[redacted]

From: [redacted]
Sent: 18 December 2018 12:39
To: EO-PresubmissionConsultation
Subject: Comments Ombudsman Inquiry on EMA pre-submission activities
Attachments: Pre-submission advice_Ombudsman consultation 2018_ECL.pdf

Dear Ms. O'Reilly,

Please see a reply to the Ombudsman inquiry on EMA pre-submission activities by the Association of European Cancer Leagues (ECL) attached.

Best Wishes,

Ms Anna Prokupkova
Policy & Project Officer
Association of European Cancer Leagues (ECL)
Chaussée de Louvain, 479, 1030 Brussels
T: +32 2 256 2000; M: [redacted]
[redacted]
ECL@europeancancerleagues.org

Association of European Cancer Leagues (ECL)
Chaussée de Louvain 479, 1030 Brussels
+32 2 256 2000; ECL@europeancancerleagues.org
www.cancer.eu

To: European Ombudsman
1 avenue du Président Robert Schuman
CS 30403 F-67001 Strasbourg Cedex
cc. EO-PresubmissionConsultation@ombudsman.europa.eu

18 December 2018

Subject: **ECL response to consultation - 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**

Dear Ms. O'Reilly,

Please see answers to you inquiry OI/7/2017/KR below.

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?

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?

Answer 1. and 2.

Due to the potential conflict of interest, EMA staff members involved in early dialogue should be different from staff members involved in scientific evaluation and granting of marketing authorisations. Giving pre-submission advice and assessing approval of a medicine made by the same company can leads to the conflict of functions, this may influence assessors' decision on the drug approval. Both staff members giving scientific advice and evaluation/MA shall have no financial or other interests in the pharmaceutical industry. Strong conflict of interest rules should apply for both staff members and national experts.

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4. Is the way in which EMA engages with medicine developers in pre-submission activities sufficiently transparent?

Answer 4.

When it comes to EMA engagement with medicine developers, is crucial to act in a transparent manner with minimal confidentiality connected to stakeholder meetings. Currently, very little information about pre-submission scientific advice is disclosed to the public. This confidential system can lead to 'regulatory capture' where waivers to existing submission guidelines can be negotiated. This system may undermine the public trust in the institution.

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; **USEFUL**
- disclosed the questions posed in scientific advice procedures; and/or **USEFUL**
- made public comprehensive information on the advice given. **USEFUL**
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.

Answer 5.

EMA should prepare publicly available guidelines and frequently asked question and answer documents – based on different types of therapies. New requests for pre-submission advice from drug developers should be limited to questions which are not yet covered in the available guidelines/Q&A documents. This would substantially reduce the number of questions to be answered and time of EMA staff members would not be wasted on redundant consultations. This would also reduce the potential for industry influence on the decisions of EMA staff members and experts. Information given during the scientific advice consultations shall be publicly available.

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

Answer 6.

Less duplication in giving scientific advice. More guidance for other researchers working on projects in the sale therapeutic areas.

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

Yes. (As per answer to question 5.)

Kind Regards,

[redacted]

Anna Prokupkova

On behalf of:
Association of European Cancer Leagues (ECL)