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European Medicines Agency set to publish clinical-trial reports

EMA promises increased transparency but will not release anonymized data on individual patients.

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The European Medicines Agency (EMA) has agreed in principle to publish clinical-trials reports on any drug that receives marketing approval in the European Union — and to do so proactively, without the need for formal freedom-of-information request.

The EMA is the first major drug regulatory agency to take such a step, which it sees as a significant move towards increasing transparency in the processes involved in approving medicines.

The agency made its announcement in a statement on 12 June. It said that it will publish the details of the new policy in mid-July, and that the policy will become effective on 1 October.

The policy will make it easier for academics to carry out research for non-commercial purposes — for example, to reanalyse data from a clinical trial or compare data from different trials to work out the best treatment for a particular disease. “That’s a good thing,” says Síle Lane from the London-based lobby group Sense About Science, which has pressed hard for transparency in a campaign called Alltrials.

But she says that her group will not relax its vigilance until the detailed policy is published. “We still don’t know how the EMA will monitor and audit its redaction policy, in which some information from clinical-trial reports can be withheld,” she explains. “The EMA has been very vague about this.”

Privacy concerns

The policy is the result of a long consultation process launched by the EMA in May 2013 following the publication of its first draft policy. This provoked a vociferous response from scientists and patient groups, who favour publication of clinical-trial results in full, and drug companies, which remain jittery about the possibility of losing out to competitors by sharing data they generated for their own purposes. Even drug companies outside Europe would have to agree to their clinical-trial reports being published by the EMA if they want their products to be marketed in the European Union.

Last October, EMA executive director Guido Rasi and his colleagues published an article in the *New England Journal of Medicine*

arguing that appropriately managed access to clinical-trial data — including data on individual patients whose identity is protected — would help to increase the efficiency and cost-effectiveness of drug development, improve the ability to compare the effectiveness of different therapies and reduce duplication of effort.

But, because of concerns over privacy, the agency is restricting the scope of its new policy to clinical-trial reports that do not include data on individual patients: Sense About Science says secure anonymization cannot yet be guaranteed. EMA spokeswoman Monika Benstetter says that, in the long run, the agency still plans to broaden the policy to include all patient data, “but there has to be a stepwise implementation”.

Tensions between stake-holders increased sharply last month when the EMA circulated a second, post-consultation, draft policy. It proposed that data be made available in a 'read-only' mode so that they could not be downloaded or printed, apparently in deference to industry concerns about unfair competition. But an outcry from the pro-transparency side prompted the agency to backtrack on this and to allow the information to be downloaded, saved or printed for academic and non-commercial research purposes.

The second draft also referred to a “redaction policy", under which some information might be withheld. Alltrials fears that this policy would give drug companies too much latitude to hold back important data, Lane says. But Benstetter says that the detailed policy, yet to be thrashed out, will specify the criteria on which requests from industry for redaction would be considered, and that the decision-making process in each case will be made transparent.

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