EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Executive Director

Médiateur européen
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Dear Ms O'Reilly

Subject: Your letter of 13 May 2014

Thank you for your letter of 13 May 2014 in which you have raised concerns about a perceived change of general policy at the EMA as regards clinical trial data transparency. In the letter you have specifically asked me to provide feedback on how EMA intends to deal with requests for public access, submitted under Regulation (EC) No 1049/2001, to clinical data in the future and "*the reasons, and the legal basis, for what appears to be an important change in direction as regards EMA's approach on transparency in this area*".

As we discussed in our videoconference some months ago, I would like to dispel any doubt about the strong commitment of EMA to pursue the objective of increasing transparency with regard to the clinical information submitted to the EMA about medicinal products authorised in the EU.

I should like to recall that the EMA still intends to adopt its new draft policy on 'proactive publication of clinical study reports' as a measure to even further increase transparency on authorised medicinal products, in accordance with Article 80 of Regulation (EC) No 726/2004. This policy is, by no means, intended to limit the exercise of the EU citizens' right to have access to documents under Regulation (EC) No 1049/2001, but it rather complements and extends the availability to the public of clinical data by creating a simple mechanism to systematically publish key clinical information as soon as the regulatory procedure is concluded.

Our new policy will ensure that all clinical study reports submitted to EMA after its entry into force in order to support an application for a centralised marketing authorisation, even those pertaining to trials performed outside the EU, will be made public once a final decision on the application has been taken. This will result in an unprecedented level of transparency, providing online both the outcome of the scientific assessment as well as the clinical trial information on which such assessment is based, immediately after the procedure has been finalised. The general public will immediately have the possibility to understand the EMA rationale for its assessments.

This new transparency measure, as also explained to you during our recent videoconference, is different in both scope and legal basis from Regulation (EC) No 1049/2001, which is applicable to EMA documents via Article 73 of Regulation (EC) No 726/2004.

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As clearly stated in our first draft submitted for consultation in June 2013, the new policy will not apply to clinical study reports submitted to the EMA prior to its entry into force (estimated between October 2014 and January 2015), the so-called 'legacy' documents, nor can it apply to clinical study reports on non-centrally authorised medicinal products which are outside of EMA's remit. Of course, for such 'legacy' documents, Regulation (EC) 1049/2001 will continue to apply.

As to the modalities to which requestors will have access to the documents under the new policy, the adoption of the 'Terms of Use' and the 'screen-only-mode' was deemed a reasonable compromise among the interests of all stakeholders and institutions we consulted, having in mind the Commission's clear message that we would also have to assure compliance with national and international obligations that all European institutions have to comply with, including but not limited to the TRIPS Agreements and copyright laws.

The new clinical trial regulation will provide a considerable increase in transparency of clinical trials conducted in the EU and of their results. It also recognises the concept of possible commercial confidentiality in the context of the EU Database, whilst confirming that the data included in clinical study reports is not in general commercially confidential. This is also the view of the Agency and is reflected in our new draft policy.

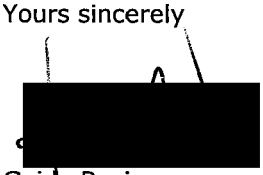
The new measure will be user-friendly, allowing the reports to be continuously available to the public and searchable so that users can consult them at will without the need for a specific request for access to EMA. Finally, there is no intention on our side to limit the academics' freedom to review the data, or refer to the reports in publications or communications with colleagues/peers.

Our new policy will make all the above mentioned clinical study reports publicly available in a systematic way. As to the relationship between this new measure and the provisions of Regulation (EC) No 1049/2001, this aspect will be considered within the framework of our on-going discussions with the European Commission. There is no intention to introduce any hurdle to the implementation of Regulation (EC) No 1049/2001.

In conclusion, I can reassure you that there is absolutely no change in direction.

We remain available to provide you with further information or discuss any issue regarding the above.

Yours sincerely



Guido Rasi

Executive Director