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NEWS

EMA scales back transparency initiatives because of workload

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The European Medicines Agency has scaled back its landmark clinical trial data policies, the drug regulator has announced.

Policy 0043, which granted public access to documents in the regulators' archives, including clinical trial data, is now limited to EU citizens only, and work related to publishing new data packages under its clinical data publication policy (policy 0070) has been suspended. The agency said that the cutbacks were a response to an "excessive workload"[1] and were part of its planning amid substantial staff loss as it prepared for Brexit.[2]

Transparency advocates have described it as a blow to critical transparency efforts with potential patient safety ramifications.

"Deaths and other serious harms are much under-reported in published trials, and we therefore need unhindered and immediate access to clinical study reports and other relevant documentation that the EMA holds," said Peter Gøtzsche, director of the Nordic Cochrane Centre. Gøtzsche is credited with "opening up" the EMA after his successful appeal to the European ombudsman over a denied request for data a decade ago.[3] He said that the EMA's announcements were "very unfortunate."

Kamal Mahtani, a GP and deputy director of the University of Oxford's Centre for Evidence Based Medicine, said: "This is very worrying. The Brexit induced scale back and suspension of activities by the EMA is a major threat to open and transparent access to important clinical data. Without this data, it may not be fully possible to independently appraise, synthesise, and implement important information related to the use of medicines in the UK. How can we be sure that UK based members of the public will not be harmed by this decision post-Brexit?"

Policy 0043 is a freedom of information policy implemented in 2010 that was adopted after a ruling of maladministration against the agency.[3] Millions of pages have been released under the policy to requesters from around the world. In releasing the content of actual dossiers of marketing authorisation applications, the EMA became the first regulator in the world to grant public access to clinical study reports. Such reports have served as the basis for systematic reviews, trial reanalyses, and studies of reporting bias, such as the Cochrane review of neuraminidase inhibitors.[4-8]

Unlike other transparency mechanisms such as ClinicalStudyDataRequest.com, a clinical trial data sharing platform spearheaded by GlaxoSmithKline, the EMA's policy was unique in that it was open to all, irrespective of citizenship, credentials, or even rationale. Requesters were not required to provide reasons for their request.[9]

The EMA executive board agreed on 15 June to begin processing requests submitted by only EU citizens and natural or legal persons residing or having their registered office in an EU member state. The EMA said in a statement that "this step has become necessary to protect EMA's ability to fulfil its legal responsibilities," which are only to those in the EU.

How requests originating from the United Kingdom will be handled after Brexit remains unclear, EMA spokesperson Henry Fitt said in a statement, and depends on whether the UK remains part of the EMA.

Requests under the EMA's access to documents policy have steadily increased, and with it staff has increased from 5 to 12.5 full time equivalents who handle between 110 and 120 requests at a time.[9 10] Over this period, the drug industry has been the largest requester of documents,[11 12] submitting 379 of the 865 requests in 2017.[13] Academia and research institutes have made substantial use of the policy as well, submitting fewer but often larger requests—170 865 pages of the 487 092 total pages released in 2017.[13]

In a statement, the agency cited many factors that have increased its workload, from requests that were "very broad in scope" or involved people who were "unfamiliar with the process" and thus required extensive communication to the processing of voluminous documents requiring considerable time for redaction and consultation.

EMA's second major data transparency policy—policy 0070—was another world first. Under it, the agency has been proactively publishing clinical data submitted by drug companies as part of marketing authorisation applications. Since its launch in October 2016, over 3000 documents totalling more than 1.3 million pages have been published on the agency's website (https://clinicaldata.ema.europa.eu/), which allows for universal viewing and downloads for non-commercial research purposes.[14]

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Although non-EU citizens are not being turned away from policy 0070, and the website will continue to operate, the suspension of processing of new data packages that went into effect on 1 August will affect all users.

In a report on its website, the agency wrote that it "will do its utmost to resume the proactive publication of clinical data to the level outlined at the start of the policy once the relocation [to Amsterdam in March 2019] is complete."[14]

But the same is not true of the policy that is no longer available to those outside the EU. "This is not a temporary measure and we are not currently planning on revisiting this decision," the EMA said.

Gøtzsche said that prescription drugs have become a leading cause of death and called on parliament to intervene. "The EU parliament needs to tell the EMA that it should prioritise its work differently, to protect the patients better than it currently does."

Competing interests: I have coauthored papers with Gøtzsche and Mahtani, quoted in this article, am coauthor of the mentioned Cochrane review, and have used both of EMA's policies.

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