Draft advice to the European Medicines Agency from the clinical trial advisory group on legal aspects

Meeting 2 SUMMARY OVERVIEW

The second virtual meeting of the Advisory Group on Legal Aspects, or Clinical Trials Data Group 5 (CTd Group 5), took place on Thursday 7 March from 2pm to 4pm UTC.

Its purpose was to discuss further on commercially confidential information (CCI) as well as on the use of clinical trial data (CTd) in third countries. It also aimed to arrive at final conclusions, or a baseline agreement, on a) commercially confidential information, b) copyright and c) legal remedies.

The participants, representing different interests (industry, patients and healthcare professionals, academia) engaged in an enriching discussion and put forward their views on CCI.

EMA recalled its commitment to implement a pro-active disclosure of CTd as of January 2014; however two diverging views emerged from the first meeting in this regard. Although no fundamental opposition to the principle of CTd disclosure is present, some participants called for setting some controls, e.g. to ensure a *bona fide* use of the information by requesters, to inquiry about the reasons for the request, etc.

The scope for this pro-active disclosure would be CTd submitted for marketing authorisation assessment, including raw data, and would include the life-cycle of the product, i.e. authorisation, supervision and other regulatory procedures. Disclosure would only take place after granting of the marketing authorisation (MA). Issues concerning the disclosure of personal data are being discussed in the CTd Group 1.

Further to these preliminary clarifications, some participants stressed their views that disclosure of CTd should be subject to certain conditions and that it should be exceptional rather than the general rule. Concern was raised as to the use that competitors can make of CTd released, yet in the case of researchers the views are more relaxed and even favourable. It was also highlighted that there is plenty of information in the public domain already, for instance EPAR, and that the information submitted to EMA is done under certain expectations and these should be respected and not affect dossiers submitted prior to a change of policy. For these reasons, prior consultation with the MA holder is the most important condition before release takes places, which will in turn allow the use of legal remedies in case of disagreement.

Other participants, on the contrary, pointed out that industry should first establish what info contained in CTd should be held as CCI, and on what grounds. The EMA would then decide on the basis of a pre-defined set of conditions, which should apply temporarily and not indefinitely.

However, a participant recalled that conditionality must not be mixed with the issue of public access. The EMA should bear the burden of proof to show that CCI is present, and the third parties should be informed with a view to trying to influence EMA's decision (rebuttable presumption). The fact that competitors can abuse the disclosed information indeed remains an issue worth exploring.

EMA recalls, in this regard, that the amount of information made public has continuously increased since the publication of EPAR. Publication of EPAR was indeed fiercely opposed as it was feared that it would hamper the industry competitiveness. But it is agreed that the nature of EPAR is different to that of documents drawn up and submitted to the EMA by MA applicants.

In this regard, it was also argued that the amount and detail of the information contained in a MA dossier would call for its treatment as CCI, as it can disclose a company's strategic and operational plans and, ultimately, its competitiveness. It was argued that the system is not designed for disclosure but solely for a technical and scientific assessment with a view to adopting a duly informed decision on the granting of a MA by the regulator.

On the use of CTd in third countries, it was alleged that regulatory data protection in certain jurisdictions such as Australia, China and Mexico would be undermined by publication of data in the EU, as this information would be used to gain a competitive advantage against the legitimate author of the information. In fact, in some countries very little information is being required by regulators to grant a MA. Moreover, poor data protection in some jurisdictions is a big issue, as well as the lack of control on how the information is being used (loss of information traceability by the author).

It was also highlighted that as a precondition to conduct clinical trials, some countries have required that there be no secondary research uses of participant data without additional permissions from national authorities, and or unless their own native citizen-scientists are included as co-authors on additional publications that have re-used participant-level data. Therefore, if the EMA were to bind pharmaceutical companies to make participant-level data available from completed clinical trials used to support MA applications, this could conflict with the conditions under which some trials were done in various non-EU jurisdictions.

It was confirmed that in certain jurisdictions like India and Bangladesh, EPAR is being relied on to file MA applications and as a proof of clinical acceptability. The question which arises is whether the same should not happen with CTd. Hence, is the use of information in third countries a justified reason to restrict access to CTd? And should a distinction between the protection against use and protection against disclosure be clearly drawn?

The question as to whether or not CTd are deemed CCI remains open and therefore the legal debate must continue. However, and albeit interlinked, the debate about the CC nature of CTd must not be confused with the overall discussion about protection from disclosure. A common place for agreement appears to be CTd disclosure to *bona fide* researchers for independent research.

As to copyright, disclosure of scientific information should not be confused with dissemination of the platform/document where that information is contained. In this regard, protection of databases should also inform the discussion.

With regard to legal remedies, it remains unclear how the EMA would implement a sound system if it is to proactively publish CTd.

In conclusion, it appears that difficulties in achieving a consensus among participants are somehow insurmountable; however this discussion exercise has been a meaningful one, enabling all participants to openly present their views, and allowing the EMA to adopt informed guidelines.

Actions

- Participants to submit to the EMA comments about the documents circulated for the 2nd meeting. Deadline: Friday 15 March.

- EMA to draw up a document with the conclusions of the two virtual meetings held and the comments submitted, which will then be circulated for further comments by the participants. This document will form the conclusions of CTd Group 5.

- No further virtual meetings will take place for CTd Group 5.