



## Joint open letter on access to clinical study reports

**EMA's transparency and access to documents policy should not be watered down: instead it deserves greater attention as it is a cornerstone for enlightened research and decision making, public scrutiny and trust in the European regulator**

19 December 2019

Over the last decade, following persistent and growing requests from researchers, academics and campaigners the European Medicines Agency (EMA) has gradually improved its transparency policy<sup>1</sup>. It was as a result of a complaint to the European Ombudsman and his subsequent recommendations that EMA accepted to provide access to clinical trial data<sup>2</sup>. EMA was the first medicines agency deciding to proactively provide public access to clinical study reports.

In 2018, academics, researchers and civil society organisations expressed their concerns on the EMA's decision to scale back transparency initiatives because of workload issues related to staff loss caused by Brexit and relocation to Amsterdam<sup>3</sup>.

EMA also faced legal challenges to its transparency policy. Pharmaceutical companies are mainly opposed to the publication of clinical study reports stressing that it undermines their commercially confidential information. One ongoing European Court case regarding public access to clinical study reports concerns the case of PTC Therapeutics International against EMA.

<sup>1</sup> Adams B. The pioneers of transparency. *BMJ* 2014;350:g7717 10.1136/bmj.g7717

<sup>2</sup> Gøtzsche PC, Jørgensen AW. Opening up data at the European Medicines Agency. *BMJ* 2011;342:d2686. See also Diamandouros PN. Ombudsman: European Medicines Agency should disclose clinical reports on anti-obesity drugs. European ombudsman press release, 7 June 2010. [www.ombudsman.europa.eu/press/release.faces/en/4940/html.bookmark](http://www.ombudsman.europa.eu/press/release.faces/en/4940/html.bookmark). [Google Scholar](https://scholar.google.com/)

<sup>3</sup> Doshi P. EMA scales back transparency initiatives because of workload. *BMJ* 2018;362:k3513. 10.1136/BMJ.k3513

In its judgment of 5 February 2018, the General Court upheld the EMA interpretation that clinical study reports in their entirety are not protected by a general presumption of confidentiality<sup>4</sup>. This Court judgment<sup>5</sup> is now under appeal. Researchers, civil society organisations as well as EMA are concerned by the opinion of the Advocate General Hogan<sup>6</sup> relating to this appeal procedure released on 11 September 2019<sup>7</sup>. The Advocate General considers that the disclosure of clinical study reports undermines companies' commercial interests. If followed by the Court in its final judgment expected by early 2020, this would represent a serious setback for the EMA transparency policy. It would also jeopardise and impede the right of access of the general public to clinical trial data and information. The Advocate General opinion and the underlying threat for clinical trial transparency was also recently debated at an event in the European Parliament in October<sup>8</sup>.

The organisations that have signed this joint letter are greatly concerned that the argument put forward by the Advocate General singularly focused on commercial and business considerations. One might even get the impression that the steps taken towards the development of a strengthened EMA transparency policy were based on misconception and misinterpretation of rules and laws. On the contrary, we consider this opinion ignores the background and motivations leading to a strengthened transparency policy being fundamental to ensure patient safety and allowing public scrutiny and duly considering public health and societal needs while enabling trust in and accountability of the regulator.

Clinical study reports include comprehensive information on the design, methods, analyses and results of clinical trials. Without any doubt, the publication and dissemination of clinical trial information improves transparency. Access to clinical study reports provides the opportunity for independent research and assessment of reporting and evaluation of bias, detailed evaluations of harms and adverse events, trial re-analyses and their integration in systematic reviews and meta-analyses<sup>9</sup>. Disclosure of clinical data and information, including clinical study reports, is literally of vital interest for patients, and also needed for healthcare professionals, researchers, HTA bodies, independent drug bulletins, healthcare payers, the global health community, the general interest and public health.

Full transparency - not secrecy - is the way forward!

#### **Supporting organisations and researchers:**

1. Prescrire, France
2. AIDES, France
3. AIM – International Association of Mutual Benefit Societies
4. Anticancer Fund, Belgium
5. AOK-Bundesverband, Germany
6. BIT Navarra, Spain
7. BUKO Pharma-Kampagne, Germany
8. CPME - Standing Committee of European Doctors

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<sup>4</sup> Regulation No 1049/2001 Article 4(2) or (3)

<sup>5</sup>

<http://curia.europa.eu/juris/document/document.jsf?text=&docid=199044&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=4302249>

<sup>6</sup> <http://curia.europa.eu/juris/document/document.jsf?docid=217636&doclang=EN>

<sup>7</sup> Coombes R European drug regulator fears return to days of data secrecy. BMJ 2019;367:l6133 10.1136/bmj.l6133

<sup>8</sup> <https://haiweb.org/clinical-trial-transparency/>

<sup>9</sup> Ferran JM, Nevitt SJ, European Medicines Agency Policy 0070: an exploratory review of data utility in clinical study reports for academic research BMC Medical Research Methodology 2019 19:204

9. DECO PROTESTE, Portugal
10. DTB, UK
11. European AIDS Treatment Group
12. EPHA – European Public Health Alliance
13. Folia Pharmacotheapeutica (BCFI/CBIP), Belgium
14. Formindep, France
15. Ge-Bu – Geneesmiddelen Bulletin, the Netherlands
16. HAI - Health Action International
17. MHE - Mental Health Europe
18. IQWiG - Institute for Quality and Efficiency in Health Care / Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, Germany
19. ISDB – International Society of Drug Bulletins
20. KCE - Belgian Health Care Knowledge Centre, Belgium
21. Knowledge Ecology International (KEI)
22. KEI Europe
23. Ludwig Boltzmann Institute for Health Technology Assessment, Austria
24. No Gracias, Spain
25. Observatoire de la transparence, France
26. OCU - Spanish Consumer Organization, Spain
27. pharma-kritik / infomed, Switzerland
28. Public Eye, Switzerland
29. RxISK
30. Salud por Derecho, Spain
31. Salud y Farmacos, USA
32. Test Aankoop/Test Achats, Belgium
33. The Therapeutics Initiative, Canada
34. TranspariMED
35. Transparency International Health Initiative, UK
36. Leeza Osipenko, LSE, Senior lecturer in practice
37. Barbara Mintzes, Associate Professor, University of Sydney, Australia
38. Professor and Director Peter C Gøtzsche, Institute for Scientific Freedom, Copenhagen, Denmark
39. Richard Laing, Professor Boston University School of Public Health, USA
40. Joel Lexchin MD, Professor Emeritus, School of Health Policy and Management, Faculty of Health, York University, Toronto, Canada
41. Liliya Ziganshina, Kazan University, Kazan, Tatarstan, Russia
42. Kirsten Myhr, Norway, independent expert EMA's PRAC Committee 2012-2018
43. Amelia Filippelli MD, PhD, Professor of Clinical Pharmacology, University of Salerno, Italy