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PROACTIVE DISCLOSURE OF COMMERCIALLY CONFIDENTIAL INFORMATION–EUROPEAN MEDICINES AGENCY JEOPARDIZES INVESTMENTS IN DRUG DEVELOPMENT, PART II

The European Medicines Agency ("EMA") has released the proposal for a guideline on publication and access to clinical trial data. Holding that clinical data are not commercially confidential information, EMA intends to proactively publish such data as of 2014. The proposal lacks a legal basis and violates European Union treaty obligations as well as fundamental rights. From a policy perspective, it will disincentivize the filing of marketing authorization applications in Europe. In the public consultation period through September, industry should clearly spell out the implications for access of European patients to innovative pharmaceuticals.

We have discussed the disqueting approach by EMA to the disclosure of commercially confidential information at the end of last year ("*European Medicines Agency Jeopardizes Investments in Drug Development*"). EMA has now released on June 24 a draft policy guideline on the "*Publication and access to clinical-trial data*" (EMA/240810/2013, reference Policy/0070). The proposal purports to strike a compromise between public access to clinical data and the protection of commercially confidential information. However, EMA is paying lip service to the latter, by arbitrarily curtailing the scope of commercially confidential information: "The Agency respects and will not divulge commercially confidential data or information [CCI]. In general, however, CT data cannot be considered CCI; the interests of public health outweigh considerations of CCI." EMA thereby expropriates developers of innovative pharmaceuticals of assets in the form of commercially confidential information worth hundreds of millions of euros and more.

Under the new policy, EMA intends to proactively publish clinical data submitted with a marketing authorization application ("MAA"), once the authorization has been granted. The policy is to take effect as of January 1, 2014, with information submitted in MAA as of March 1, 2014 being subject to proactive disclosure, once authorization has been granted.

Information is divided into three categories:

- Category 1, documents containing commercially confidential information—EMA adding that (only) "a small number of CT data/documents can contain CCI";
- Category 2, documents without protection of personal data ("PPD") concerns;
- Category 3, documents with PPD concerns.

Category 1 documents shall not be disclosed proactively but may be accessible under freedom of information access request. Category 2 documents—the bulk of the information contained in an MAA—are classified open access and shall be proactively published. Category 3 documents are subject to "controlled access" and will not be proactively published.

The draft guideline provides for a mechanism to vet applicants that apply for Category 3 data, and imposes on them a publication obligation regarding their analysis. However, this is much ado about nothing from an industry perspective, as the commercially relevant parts of an MAA are classified open access in the first place.

In essence, only patient raw data (patient data listings, case report forms, etc.) are excluded. By contrast, the full clinical trial reports that have to be submitted with the MAA (contained in Module 5, section 5.3 of the Common Technical Dossier ("CTD")) shall be proactively released. In Category 1, EMA intends to review only special parts of the dossier with clinical data for potential commercially confidential information, namely the parts relating to biopharmaceutic studies and studies pertinent to pharmacokinetics using human biomaterials.

The draft guideline does not discuss the legal basis for such proactive disclosure, for good reason: There is none. Neither does the draft discuss the clear concerns of the General Court of the European Union, which, in two freedom-of-information cases involving data submitted for Humira and Esbriet, issued preliminary injunctions to prevent EMA from releasing requested data prior to the decision of the Court in main proceedings (*AbbVie v. EMA*, Case T-44/13 and *InterMune v. EMA*, Case T-73/13). The Court highlighted that the submitted data are covered by the fundamental right of control of information, which may be infringed by a release of such data:

> As the Court of Justice has recognised in its judgment in Case C-450/06 Varec [2008] ECR I-581, paragraphs 47 and 48, referring to the case-law of the European Court of Human Rights, it may be necessary to prohibit the disclosure of certain information which is classified as confidential in order to protect the fundamental right of an undertaking to respect for its private life, enshrined in Article 8 of the ECHR and in Article 7 of the Charter, it being made clear that the concept of "private life" cannot be interpreted in such a way that the commercial activity of a legal person is excluded.
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> Moreover, the Court of Justice added that it had already acknowledged that the protection of business secrets is a general principle and that the undertaking concerned might suffer "extremely serious damage" if there were improper communication of certain information (see, to that effect, Varec, paragraphs 49 and 54) (Case T-44/13, para. 47).

Last but not least, the draft guideline does not discuss the international treaty obligations assumed by the European Union under Article 39 TRIPS, according to which Contracting Parties have to protect undisclosed test data against unfair commercial use. The question how the EU intends to comply with this obligation, if EMA is the one to disclose such data to the public, is not even asked in the draft, let alone answered.

From a policy perspective, EMA unfortunately does not take an iterative view. EMA claims that "[a]ccess to CT data in an analysable format will benefit public health in future." However, if originators refrain from submitting MAA in the EU in the future, justly fearing that the clinical data representing hundreds of millions of euro of investment into drug development can simply be downloaded by any competitor from EMA's web site, there will be no access by European patients to innovative pharmaceuticals any longer. Just to

clear: if Module 5 of the CTD can be obtained from EMA, nothing will stop competitors from using this full data set for their own applications, be it in Europe, or, even more probable, in other jurisdictions (including the U.S., for example under a section 505(b)(2) application).

Contrast this with the acknowledgment of Peter Gøtzsche of the University of Copenhagen, who had obtained a favorable opinion of the European Ombudsman regarding access to clinical data in 2010: As of spring this year, he had not reviewed the obtained information in detail. So much for the interest in substance for access to data.

The consultation period runs through September 30. Industry should use this time window to stress the long-term implications for development of innovative drugs and access by European patients to those drugs.

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