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EUROPEAN MEDICINES AGENCY JEOPARDIZES INVESTMENTS IN DRUG DEVELOPMENT

The heart of a marketing authorization application ("MAA") is the pre-clinical and clinical data that proves the drug's safety and efficacy. This data is collected through substantial investments in time and money. The current and proposed policies of the European Medicines Agency ("EMA") threaten the confidentiality, and hence the business value, of these investments.

At a workshop in November 2012, the EMA proposed to proactively publish clinical data submitted with MAAs. Even worse, EMA currently does not view pre-clinical or clinical data as qualifying as commercial confidential data. EMA is therefore willing to disclose the data in response to freedom-of-information ("FOI") requests. EMA is even of the opinion that data owners do not have to be asked for comments before release.

EMA's position is inconsistent with EU legislation. It stands in stark contrast to the regulations of the United States Food and Drug Administration ("FDA"), and to Japanese regulations. EMA's position endangers investments in drug development and, in the mid to long term, risks cutting off European patients from access to innovative treatments.

Originators therefore should strongly advocate protection of commercial confidential data in the ongoing public consultation process. In addition, if their data is subject to FOI requests, they should consider taking legal action against EMA.

BACKGROUND

The question of public access to data from drug development, both clinical and pre-clinical, has turned into a battlefield where the pharmaceutical industry risks losing out on their multimillion-dollar investments in innovative therapies. While EMA initially acknowledged that data submitted with the MAA is commercial confidential information, EMA has since reversed course.

In July 2012, EMA invited stakeholders to further discuss proactive release of clinical data in a November 2012 workshop. However, at the workshop, it became apparent that EMA had already mapped its policy preferences, aiming for proactive disclosure of clinical data upon marketing authorization.

EMA has taken similar legal and administrative positions in FOI request cases. EMA has held that neither pre-clinical nor clinical data are commercial confidential information of originators, and may thus be disclosed on request. EMA considers this "obvious," curtailing the right of the data owner to be consulted. Accordingly, while in some cases EMA advised data owners that it intended to release data from the MAA, EMA considered such warnings to be voluntary. Thus, in other cases, originators learned about the disclosure only when data they thought confidential was presented to them by third parties.

EMA might thus release full sets of pre-clinical and clinical data—thousands of pages that the originator would consider to be commercial confidential information (unless already published).

LEGAL ASSESSMENT

Current European legislation provides no legal basis for EMA to proactively release clinical data, even after marketing authorization. On the contrary, the Community Code on Medicinal Products for Human Use (directive 2001/81/EC as amended) confirms that data filed with an MAA enjoys data exclusivity. Even after expiry of data exclusivity, generics may only reference data on file with EMA—but not access it.

The proposed draft EU regulation on clinical trials reinforces this conclusion. While the draft regulation proposes to set up a database containing data submitted under the regulation, such a database would contain only summary results of clinical trials (not the full data set that has to be filed with an MAA), and the draft explicitly protects commercial confidential information from public access.

Regarding the release of data upon FOI requests, EMA's position that such data does not constitute commercial confidential data is fundamentally flawed and without basis in EU legislation. Such data loses its status as confidential only if the originator decides to publish it.

Transparency in the European authorization process is already provided for through the European public assessment report ("EPAR"), which summarizes the basis of the decision of the Committee for Human Medicinal Products. (An EPAR is comparable to the Summary Basis for Approval released by the FDA and the summary of clinical data released by the Japanese regulator, PMDA.)

Providing an EPAR is itself an exception to the rule that technological developments, even if of public interest, remain confidential; nobody would seriously claim access to the building plans for a department store (reviewed by the building authority) or to the blueprints of an airplane or high-speed train (certified by an aviation or public transport authority, respectively).

The special European rules on data exclusivity should take precedence over the general rules on FOI requests. Until expiry of data exclusivity, no data may be released except as explicitly stipulated in the European legislation (e.g., safety data). Even after expiry of data exclusivity, data must be treated as commercial confidential, if it can be used as the basis for marketing authorization applications in other jurisdictions.

In addition, to the extent data is relevant for obtaining patent protection, and where public release might create prior art, such data has to be treated as commercial confidential information.

The confidentiality of commercial information is a property right protected by the European fundamental rights, as acknowledged by the Court of Justice of the European Union. The illegal disclosure of information would violate this right. Therefore, EMA's disclosure policy (and any parallel policy of national regulators) would cause EMA to become liable for resulting damages. In addition, officers of national authorities may face criminal sanctions under national legislation protecting commercial confidential information entrusted to authorities.

It further follows that EMA must consult the originator before releasing data. There is no overriding public interest that would dispense with such consultation; the general public interest of access to information held by public authorities is outweighed here by the public interest in maintaining a regulatory environment that allows investment into drug development.

THE INTERNATIONAL PERSPECTIVE

EMA's proposal and current practice stands apart from treatment of commercial confidential information by other regulators.

The FDA is generally careful to protect the confidentiality of submitted data, including data from clinical trials. Indeed, while drug applications are pending, the FDA will not even disclose their existence unless that fact is already publicly known. With limited exceptions, regulations prohibit the FDA from revealing any data contained within the pending drug applications.

Once a new drug application ("NDA") is approved, the FDA automatically publishes a series of summary reports, including a summary of the safety and efficacy data (a category that includes all studies and tests of the drug). The summary reports, however, are generally prepared by the company that submitted the NDA. The summaries do not include the raw data, and "do not constitute the full reports on which the safety or effectiveness of the drug may be approved." If an application is abandoned, rejected, or withdrawn, the FDA does not automatically publish data, but the full safety and efficacy file is available to the public upon request. The file likewise becomes available upon request following approval of an abbreviated NDA ("ANDA") (which permits the marketing of a generic), or after the date on which an ANDA could have been approved.

A person who wants more information than is automatically published may request disclosure under the Freedom of Information Act ("FOIA"). With significant exceptions, FOIA requires the government to disclose any document in its possession. The most important exception shields from disclosure "trade secrets and commercial or financial information obtained from a person and privileged and confidential." The FDA defines "commercial information" to include "valuable data or information which is used in one's business and is of a type customarily held in strict confidence."

The FDA has a well-defined procedure for responding to FOIA requests. If the submitting party designated its data as confidential, or if the confidentiality of the data is uncertain, the FDA will notify the submitting party of any request for disclosure. Should the FDA determine that the information is subject to disclosure, the submitting party has the opportunity to seek judicial review of this decision. The reviewing court will then have the last word, and the FDA will not disclose the information until the court determines the issue.

In court, the party resisting disclosure has the burden of proving that the document is shielded by an exception to FOIA's presumption of open access. Courts do not have a uniform rule regarding how clinical data is to be treated. The outcomes depend upon the evidence provided and often turn on whether there is proof that disclosure will cause competitive harm to the company that submitted the data.

Likewise, the Japanese regulator, PMDA, only discloses summaries of clinical data proactively on its web site. Data submitted with MAA is otherwise treated as commercial confidential information and thus protected against FOI requests. Unlike EMA, PMDA is not envisaging any changes to these policies.

IMPACT ASSESSMENT

If EMA were to deviate from international practice and release data, whether proactively or on request, it would endanger the multimillion dollar investments made in the development of the drug. As competitors could freely use such data to file stand-alone MAA of their own (NDAs in U.S. parlance), without patent protection originators would quickly face competition in the market, long before expiry of data exclusivity.

In the long run, however, industry might think twice about filing with EMA before other relevant markets became open to generics. This would deprive patients of access to innovative products in Europe, or at least significantly delay introduction of new drugs.

POSSIBLE ACTION

The consultation process on the proactive release of clinical data runs through April 2013. Industry is well advised to engage in the process and to clarify the impact an imbalanced aim for transparency would have.

When fending off FOI requests, originators can take legal action to protect their commercial confidential information; courts can enjoin EMA from releasing such data. Where EMA has released data without consultation, declaratory action should be sought to prevent additional disclosures.

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