Letters

RESEARCH LETTER

Transparency Interrupted: The Curtailment of the European Medicines Agency's Policy on Access to Documents

A colleague and I recently reported on the first 2 years of the European Medicines Agency's (EMA's) November 2010 freedom of information policy on access to documents.[1] The policy made a wide range of regulatory documents potentially accessible to anyone who asked for them, including clinical study reports. As of November 19, 2012, the EMA had released approximately 1.66 million pages of clinical trial data and other documents in response to 457 requests.[1]

On April 25, 2013, the General Court of the European Union, in 2 interim decisions, ordered the EMA not to provide documents in response to 3 specific requests. The injunction followed legal action by AbbVie (Wilmington, Delaware) about 2 separate requests for clinical study reports for adalimumab (Humira), a drug for rheumatoid arthritis, and legal action by InterMune (Brisbane, California) about a request for similar documents on pirfenidone (Esbriet), a drug for idiopathic pulmonary fibrosis. Both companies contended that the requested EMA documents contain commercially confidential information.[2,3] The EMA had planned to provide the documents, consistent with the view that "clinical trial data should not be considered commercial confidential information."[4] A hearing on the case may not be held until 2014.[5]

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On April 30, the EMA responded to the court order by declaring an intention to "continue with its policy to grant access to documents" but that "requests for access to documents similar to those contested by AbbVie and InterMune will be considered on a case-by-case basis."[6] In addition, the EMA confirmed that it would continue to develop a forthcoming policy on proactive publication of clinical trial data, pending the final decision of the court, and has since released a draft policy for public comment.[7]

I recently obtained a logfile (eAppendix in Supplement) from the EMA of all 728 requests for documents handled under its policy through June 4, 2013. The logfile showed that on May 28, 2013, the EMA rejected requests for documents related to 54 products. Academia/research institutes (27 requests), health care professionals (11), legal professionals (11), the pharmaceutical industry (8), and media (3) made the requests. (I received 1 such rejection letter, which cited the ongoing lawsuits as the reason for rejection.) The rejected requests were primarily for clinical study reports (46) and other regulatory documents related to the marketing authorization applications for medications, including Common Technical Document summaries (13) and nonclinical study reports (8). Previously, the EMA had released all these types of documents, with redactions as deemed necessary by the agency. The summary rejection of so many requests indicates that the EMA has substantially curtailed its release of documents, most likely as a result of the ongoing lawsuits.

The logfile showed an increase in the rate of requests between November 19, 2012, and June 4, 2013. Compared with the period before November 19, 2012, the number of pages released per month has decreased (**Table**). The logfile also indicated that regulators outside the European Union have requested and received documents and that the majority of requests originated from the pharmaceutical industry, legal professionals, media, and academia/research institutes. Industry has consistently made more requests for documents than other groups (**Figure**).

Before releasing documents about a product, the EMA informs the company and, depending on the specifics of a request, may seek the company's view regarding the release and possible redactions. As of July 27, 2013, AbbVie and InterMune are the only companies to challenge the release of documents in court. Other companies, such as GlaxoSmithKline and Roche, have recently announced new data transparency policies emphasizing a commitment to transparency.[8,9] However, the Pharmaceutical Research and Manufacturers of America and the European Federation of Pharmaceutical Industries and Associations, the leading trade organizations that represent most major companies,

Table. Requests for Documents Handled Under the European Medicines Agency's Policy Announced on November 30, 2010 (as of June 4, 2013)[a]

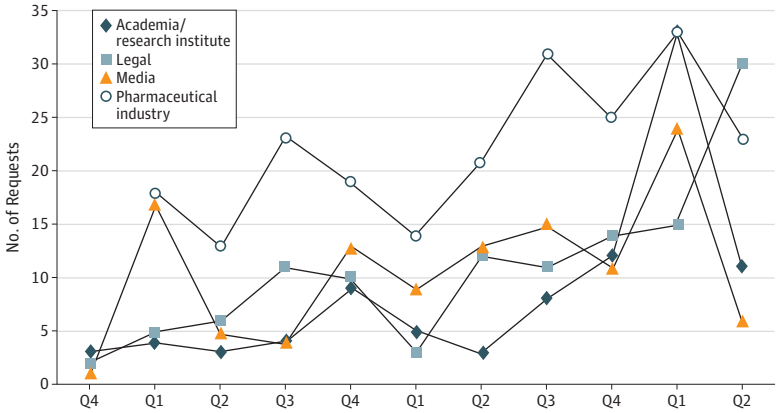
	No.		No. per Month[b]	
Time Period	Requests[c]	Pages Released	Requests[c]	Pages Released
Nov 30, 2010 to Nov 19, 2012	473	1 656 285	20.0	69 970
Nov 20, 2012 to Feb 25, 2013	132	137 000	41.0	42 521
Feb 26, 2013 to Jun 4, 2013	123	145 521	37.8	44 710

[a] Source: Analysis based on European Medicines Agency logfiles dated Nov 19, 2012, Feb 25, 2013, and June 4, 2013, of requests for agency documents.

[b] Month defined as 365/12 d.

[c] Requests from 1 individual for more than 1 product are counted as separate requests.

Figure. Requests for Documents Handled Under the European Medicines Agency's Policy Between November 30, 2010, and June 4, 2013



	Q4 2010	Q1 2011	Q2 2011	Q3 2011	Q4 2011	Q1 2012	Q2 2012	Q3 2012	Q4 2012	Q1 2013	Q2 2013
Academia/research institute	3	4	3	4	9	5	3	8	12	33	11
Legal	2	5	6	11	10	3	12	11	14	15	30
Media	1	17	5	4	13	9	13	15	11	24	6
Pharmaceutical industry	0	18	13	23	19	14	21	31	25	33	23

Requests from 1 individual for more than 1 product are counted as separate requests. I am responsible for 17 of the 33 requests in the academic/research institute category in the first quarter (Q) of 2013. The first quarter of 2010 and the second quarter of 2013 are not full (3 month) quarters.

including Roche and GlaxoSmithKline, have filed briefs supporting AbbVie. The views of most companies are unclear. Nonetheless, the curtailment of EMA's policy on access to documents is a major step backward for the transparency of clinical trials and for public health.

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Conflict of Interest Disclosures: Dr Doshi is a corecipient of a UK National Institute for Health Research grant to carry out a Cochrane review of neuraminidase inhibitors (http://www.hta.ac.uk/2352), which used as its basis more than 25,000 pages of clinical study reports for oseltamivir obtained from a 2011 request to the EMA. In addition, Dr Doshi received €1500 from the European Respiratory Society in support of his travel to the society's September 2012 annual congress, where he gave an invited talk on oseltamivir.

Additional Contributions: David Mackay, BVetMed, MSc, PhD, MRCVS, of the European Medicines Agency, reviewed the manuscript for accuracy and clarified the EMA's policy. Dr Mackay received no compensation for his assistance.

Additional Information: Dr Doshi is personally acquainted with some European regulators who share an interest in this topic.

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