

[REDACTED]

From: [REDACTED]
Sent: 28 January 2019 08:03
To: EO-PresubmissionConsultation
Cc: BEUC – Health
Subject: BEUC Comments Ombudsman Inquiry on EMA pre-submission activities
Attachments: BEUC comments to EO inquiry (OI.7.2017.KR) EMA pre-submission activities.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Sir, dear Madam,

Please find attached BEUC - The European Consumer Organisation's comments to the European Ombudsman's strategic inquiry (OI/7/2017/KR) into pre-submission activities organised by the EMA.

We trust you will find our comments useful, and remain at your disposal for any follow up questions or clarifications.

Kind regards,

Pelle Moos, PhD
Team Leader, Safety and Health



Rue d'Arlon 80
B-1040 Brussels
Tel. +32(0)2 789 24 05
Mob. +32(0) [REDACTED]
[REDACTED]

www.beuc.eu



The Consumer Voice in Europe

[Consult our entry in the EC register for interest representatives](#)

Think before you print

BEUC comments to

The European Ombudsman's strategic inquiry (OI/7/2017/KR) into pre-submission activities organised by EMA

BEUC, The European Consumer Organisation welcomes the opportunity to comment on the European Ombudsman's strategic inquiry (OI/7/2017/KR) into pre-submission activities organised by the European Medicines Agency (EMA).

Interactions between the EMA and medicine developers in the development phase of a medicinal product offer opportunities for medicine developers to obtain procedural advice and guidance for developing their medicine. As such, **these pre-submission activities, including in-person meetings, can facilitate the development and availability of high-quality, effective and safe medicines to the benefit of patients and consumers.** Pre-submission activities can moreover be particularly valuable for non-for-profit bodies that have fewer resources and limited experience with the marketing authorisation process.

As correctly [observed](#) by Ombudsman, such activities may nonetheless pose a risk that the EMA's eventual decision on granting marketing authorisation is influenced by the pre-submission exchanges between the Agency and medicine developers. This practice may in parallel also contribute to a public perception of bias in the Agency's assessment of marketing authorisation applications as a result of the relationships developed between EMA staff and medicine developers in the course of these activities.

It is imperative that the EMA carefully manages these risks. BEUC acknowledges the Agency's efforts in this respect, including the Agency's policy for managing conflict of interests and its efforts to ensure a rigorous and independent process for evaluation of medicines.

We nonetheless encourage the EMA to further strengthen its safeguards to better manage any potential risks, including in particular that the Agency improves its communication and level of transparency surrounding these pre-submission activities.

The EMA should for example strive to ensure a clearer separation of roles in the scientific evaluation process: where an expert provides pre-submission advice to a medicine developer that expert should not take part in the further assessment of the medicinal product, including the drafting of the opinion evaluating the developers' product. **A clear separation of roles will contribute to reassure the public that the final assessments are based only on scientific evidence and not influenced by the relationship, and expectations, developed between the developer and the expert during their pre-submission interactions.** Where this separation of roles cannot be achieved, *i.e.* where the complexity of a dossier makes it impossible to identify two different experts, the EMA should ensure that the justification for this 'double' role is transparent and communicate this to the public.

To increase transparency, **the EMA should also systematically publish on its website minutes and other material documenting its pre-submission exchanges with a medicine developer once a medicinal product has been approved.** This would allow better scrutiny – and facilitate public acceptance – of the Agency's pre-submission activities.

It is further crucial that the EMA improves transparency on those situations where advice is *not* followed by a developer, including the reasons given by the developer and the consequences for the subsequent development process and/or marketing authorisation procedure.

To manage the risks identified by the Ombudsman, the EMA should further seek to limit its pre-submission activities to those that are strictly necessary, also with a view to ensure efficient use of the Agency's limited resources. This should moreover include a commitment from the EMA to continuously assess and evaluate the extent to which its pre-submission activities in fact contribute to the development and availability of high-quality, effective and safe medicines.

The EMA for example already makes different guidelines for the marketing authorisation process available on its website. If a developer has questions with regard to topics covered in guidelines, the EMA should in a first stage inform the developer about the existence of these guidelines. This will in some cases be sufficient, and an in-person meeting might not be necessary. Other questions may simply be handled by e-mail.

We finally encourage the EMA to provide a better basis for assessing the 'actual' benefits for consumers and patients of its pre-submission activities. [According to the EMA](#), pre-submission activities entail a number of benefits. While we do not dispute these potential benefits, we would however expect an in-depth evaluation of the Agency's pre-submission activities, including with regard to the efficiency of EMA's activities, for instance concerning the following questions:

- How many pre-submission activities concern questions for which Agency guidelines already exist? For these cases, why was advice deemed necessary, *e.g.* because some topics are not adequately covered in the guidelines or because the guidelines do not address certain topics with sufficient clarity. Addressing these types of questions would help the Agency assess the need to either extend or clarify its existing guidelines.
- In how many cases is the advice followed by the developer? If advice is not followed, what were the reasons for this? What were the consequences for the subsequent development process and/or marketing authorisation procedure?
- How do the EMA's pre-submission activities contribute to the development of safe and effective medicines? A growing number of medicines seem to come to the market for which less robust data is available. How do pre-submission activities contribute to the availability of robust and useful data, while also minimising the number of unnecessary clinical trials?

ENDS