



Joint press release
Brussels, 7 May 2013

Medical devices legislation Regaining the trust of European citizens

On 12 April 2013, MEP Dagmar Roth-Behrendt (ENVI committee) published her draft report on the European Commission's proposal for a Regulation on medical devices (1).

The *Association Internationale de la Mutualité* (AIM), the *International Society of Drug Bulletins* (ISDB) and the *Medicines in Europe Forum* (MiEF) support this draft report, which improves the European Commission's proposal. Notably, it provides greater protection for patients by strengthening the evaluation of high-risk medical devices before marketing approval.

Patients' safety is not guaranteed by the current medical devices regulatory framework

Over the years, too many serious safety problems have shown the failures and limitations of the current medical devices legislative framework.

The **absence of a pre-marketing approval** procedure allows high-risk medical devices to enter the market without proper clinical evaluation. These devices can have terrible consequences on patients' lives, as did ASR (articular surface replacement) hip implants (**a**) and intracranial stents (**b**).

The **weakness of post-marketing monitoring of medical devices** has devastating consequences for patients. For instance, worldwide, more than 300 000 women have received defective breast implants from the company Poly Implant Prothèse (PIP).

These scandals are testament to the failure of the current legislative framework for medical devices under the "new approach", which relies too heavily on industry self-regulation.

The European Commission's proposal does not guarantee patient safety either

The European Commission's proposal, published in September 2012, focuses on strengthening post-marketing surveillance and therefore fails to ensure the efficacy and the safety of medical devices entering the EU market.

In fact, even for high-risk medical devices, **the Commission persists in:**

- **requiring manufacturers to demonstrate the device's "performance"** (compliance with technical specifications) **rather than requiring demonstration of clinical efficacy;**
- **relying on notified bodies to grant a European Conformity (CE) marking**, despite the overwhelming evidence that their conflicts of interest make them unfit for this purpose (see below).

a-Called "*one of the biggest disasters in orthopaedic history*", the ASR hip implant was available in Europe for seven years before being withdrawn from the market for safety reasons. Yet in the USA they had not been authorised: during the pre-marketing authorisation procedure, where clinical efficacy — not mere "performance" — must be demonstrated, clinical trials had revealed their dangerous side effects (metal debris from wear of the implant led to a reaction that destroyed the soft tissues surrounding the joint; ions of the metals from which the implant was made were also released into the blood and cerebrospinal fluid in some patients). These implants were subsequently removed from the European market, but unfortunately, the harm had already been done. Many patients are still suffering from chronic pain and irreversible disability (ref. 4).

b-A randomised clinical trial in patients with intracranial arterial stenosis — an important cause of stroke — showed that intracranial stenting (percutaneous transluminal angioplasty and stenting) was less effective in preventing recurrent stroke than medical management, mainly because of an increased risk of early stroke(ref. 5).

Healthcare professionals, social insurance providers, consumer groups, and patient advocacy groups are calling for:

- **the demonstration of clinical efficacy** — not of mere “performance” — **and of clinical safety** for high-risk medical devices **before centralised marketing authorisation is granted**;
- **health authorities — not notified bodies — to be responsible for granting such marketing authorisation**, and for their decision to be based on high-quality clinical studies (2).

The ENVI committee’s draft report contains positive recommendations, which we support

For high-risk medical devices, a marketing authorisation procedure would replace the conformity certification procedure

For high-risk medical devices, as an alternative to a mere CE conformity marking, which has proved to be insufficient, the ENVI rapporteur proposes **more comprehensive and swift procedures**:

- **a centralised marketing authorisation procedure for “innovative” devices (c)**;
- **a decentralised marketing authorisation procedure for “non-innovative” devices (d)**.

Currently, even for high-risk medical devices, **notified bodies are “cherry picked” and remunerated by manufacturers to certify their medical devices**. This situation — which would persist if the European Commission’s proposal were to be accepted — creates competition among the 84 notified bodies in the European Union to provide faster and cheaper approvals. A recent BMJ investigation using a fake and dangerous hip implant is most enlightening (3).

Moreover, **notified bodies lack the clinical expertise** needed to properly assess the results of clinical trials on high-risk medical devices.

► **AIM, ISDB and MiEF therefore fully support the rapporteur’s proposal for a centralised procedure for innovative implantable devices. This new procedure, which would reinforce public health protection, is both feasible** (it would apply to only a few dozen medical devices a year) **and efficient** (it would encourage work-sharing among independent experts from national drug regulatory agencies and from national health technology assessment (HTA) bodies).

The new authorisation procedure would be based on real clinical evidence

Too often, when seeking certification even for high-risk medical devices, manufacturers only need to submit scientific literature. For high-risk medical devices, manufacturers must be **required to have demonstrated the safety, efficacy and positive harm-benefit balance of the device in high-quality clinical trials using patient-relevant outcomes** before applying for marketing authorisation.

► **AIM, ISDB and MiEF therefore welcome the rapporteur’s proposal to define the notions of “performance” such that it includes “any effects and any benefit of the device” (amendment 25), “benefit” (amendment 26) and “clinical investigation” (amendment 28).**

Greater transparency

Currently, no information describing the basis on which certification was granted is made publicly available. This means that the grounds for approval (efficacy and safety data) are not subject to public scrutiny.

► **AIM, ISDB and MiEF welcome the rapporteur’s proposal to make publicly available the content of an “electronic system for the registration of applications, the granting, the suspension and the revocation of marketing authorisations” (amendment 9).**

► **AIM, ISDB and MiEF support the rapporteur’s proposal to require sponsors to publish on the Eudamed database a summary of clinical investigations “in a way that is easy for a lay person to understand” (amendment 90), but also call for publication of the full assessment report.**

c- This authorisation would be granted by a new “Committee for the Authorisation of Medical Devices”, which would be established within the European Medicines Agency (EMA) (*amendments 68 and 70 of the draft report*).

d-The mutual recognition principle would apply to the decentralised procedure, and the European Commission’s Medical Devices Coordination Group (MDCG) would act as a facilitator in the event of disagreement between Member States.

**Medicines in Europe Forum (MiEF)
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**Joint communication campaign
“Medical Devices: True or False?”**

AIM, ISDB, MiEF and the *European Social Insurance Platform (ESIP)* have also worked on a **joint communication campaign**, entitled “Medical Devices: True or False?”, sent to Members of the European Parliament and European newspapers on 6 and 7 May 2013.

About Us

The Association Internationale de la Mutualité (AIM) is a grouping of autonomous, not-for-profit health insurance and social protection bodies that operate on the principle of solidarity. Currently, AIM’s membership consists of 42 national federations representing 25 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

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> > Medicines in Europe. 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.

References:

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- 2- AIM, ESIP, ISDB, MiEF “High-risk medical devices should be made subject to approval at European level and the rights of patients harmed should be improved” Joint Position Paper; 22 October 2012: 7 pages. http://english.prescrire.org/Docu/DOCSEUROPE/20121022_ESIP-AIM-ISDB-MiEF-MedicalDevices.pdf
- 3- Cohen D “EU approval system leaves door open for dangerous devices” *BMJ* 2012; 354:e7173 doi: 10.1136/bmj.e7173.
- 4- Cohen D “[Out of joint: the story of the ASR \[articular surface replacement\]](#)” *BMJ* 2011;342:d2905.
- 5- Chimowitz MI et al. “Stenting versus aggressive medical therapy for intracranial arterial stenosis” *N Eng J Med* 2011; 365 (11): 993-1003. <http://www.neim.org/doi/pdf/10.1056/NEJMoa1105335>.