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Access to data: EMA in key position

● **The European Medicines Agency must fulfil its transparency obligations and resist industry pressure.**

In June 2013, the European Medicines Agency (EMA) intended to proactively publish on its website almost all of the clinical data submitted, in line with standard procedure, in support of applications for marketing authorisations, and in particular the data contained in clinical study reports (1).

Industry opposition. In late November 2013, the European Commission published a proposal for a European directive on trade secrets (1). To the delight of the association that represents the European pharmaceutical industry, the proposal covered aspects of the clinical development of drugs (1). And in early 2014, the organisation representing the US pharmaceutical industry expressed its opposition to the EMA's intention to release clinical data. In particular, it asked the US government to take action against the EMA's proposal within the framework of the free trade agreement between the US and the EU that was under negotiation (2).

The EMA's U-turn. In mid-May 2014, despite the support for this policy expressed by the European Parliament and the Council of health ministers during the procedures that led to the adoption of the new European Clinical Trials Regulation, the EMA backtracked on its commitment to transparency (3).

On the pretext of aligning its policy with "*the Commission's clear message that [the EMA] would also have to assure compliance with national and international obligations (…) including (…) the TRIPS* [trade-related intellectual property rights] *Agreements and copyright laws*", the EMA proposed that anyone requesting access to clinical study reports would first have to sign a confidentiality agreement (3,4). It also proposed a procedure that would enable pharmaceutical companies to censor certain parts of clinical study reports, and various measures that would hinder the analysis of clinical study reports: the data could only be viewed on screen and could not be downloaded or saved (3).

This is actually a misinterpretation of one article of the World Trade Organization's TRIPS agreement, intended to protect companies that have produced clinical data from their use by a competitor for the purposes of obtaining marketing authorisation. This article does not refer to the disclosure of clinical data to the public; indeed, public health and safety concerns are an exception to the provisions protecting these data (5).

Transparency should not be sacrificed. Many civil society organisations as well as the European Ombudsman and the MEP appointed as the rapporteur for the Clinical Trials Regulation urged the EMA to fulfil its transparency obligations (3,6).

In the face of this mobilisation, the EMA published a final version of its policy, with a few improvements, that was implemented in January 2015 (7).

The requirement for researchers to sign confidentiality agreements was deleted, as was the definition of the "information owner", which referred to pharmaceutical companies (**a**)(7,8). Although researchers will be able to download the files, once they have identified themselves, the public will only be able to view the documents on screen, and will not be permitted to "*download, save, edit, photograph, print, distribute or transfer*" them (7).

Unfortunately, the EMA maintained the procedure that enables pharmaceutical companies to censor "*any information contained in the clinical reports (…) where disclosure may undermine the legitimate economic interest of the applicant/MAH*" (**b**)(7).

Several civil society organisations, including the Medicines in Europe Forum and the International Society of Drug Bulletins, urged the EMA to continue its efforts, in particular by finally complying with the requirement to establish a register of the documents in its possession, as stipulated in the regulation on access to administrative documents (Regulation (EC)) No 1049/2001), adopted in 2001 (8).

a- Researchers and the public must however "acknowledge that the Clinical Reports are protected by copyright or other intellectual property rights (…)" (ref 7).

b- If the EMA disagrees with a company's proposed redactions, the EMA undertakes that, before publishing the data, it will allow the company sufficient time to "challenge the decision before the courts" (ref 7).

Selected references from Prescrire's literature search.

1- Prescrire Rédaction "Débat mondial sur l'accès aux données cliniques: l'Agence européenne en position clé" *Rev Prescrire* 2014; **34** (367): 377-379.

2- Cohen D "Trade talks between US and EU could increase cost of drugs, new report says" *BMJ* 2014; **348**: g2402, 1 page.

3- AIM, Medicines in Europe Forum, HAI Europe, ISDB, Nordic Cochrane Centre "Backpedalling on EMA's "proactive publication of clinical-data" draft policy: Was it all just a window-dressing exercise? Who or what is the EMA afraid of?" Joint press release; 20 May 2014: 4 pages.

4- Rasi G "European Medicines Agency response to European Ombudsman letter regarding proactive publication of and access to clinical trial data" 22 May 2014: 2 pages.

5- Wadlow C "Regulatory data protection under TRIPs Article 39(3) and Article 10bis of the Paris Convention: Is there a doctor in the house?" *Intellectual Property Quarterly* 2008: 355-415.

6- AIM, Medicines in Europe Forum, HAI Europe, ISDB, Nordic Cochrane Centre "EMA's new policy on access to clinical data: About to privatise pharmaceutical knowledge? The proof will be in the pudding". Joint press release, 23 June 2014: 4 pages. english.prescrire.org.

7- European Medicines Agency "European Medicines Agency policy on publication of clinical data for medicinal products for human use (Policy/0070) (EMA/240810/2013)" 2 October 2014: 22 pages.

8- AIM, HAI Europe, ISDB, MiEF, NCC "EMA's final policy on access to clinical data: proactive access to some data, but strings attached" Joint statement; 16 October 2014: 4 pages. english.prescrire.org.