EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency

Dear Dr Lane

Subject: EMA draft policy on proactive publication of and access to clinical trial data

Thank you for your letter of 2 June 2014 concerning the draft policy on proactive publication of and access to clinical trial data.

I very much welcome the constructive contributions we received from AllTrials supporters and I can assure you that the support we received has had an important impact on the draft policy that will be presented to the Agency's Management Board next week.

You raise a number of concerns in your letter and I will try to address each in turn, but first let me be clear that the Agency maintains its commitment to increasing transparency of clinical trial data and that the vast majority of data within clinical study reports are not commercially confidential information, and this forms the starting point for our draft policy.

1. On-screen access to clinical study reports

It is important to understand that the Agency does not have law-making powers, and that the draft policy has been shaped in the absence of any specific legal provision mandating the EMA to publish documents submitted to the Agency by third parties, as is the case for some other EU agencies. Consequently a balanced approach was needed taking into account different stakeholders' competing interests, within the limitations of the current legal framework.

While we have overcome many of the objections raised by stakeholders, there remain some that we have had to accept as real issues. It is as a consequence of these issues that we have found it necessary, in the context of this draft policy, to propose a managed publication process that includes that clinical data will be available in an on-screen only mode. This compromise allows access to clinical trial data, but at the same time aims to discourage unfair commercial use of the data.

The issue of the usefulness of on-screen access to data was discussed with academics during the whole consultation process and we do not accept that this is a superficial or useless gesture. The policy provides access to clinical trial data to all stakeholders, not just to academics, and the fact that it will be available as soon as a medicinal product has been through the decision-taking process, searchable and continuously available to whosoever wants to view them is a significant step forward in terms of transparency.

2. Redaction principles

I do not agree that the principles are either ambiguous or will permit excessive redaction. There will be no difference in the understanding of commercially confidential information and how it is applied to documents held by us that are requested through 'access to documents' or that will be proactively published by the Agency.

The starting point of the redaction principles is that clinical study reports do not in general contain commercially confidential information. The draft principles therefore contain just a small number of exceptions where the Agency will consider duly-justified requests from pharmaceutical companies. In all instances, the decision on what is and is not redacted is controlled by the Agency.

3. Redacting clinical study reports

One of the reasons for producing redaction principles is to ensure a clear and transparent understanding on the part of applicants, and indeed all stakeholders, of what we are prepared to consider. Under the draft policy, applicants will be asked to submit clinical study reports in view of their publication. If they believe that some elements should be redacted, then they may propose this.

As mentioned above, each and every proposed redaction will need to be justified by the applicant and the final decision on what is and is not redacted lies with the Agency. The extent of redaction will be clearly visible as always. As a public body, it is of course open to any stakeholder to challenge any instance in which redaction inconsistent with the redaction principles is suspected.

4. Terms of use

The Agency believes that the proposed terms of use should be seen from an alternative perspective. The proposed terms clarify that researchers, academics and other stakeholders are entitled to use the data for information, research, academic and other legitimate purposes. As such, the EMA recognises the value of such uses.

The terms of use seek to discourage unfair commercial use of the data, for example using the data to support a marketing authorisation application in a non-EU jurisdiction. This does not impact on legitimate academics or researchers.

The proposed terms of use under the policy do not create any new legal restrictions on academics and researchers, but rather increase transparency and their access to clinical trial data.

I believe that the actions of the Agency, backed up with the support of organisations like yours, have changed the debate over access to clinical trial data. There has been a clear change of direction, which will be reinforced with the clear legal framework that the clinical trials regulation brings. The proposed EMA policy will provide a 'bridge' until the regulation comes into force sometime after May 2016.

We have moved stakeholders closer together to a position that would not otherwise have been reached. Many stakeholders have shifted their position out of their comfort zone, in particular the pharmaceutical industry. I very much welcome this shift.

Yours sincerely

Guido Rasi
Executive Director