Euroopan oikeusasiamies

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

Julkinen kuuleminen - 08/10/2018

Kuuleminen on päättynyt.
Tämän asiakirjan suomenkielisen käännöksen saa pyydettäessä.

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 [Linkki] (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 [Linkki] 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.
- 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?
- 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?
- 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?
- 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?
- 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.
- What would the advantages and disadvantages be of making scientific advice, given to one medicine developer, available to all medicine developers?
- Should EMA be limited to providing scientific advice only on questions not already addressed in its clinical efficacy and safety guidelines [4] ?
- Any other suggestions on how EMA can improve its pre-submission activities? If so, please be as specific as possible.

How to contribute

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

By e-mail: EO-PresubmissionConsultation@ombudsman.europa.eu [Linkki]

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, koen.roovers@ombudsman.europa.eu

[1] See: https://www.ombudsman.europa.eu/en/cases/correspondence.faces/en/81555/html.bookmark [Linkki].

[2] For a more detailed overview of these activities, see EMA's website http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001768.jsp&mid=WC0b0

[3] See: https://www.ombudsman.europa.eu/en/cases/correspondence.faces/en/83875/html.bookmark [Linkki].

[4] An overview of EMA's clinical efficacy and safety guidelines are available here: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000085.jsp&mid=WC0b0 [Linkki].

[5] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, OJ 2001 L 8, p. 1. See also: http://www.ombudsman.europa.eu/en/resources/dataprotection/home.faces [Linkki].