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EDITORIALS

Redacted policy on sharing drug trial data in Europe

The European Medicines Agency gets cold feet at the last minute

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In early April, the drug company AbbVie dropped its lawsuit against the European Medicines Agency (EMA). This lawsuit, along with another case mounted by InterMune, delayed the agency's plans to release previously hidden clinical trial data about drugs considered for marketing authorisation.[1] It also posed such a threat to public health that *The BMJ* and BMA were jointly granted permission to intervene at the General Court of the European Union.[2 3] AbbVie withdrew its case after the agency agreed to allow redaction of some clinical trial information deemed to be commercially sensitive.[4] Now, shortly before the EMA's policy is to be set in stone, we know the extent of that compromise.

Documents shared with participants at a recent EMA workshop suggest that the agency is backtracking both on its principle of public access to clinical trial data "in an analysable format" and its assertion that "in general, clinical trial data cannot be considered commercially confidential information (CCI)" because "the interests of public health outweigh considerations of CCI."[1] Instead, clinical study reports (CSRs) and other detailed information will be available only to registered users, and only through "controlled access" and in a "view on screen only" mode. Furthermore, some information—even details of study designs, statistical analyses, and study results—could be redacted if study sponsors deem it to be commercially confidential.[5]

There are just a few days left to voice concerns about this—the agency's management board meets on 12 June to finalise the policy. The authors of the first ever Cochrane reviews using clinical study reports are aghast.[6 7] They could not have properly reviewed and cross checked the thousands of pages from Roche and GlaxoSmithKline if those companies had imposed the conditions that the EMA is now proposing ("the User is not permitted to download, save, edit, photograph print, distribute or transfer the Information").[8 9] Nor could these Cochrane reviewers have deposited the full clinical study reports in the public Dryad repository for others to scrutinise and reanalyse.[10] In a *BMJ* rapid response, Beate Wieseler and colleagues from the German Institute for Quality and Efficiency in Health Care warn that "data we cannot work with are still hidden—even if we see them on a screen" and are worried that CSR redaction will scupper comprehensive health technology assessment.[11]

The European ombudsman, Emily O'Reilly, wrote on 13 May to the EMA questioning the legal basis of the revised policy. She wanted to know how it squares with the fundamental right of public access to EU documents, with no requirement to give reasons or to explain subsequent use of the information.[12] In reply, the EMA's executive director, Guido Rasi, rebutted that concern, but conceded that the revised access policy was deemed a reasonable compromise among all the interested parties. He also said that it was in line with "the commission's clear message that we would also have to assure compliance with national and international obligations . . . including but not limited to the TRIPS [Trade Related Aspects of Intellectual Property Rights] agreements and copyright laws."[13]

That sounds pretty final. It's important to remember, however, that, despite setbacks, great strides have been made in the past three years towards clinical trial transparency. Even with this watered down policy, the EMA will be making visible—probably from next year—vast quantities of new regulatory information submitted by study sponsors about randomised controlled trials of drugs, including overviews, summaries, clinical study reports, and anonymised patient level data. It will also provide information on "other types of interventional or observational clinical research methodologies, such as large simple trials, cohort studies, case control studies, and registry data." And, from 2016, there will be a European clinical trials registry that will give summary results plus a lay summary within one year of study completion and, where available, CSRs (with redactions, perhaps).

Yet a great deal of information on the benefits and harms of drugs in current use remains hidden from policymakers, clinicians, and patients. If the new European policies for "proactive" disclosure close the EMA window that has been allowing ad hoc "retroactive" access to older CSRs and data, we will all be even more in the dark when making decisions about current treatments.[14] That is why AllTrials continues to campaign for all clinical trials to be registered and all results reported.[15] The research, advocacy, haggling, and politics must go on.

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applied to the European General Court to intervene in the case of AbbVie *v* EMA. *The BMJ* cofounded the AllTrials campaign with Bad Science, the Centre for Evidence-based Medicine, the Cochrane Collaboration, the James Lind Initiative, PLOS, and Sense About Science.

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