

Comments on draft revision of EudraVigilance access policy for medicines for human use from the AllTrials campaign

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This is a response to the consultation on the “Draft revision of EudraVigilance access policy for medicines for human use” from the AllTrials campaign.

The AllTrials campaign was launched in January 2013 to call for all clinical trials to be registered and results reported. It is an initiative of Bad Science, BMJ, Centre for Evidence-based Medicine, Cochrane Collaboration, James Lind Initiative, PLOS and Sense About Science. It is supported by nearly 80,000 people and over 500 organisations including regulators; medical schools and universities; medical bodies and Royal Colleges; research funders and more than 200 patient groups from across the world.

Principles of access for research organisations

We are very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations.

A. We object strongly to the following two conditions:

- *“The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.”*
- *“A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.”*

These principles would seem to give the EMA the right to suppress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data.

Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny.

Consequently, what is proposed is unworkable and these two principles should be removed.

B. We are also concerned by the following principle:

- *“An ad-hoc EMA panel will review requests for research access to data based on a research request. The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.”*

The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls.

C. Finally, we believe the following principle could be strengthened to require research organisations to submit the results of their research for publication:

- *“Those given access to EudraVigilance data should make appropriate efforts to publish their research.”*

There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community.

Proactive publication of ICSR data

We support the EMA’s aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers.

Restrictions on access

There is disparity in the access provided to the different stakeholder groups listed in Table 1 “Number of ICH E2B(R3) ICSR data elements” (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects.

We are concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments.

Additional question

1. As regards stakeholder group II “Healthcare professionals and the public” would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection?

Yes. We must ensure that healthcare professionals and the public have useful access to up-to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.

Signed by

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