

Amsterdam, 2nd March 2009

Response to the Public consultation on the draft Eudra Vigilance Access Policy for medicines for human use

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.

Response Summary

Health Action International Europe (HAI Europe) welcomes the EMEA's decision to hold a consultation on the draft Eudra Vigilance Access Policy for medicines for human use.

Giving stakeholders access to Adverse Drug Reaction (ADR) data is an important step. However, 'access' is not the end of the story and it is vital that the process of retrieval and format of information is suitable for those who wish to use the data. As it stands, there is no evidence that the EMEA or any other part of the EU has asked stakeholders, in particular health professionals, patients and consumers how they wish to use this information.

Main principles - What we need to know

The information should address the quality as well as the quantity of data. Some of the most common questions that are likely to be asked about a medicine are:

- What adverse effects might the medicine cause?
- How are they caused and how might they be prevented or mitigated?
- What is the severity, duration, reversibility etc. of those effects?
- In what circumstances do they occur?
- What might be the consequences for patients?

At a minimum, the ADR data provided by the EMEA should be capable of responding to these issues. Simply offering access to tabulations of suspected but unverified ADR reports will do little to help anyone answer such questions.

Analysis, not just Access

People need to understand the reactions, and this requires clear and detailed descriptions - at least the free text of the reports - not just the use of standardised technical Medical Dictionary for Regulatory Activities (MedDRA) terms, which were developed for quite a different purpose.

Regrettably, the EMEA has not shown much interest in analysing the adverse effects and it has not contributed to their investigation. A detailed description and analysis of individual reports should be available to facilitate investigation and the EMEA should play the leading role in facilitating this.

The role of regulation

Elaborate regulation of access to largely unhelpful or useless data misses the point and in no way satisfies the aims of openness, transparency and accountability. The concern surrounding personal data protection is understandable from a legal perspective but does not inherently interfere with the provision of ADR data. It is possible to achieve a balance between data protection and providing useful and transparent data on adverse drug reactions. Most people who suffer an ADR want others to benefit by helping to prevent similar events. Lawsuits against clinicians, pharmaceutical companies, or the state could be precluded with a disclaimer that “Eudravigilance data cannot be used as the basis of litigation.”

A lack of comprehensive data

It is unacceptable that access to safety data generated in interventional and non-interventional trials will not be available to healthcare professionals and the general public. HAI strongly opposes this provision as it further entrenches the idea that it is acceptable to withhold certain data generated in clinical trials. This data is vital for interpreting safety issues that occur once a medicine is on the market. We request that the EMEA reconsider the inclusion of this provision.

Facilitating access

It is not clear from the text whether the database will be searchable but it is important that there are a variety of criteria to retrieve the data. Search criteria for the database should include: sex, age, product (brand and generic names), type of reaction, date reported. The database should also be constructed to enable searches on more than one criterion, e.g. age *and* type of reaction.

Concrete proposals

- The database and format of information should be devised with the needs of stakeholders in mind.
- The EMEA should take the lead in providing clear and detailed descriptions of the reports.
- A disclaimer on the database would prevent restrictions on access due to fears about lawsuits.
- All safety data generated in interventional and non-interventional trials should also be made available to healthcare professionals and the general public.
- All information in the database should be easy to retrieve using a variety of search criteria in isolation and/or combination.