Broad definition of 'commercially confidential' endangers transparency

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In April 2014 the EU Parliament and Council commissioned the European Medicines Agency (EMA) to establish a publicly accessible database containing comprehensive data from clinical studies. The deadline for comments on the transparency aspect of the database specifications was the 18th of February.

The German Institute for Quality and Efficiency in Health Care (IQWiG), which has long been accompanying EMA on its path to more transparency, also submitted comments. These comments have now been published on the IQWiG website.

Study data are not commercially confidential

In 2014 the EU Parliament made clear that clinical study data generally should not be considered commercially confidential and cannot readily be exempt from publication in the EU study database. Exceptions must be well justified, and redactions or even the non-publication of whole documents must not interfere with overriding public interests, such as the health of patients. The precondition for a database fulfilling these requirements is a precise and narrow definition of "commercially confidential information". IQWiG researchers have reviewed the comprehensive EMA proposal and found a very broad definition in several sections of the document.

Beate Wieseler, Head of IQWiG's Drug Assessment Department,

explains: "The decision on which data remain confidential is thus more or less left up to the study sponsors. This contradicts the spirit of the EU regulation and the aim of achieving transparency in clinical research. In addition, the non-publication or long delays in the publication of study results and methods would not be compatible with the ethical principles of studies in human beings, as, for example, stipulated in the Declaration of Helsinki."

Interests of patients override interests of specific groups

IQWiG's point of view is that neither the results nor the methods of clinical studies are commercially confidential information. Interests of specific groups must be subordinate to the public interest in the swift and complete publication of study data and documents. This public interest especially refers to the desire of patients for a thorough assessment of their treatment options.

Some sections of the EMA proposal do not do justice to this change in paradigm outlined in the new EU regulation. EMA has even left a loophole for publicly funded studies: If, for example, the publication of study data could affect the acquisition of further third-party funds, the study sponsors would be allowed to redact information. The planned publication of a study in a scientific journal would also suffice to withhold data. "Especially this example illustrates the imbalance of EMA's proposal", says Wieseler. "In our opinion, a research group's wish to publish an article that might not even be freely accessible must give way to the public interest."

Her conclusion: "The non-publication of certain information must be the absolute exception. Those wishing to redact documents must in each case provide a precise justification to EMA, and EMA must

meticulously evaluate these justifications."

More information: www.iqwig.de/download/15-02-18 … EMA-641479-2014_.pdf

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