May 7, 2013

Prof. Guido Rasi
Executive Director
European Medicines Agency
7 Westferry Circus
Canary Wharf
London E14 4HB
United Kingdom

Re: IPO Opposition to EMA Disclosure of Data in Marketing Authorisation Dossiers

Dear Professor Rasi:

Intellectual Property Owners Association (IPO) writes to express its opposition to the policy of the European Medicines Agency (EMA) regarding the public release of data contained in Marketing Authorisation dossiers, as articulated in the Heads of Medicines Agencies and EMA joint guidance document published in March 2012.

IPO is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in intellectual property rights. IPO's membership includes more than 200 companies and more than 12,000 individuals involved in the association either through their companies or as inventors, authors, executives, or law firm members.

The valuable trade secret rights of all IPO members, particularly members from the pharmaceutical industry, are significantly impacted by the EMA policy. IPO strongly opposes the EMA policy for the following reasons.

First, the EMA policy lacks an appropriate process for determining whether a requested document should be released. IPO believes the policy should include a presumption that the non-public, non-clinical and clinical data and other information in Marketing Authorisation (MA) dossiers is confidential commercial information. Parties who request MA information should be given an opportunity to overcome that presumption or to demonstrate an overriding public interest. MA holders should be afforded a meaningful opportunity to obtain judicial review of any EMA decision to disclose MA information. Such a process would permit MA holders and the EMA to evaluate the information on a case-by-case basis and protect commercially valuable confidential information from unwarranted disclosure.

Second, the EMA policy does not achieve an appropriate balance between the need for institutional transparency and the societal interest in promoting innovation. Although the EMA policy attempts to institute Regulation (EC) No. 1049/2001, which promotes transparency in EU institutions by providing EU citizens access to documents, the EMA policy fails to recognize the exceptions to the Regulation. For example, the Regulation provides:

> The institutions shall refuse access to a document where disclosure would undermine the protection of:
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> – commercial interests of a natural or legal person, including intellectual property,
> – court proceedings and legal advice,
> – the purpose of inspections, investigations and audits,
>
> unless there is an overriding public interest in disclosure.

See Regulation (EC) No. 1049/2001 at Article 4(2). Instead of balancing the commercial interests in the requested document against the public interest in disclosing the information to the requester, the EMA may simply post reports of non-clinical tests and clinical trials online. This policy stifles innovation by subjecting research-based manufacturers to public release of proprietary commercial information in which they invested heavily, with no effective mechanism for challenging this release.

Third, the EMA policy fails to protect innovators' legitimate trade secrets and other confidential information from disclosure to competitors and from loss of trade secret status in other jurisdictions. The policy could lead to the disclosure of summaries of safety data, efficacy data, and demographic data, as well as thousands of pages of tables and lists that relate to individual patient data and other highly detailed study design, implementation, and results information. This information represents the culmination of a company's immense expenditure in research and development. The disclosure of these trade secrets and other confidential information provides the competitors of research-based manufacturers with a virtual "roadmap" to obtaining a MA. From it, a competitor could learn about the type and amount of data required to reach a given regulatory objective and how to conduct its own clinical development program, for instance for a drug of the same class. This will stifle the incentive to invest in innovation.

Competitors could also submit this information to support approval of their own products. Even countries with advanced regulatory regimes might accept these data in support of approval. Indeed, this is one of the key reasons the preclinical and clinical data in marketing applications have long been protected by the United States Food and Drug Administration. There is no guarantee that regulators in Europe would refuse MA applications containing data obtained through transparency laws, and the risk is greater still in developing areas of the world.

Fourth, the EMA policy is inconsistent with provisions of the Agreement on Trade Related Aspects of Intellectual Property (TRIPS) and the Treaty on the Functioning of the European Union (TFEU). The disclosure of confidential non-clinical and clinical information fundamentally undermines the industry's ability to rely on the protections of TRIPS. Article 39.3 of this agreement provides that World Trade Organization members, "when requiring, as a condition of approving the marketing of pharmaceutical . . . 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." Further, Article 39.3 provides that WTO members must "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." If the European government allows the release of safety and efficacy data from MA dossiers – indeed, engages in wholesale disclosure on the EMA website – the industry's ability to invoke Article 39.3 in developing countries and countries with weaker intellectual property regimes will be eviscerated.

The EMA policy also contravenes Article 339 of the TFEU, which prohibits EU agencies and their employees from disclosing "information of the kind covered by the obligation of professional secrecy, in particular information about undertakings, their business relations or their cost components." European case law is clear that "professional secrecy" includes rules not only preventing disclosure but also "making it impossible for the authorities legally in possession of such information to use it, in the absence of an express provision allowing them to do so, for a reason other than that for which it was obtained." Case C-67/91, *Dirección General de Defensa de la Competencia v Asociación Española de Banca Privada et al.* [1992] ECR I-4820.

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For these reasons, IPO opposes the EMA policy concerning the public release of data contained in MA dossiers. IPO appreciates your consideration of our members' interests in connection with this important issue.

Sincerely,

Richard F. Phillips
President

cc: Tomasz Jablonski, Head (acting), Legal Service