Brussels, 14 October 2014

Press release

EU Pharmacovigilance public hearings should be as transparent and independent as in the US

● ***In their joint comments to EMA's public consultation, Health Action International (HAI) Europe, the International Society of Drug Bulletins (ISDB), the Medicines in Europe Forum and the Nordic Cochrane Center (NCC) call for more independence and transparency to make the most of EU pharmacovigilance public hearings.***

The European Medicines Agency (EMA) is finally working on the implementation of public hearings at the European Pharmacovigilance Committee, a provision included in the 2010 pharmacovigilance legislation (1).

In our response to EMA's public consultation, we encourage the EMA to ensure that EU pharmacovigilance public hearings are as transparent and independent as the public sections of advisory committees in the USA (2). In fact, there is still room for improvement in the EMA's draft proposal.

Independence must be ensured. EMA's draft rules would allow pharmaceutical companies to use public hearings as a platform to minimise/deny genuine safety concerns, as companies would systematically be granted *"the opportunity to present its/their view(s) to the participants of during the public hearing*" by the EMA (1). In contrast, the US Food and drug administration (FDA) guidance on advisory committee prevents "*the sponsor whose product is under review*" from participating in the open panel of public hearings (2).

> According to Sophie Le Pallec, member of the *Medicines in Europe Forum* (MiEF) and President of the association of victims of Lyell's and Stevens Johnson syndromes:
> "*The EMA explains that "the primary purpose of a public hearing is to hear the public's view on the acceptability of the risks". Paradoxically, the added value that victims' testimonies can bring is not emphasised when marketing authorisation holders (MAHs) - with vested interests in downplaying signals - benefit from a preferential treatment*".

Transparency needed. The EMA proposes non-public hearings "*where a marketing authorisation holder or another person intending to submit information that has confidential data relevant to the subject matter of the procedure*" (1). We underline that **non-public hearings hinder public scrutiny** and should be **reserved to protect whistleblowers**, and should not offer MAHs an opportunity to influence the decision-making process.

> Jörg Schaaber, President of the International Society of Drug Bulletins (ISDB) underlines:
> *"Clinical data, including pharmacovigilance data, should never be considered commercially confidential. They are scientific data of public interest, which are urgently needed to protect patients from avoidable harm. Further, as these data are produced by patients, and as some of them have died because of the drugs they have taken, it is utterly disrespectful to consider such data to be commercially confidential information."*

Moreover, instead of being reluctant to organise live-broadcast and web-streaming of public hearings by adding everywhere the condition "*when technically feasible*", we expect the EMA to make the most of modern communication tools to ensure wider participation by the general public.

In short. Public hearings at the PRAC are a long awaited, welcomed initiative but several major improvements are still needed to make the most of these hearings.

Our **full response to EMA's consultation** is available at:
http://english.prescrire.org/Docu/DOCSEUROPE/20141014_PharmacovigilancePublicHearings.pdf

HAI Europe, the ISDB, the MiEF, the NCC

References:

1- European Medicines Agency "Draft rules of procedures on the organisation and conduct of public hearings at the Pharmacovigilance Risk Assessment Committee (PRAC) (EMA/624809/2013) – draft for consultation" 24 July 2014: 9 pages.

2- US Food and Drug Administration (FDA) "Guidance for the public, FDA advisory committee members, and FDA staff: the open public hearing at FDA advisory committee meetings" Final guidance; 15 May 2013: 13 pages.

Short presentation of the signatory organisations

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 the pharmaceutical industry. Currently ISDB has about 80 members representing 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 organisations representing the four key players on the health field, i.e. patient 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 to the importance of European medicines policy. More info: english.prescrire.org; Contact: pierrechirac@aol.com.

NCC. The Nordic Cochrane Centre is part of the Cochrane Collaboration, an international not-for-profit international network of more than 28,000 dedicated people from over 100 countries preparing, maintaining and promoting the accessibility of systematic reviews of the effects of health care. More information: www.cochrane.org. Contact: Peter Gøtzsche (pcg@cochrane.dk)