

[REDACTED]

From: [REDACTED]
Sent: 16 January 2019 16:00
To: EO-PresubmissionConsultation
Subject: RE: European Ombudsman invitation to comment: inquiry into EMA's pre-submission activities - deadline: 31 January 2019
Attachments: Network of Primary Health Care to European Medicines Agency feedback to EMA_final draft.pdf

Dear European Ombudsman,
Please find attached the comments of the European Forum for Primary Care on the public consultation on how the European Medicines Agency engages with medicine developers before they apply for authorisations to market their medicines in the EU.
It has been endorsed by our membership after preparation by a special working group.
Best wishes,

Diederik Aarendonk
Forum Coördinator
European Forum for Primary Care (EFPC)
Address: Otterstraat 118 - 124, 3513 CR Utrecht, The Netherlands
e-mail [REDACTED]
Web-site: <http://www.euprimarycare.org/>
Mob: +31 [REDACTED]
Fax: +31 30 27 29 729
Skype: [REDACTED]
Twitter: www.twitter.com/PrimaryCare4um



europaean forum for primary care

Van: StakeholdersDB [REDACTED]

Verzonden: woensdag 10 oktober 2018 18:47

Aan: StakeholdersDB

Onderwerp: European Ombudsman invitation to comment: inquiry into EMA's pre-submission activities - deadline: 31 January 2019



Dear eligible organisations,

We would like to inform you of a [public consultation](#) from the European Ombudsman on how the European Medicines Agency engages with medicine developers before they apply for authorisations to market their medicines in the EU.

This public consultation is part of an [inquiry](#) conducted by the European Ombudsman and aims to elicit information, views and concerns of all stakeholder groups with an interest in the EMA “pre-submission activities”. Respondents are invited to take part in the consultation by sending their comments by email at [REDACTED]

[REDACTED] or letter at European Ombudsman, 1 avenue du Président Robert Schuman, CS 30403 F-67001 Strasbourg Cedex.

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 should inform the Ombudsman.

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

Should you require any further information, please contact directly Mr Koen Roovers at

[REDACTED]

Thank you very much for your interest and participation.

Kind regards,

Nathalie Macle

Public Engagement Department

Stakeholders and Communication Division

European Medicines Agency

30 Churchill Place | Canary Wharf | London E14 5EU | United Kingdom

[REDACTED]

Follow us:



This e-mail has been scanned for all known viruses by European Medicines Agency.

This message contains information that may be privileged or confidential and is the property of Nivel. It is intended exclusively for the person to whom it is addressed. If you are not the intended recipient you are not authorized to use this message or any part thereof. If you receive this message in error please notify the sender immediately and delete all copies of this message. Nivel rules out any and every liability resulting from any electronic transmission. No rights may be derived from the contents of this e-mail message.

Network of Primary Health Care to European Medicines Agency (EMA) - EFPC Working Group

Chair Walter Marrocco
Via Eliano 36
00036 Palestrina (RM)

Co-chair Pieter van den Hombergh
Kolhornseweg 67
1213 RS Hilversum
Home +31(0)35-
E-mail



In close collaboration with members of the working group:

Utrecht, 16/1/2019

Answers to a public consultation from the European Ombudsman on how the European Medicines Agency engages with medicine developers before they apply for authorisations to market their medicines in the EU.

Questions:

- 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?**

The question is an answer in itself. The question suggests that there are justified doubts that EMA staff members and experts may have certain interests or just may be opined on a drug. So to prevent doubt on their neutral and objective opinion it should be a standard policy to withdraw, when conflict of interest is suspected. Staff and experts should have transparent well maintained public accounts on their appropriate activities and interests.

It is different in the case of a possible conflict of interest for an EMA evaluator who has directly participated in the "in vitro" or subsequent "in vivo" phase of production compared to the production of a recommendation regarding the clinical development of a drug. The latter, in fact, despite being a performance aimed at a possible industrial use, is purely of an intellectual nature and does not have the operational and concrete nature of an ongoing research that, in the event of success, may lead to the use of patent protection.

The current legislation on conflict of interests is exhaustive, providing the obligation of abstention from the evaluation and assessment of evaluators involved in the development of the drug.

- 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?**

Office address
Otterstraat 118 – 124
3513 CR, Utrecht
The Netherlands

Telephone
+31 (0)
Fax
+31 302 729 729

Internet
www.euprimarycare.org
E-mail

The point of reference for the assessment activity is scientific evidence. Correct information from national experts, who were consulted at the national level can be useful for a better evaluation of the drug. The variation between countries in assessment is a valuable source of information.

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 authorization?

If every staff member or expert is transparent on their activities and on their gratifications for their scientific activities or other participation concerning a drug, it will then be clear to the public what their involvement is. EMA still has a responsibility to check this information before asking experts for advice and be aware of the bias caused by being opined on matters.

The scientific advice activity should preferably be carried out by a third party or, alternatively, by professional EMA employees experienced in the evaluation and with no ties to the pharmaceutical industry or lobby. The third party, which therefore can also be an articulation of the same European Agency, should be composed of personnel dedicated solely to the pre-submission activities with periodic updating and comparison meetings. Guidelines to ensure this could be useful.

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?

The considerable participation and contribution of the Pharmaceutical industry in EMA and the enormous interests and threats surrounding the approval of drugs and the information leading to approval, all these demand considerable scrutiny to maintain trust in EMA.

In case this greater transparency would affect the medicine development negatively this should be seen as unavoidable collateral damage and accepted as such by both parties, EMA and industry.

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.

The culture of EMA should be of utmost transparency because any biased expert advice harms the interest of the patient. So disclosure “yes” but up to a point. People may need

Office address
Otterstraat 118 – 124
3513 CR, Utrecht
The Netherlands

Telephone
+31 (0) [REDACTED]
Fax
+31 302 729 729

Internet
www.euprimarycare.org
E-mail
[REDACTED]

protection. But any contact with Pharma, their requests and lobby should be transparent, attached to the specific drug file and open for comment.

In summary the transparency is an added value of the regulatory processes and therefore, the publication of the names of officials and experts involved in the procedures, disclosing the questions asked in the scientific advisory procedures and / or disclosing information on the advice provided are, in general, positive initiatives.

However, it is a different problem to understand at what point the above disclosable information can be advertised, to avoid any possible interference. Probably the best time to make such news public is at the end of the activities (during which the proposing companies can provide the necessary clarifications upon request of the Offices) before these investigations are submitted to the CHMP's attention .

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

Sensitive information or information that is protected because of the risk of being copied, should be handled carefully. Yet, as in the answer to question 5, EMA advice is open to the public and thus Pharma should be warned about what will be disclosed.

7. Should EMA be limited to providing scientific advice only on questions not already addressed in its clinical efficacy and safety guidelines^[4]?

IF EMA is having a role in the protection of the European citizen concerning drug use, their task should not only be scrutinizing drugs for their efficacy and safety, but also the context of the drug dispensing. That includes also recommendations and guidelines on the daily management and emission of drugs, the marketing and availability, all in the interest of the patient and their safety.

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

This requires detailed knowledge of the pre-submission activities. We may not be knowledgeable enough for comment. But we see a much wider and extensive role for EMA. An example may help. Concerning AMR it is not only the safety of the drug that is relevant, but also the context of its use. Guidelines on AB prescription in our opinion should therefore encompass for example:

1. AB should only be prescribed by or prescribed under the supervision of doctors, who take responsibility for the indication.
2. Doctors should have point of care testing facilities to do CRP or other tests to improve the clinical indication and necessity of the prescription.
3. Patient information on AB approved by the scientific societies/ associations of Family Medicine (WONCA) should accompany any dispensing of AB.

Such guidelines on the context are now left to the professionals and national organizations responsible for drug dispensing, but they may be helped by a European guideline from EMA.

This example is incomplete and only concerns AB-use, but it hopes to clarify what EFPC expects from EMA. EMA could e.g. also be very specific on the evidence needed for approval. For example **research from seeding trials, research organized by the**

Office address
Otterstraat 118 – 124
3513 CR, Utrecht
The Netherlands

Telephone
+31 (0) [REDACTED]
Fax
+31 302 729 729

Internet
www.euprimarycare.org
E-mail
[REDACTED]

pharmaceutical companies etc., should not be accepted as relevant. Such policy would help to direct research money to independent third parties, like universities or independent research organizations working in Primary Care or hospitals.

Office address
Otterstraat 118 – 124
3513 CR, Utrecht
The Netherlands

Telephone
+31 (0) [REDACTED]
Fax
+31 302 729 729

Internet
www.euprimarycare.org
E-mail
[REDACTED]