PRESS RELEASE
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TRANSPARENCY IN THE PUBLIC INTEREST:
How the EMA policy on publication and access to clinical-trial data could help save lives

The European Medicines Agency (EMA) draft policy on "publication and access to clinical-trial data" could pave the way to a new era in the disclosure of clinical data on medicines.

On 22 November 2012, building on its previous efforts to increase transparency, the EMA organised a workshop on clinical-trial data and transparency. Following that workshop, the Agency established advisory groups to help develop a policy on publication of and access to clinical-trial data, which has recently been released for public consultation.

In its draft, the EMA proposes *"proactive publication of clinical-trial data*" submitted in support of a marketing-authorisation application. Many elements from clinical study reports (CSRs) would finally become publicly available. This is a step in the right direction, as there is currently a lack of public access to the full body of available scientific evidence about the effects of medicines on human health (with data frequently being withheld or manipulated when results do not favour the trial sponsor's product, as shown during recent litigation brought against pharmaceutical companies). Clinical trials have to comply with the Declaration of Helsinki, which explicitly mentions the ethical obligation to disclose research results.

A CRITICAL TIME FOR CLINICAL-TRIAL DATA. Earlier this year, seizing the opportunity provided by the ongoing discussions on the European Commission's proposal for a new regulation on clinical trials, the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) aligned the proposed clinical trials regulation with the EMA's 2010 policy, and publicly supported the Agency's commitment to transparency.

Not surprisingly, the news of the EU Parliament's endorsement of the EMA's efforts has travelled far beyond Europe. In a move to maintain data secrecy, pharmaceutical industry trade associations in the EU and US are counteracting the EMA's initiatives by supporting the litigation initiated by two pharmaceutical companies against the EMA at the European Court of Justice. Among other measures, these trade associations are seeking to prevent data transparency by "mobilizing patient groups to express concern about the risk to public health by non-scientific re-use of data" and by proposing deficient and non-binding self-regulation principles that would maintain the *status quo*.

THE EMA'S TRANSPARENCY EFFORTS ARE IN THE INTERESTS OF 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:

- Extend the scope of its transparency policy to provide access, retrospectively, to clinical-trial data concerning all medicines approved over the last 10 years (2004 to 2014), whether centrally (by the EMA) or through the decentralised procedure or mutual recognition (by the CMDh);
- Introduce a more stringent definition of "commercially confidential information" in order to ensure that transparency remains the rule rather than the exception. Any exception to disclosure should only involve the removal of specific elements within a document and should never be applied to entire sections or certain types of documents;
- Beware of the use of "patient confidentiality" as a pretext to prevent the disclosure of clinical data;
- Incorporate access to data concerning medicines into other EMA processes, particularly pharmacovigilance (e.g. European public assessments reports (EPARs) should be immediately updated and made available, particularly in the case of a "variation" prompted by safety issues).

By proactively granting public access to information on the efficacy and safety of medicines, the EMA new draft policy could prevent drug-induced harm and help save patients' lives, provided that it is properly structured and implemented.

Association Internationale de la Mutualité (AIM)
Health Action International (HAI) Europe
International Society of Drug Bulletins (ISDB)
Medicines in Europe Forum (MiEF)

About us

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. Contact: corinna.hartrampf@aim-mutual.org

HAI Europe. Health Action International (HAI) Europe is a non-profit, European network of consumers, public interest NGOs, health care providers, academics, media and individuals working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy. More info: www.haieurope.org. Contact: ancel.la@haieurope.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. Contact: 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