

Amsterdam, 27 February 2009

Response to the Public consultation on the draft EMEA Policy on the Practical Operation of Access to EMEA documents

This response has been prepared by Health Action International (HAI) Europe. HAI Europe is a non-profit, growing, European network of consumers, public interest NGOs, health care providers, academics, media and individuals with over 25 years experience in representing the voice of civil society, and poor and marginalised people in medicines policy debates.

Our authority rests on our integrity and independence from commercial and political party interests, our research excellence and evidence-based advocacy.

- HAI Europe promotes increased access to essential medicines, the essential medicines concept and the rational use of medicines.
- HAI advocates for greater transparency in all aspects of decision making around pharmaceuticals, for example, by reducing industry secrecy and control over important clinical data.
- HAI promotes the rational use of medicines; that all medicines marketed should meet real medical needs; have therapeutic advantages; be acceptably safe and offer value for money.
- HAI works for better controls on drug promotion and the provision of unbiased and independent information for prescribers and consumers.

Summary

Health Action International Europe (HAI Europe) welcomes the EMEA's decision to hold a consultation on the draft EMEA Policy on the Practical Operation of Access to EMEA documents.

Public accountability of regulatory decisions is only possible if the public has access to the evidence on which those decisions are based, and is provided with a rationale for decisions.

Medicines can be both life-saving and life-threatening. Lack of full public access to the body of available scientific evidence about the effects of medicines on human health leaves European citizens at greater risk for otherwise preventable harm. This is unacceptable. A broad definition of commercial confidentiality that puts commercial interests before human health is both inconsistent with EU regulations and almost certain to lead to otherwise preventable harm. Two steps are needed to prevent future harm: a precise and limited definition of commercial confidentiality and regulatory procedures that make transparency the norm and secrecy the exception.

Main Principles

The role of medicines regulatory agencies is to act as firm gatekeepers of public health. As required by EU legislation, this role includes a duty to publicly disclose information which is of public interest. The EMEA should ensure that all data related to the efficacy and safety of medicines, submitted to regulatory authorities (at national and supranational levels) is publicly available, including all pre-market laboratory and clinical data and post-marketing studies. In addition, the EMEA should encourage national regulatory agencies in all EU Member States to implement these same transparency obligations. Access to safety and effectiveness medicines' information encourages independent analysis. When that same scrutiny corroborates the decisions taken by regulators, it confers greater public trust on the agency's capacity, competence, and decision-making process.

Commercial Confidentiality: a barrier to transparency

There is a strong public health imperative for full public access to the research evidence establishing the effectiveness and safety of a medicinal product. One of the key principles enshrined in reforms to EU pharmaceutical legislation introduced in 2003 was improvement in transparency of procedures and decision making.¹

The provisions for transparency in pharmaceutical regulation allow for an exception to be made for commercially confidential information. From a public health perspective, it is crucial that the definition of commercial confidentiality be explicitly limited to information that is unrelated to a product's safety and effectiveness, or more broadly to any scientific evidence of its effects on the human body.

The EMEA definition of commercial confidentiality, (EMEA/45422/2006), is vague and all-encompassing, giving priority to commercial interests over public health, and creates an important barrier to transparency and public access to information.

The notion of 'public interest', as referred to in the definition of commercial confidentiality, is determined by the agency itself and barely challengeable by any independent authority. This principle is unacceptable from a public interest perspective and inconsistent with the provisions on transparency within EU pharmaceutical legislation. It gives companies virtually unlimited and unchallengeable rights to insist on nondisclosure.

Which information should be made available by the EMEA: Some examples

EMEA should provide public access to comparative information on availability and prices of different treatments and could provide easy links to approved product information in a centralized location, including patient information leaflets, EPARS, reports such as pre-market drug reviews that form the basis for regulatory decisions, post-market regulatory documents including Periodic Safety Update Reports (PSURs), safety advisories etc.

The EMEA should provide public access to information on available drug treatments:

- What products have been approved in the European Union;
- Links to approved product information and European Public Assessment Reports (EPARs);
- Links to pre-market drug evaluations complete clinical trial information concerning all drugs approved through the centralized or decentralized procedures, and any reviews of drugs carried out by the Committee of Medicinal Products for Human Use (CHMP), since the EMEA came into existence in 1995;
- Comparative pricing information between products and countries;
- National and European safety advisories on medicinal products;
- Links to sources of independent, unbiased comparative information.

Aspects relating to process and format

Dissemination is an important step, yet both the format and process through which the information is made available are equally important:

- No or minimal fees should be associated with any requests for information and no fees should be associated with photocopying documents.
- Acknowledgement of request within a very short period of time (e.g., under a week).
- Expectation of a response to a request within 30 days – extensions only granted under very exceptional circumstances and requests for extensions can be appealed by the person requesting the documents.
- Documents need to be provided in legible form, e.g., photocopies should be clear.
- Forms for requesting documents should be available on-line and should be written in easily understood language.
- Should be easy access to personnel who can provide information about how to fill out requests so that the person making the request will actually get the information that they want.
- All information made available online should be on a searchable format, so that users can retrieve it easily using key words.



This response arises from the Developing Rational Use of Medicines in Europe project, which has received funding from the European Union, in the framework of the Health programme

ⁱ EMEA. The European Medicines Agency Roadmap to 2010: Preparing the ground for the future. Part II the European Medicines Agency Road Map Implementation Plan. PublicEMEA/H/34163/03/Final. March 2005.