



Paris, 12 June 2013

Letter to the Director of the European Medicines Agency

Copy to:

The Directors of national drug regulatory agencies
European Commissioners for Health and Research
MEPs of the ENVI Committee
The Permanent Representatives of Member State Health Ministers
The Ombudsman of the European Union
European Court of Auditors

**The European Medicines Agency
refusing access to administrative documents:
Prescrire denounces an unacceptable retrogression**

Dear Professor Rasi,

The clinical data on medicinal products held by drug regulatory agencies are a public good. Withholding such data is a practice from another era that compromises the protection of public health, as evidenced by the *benfluorex* (Mediator^o) disaster, the *oseltamivir* (Tamiflu^o) missing data scandal, etc. (1,2,3)

The independent medical journal *Prescrire* systematically analyses medicinal products in the indications for which they are authorised in order to help its 35 000 subscribers (mainly doctors and pharmacists) improve the quality of care they provide to patients. To obtain unpublished data, *Prescrire* requests documents from pharmaceutical companies and drug regulatory agencies. For nearly 10 years, *Prescrire* has in particular been requesting information from the European Medicines Agency (EMA) (4).

In April and again in May 2013, *Prescrire* submitted two requests for access to administrative documents, both of which were refused by the EMA on the grounds that ongoing legal proceedings before the European Court of Justice prevent implementation of EMA policy on access to documents (5). *Prescrire* is appealing these decisions.

In its refusal letter, the EMA cites Article 4.2 of Regulation (EC) No 1049/2001, which refers to the protection of commercial interests.

But our requests pertain to **clinical data and the quality of drug packaging, which are matters of public interest** and therefore not covered by the definition of “commercially confidential” information under Article 4.2 of Regulation (EC) No 1049/2001 (see boxed text on page 3). If these documents indeed contained “commercially confidential” information (for example, detailed explanations of the manufacturing process), those parts could just be redacted. **EMA’s refusal of access to entire documents is unjustifiable.**

These refusals take us back to where we were 5 years ago, before the Mediator^o disaster erupted, serving as a forceful reminder of the deadly effects of the concealment of clinical data by drug regulatory agencies; to a time when the EMA refused to inform the public through paternalism

or neglect of its role to defend the public interest (6), under the pretext of protecting “commercially confidential” information and the commercial interests of the pharmaceutical industry (4).

Prescrire appreciates that, against the background of the legal action brought by the two pharmaceutical companies AbbVie and InterMune against the EMA (cases T-44/13 and T-73/13), the EMA must consider requests for access to clinical trial modules, and even to certain sensitive clinical data, on a case-by-case basis (7). However, the ongoing legal proceedings before the European Court of Justice must not serve as a pretext for the EMA to duck its responsibility to inform researchers and the public.

It is unacceptable, in 2013, to refuse to provide documents to a team such as *Prescrire* and other independent researchers.

On 29 May 2013, the European Parliament vote on the Clinical Trials Regulation by the Environment, Public Health and Food Safety (ENVI) Committee confirmed the need for more transparency concerning the results of clinical trials, by adopting a new Recital that refers to the EMA’s 2010 policy of access to documents and specifies that clinical trial data should not be considered “commercially confidential” once a marketing authorisation procedure has been completed (8).

We ask you to **send us the documents requested** and to **continue to provide *Prescrire* with documents** throughout cases T-44/13 and T-73/13 on the basis of overriding public interest, as clearly provided for in Article 4.2 of Regulation (EC) No 1049/2001.

We would like to take this opportunity to encourage you to **uphold the transparency policy introduced by the EMA in 2010** following many complaints against the EMA prior to 2010 (9), **and to strengthen this policy as part of the consultation announced for late June 2013** (8).

An ambitious EMA access-to-documents policy is essential if the EMA is to effectively implement the European Regulation on freedom of information (Regulation (EC) No 1049/2001) and in order to ensure that European citizens benefit from the best possible healthcare.

Yours sincerely,

A handwritten signature in black ink, appearing to be 'BT' or similar initials, written in a cursive style.

Bruno Toussaint
Editorial Director
Prescrire

**Prescrire's requests:
why deny access to administrative documents?**

In April and again in May 2013, *Prescrire* submitted **two requests for access to administrative documents that do not contain "commercially confidential" data:**

- A request for access to modules 2.5 (clinical overview) and 2.7 (clinical summary) of the harmonisation dossier for medicinal products containing oral *cefuroxime* (in response to an earlier request, the EMA sent us documents in October 2012 that were based on these modules but insufficient for the purposes of informing health professionals);
- A request for access to packaging mock-ups or specimens for Signifor^o (*pasireotide*).

Harmonisation procedures: the marketing authorisation dossiers are no longer protected.

Generally, harmonisation procedures extend the indications of a drug in Member States that had previously authorised it through a national procedure. Usually these drugs are of little commercial importance to the pharmaceutical companies that invented them, and their marketing authorisation dossier is no longer protected. In fact, harmonisation procedures often precede extensive distribution of generic versions of the drug. However, drug regulatory agencies release very little data on each separate indication of a medicinal product that has been harmonised. For example, for oral *cefuroxime*, the French marketing authorisations have been broadened to include 6 new indications. The documents in *Prescrire's* possession are insufficiently detailed to enable us to assess the harm-benefit balance of *cefuroxime* in these 6 new indications. The EMA's assessment report is useful but merely summarises the analysis of the data.

Packaging mock-ups or specimens: mere administrative documents. Poorly designed packaging is a major cause of medication errors. *Prescrire* staff systematically analyse drug packaging in order to alert health professionals to any potential risks, to prevent medication errors. Representations (photocopies, scans, diagrams) of drug packaging are mere administrative documents that form part of the official information that the EMA has evaluated and must make publicly available. They are representations of actual packaging materials that are already marketed by pharmaceutical companies.

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- 1- "Affaire du Mediator: deux ex-responsables de l'agence du médicament mis en examen" Le Monde (lemonde.fr) 18.02.2013.
 - 2- Gøtzsche PC, Jørgensen AW "Opening up data at the European Medicines Agency" *BMJ* 2011; 342:d2686 doi: 10.1136/bmj.d2686.
 - 3- Doshi P, Jefferson T "Clinical study reports of randomised controlled trials: an explanatory review of previously confidential industry reports" *BMJ Open* 2013; 3: e002496. Doi: 10.1136/bmjopen-2012-002496.
 - 4- *Prescrire* Editorial Staff "Legal obligations for transparency at the European Medicines Agency: *Prescrire's* assessment over four years" *Prescrire International* 2009; 18 (103): 228-233.
 - 5- Dyer C "European drug agency's attempts to improve transparency stalled by legal action from two US drug companies" *BMJ* 2013; 346:f3588.
 - 6- European Medicines Agency "Activities of former EMA Executive Director Thomas Lönngren: Management Board emphasises ongoing obligation to inform Agency of future activities" press release 21/03/2011.
 - 7- European Medicines Agency "European Medicines Agency receives interim decisions of the General Court of the EU on access to clinical and non-clinical information" press release; 30 April 2013.
 - 8- Consolidated amendment 41: "Recital 20a (new): *According to the policy of European Medicines Agency on access to documents, the Agency releases documents submitted as part of applications for marketing authorisation, including clinical trial reports, on request once the decision-making process for the medicine in question has been completed. Furthermore, the Agency continues to extend its transparency policy to proactive publication of clinical-trial data for medicines once the decision-making process on an application for a Union-wide marketing authorisation is complete. Those standards on transparency and access to documents should be upheld and reinforced. Therefore, for the purposes of this regulation, clinical trial data should not be considered commercially confidential once a marketing authorisation has been granted or the decision-making process on an application for marketing authorisation has been completed.*"
 - 9- Joint letter of support by 18 organisations and 10 researchers "EMA's efforts to increase transparency serve public health and general interest at large" Brussels, 12 April 2013: 3 pages.