EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Ms Emily O'Reilly
European Ombudsman
1 avenue du Président Robert Schuman
CS 30403
F-67001 Strasbourg Cedex

21 November 2019
EMA/627113/2019
European Medicines Agency

Dear Mrs O'Reilly,

Subject: OI/7/2017/KR: European Medicines Agency's actions to address the European Ombudsman's decision on EMA's pre-submission activities

I am writing to update you on EMA's progress to address your decision of 17 July 2019 regarding EMA's pre-submission activities. You asked to be informed by 30 November 2019 of any action EMA has taken in relation to your suggestions for improvement.

Your findings and recommendations have reassured us that the work we had already initiated to improve our processes, aimed at further enhancing transparency, is going in the right direction. Following your decision, we have worked internally to address your findings and recommendations in detail. This work is based on your recognition of the value of scientific advice and its positive contribution to public health, but also on the need to reassure the public that robust and independent assessment procedures are in place at EMA from the early development of a medicine until a marketing authorisation is granted and then throughout the medicine's entire life cycle.

We acknowledge that your recommendations will significantly help in striking even further a good balance between providing the best possible scientific advice and guaranteeing the independence of the medicine assessment which takes place at a later stage, taking due consideration of expertise needs and while, most importantly, ensuring that these procedures are correctly understood and perceived by the general public.

Therefore, in addition to the set of transparency measures already initiated and recognised in your decision, we are looking at our procedures to formally introduce to the greatest extent possible the separation in prominent roles between those acting as coordinators for providing scientific advice and those subsequently involved as rapporteurs in evaluating an application for marketing of the same medicine. In particular, we will pursue a model whereby any prior prominent role as coordinator for scientific advice will be recorded and considered during the rapporteur appointment process; if exceptionally due to specific expertise needs such prior involvement is considered needed and justified

for an individual, this will be documented. In any case, the process should ensure that at least one of the two rapporteurs had no prominent role in the pre-submission activities concerning that medicine.

These measures would be introduced through the revision of our internal procedural documents for rapporteurship appointments. Furthermore, in extension of the transparency measures previously implemented, we are planning to introduce a log of scientific advice related to a particular evaluation in the medicine's EPAR by amending respective templates. Where applicable, this will include the names of the co-ordinators involved in scientific advice. As you know the EPAR is made publicly available once the medicine is granted an EU marketing authorisation.

We will inform our Management Board at its December 2019 meeting how we are planning to address your suggestions for improvement, and we will write to you again after that meeting to provide further details of the proposed actions and their implementation, which will likely happen in the first quarter of 2020 once EMA has relocated to its permanent location in Amsterdam.

I would like to thank you and your team again for the very constructive collaboration throughout the entire process, the outcome of which, I believe, will be of benefit to the EU system of medicines evaluation.

Yours sincerely,

[redacted]

Guido Rasi
Executive Director