PRESS RELEASE
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BLACK TRIANGLE FOR MEDICINES: POSITIVE MOVE BUT POOR IMPLEMENTATION PLAN

The draft paper on the quality review of documents[1] submitted for consultation by the European Medicines Agency (EMA) does not reflect the spirit of the new pharmacovigilance legislation, which is to prevent drug-induced harm.

The medicines' surveillance legislation that has recently come into effect brought along a positive step in health literacy: the implementation of a black triangle, to allow healthcare professionals and patients to easily identify medicines subject to additional monitoring by health authorities.

The EMA plan for the implementation of this legal provision into pharmaceutical product information has been circulated for review. Yet, the proposed draft falls short of expectations, as it does not clarify why the black triangle is being introduced, does not set limits to its applications, and does not even explain what a suspected adverse reaction is, or how to report it.

"Good product information is an essential resource for healthcare professionals and medicines users. To improve public health and safety, the few positive changes introduced by the pharmacovigilance legislation should not be watered down " argues Florence Vandevelde, responsible for Public Actions at La Revue Prescrire and a Committee member of the International Society for Independent Drug Bulletins.

To be actively engaged in care and make informed choices, both professionals and patients have the right to know what to expect from a treatment. This means being aware of the treatment's benefits and harms. Against this background, product information should:

- Easily identify products subject to additional monitoring;
- Easily identify whether a medicine's marketing authorisation has been granted under special conditions or exceptional circumstances;
- Identify recent clinically relevant changes to the product information, in particular those due to safety reasons;
- Enable patients to grasp the meaning of harm-benefit balance;
- Encourage health professionals and patients to report any suspected adverse drug reactions.

Should these criteria remain unmet, this will represent a lost opportunity to improve medicines use and achieve better patient health outcomes.[2]

The International Society of Drug Bulletins
The Medicines in Europe Forum

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. patients groups, family and consumer bodies, social security systems, and health professionals. It is a unique group and a testament of the importance of European medicines policy. Admittedly, medicines are no mere consumer goods, and the Union represents an opportunity for European citizens to seek further guarantees of efficacy, safety and pricing. Contact: pierrechirac@aol.com

[1]- European Medicines Agency "Quality Review of Documents (QRD) human product information annotated template: revision of the product information" EMA/468498/2012; 12 July 2012: 15 pages.
[2] The joint response of Prescrire, MiEF and ISDB is available at: http://english.prescrire.org/Docu/DOCSEUROPE/AnswerQRD_BlackTriangle.pdf