EUCOPE Position

EMA Policy on Proactive Disclosure of Clinical Trials Data

Summary

The European Medicines Agency (EMA) has announced its commitment to the proactive publication of data from clinical studies, and to giving interested parties access to full datasets. The concept of transparency in relation to research on medicinal products is welcomed in general by EUCOPE, in particular, where it serves the expansion of scientific knowledge, e.g. through bona fide research, and constitutes the basis for an educated risk-benefit advice to patients. However, the Agency has to strike the balance between an increased degree of transparency and the rights of the industry and patients to have their confidential information duly protected in order to stimulate research and development in new medicinal products.

EUCOPE therefore considers it vital that

1. EMA acknowledges that clinical trial data may contain commercially confidential information and carefully assesses document by document whether or not a piece of information must be considered commercially confidential releasing this data only after the granting of the marketing authorisation if this is justified.

2. the consultation of the marketing authorisation holder before disclosure remains mandatory not only where third parties’ request access to this information but also where the information is proactively disclosed by the Agency.

3. EMA furthermore acknowledges that the disclosure of commercially confidential information is not per se justified by an overriding public interest but that it has to be decided on a case-by-case basis under participation of the marketing authorisation holder whether the disclosure of commercially confidential data is justified by an overriding public interest.

4. no data will be disclosed before the grant of the marketing authorisation.

EMA has announced that it will ensure widest-possible access to its documents including clinical trial data not only on the basis of Freedom of Information requests but also proactively. The Agency has also declared that clinical data as such should not be considered commercially confidential information or only in exceptional cases. This has already been laid down in the HMA/EMA Guidance Document on the identification of commercially confidential information (the respective document can be found here: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/03/WC500124536.pdf). EMA expects that the proactive publication of clinical trial data comes into force on 1 January 2014.
However, whereas EMA in the past has explicitly acknowledged that unrestricted and easy access to clinical trial data might be a risk for patient confidentiality, the issue of commercial confidentiality has not been sufficiently addressed so far. The Agency has to ensure that not only information held on patients but also the commercial interests of sponsors and marketing authorisation holders (MAH) are protected. Thus, it has to refuse access where disclosure would undermine the protection of commercial interests, including intellectual property rights. Consequently, it is crucial that the Agency establishes safeguards to protect these interests before it starts making documents publicly available.

1. **Consideration of Commercially Confidential Data**

First, it is necessary that EMA acknowledges that clinical trial data has to be considered commercially confidential not only in exceptional circumstances. It needs to be borne in mind that know-how and valuable intellectual property especially regarding the manufacturing, certain technological approaches and certain data in the development of an innovative medicinal product are often part of the data submitted by the applicant for a marketing authorisation. Therefore, EUCOPE does not agree with EMA’s view outlined in the above mentioned HMA/EMA Guidance Document on the identification of commercially confidential information that clinical data as such should not be considered commercially confidential information. Also, it should be considered that the Commission only recently explicitly stated “that keeping valuable information secret is often the only or the most effective way that companies have to protect their intellectual property” (Public consultation on the protection of business and research know-how http://ec.europa.eu/internal_market/consultations/2012/trade-secrets_en.htm).

In the HMA/EMA Guidance Document on the identification of commercially confidential information and personal data within the structure of the marketing authorisation (MA) application – release of information after the granting of a marketing authorisation the Agency itself has explicitly acknowledged that commercially confidential information has to be protected and stated that commercially confidential information is considered to be any information, including know how, trade secrets and information which is not in the public domain or publicly available and where disclosure could undermine or damage the economic interest or competitive position of the proprietor of such information.

A marketing authorisation dossier includes, *inter alia*, details of manufacturing and bioanalytical methods; details of specific formulation, and information and data relating to experimental design, methodologies, and patient disease diagnosis. Disclosure of such data which is, in general, not in the public domain, would doubtlessly undermine and damage the interests of the proprietor of such information. Competitors would benefit from access to this data by avoiding the investment in own experiments. In this regard, the European Court of Justice has underlined in its decision of 6 December 2012\(^1\) that where applications for marketing authorisations in the abridged procedure are concerned, national authorities do not disclose clinical data to applicants (although they benefit from these data after the expiry of the data exclusivity period) and therefore do not prejudice its confidentiality (Case C-457/10 P, at no.152). **Obviously, the Court assumes that clinical data may contain commercially confidential information which should be protected from disclosure.**

The EU is further obliged to protect undisclosed test or other data under Article 39.3 of the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) which forms, according to the European Court of Justice an integral part of the Community legal order.\(^2\) The cited provisions read as follows:

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\(^1\) Case C-457/10 P, “Astra Zeneca”, at no.152.

\(^2\) Case C-431/05 “Merck Genéricos Produtos Farmaceutêuticos”.
“Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”

Consequently, EMA has to take due account of these principles when assessing its right to disclose clinical trials data, be it re-actively or pro-actively. In particular, EMA has to protect such data against unfair commercial use where competitors who intend to use such information for their commercial purposes benefit from the clinical data submitted by the MAH.

Therefore, a general view that clinical trials data are per se not commercially confidential is not justified. The EMA has to assess whether this is the case by a careful and impartial individual review of the documents concerned in line with the provisions laid down in Article 4(2) of Regulation No. 1049/2001 regarding public access to European Parliament, Council and Commission documents which states that “the institutions shall refuse access to a document where disclosure would undermine the protection of commercial interests of a natural or legal person, including intellectual property…”

2. Consultation of the marketing authorisation holder

Furthermore, Article 4(4) of Regulation No. 1049/2001 stipulates that “as regards third-party documents, the institution shall consult the third party with a view to assessing whether an exception in paragraph 1 or 2 is applicable, unless it is clear that the document shall or shall not be disclosed.”

The consultation of the MAH by EMA is an important step in assessing whether or not data submitted in the authorisation process contain commercially confidential information that was previously unpublished and would be valuable in the hands of competitors. Therefore, the consultation of the MAH before disclosure must remain mandatory not only where third parties’ request access to this information but also where the information is proactively disclosed by the Agency.

3. No per se overriding public interest in disclosure of clinical trials data

EMA has to take into consideration that the publication of commercially confidential information contained in the marketing authorisation is not generally justified by an overriding public interest in disclosure. Publication as such does not necessarily lead to an improvement of public health. On the contrary, it is vital that the Agency assesses whether or not information may be made publicly available. The use of such data by competitors of the MAH can never establish an overriding public interest in the publication of these data due to its pure commercial intent.

Furthermore, know-how and trade secrets especially regarding the manufacturing and technological approaches in the development of an innovative medicinal product are of crucial value for the development of new medicinal products. Without any protection of this value innovation might be impeded significantly. Clinical trials would be - even more than today - conducted in third countries in order to safeguard the innovation and the intellectual property. This would contradict the main objective of the current Commission proposal on clinical trials (COM(2012) 369), namely to improve the legal framework for clinical trials within the EU in order to increase the number of trials performed within the Union and to support clinical research and development. The public interest in an improvement of the conditions for research and development of innovative medicinal products has to be taken into account when assessing whether or not clinical trials data may be disclosed.
Additionally, the use of disclosed clinical trials data by competitors would grant them an unfair advantage of the substantial investments the MAH has made in the development of a new product. Competitors could avoid conducting their own clinical trials and instead use the data disclosed by the Agency for obtaining marketing authorisations either within the EU and/or in third countries.

Consequently, the Agency has to assess on a case-by-case basis whether or not a disclosure of commercially confidential data is justified under exceptional circumstances. In this regard, the Agency has to consider on the one side the interests of the MAH given the damaging effect such disclosure has upon its property and business rights as well as the interests of the public to have access to new and innovative medicinal products and, on the other side, the public interest to make clinical trial data publicly available, in particular to patients and healthcare professionals. Also in this regard, an involvement and a detailed debate with the MAH before dissemination should be mandatory to enable the Agency to consider all relevant facts and matters when reaching a decision. However, the Agency cannot rely on the general and unsubstantiated assertion that publication of clinical trials data is in any case justified by an overriding public interest.

4. **Release of data only after the granting of the marketing authorisation**

Data contained in a pending marketing authorisation procedure should not be disclosed as this could undermine an independent decision making process. This general rule is included in Article 4(3) of Regulation No. 1049/2001. Any EMA policy should reflect the principles of the access-to-documents legislation of the European Union.

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