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NEWS

Drug company drops case after EMA agrees to redactions in some documents to be published

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AbbVie, one of two US drug companies that took legal action against the European Medicines Agency to try to stop it releasing previously secret clinical trial data, has dropped its lawsuits after agreeing that the documents may be disclosed with redactions to protect commercially sensitive information.

The London based drug regulator began a transparency initiative in 2010, resolving to disclose, on request, clinical study reports on drugs that had gone through the approval process. The policy saw it release nearly two million pages of data without legal challenge, but the process was put on hold after the two US companies obtained an interim injunction from the general court of the European Union last April, pending a full hearing.[1]

In November 2013 the agency won an appeal to the European Court of Justice, which sent the case back to the general court with a stipulation that the companies must prove that serious and irreparable harm would result from publishing the data.

Campaigners for openness, including the *BMJ*, say that researchers need access to clinical study reports, the detailed documents normally provided as part of the regulatory process, to properly evaluate the safety and effectiveness of drugs. Drug companies, on the other hand, say that they need to protect commercially confidential information from disclosure to competitors. One of AbbVie's two lawsuits concerned adalimumab (Humira), its blockbuster treatment for rheumatoid arthritis.

The agency said that the "very limited redactions" now proposed by AbbVie were consistent with its redaction policy and had "no significant impact" on the readability of the reports. The other case, brought by the biotechnology company InterMune, continues.

AbbVie's decision was announced a day after members of the European Parliament voted overwhelmingly for a new law, coming into force in 2016, that will require all future clinical trials in Europe to be registered and their results published on a public database. The law will include a requirement for clinical study reports to be made publicly available.[2]

Ilaria Passarani, of the EU consumer organisation BEUC, which intervened in the case, said, "We don't know what are the reasons that led AbbVie to withdraw its applications in the cases filed against the EMA, but we hope InterMune will do the same. The new clinical trials regulation adopted by a large majority in the European Parliament and more generally the public attention to the issue of transparency of clinical trials over the last year clearly show that the time of secrecy is over."

The European Medicines Agency is working towards a policy of proactively publishing clinical trial data—not just providing data on request—once marketing authorisation for a medicine has been granted. Its board is expected to endorse the policy in June.[3]

1 Dyer C. European drug agency's attempts to improve transparency stalled by legal action from two US drug companies. *BMJ* 2013;346:f3588.
2 Kmietowicz Z. Transparency campaigners welcome new rules for clinical trials in Europe. *BMJ* 2014;348:g2579.
3 European Medicines Agency. Release of data from clinical trials. 2014. www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000555.jsp&mid=WC0b01ac0580607bfa.

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