



Press release
Bielefeld, 2 March 2009

EMA: excessive secrecy beyond the law! Transparency should be the norm

• **Answer to the consultation on the "Draft EMEA policy on the practical operation of access to EMEA documents"** (1) (Addressed to: documents.access@emea.europa.eu)

The *International Society of Drug Bulletins* (ISDB) read with great interest the Agency's draft on policy of access to the European Medicines Agency (EMA) documents¹. It is, in fact, urgent to improve openness and accountability regarding drug regulation in Europe by implementing a consistent policy and explicit routines for dealing with access to any data requested. Unfortunately, the "Draft EMEA policy on the practical operation of access to EMA documents" is extremely disappointing.

Excessive secrecy. In agreement with article 255 of the Treaty establishing the European Community, citizens have a right of access to European Institutions' documents in accordance with the transparency principles. However, for decades, the international scientific community and the public have seen different strategies used by the regulatory agencies, which has led to excessive secrecy in drug regulation (read "Development of excessive secrecy" section of the Uppsala Declaration²).

The draft "EMA policy on the practical operation of access to EMA documents" unfortunately uses many of these strategies to justify EMA secrecy (see "Specific principals" section on page 3 of EMA's document)¹.

► ***If the protection of legitimate business interests and the protection of confidential personal information are two important exceptions that can reasonably be made with regards to the principle of transparency, their definition shouldn't be too extensive. These two exceptions should not serve as a pretext to excessive secrecy, so jeopardising public health.***

For example, the joint EMA and Heads of Medicines Agency's "Recommendations on transparency related to agenda/minutes" published in November 2008 are caricatures: "*for ongoing procedures and in order to avoid undermining the decision-making process, only the following information should be disclosed (...): name of the active substance, type of application (...), therapeutic class (...). This would apply for agendas and minutes*"³. This is the opposite of the transparency spirit of the 2004 review of the medicines frame, and constitutes a misleading, much too restrictive, implementation of the texts. In fact, Article 126b of Directive 2001/83/EC as amended by Directive 2004/27/EC states: "*the Member States shall ensure that the competent authority makes publicly accessible its rules of procedure and those of its committees, agendas for its meetings and records of its meetings, accompanied by decisions taken, details of votes and explanations of votes, including minority opinions*"⁴. The EMA should be at least as transparent as Member States!

Regulation (EC) No 1049/2001 states that public access "*shall apply to all documents held by an institution, that is to say, documents drawn up or received by it and in its possession, in all areas of activity of the European Union*" (Article 2 point 3)⁵. Prior agreement for access to "documents of 3rd party" (i.e. documents received by the EMA from Member States, other Institutions, etc.) shouldn't be "*always needed before access can be granted*" (proposition on page 4 of EMA's document). They functionally become "*EMA documents*":

¹- "Draft EMA policy on the practical operation of access to EMA documents"
www.emea.europa.eu/pdfs/general/direct/11019606en.pdf

²- The "Statement of the international working group on transparency and accountability in drug regulation" (so called "Uppsala Declaration") published in 1996 is more than ever appropriate to the European current context. The "Uppsala Declaration" Freely available at: www.isdbweb.org/pag/uppsala.php.

³- EMA-HMA "Recommendations on transparency related to agenda/minutes"
www.emea.europa.eu/pdfs/general/direct/62310708en.pdf

⁴- See for example the detailed agendas and the extensive minutes of the meetings of the Food and Drug Administration in the United States.

⁵- "Regulation (EC) N° 1049/2001 regarding public access to European Parliament, Council and Commission documents" <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:145:0043:0048:EN:PDF>

“documents held by an institution”. Also, the documents prepared by marketing authorisation holders, such as the periodic safety update reports (PSURs), and received by EMEA must be publicly available⁶.

► **Transparency principles should apply by default for all documents covered by Regulation (EC) No 1049/2001.**

EMEA shouldn't develop different procedures to deal with the different forms of information, which are either contained in documents (and in electronic registers of documents), or in databases, or which are considered as “requests for information” (see “Scope of the draft EMEA policy” on page 2 of EMEA's document). The ISDB bulletins' experience, often requesting data in order to properly inform their readers about health issues, is that such a distinction makes it very difficult to write a demand. In fact, how can one ask for a specific document if one is not aware of the detailed agenda of EMEA meetings and of all the documents the EMEA holds? In the case of disclosure refusal, how can one argue for overriding public interest not knowing what information the document in question contains? Facing a request explaining a need for information, EMEA should try to tailor its answer to meet this need with a real commitment to serve public interests (which doesn't prevent EMEA using procedures in order to improve efficiency of answers).

► **The difference made between information supports (document, information or database access requests) shouldn't be used to undermine public access to the data they need.**

Transparency is a duty for EMEA. Full availability of information is essential if all parties involved in health care are to participate effectively, and to improve rational use of medicines. Transparency facilitates adequate feedback, proper setting of priorities and development of accountability from one side, and trust from the other side.

With reference to the supposed need for institutions to “protect their internal consultations and deliberations (...) to safeguard their ability to carry their tasks” (page 2 of EMEA's document), it should be noted that a culture of transparency protects conscientious individuals working in organisations of all kinds.

EMEA should also remember that transparency at an European level is key to encourage transparency at a National level in EU Member States. And European citizens should at least expect the EMEA to be as transparent as National Agencies. For example, the MHRA, the UK Agency, clearly states: “Subject to exemptions, the Freedom of information (FOI) Act gives individuals the right to request any information held by the MHRA. Requestors have the right: to be told whether the information exists; to receive the information”⁷.

► **ISDB therefore requests EMEA to apply the general principles available in the international Uppsala Declaration² to substantially improve its transparency policy.**

Bureaucratic habits, inertia, lack of resources, or over-caution, with EMEA's exaggerated fear of upsetting commercial susceptibilities, must be tackled effectively. Not only EMEA's credibility and accountability are at stake, but also citizens' confidence in health authorities.

► **Commercial confidentiality must not supersede public interest, especially when the safety of European citizens is at stake.**

Use current regulatory issues as an opportunity to foster a culture of transparency in Europe. The ISDB hopes that the ongoing revision of Regulation (EC) No 1049/2001/CE on access to documents will lead to improvement, and not to regression as feared by the European ombudsman itself⁸ because of the restrictive definition of a document proposed in the European Commission proposals⁹. The Committee responsible (Committee on Civil Liberties, Justice and Home Affairs) also asked for more transparency in its draft report⁷.

In addition, if patient safety is to be improved, the transparency provisions contained in the “pharmacovigilance proposals”¹⁰, have to be much strengthened by citizens' Representatives in the EU Parliament during the coming legislative process.

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⁶ - However, in the EMEA document in attachment of the "Draft EMEA policy on the practical operation of access to EMEA documents", the access to the PSURs is not permitted (page 19) <http://www.emea.europa.eu/pdfs/general/direct/65931608en.pdf>. The whole document needs to be rewritten tacking into account that transparency should be the norm and secrecy the exception.

⁷ - MHRA Freedom of information (FOI) Act

<http://www.mhra.gov.uk/Aboutus/Freedomofinformationanddataprotection/Freedomofinformation/index.htm>

Guidance on the Disclosure of Types of Human and Veterinary Medicines - Information Held by the Human and Veterinary Regulatory Authorities: <http://www.mhra.gov.uk/home/groups/l-unit1/documents/websitesources/con2033020.pdf>.

⁸ - Contribution of the European Ombudsman <http://www.statewatch.org/news/2008/jun/eu-ep-ombudsman-on-com-proposals-speech.pdf>.

⁹ - Public access to European Parliament, Council and Commission documents (repeal. Regulation (EC) No 1049/2001) – Procedure file: www.europarl.europa.eu/oeil/FindByProcnum.do?lang=1&procnum=COD/2008/0090.

¹⁰ - The “Pharmacovigilance Proposals” are part of the Pharmaceutical package and available at: http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/pharmpack_en.htm.



ISDB. *International Society of Drug Bulletins* (ISDB), founded in 1986, is a world wide Network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of pharmaceutical industry. Currently, their members include 79 members in 40 countries around the world. More info: www.isdbweb.org.
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This press release was also sent to Thomas Lönngren (EMA executive Director), **to Christine Link** (EMA document management), **to Androulla Vassiliou** (European Commissioner DG Health and Consumers), **to Martin Terberger** (Head of Unit Pharmaceuticals), **Claire Joan Scharf-Kröner** (Unit Pharmaceuticals), **Nikiforos Diamandouros** (European Ombudsman).