➢ *Common Press Release*

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EU Parliament missed needed improvements in the medical devices legislation

On 22 October, the European Parliament voted in the plenary on the report of MEP Roth-Behrendt as adopted by the ENVI Committee on the regulation of Medical Devices. While the Report of MEP Roth-Behrendt had managed to introduce more transparency on clinical data and the ENVI Committee proposed stricter rules for assessment before certain high-risk medical devices can reach the market (novelty of the device, safety concerns), MEPs in the plenary largely watered down this compromise. AIM, ISDB and MiEF warn that the opportunity to prevent large-scale scandals such as the hip implants case should now be seized by the Council.

Public health defenders - mutual and health insurance funds, patients' and consumers' organisations, health professionals and independent drug bulletins - have been struggling for years for safer high-risk medical devices submitted to pre-market assessment of their efficacy, based on strong evidence. We therefore require high-risk medical devices to be systematically submitted to pre-market assessment of their efficacy and safety, which is not happening now[1] [2]. The introduction of specialised notified bodies approved by the European Medicines Agency and the creation of an Assessment Committee for Medical Devices (ACMD) giving a binding opinion on high-risk devices are indispensable measures if patients' safety is to be improved. These measures formed the basis of the compromise as adopted by the ENVI Committee. However, in plenary, MEPs put economic interest ahead of patient safety, watering down this compromise. They decided to reduce the scope of the ACMD making its opinion optional (if the MDCG requests it) and submitting only some of the high-risk medical devices of Class III and IIb to a clinical assessment. In fact, the opinion of this Committee should be binding.
This is a disappointing result: patients remain exposed to possible flaws for the many high-risk devices escaping specific assessment of the ACMD (and the MDCG)[3].

On the issue of clinical data, small improvements have been made. MEPs approved a measure whereby the industry can no longer deny access to scientific data by claiming commercial confidentiality. Access to clinical investigations' results on medical devices should be easier. Anyhow, they rejected the evaluation of new medical devices versus comparator, which was a great proposal to improve the quality of medical devices.

A positive aspect is the introduction of compulsory liability insurance for manufacturers. The liability insurance covering insolvency and damages to patients will make sure that the patients who suffered harm caused by a faulty medical device will be covered if the damage is recognised.

In conclusion, some small improvements have been made on the assessment of high-risk medical devices but major flaws remain in the legislation. The gap has not been filled, to help prevent any future scandal. AIM, ISDB and MiEF therefore ask the Council to go further and strengthen pre-market assessment of all high-risk medical devices in order to protect patients.

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[1] Nicola Kuhrt "Sales Over Safety: Medical Device Makers Battle Tougher EU Laws" October 17, 2013, Der Spiegel www.spiegel.de/international/europe/medical-device-makers-lobby-against-tighter-eu-licensing-rules-a-928191.html

[2] Deborah Cohen "Devices and desires: industry fights toughening of medical device regulation in Europe" October 16, 2013 BMJ 2013; 347: f 6204. http://www.bmj.com/content/347/bmj.f6204 *(with a quotation of Christian Zahn, AIM Vice-President)*

[3] Christian Zahn, AIM Vice-President, "EU medical devices directive a 'missed opportunity'" October 22, 2013, The Parliament, http://www.theparliament.com/latest-news/article/newsarticle/eu-medical-devices-directive-a-missed-opportunity/#.Um4hVZ1kCP8

About Us

The International Association of mutual benefit societies (AIM), founded in 1950, is a grouping of autonomous health insurance and social protection bodies operating according to the principles of solidarity and non-profit-making orientation.
Currently, AIM's membership consists of 50 national federations representing 28 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/blandine.cassou-mounat@aim-mutual.org

The Medicines in Europe Forum (MiEF) was founded in March 2002 and brings together over 70 member organisations from 12 European member states, representing four major groups active in the healthcare field: patient advocacy groups, family and consumer groups, health insurance providers, and healthcare professionals. This movement is unprecedented in the EU's history. It goes to show just how great the stakes are, and how great the hopes raised by European medicines policy. It also goes to show that medicines are not just a commodity like any other, and that Europe offers an opportunity for all of its citizens to benefit, in this domain, from the very best guarantees in terms of efficacy, safety and prices.
More info: http://english.prescrire.org. Contact: pierrechirac@aol.com

The International Society of Drug Bulletins (ISDB), 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 around 80 members representing 41 countries around the world.
More info: www.isdbweb.org. Contact: press@isdbweb.org.