



June 19, 2012

Joint open letter to:

- CoRePers
- José Manuel Barroso, President of the EU Commission
- John Dalli, Commissioner for health and consumers

Copy to:

- **Members of the EU Parliament**
ENVI Committee
Civil Liberties Committee
- **EU Ombudsman**

Access to EU Institutions' documents is essential to advance transparency and to serve public health

In June 2012, the Council's negotiations attempting to recast the current rules on access to documents in the EU have failed. The proposals of the Danish Presidency could have reduced the transparency of European Institutions. Should the reform of Regulation (EC) 1049/2001 regarding public access to EU institutions' documents be up for discussion again, then the Medicines in Europe Forum (MIEF), the International Society of Drug Bulletins (ISDB) and Health Action International (HAI) Europe call on Member States and on the Commission to take a clear and unequivocal position in favour of strengthened transparency in Europe.

Dear Permanent Representatives of Member States, Dear President Barroso, Dear Commissioner Dalli,

On 12 June 2012, the Danish Presidency abandoned attempts to agree on a common position on new rules on access to EU documents. The failure of the negotiations on the recast of Regulation (EC) 1049/2001 among Council members triggered this decision.

Good news: the worst case scenario has been avoided. On the one hand, this is a positive outcome. As civil society organisations working in the area of medicines and medical devices policy, **we were extremely concerned about the position taken by several Member States to weaken access to documents from EU institutions, even beyond the current requirements of Regulation (EC) 1049/2001** (i.e. more restrictive definition of "documents", limiting access to databases, "considerations" against transparency for entire classes of documents, etc.). **Regulation (EC) 1049/2001 needs to be strengthened, not weakened (a).**

A missed opportunity to strengthen transparency in Europe. Nevertheless, the lack of consensus in the Council about the proposals of the EU Parliament, which would have extended Regulation (EC) 1049/2001 to **all EU institutions, bodies, offices and agencies (b)**, represents **a missed opportunity to strengthen transparency in Europe and to fully implement the Lisbon Treaty and the Charter of Fundamental Rights of the European Union.** In particular, as foreseen in the Lisbon Treaty (article

a- In that respect, we welcome the position of the Finnish and Swedish Ministers of Justice (ref. Beatrice Ask, Swedish Minister for Justice and Anna-Maja Henriksson, Finnish Minister of Justice "True friends of transparency?" 31.05.2012 Open letter: 1 page. www.wobbing.eu)

b- "European Parliament legislative resolution of 15 December 2011 on the proposal for a regulation of the European Parliament and of the Council regarding public access to European Parliament, Council and Commission documents (recast)" ([COM\(2008\)0229 – C6-0184/2008 – 2008/0090\(COD\)](http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2011-0580&language=EN&ring=A7-2011-0426))" <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2011-0580&language=EN&ring=A7-2011-0426>

15.1 on Good Governance), all documents concerning legislative procedures have to be made public, including those discussed between the Council, the European Parliament and the EU Commission in first and second reading triologue meetings. At present, they are kept secret and this has to change (c).

Regulation (EC) 1049/2001 must be strengthened: health as a case study.

Health is a field where the decisions of EU institutions affect citizen's daily lives. Within the pharmaceutical, cosmetic and food sectors, lobbies are powerful. Conflicts of interests are ubiquitous, even at the top level of authorities' management (d). Bearing this in mind, **accountability and public scrutiny of Health Authorities' decisions are only possible when the public has access to both the body of evidence and the rationale on which decisions are based.**

Unfortunately, in 2012, despite their clear mandate to uphold transparency, the **European Medicines Agency (EMA), the Heads of Medicines Agencies (HMA) and the National Drug Regulatory Agencies still fail to provide full public access to scientific evidence about the effects of medicines on human health.** In practice, an overly broad definition of "commercially confidential information" is used to defend this secrecy (e). This leads to undue delays in access to documents, even if they contain no commercially confidential information as the EU Ombudsman's investigations of complaints have shown (f,g,h).

Strengthening Regulation (EC) 1049/2001 would improve access to scientific evidence about the effects of medicines on human health, and thereby prevent some drug-induced harm for EU citizens.

Civil society requirements. At the moment, Regulation (EC) 1049/2001 remains in force and unchanged. If the Cypriot Presidency were to take further steps to recast this Regulation, **we call on you to defend and foster EU transparency during the discussions.** It is the only way to ensure accountability of EU decision-making bodies to Member States and EU citizens alike.

We want to stress the importance of the following 10 points:

- 1. To support the extension of Regulation (EC) 1049/2001 to all EU institutions, bodies, offices and agencies** (among them particularly the Heads of Medicines Agencies (HMA) which manages the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human, *CMDh*);
- 2. To clarify that all documents concerning EU legislative procedures have to be proactively publicly**

c- Ironically, during the recast of the access rules in the EU, the public was denied access to documents during the triologue process (ref. <http://www.statewatch.org>). This is inconsistent with the Lisbon Treaty requirements for greater legislative transparency and for open and inclusive EU decision-making.

d- Gaffney A "European Parliament Still Dissatisfied With EMA's Conflict of Interest Policies" News on Regulatory Focus.org ; 14 May 2012.

"European Parliament postpones EFSA budget approval over conflicts of interest" News on www.corporateeurope.org : 10 May 2012.

e- European Medicines Agency & Heads of Medicines Agency "HMA/EMA guidance document on the identification of commercially confidential information and personal data within the structure of marketing authorisation (MA) application" March 2012 : 40 pages. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/03/WC500124536.pdf

f- In June 2012, there is still no full public access to EU databases on adverse drug reactions (Eudravigilance), clinical trials (EudraCT) and medical devices (Eudamed) and no online public access to periodic safety update reports (PSURs).

For more information about the experience of independent drug information providers, read: Prescrire Editorial Staff "[Legal obligations for transparency at the European Medicines Agency: Prescrire's assessment over four years](#)" *Prescrire Int* 2009; 18 (103): 228-233, and read page 4: a safety report about a drug that was since withdrawn from the market was provided with 64 out of 68 pages blacked out.

g- Various reasons underline excessive secrecy, among others:

- the lack of legal obligation or the lack of clarity within the regulations, leaving room for manoeuvre by some Member States to narrowly interpret their transparency obligations (i.e. it can be more convenient to apply confidentiality clauses broadly rather than narrowly, particularly when agencies lack capacity and resources to process requests for information);

- paternalism: the frequent belief that those outside Health Authorities and Institutions do not need, cannot cope with or would misinterpret the information provided;

- embarrassment or industrial influence: a health authority may hesitate to publicly disclose those decisions which are poorly documented, internally contested, or surrounded by conflicts of interest and which do not serve the general public interest (ref. "Uppsala Declaration - Statement of The International Working group on Transparency and Accountability in Drug Regulation" September 1996 <http://www.isdbweb.org/pages/35>).

h- One example is that of Danish researchers who, in 2007, appealed to the European Ombudsman following the Agency's failure to grant access to unpublished clinical study reports and corresponding trial protocols for two medicines, on the grounds of commercial confidentiality. In his examination, the European Ombudsman reiterated that the Regulation (EC) 1049/2001 is such that "*even if commercial interests are specifically and actually undermined by disclosure, access still has to be granted if there is an overriding public interest in disclosure*" (ref. Paragraph 32 of European Ombudsman's Draft Recommendation: <http://www.ombudsman.europa.eu/en/cases/draftrecommendation.faces/en/4883/html.bookmark>).

disclosed (including the documents of first and second reading triologue meetings);

3. To support the **extension of Regulation (EC) 1049/2001 to National Competent Authorities** in order to harmonise their practices according to the highest standards and to limit the future use of national exceptions;

4. To support a **broad definition of a document to include databases content**;

5. Not to accept block exemptions that would permit the systematic denial of access to certain types of documents under the pretext of protecting “commercial confidentiality”: **transparency should be the norm, not the exception**. For specific and exceptional circumstances, where confidentiality is a real concern duly documented, decisions should be made on a case-by-case basis using a public interest test. A document must always be provided, even when much is blacked out;

6. To refuse that access to documents be delayed on the pretext that it would undermine the decision-making process (i);

7. To support the **extension and full application of Regulation (EC) 1049/2001 to the coming recast of EU Clinical Trial Directive**, including access to raw data of clinical trials;

8. Not to grant exceptions to the disclosure of documents concerning staff selection and awarding of contracts and grants;

9. Not to extend response timelines by EU institutions to citizens’ requests for documents (presently 15 days);

10. Not to accept that protection of personal privacy be used as a pretext for unduly undermining the fundamental human right of access to documents: personal data can be redacted or blacked out.

We trust that you will consider our request and uphold the rights of EU Citizens.

Yours Sincerely,

Medicines in Europe Forum

ISDB

HAI Europe

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. patients groups, family and consumer bodies, social security systems, and health professionals. Such a grouping is unique in the history of the European Union and is testament of the importance of European medicines policy. Admittedly, medicines are no mere consumer goods, and the Union represents an opportunity for European citizens to seek further guarantees of efficacy, safety and pricing. Contact: pierrechirac@aol.com.

ISDB. The International Society of Drug Bulletins (ISDB), 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. Contact: press@isdbweb.org.

HAI Europe. Health Action International (HAI) is an independent global network of health, consumer and development organisations working to increase access to essential medicines and improve their rational use. More info: www.haieurope.org. Contact: Katrina@haieurope.org

i- For example, withholding the opinion of the Committee for Medicinal Products for Human Use (CHMP) until the EU Commission signs the administrative decision can delay access to important information about the safety of health products during several months. This information could prevent otherwise avoidable harm if released earlier.