

## 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?

According to documents shared by the agency during a stakeholder consultation mid-May 2014, the EMA's long awaited proactive publication of clinical-data policy –to be adopted in June 2014– could undermine EU citizens' fundamental right of public access to documents, instead of improving it.

We call on the EMA to ensure that its final proactive publication of clinical-data policy improves public access to scientific evidence about the effects of medicines on human health, which is necessary to protect public health.

Public access to clinical trial data allows for **independent analysis**, enhancing knowledge about the real benefits and harms of medicines. Such analyses allow researchers and health technology assessment (HTA) bodies to compare treatments' effectiveness. They also provide healthcare professionals and patients with information to support informed choices.

**Clinical trial data are public goods** that belong to society, not to a particular company (1). Patients taking part in clinical trials are willing to put themselves at risk also in the hope that their participation will benefit society through the advancement of science.

### 2013: Promising draft policy on access to clinical-data released by the EMA

In June 2013, the European Medicines Agency (EMA) released for public consultation a draft policy on "publication and access to clinical-trial data" (2). In that draft, the agency proposed to proactively publish clinical-trial data submitted in support of marketing-authorisation applications (only for centrally approved medicines from 2014 onwards). The idea was that interested parties would no longer need to invoke the European Freedom of Information Regulation (Regulation (EC) N°1049/2001), when exercising their fundamental right to access documents held by the EMA (a). Many respondents to the public consultation welcomed such a positive step (3).

### 2014: Despite an overwhelming political support for transparency, EMA steps backwards

On 2 April 2014, the adoption of the new EU Regulation on clinical trials showed a strong political support to EMA's commitment to transparency by both the European Parliament and the Council, which represents the 28 European Member States (see below).

Yet, **according to documents shared by the agency during a stakeholder consultation mid-May 2014, the EMA is about to water down its 2013 draft policy** by: allowing systematic censorship by pharmaceutical companies, imposing strict confidentiality requirements and imposing wide restrictions on the use of the data (4).

This backwards step occurs in a context of negotiations of the Transatlantic Trade and Investment Partnership (TTIP), a bilateral trade agreement between the European Union (represented by the European Commission - Directorate General Trade) and the United States of America, where a strong pressure is being exerted to uphold commercial interests (b).

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a - Regulation (EC) No 1049/2001 is a reactive policy: the applicant must request access to documents. Through the application of this legislation, the EMA has released 2 million pages of clinical study reports and other internal documents (ref. 5).

b- To be noted, beginning of 2014, the Pharmaceutical Research and Manufacturers of America (PhRMA) asked "the US government to "continue to seek assurances that the problems described" [including the European Medicine Agency's plan to disclose clinical trial data] were "quickly and effectively resolved."" (ref. 6).

## Public access only to censored documents would provide a level of transparency inferior to what is guaranteed by Regulation (EC) N°1049/2001

When clinical study reports (CSR) are received at the EMA, they become a “document held by the Agency”. As the EMA is a European Institution, the European Freedom of Information Regulation (N° 1049/2001) therefore applies.

According to a draft “terms of use” document recently prepared by the EMA legal services, those interested in gaining access to the CSRs would have to register and accept conditions vis-à-vis the use they intend to make of the documents. This is not required when requesting access to documents under Regulation (EC) N° 1049/2001.

Most notably, according to a draft of so-called “redaction principles”, **the requester would no longer gain access to the original documents, but to censored versions of the documents.** The EMA proposes to publish online a version of the clinical study reports (CSR) that might have been “redacted” by the pharmaceutical company to hide so-called “commercially confidential information” (CCI) (c,d).

The EMA also intends to ask requesters to sign a contract in which they recognize that the data they will access is “*protected by proprietary and copyrights and can constitute commercial confidential information*”. Such a contractual recognition of proprietary and copyrights in the clinical data is highly contested and questionable according to legal literature, case law and ethics (1).

As a consequence of these important changes, **EMA’s policy would provide a level of transparency inferior to what is currently guaranteed by Regulation (EC) N°1049/2001.** If the EMA proactively publishes CSRs (even redacted), the EMA will no longer grant access to the original documents! **In practice, rather than improving the fundamental right of EU citizens to access documents, the EMA’s policy would undermine it.**

### “View-on-screen-only”: documents only available in a non-usable format

In addition, the EMA proposes that CSRs (whether redacted or not) are only to be made available in a view-on-screen format, and any downloads or screen shots will be prohibited. This format makes checking of the data and results, as well as independent research, virtually impossible.

## Freedom of information is a fundamental right of European citizens, underlined by the recently approved EU Clinical Trials Regulation

According to the Charter of Fundamental Rights of the EU and to Regulation (EC) N°1049/2001, freedom of information is a fundamental right of European citizens. In addition, as regards clinical trials, the Declaration of Helsinki explicitly refers to the ethical obligation to disclose the results from research and insists on the completeness and accuracy of these reports.

Democratically adopted on 2 April 2014, **the new EU Regulation on clinical trials shows a strong political commitment to transparency by the European Parliament and the Council:** “*the data included in a clinical study report should not be considered commercially confidential once a marketing authorisation has been granted*” (recital 68); “*the EU database should be publicly accessible and data should be presented in an easily searchable format, with related data and documents linked together (...), for example linking together (...) the protocol and the clinical study report*” (recital 67).

The EMA policy must comply with the EU Regulation on clinical trials.

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c- To be noted, several sections in the clinical study reports that were considered as open in the 2013 draft policy are now being considered as “*may be commercially confidential information*”. These overlap with the sections that the EMA has accepted to redact in its compromise agreement with AbbVie, which then dropped the court case against the EMA at the European Court of Justice. More than a mere coincidence, this agreement seems to have set a precedent with negative consequences for future EMA policy.

d- The EMA foresees a consultation process with the marketing authorisation holder when discussing the CSR publication and the sections to be “redacted”, but these bilateral exchanges between companies and agency are not to be made public and the rationale for withholding the information will not be known. The EMA has clearly mentioned that the reasons for redaction would not be revealed. As mentioned by researchers: “*EMA is reversing its principle of public access to clinical trial data as it sets up a system of controlled access similar to those established by industry. (...) The scheme puts primary responsibility for reaction in the hands of sponsors.*” (ref. 7).

## In conclusion: The EMA must uphold transparency to defend public health

Having actively participated in the Agency's policy development process, our organisations re-iterate their commitment to full transparency and urge the EMA to:

- **Refuse to release censored documents**, a practice which will prevent citizens' access to the original documents under Regulation (EC) N°1049/2001, thereby undermining EU citizens' fundamental right of public access to documents (e);
- Extend the scope of its transparency policy to **provide access, retrospectively, to clinical-trial data concerning all medicines approved** whether centrally (by the EMA) or through the decentralised procedure or mutual recognition (by the CMDh);
- Extend the scope of its transparency policy to proactively provide access to comprehensive **pharmacovigilance data** (also through Eudravigilance and not just ADRreports) and to periodic benefit-risk evaluation reports (ex-periodic safety update reports, PSURs);
- Ensure that all information made available is in a **legible, easily usable, downloadable and searchable format**, to allow secondary research and analysis, in accordance with the recent EU Regulation on clinical trials;
- Foresee the publication and access to individual anonymised patient-data (**raw data**);
- **Postpone the adoption of this policy pending the outcome of the ombudsman's enquiries**, as the new policy is contrary to the recommendations of the Ombudsman in Case 2560/2007 BEH, and in breach of the commitments made by the EMA following that case.

Moreover, we call on the new elected European Parliament and the forthcoming European Commission to fully fund the EMA from the central EU Budget, in order to prevent the agency from acting as a service provider to pharmaceutical companies, at the expense of its public health mandate (f).

***Association Internationale de la Mutualité (AIM)***  
***International Society of Drug Bulletins (ISDB)***  
***Medicines in Europe Forum (MIEF)***  
***Nordic Cochrane Centre***

Press Release disseminated to:

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**DG HEALTH** Tonio Berg (Commissioner); Harald Kandolf (Deputy Head of Cabinet);

**Court of Auditors** Igors Ludboržs;

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**European Parliament** MEP Corinne Lepage, MEP De Jong, MEP Monica Louisa Macovei, MEP Antonyia Parvanova, MEP Michèle Rivasi; MEP Petri Sarvamaa.

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e- EMA's default position must be that information is not commercially confidential and that companies should have to prove otherwise. Any exception to disclosure should be justified by the companies who should have to explain how the release of the information they claim to be commercially confidential would truly harm their interests; it should only involve the removal of specific elements within a document and should never be applied to entire sections or certain types of documents or information. Then, the EMA should ensure that non-disclosure would not be detrimental to public health.

f- Since its creation in 1995, revenue for the European Medicines Agency (EMA) has increasingly been derived from fees charged to the pharmaceutical industry. Fees from industry are now forecast to account for approximately 85% of EMA's revenues, and the remaining 15% from the EU budget.

## References:

- 1- Lemmens T "Access to pharmaceutical data, not data secrecy, is an Essential Component of Human Rights" 8 April 2014. <http://www.law.utoronto.ca/blog/faculty/access-pharmaceutical-data-should-be-framed-human-right-not-data-secrecy> : 3 pages.
- 2- "EMA [Draft policy on publication and access to clinical-trial data](#)" [www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2013/06/WC500144730.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/06/WC500144730.pdf)
- 3- AIM, HAI Europe, ISDB, MiEF "EMA's 2013 policy on access to clinical-trial data: Transparency in the public health interest" Joint Submission of comments on Policy 0070 on publication and access to clinical-trial data; September 2013: 15 pages.
- 4- European Ombudsman "Ombudsman concerned about change of policy at Medicines Agency as regards clinical trial data transparency" <http://www.ombudsman.europa.eu/en/press/release.faces/en/54348/html.bookmark>
- 5- Doshi P, Jefferson T "Clinical study reports of randomised controlled trials: an exploratory review of previously confidential industry reports" *BMJ Open* 2013;3:e002496 doi:10.1136/bmjopen-2012-002496.
- 6- Cohen D "Trade talks between US and EU could increase cost of drugs, new report says" *BMJ* 2014;348:g2402.
- 7- Doshi P, Jefferson T "Is the lady U-turning" *Statement to Science Insider*; 16 May 2014.

## About us

**AIM.** The Association Internationale de la Mutualité (AIM) is a grouping of autonomous, not-for-profit health insurance and social protection bodies that operate on the principle of solidarity. Currently, AIM's membership consists of 42 national federations representing 25 countries. In Europe, they provide social coverage against sickness and other risks to more than 160 million people. AIM strives via its network to make an active contribution to the preservation and improvement of access to health care for everyone. More info: [www.aim-mutual.org](http://www.aim-mutual.org). Contact: [corinna.hartrampf@aim-mutual.org](mailto:corinna.hartrampf@aim-mutual.org)

**ISDB.** The International Society of Drug Bulletins, founded in 1986, is a worldwide Network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of pharmaceutical industry. Currently ISDB has around 80 members in 41 countries around the world. More info: [www.isdbweb.org](http://www.isdbweb.org). Contact: [press@isdbweb.org](mailto:press@isdbweb.org).

**MiEF.** The Medicines in Europe Forum (MiEF) was launched in March 2002 and reaches 12 European Member States. It includes more than 70 member organizations representing the four key players on the health field, i.e. patient groups, family and consumer bodies, social security systems, and health professionals. It is a testament to the importance of European medicines policy. Medicines are not merely consumer goods, and the European Union represents an opportunity for European citizens to seek further guarantees of efficacy and safety. Contact: [pierrechirac@aol.com](mailto:pierrechirac@aol.com)

**NCC.** The Nordic Cochrane Centre is part of the Cochrane Collaboration, an international not-for-profit international network of more than 28,000 dedicated people from over 100 countries preparing, maintaining and promoting the accessibility of systematic reviews of the effects of health care. More information: [www.cochrane.org](http://www.cochrane.org). Contact: [pcg@cochrane.dk](mailto:pcg@cochrane.dk)