information on the advice given.

Harmful: part of data protection.

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.

Any time after the EPAR is made public.

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

Data protection/CCI topic/Patent Law!!!! Although depending on the stage of development a medicine's developer will always see more disadvantages than advantages on that.

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

There is still a lot of interpretation possible with regard to the guidelines. How can one make sure that there is no misinterpretation if you are not allowed to ask?

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

None

How to contribute

The deadline for submitting comments is **31 January 2019**.

By e-mail: [REDACTED]

or

By letter: European Ombudsman, 1 avenue du Président Robert Schuman, CS 30403 F-67001 Strasbourg Cedex

Please clearly indicate 'Comments Ombudsman Inquiry on EMA pre-submission activities' at the start of your response.

Responses may be submitted in any of the 24 official languages of the EU. All responses will be published on the Ombudsman's website. Individuals who do not wish to have their name published, in accordance with Regulation 45/2001 on the protection of personal data⁽⁵⁾, should inform the Ombudsman.

Should you require any further information, please contact Mr Koen Roovers,
[REDACTED]