

Brussels, 19 November 2013

EU regulation on Medical Devices: Patient safety should be of paramount importance

AIM, ISDB and MiEF open letter
on the proposal for a regulation on medical devices, and amending Directive 2001/83/EC,
Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009
[COM (2012) 542]

Dear Health Ministers of Member States,

Dear Health Attachés, Permanent Representative of Member States,

As representatives of mutual health and insurance funds, patient and consumer advocacy groups, and healthcare professionals' organisations, **we jointly welcomed the improvements made** to the initial insufficient EU Commission proposal **by the Environment and public health (ENVI) Committee** of the European Parliament on 25 September 2013 (ENVI report by Mrs Dagmar Roth-Behrendt)¹.

However, during the plenary vote of the European Parliament on 22 October 2013, the ENVI report was weakened². This occurred as a consequence of intense lobbying by the medical devices industry^{3,4}.

In order to ensure patient safety, **we urge you to reinstate many improvements as adopted by the ENVI Committee before they were weakened in plenary**¹.

In particular, we urge you to:

- ***Require an Assessment Committee for Medical Devices (ACMD) to systematically give a binding opinion on all high-risk and implantable devices (class III non implantable devices and some class IIb implantable devices should also fall into the scope of health authorities' scrutiny procedure).***
- ***Prevent the misuse of "commercial confidentiality" to deny access to scientific data once the product is marketed.***
- ***Ensure that manufacturers have appropriate liability insurance with a level of coverage proportionate to the potential risk.***
- ***Establish a central mandatory European registry or national registries to strengthen post-marketing surveillance and to allow as early detection as possible of the risks of defective medical devices.***

Over the years, too many serious safety problems with high-risk and implantable medical devices (e.g. the breast implant PIP disaster, defective hip implants, intracranial stents) have shown the **failure of the current EU legislative framework to ensure public health protection**.

Since the European Conformity (CE) marking is very often obtained without any clinical evidence of a benefit to patients⁵, **several dangerous and ineffective medical devices have been allowed to enter the**

European market even though they were not authorized in the US⁶. As a consequence of this poor scientific and ethical approach, hundreds of thousands people were harmed.

In order to ensure patient safety, the medical benefit and efficacy of innovative medical devices should have to be proven.

Therefore, as many other health professionals and patients' organisations calling for strengthened pre-market assessment of medical devices (a), the *Association Internationale de la Mutualité* (AIM), the *Medicines in Europe Forum* (MIEF) and the *International Society of Drug Bulletins* (ISDB) regret that the central marketing authorisation for high-risk medical devices proposed by Mrs Roth-Behrendt has not been considered in the discussions. Indeed several Health Ministers and the European Parliament had asked for such a central marketing authorisation for high-risk medical devices previously in early 2012⁷.

In order to **not fully lose the opportunity of strengthening patients' protection from insufficiently evaluated high-risk medical devices**, AIM, MIEF and ISDB call upon you to support the following proposals during the trilogue process with the European Parliament and the European Commission:

1. *Assessment of high risk medical devices and implantable devices (class III) through Special notified bodies (SNB) and a systematic scrutiny procedure by an Assessment Committee for Medical Devices (ACMD)*

We welcome the Parliament proposal adopted in plenary that **special notified bodies will be in charge of assessing high-risk devices** (amendments 360 & 371 of EU Parliament final report²).

However, we call upon you to reinstate the **formalisation of an Assessment Committee for Medical Devices (ACMD)**, required to systematically give an opinion on all high-risk and implementable devices rather than on a case-by-case basis (b).

Moreover, the ACMD opinion should be binding for the notified bodies (in case of disagreement, the European Commission (Medical Device Co-ordination Group, MDCG) should therefore be required to justify why it does not follow the ACMD opinion).

We furthermore recommend that the ACMD should include experts with a background in evidence based medicine and biometry/biostatistics. All Committee members should be free from conflict of interests in order to ensure their independence.

2. *Transparency on clinical data & ethics*

AIM, MIEF and ISDB welcome the improvements adopted by the European Parliament in plenary as regards the transparency of clinical data. Restricting misuse of the claim of "commercial confidentiality", which should remain an exception, is an important improvement to ensure researchers, health professionals and patients are not denied access to scientific data once the product is marketed (amendments 32, 130 & 131 of EU Parliament final report²).

a- The positions of the following organisations are accessible here (click on the hyperlink): [European Association of Hospital Pharmacists \(EAHP\)](#), [Standing Committee of European Doctors \(CPME\)](#), [European Society of Cardiology](#), [the European Consumers' organisation \(BEUC\)](#), [European Association for the Study of Diabetes \(EASD\)](#).

b- **This scrutiny procedure is especially important in some cases** (public health concern, novelty of the device, device incorporating a medicinal product), which amount to no more than a few dozen medical devices per year.

Moreover, the ethical issue of requiring that medical devices are tested against a comparator when it is available as adopted in ENVI Committee should be reinstated by the Council (**amendments 85 & 176 of ENVI Committee report¹**). This requirement is in fact in line with the declaration of Helsinki “Ethical Principles for Medical Research Involving Human Subjects”⁸.

3. Liability insurance: Right of patients to information about a medical device

AIM, MiEF and ISDB welcome the proposals that make it mandatory for manufacturers to ensure that they are covered by an appropriate liability insurance covering the risk of insolvency and any damages to the patients or user before placing a medical device on the market. We urge you to ensure that the liability insurance will have a level of coverage proportionate to the potential risk.

4. Post-marketing surveillance: Registries to early identify the risks of the medical devices and to inform the health professionals and patients

AIM, MiEF and ISDB support the establishment of a centralised European registry or of national registries. Registries have proven to be effective in the early detection of safety signals in case of defective medical devices (c)⁹.

A centralised European registry could collect high quality and relevant data on implants and artificial joint replacement, thereby helping to monitor the performance of these implants and the effectiveness of different types of surgery. Furthermore, registries would help clinicians and the medical devices industry to improve the clinical standards, which will lead to a greater benefit for patients. A European registry would furthermore help to ensure the quality and cost-effectiveness of implant replacements.

We count on your commitment to patients’ safety and sincerely hope that you will support the above listed proposals, as they would improve both patients’ safety and EU competitiveness in the mid-term by restoring trust in the EU medical device industry.

**Association Internationale de la Mutualité (AIM),
International Society of Drug Bulletins (ISDB),
Medicines in Europe Forum (MiEF)**

c- Examples of national registries, which already exist in different Member States: German EndoprosthesisRegistry (EPRD) set up by Verband der Ersatzkassen (vdek), AOK-Bundesverband (health insurers) and Bundesverband Medizintechnologie e.V. (BVMed) (medical devices industry), German Society for Orthopaedics and Orthopaedic Surgery (DGOOC) and the Institute for quality and patient safety (BQS); National Joint Registry (NJR) for England, Wales and Northern Ireland, managed by the Healthcare Quality Improvement Partnership (HQIP) under a contract with NHS England; Swedish Hip Arthroplasty Register (SHPR) a National Quality Register, Swedish Association of Local Authorities and Regions (SKL) and the Western Götaland Region, works in consultation with the Swedish Orthopaedic Association and the Swedish Knee Arthroplasty Register (NKO) with links to other foreign registries in Europe.

References:

- 1- Mrs Dagmar Roth-Behrendt, rapporteur for the ENVI Committee "[Report on the proposal for a regulation of the European Parliament and of the Council on medical devices](#), and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 (COM(2012)0542 – C7-0318/2012 – 2012/0266(COD))" 9 October 2013: 336 pages.
- 2- "[Amendments adopted by the European Parliament on 22 October 2013](#) on the proposal for a regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 (COM(2012)0542 – C7-0318/2012 – 2012/0266(COD)) 22 October 2013 – Strasbourg.
- 3- 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
- 4- 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>
- 5- Cohen D "[EU approval system leaves door open for dangerous devices](#)", *BMJ* 2012.
- 6- FDA report "[Unsafe and Ineffective Devices Approved in the EU that were Not Approved in the US](#)" May 2012.
- 7- Health Ministers from Austria, France, Belgium, Latvia, Luxembourg, Slovenia "Joint letter to Commissioner Dalli" 20 February 2012 : 2 pages. FDA report "Unsafe and Ineffective Devices Approved in the EU that were Not Approved in the US" May 2012
- 8- Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects"
<http://www.wma.net/en/30publications/10policies/b3/>.

About Us



The International Association of mutual benefit societies (AIM) 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.

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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 about 80 members representing 41 countries around the world.

More info: www.isdbweb.org. Contact: press@isdbweb.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: pierre.chirac@aol.com