AIM - ESIP - ISDB - MiEF Joint Position Paper

22 October 2012

on

Proposal of the European Commission for a Regulation relating to Medical Devices[1]

COM(2012) 542 final

Summary of the key proposals

- High-risk medical devices should be made subject to approval at European level and the rights of patients harmed should be improved -

Various scandals and serious safety problems have shown the failures and limitations of the CE (for "European conformity") certification system for high-risk medical devices.

The revision of the European medical devices legislation is therefore a great opportunity to entirely overhaul the European authorisation and surveillance system for high-risk medical devices notably by making high-risk medical devices subject to a true market authorisation.

AIM, ESIP, ISDB and MiEF believe that the European Commission's proposal of 26 September 2012, revising the medical devices legislation, are insufficient to ensure a high level of quality, safety and efficacy of medical devices entering the market. The Commission's proposal provides solely for stronger monitoring once a device is brought onto the market.

Several issues need to be addressed:

1. The current certification system by private Notified Bodies remains insufficient in guaranteeing effective protection of patients

- Several medical devices that were rejected in the US thanks to the federal preapproval system by the Food and Drug Administration were marketed in Europe, and then removed from the market for safety reasons.

2. A centralised approval procedure is required for high-risk medical devices

- Instead of the current CE certification by private Notified Bodies, high-risk medical devices (i.e. class III or implantable devices) must be subject to a centralised approval procedure at European level, in which safety, efficacy as well as a positive risk-benefit balance must be proven by the results of high quality clinical investigations.
- The results of clinical investigations should be stored in a publicly accessible central database.
- For high-risk medical devices which are already in use, the procedure for re-approval set up in article 45 of the proposed Regulation – in which safety and efficacy have to be proven – should be provided for in the mid-term, in the context of the centralised approval of medical devices.

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[1] Proposal for a Regulation of the European Parliament and the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009

3. Rights of patients harmed need to be strengthened

- To ensure adequate provision for coverage in case of harm, medical device manufacturers must be obliged to take out compulsory liability insurance including coverage of direct action by the injured party.
- In the interest of patients harmed as well as in the interest of payers, a right of access to information held by medical device manufacturers as well as the supervisory bodies should be embodied in the law.
- The burden of proof that a faulty device is / is not the cause of harm should be transferred from the patient to the manufacturer. The patient should only be required to demonstrate that it is objectively possible that the device may have caused the harm.

Insufficiencies of the current and the proposed system

Given the safety gaps in the medical device sector which have come to light most recently and drastically in the silicon implant issue, as well as in the matters of large diameter metal-on-metal hip replacements and intracranial stents, AIM, ESIP, ISDB and MiEF demanded – in their joint position paper of 27 March 2012 – an improvement in market transparency and improved protection for patients.

Pursuant to the Commission's proposal for a Regulation, post market monitoring of medical devices is to be strengthened. The proposal, however, does not envisage a pre-market approval system for high-risk medical devices (i.e. falling within class III or implantable devices), nor does it provide any substantive improvement in patient rights in the event of harm suffered due to faulty medical devices.

1. Insufficiency of premarket evaluation: the certification system by Notified Bodies is not sufficient in guaranteeing safety and efficacy of high-risk medical devices

Insufficiently evaluated medical devices falling within class III or implantable devices, which will remain inside the human organism permanently, may cause serious damage to the patients' health (e.g. an implanted defibrillator firing without reason because of an incorrectly dimensioned cable is life threatening, a hip implant breaking after only five years carries the risk of essential rectifying surgery).

However, the current EU certification procedure by private Notified Bodies does not guarantee effective protection of patients. In fact, several medical devices that were rejected in the United States thanks to the federal preapproval system by the Food and Drug Administration were nevertheless marketed in Europe, and then removed from the market for safety reasons.[2]

[2]- FDA "Unsafe and Ineffective Devices Approved in the EU that were Not Approved in the US" Report; May 2012. Freely accessible at: http://www.elsevierbi.com/~/media/Supporting%20Documents/The%20Gray%20Sheet/38/20/FDA_EU_Devices_Report.pdf

The main problems of the "European Conformity" certification procedure are:

1.1. Insufficient requirement for the proof of a positive risk-benefit balance

The proposal takes some account of this aspect but remain unclear. The CE certification procedure is not sufficiently focussed on clinical efficacy, which can only be proven in high quality clinical investigations, generally randomised controlled trials. In fact, a demonstration of efficacy is not synonymous with a demonstration of performance[3].

The current European regulatory provisions are unclear as to when clinical investigations of a medical device are required in order to prove conformity with the essential requirements pursuant to Annex I of Directive 93/42/EEC. Insofar as clinical investigations on medical devices have been conducted at all in the past, they have mostly involved only a few patients with no control group, and specifically in the case of implants, were limited to observational periods which were too short. Further, too often, manufacturers chose to submit only existing scientific literature instead of having their products tested (i.e. physical resistance tests) by the Notified Bodies.

However, the Commission's new proposal does little to improve the current lack of clarity. According to the proposal, the depth and extent of the clinical evaluation should be "proportionate and appropriate" to the nature, classification, intended use and manufacturer's claims and risks of the device in question (Annex XIII, Part A, No. 3). Even for medical devices falling within class III or implantable devices, the draft still allows for clinical studies to be waived if it is "*duly justified to rely on existing clinical data alone*" (Annex XIII, Part A, No. 5). Therefore, the relevant provisions still leave a wide scope of choice for the manufacturer, as well as for the Notified Body, to decide whether it is necessary to generate clinical data by conducting clinical studies or to, e.g. rely merely on existing scientific literature.

1.2. Insufficiency of the certification system by Notified Bodies

The system of private Notified Bodies shows a conceptual weakness in that it enables medical device manufacturers to choose for their products to be reviewed by any one of 80 or so Notified Bodies based in the EU Member States. It is in the nature of things that the manufacturers will choose those Notified Bodies which they believe are most likely to certify their medical device.

[3]- For example, "*If a manufacturer wishes to market a laser to incise heart tissue to treat arrhythmia (abnormal heart rhythm) in the EU, the manufacturer must show that the laser incises heart tissue only. In the US, however, the manufacturers must show that the laser incises heart tissue and also treats the arrhythmia*" (ref. Cohen D & Billingsley M "Europeans are left to their own devices" BMJ 2011;342:d2748).

2. Key structural prerequisites of a centralised approval procedure for high-risk medical devices

The structural deficits described above cannot be remedied solely by improving monitoring of the Notified Bodies. Instead, effective patient protection can only be achieved by harmonising the regulatory provisions for devices falling within class III or implantable devices with the requirements and standards that have long been customary in the area of medicinal products.

For this purpose, the following structural changes in medical devices legislation at European Union level need to be undertaken:

2.1. Requirement for a centralised approval at European level

The inconsistent certification model of private Notified Bodies needs to be replaced by a centralised and independent approval procedure at European level, in which a common approval authority decides conclusively on whether to approve a medical device for the entire Single Market. It should also include the submission and review of product information distributed together with the product: this information should be made available in a database accessible to the public, in particular to professional users so they can obtain comprehensive information on the product and its use.

2.2. Proof of safety and clinical efficacy through randomised clinical investigations

In the framework of a centralised approval procedure, a positive risk-benefit balance and therapeutic value for patients should have to be proven by high quality clinical investigations before a high-risk medical device can be brought onto the market. Ideally this means high quality controlled clinical investigations (generally randomised trials) comparing the new device with the existing standard treatment or – in cases where no standard therapy exists – comparing it with no therapy or sham therapy. Proof of at least comparable effect must be shown compared to the standard treatment.

The results of clinical investigations should be made public on a central database. The Commission's proposal to "*provide a summary of safety and performance with key elements of the supporting clinical data*" is not sufficient.

2.3. Possibility of referring to documentation of a previous applicant for identical devices

In order to avoid carrying out unnecessary clinical investigations, it should be possible for a manufacturer to refer to the results of previous clinical investigations if the new medical device is completely identical to the one already approved. Incremental innovations can in fact have deleterious effects (e.g. the enlargement of the head of a hip replacement can lead to severe tissue destruction and high revision rates). In the case of any modification, there should be clear evidence that the modification has no impact on the safety of the medical device.

If a manufacturer claims that his device has different properties compared to a product already approved (e.g. in commercial communications), then that means that the second product is different

from the one already approved. The new product can therefore not be approved by simply referencing the data of the approved device: separate clinical investigations are required for approval.

2.4. Re-approval procedure for medical devices already certified

High-risk medical devices that comply with current statutory requirements, including a conformity assessment procedure, should be deemed to have been approved for a five-year period. After this period, safety and efficacy should be proven in a re-approval procedure.

3. Improving the position of patients harmed by medical devices

Patients who have suffered harm to their health due to medical devices are insufficiently protected under the current European product liability framework. In particular, and as the PIP and Solysafe (Swissimplant) scandals have shown, the medical device manufacturer will quickly face insolvency if many patients have been affected. For this purpose, the following improvements to patients' rights need to be undertaken:

3.1. Medical device manufacturers' obligation to provide for coverage

Under the current Product Liability Directive 85/374/EEC, manufacturers of medical devices are not obliged to provide for coverage in the form of compulsory liability insurance. This unfairly shifts the damage risk onto the patients harmed and to the payers liable for the cost of treatment. Therefore, medical device manufacturers should be obliged to make adequate financial provision in the future by means of compulsory liability insurance so that they can in fact comply with their obligations under product liability law and to provide compensation in case of an insurance claim. A breach of the normative duty at European level to provide for coverage should be made an offence in the legal systems of the Member States.

Patients and payers should be entitled to file direct actions against the manufacturer's insurer. Therefore, the Commission's proposals should request Member States to lay down provisions and take all measures necessary to ensure that manufacturers or other persons liable under the Product Liability Directive (e.g. importers) provide for sufficient coverage in order to compensate the patient harmed and/or the public or private insurance bodies who are liable for the cost of treatment. The provision for coverage should be made in the form of compulsory liability insurance, to be taken out by the medical device manufacturer, as a pre-condition for market access. The insurance should include the right for direct action by the injured party and/or the third party payers against the manufacturer's insurance undertaking.

3.2. Codification of the right to information held by the medical device manufacturer and the approval authority

The Product Liability Directive establishes medical device manufacturers' liability. However, the person harmed and/or the payer liable for the cost of treatment has to prove the harm, the faultiness of the medical device, and the causal relationship between the fault and the harm suffered. The patient often lacks the information required to prove faultiness while the manufacturer can argue that the medical device can be considered as safe and not defective due to its successful certification.

Therefore, the manufacturer should be obliged to make all necessary documents and information regarding safety and efficacy as well as the risks of use available to the person harmed and to the payer liable for the cost of treatment. A right of access to the same information held by the European approval authority, the national monitoring authorities as well as the Notified Bodies should also be provided for.

3.3. Facilitating proof of causality for the person harmed

The requirement to prove causality between the harm which has occurred and the faultiness of the medical device represents a considerable obstacle for patients in successfully asserting claims for compensation. For this reason, the burden of proof needs to be reversed. Instead of the full proof of causality, it should suffice if the person harmed proves that upon objective consideration the probability exists that the harm was caused by the medical device. It should then be the obligation of the medical device manufacturer to prove otherwise.

4. Summary

- For high-risk medical devices (i.e. Class III devices and implants), the current "European conformity" certification system involving private Notified Bodies needs to be replaced by a centralised approval procedure guaranteeing safety and efficacy - improvement in post-market monitoring alone is not sufficient.
- In this procedure, safety and efficacy including a positive risk-benefit ratio need to be rendered on the basis of the results of high quality clinical investigations - in general, randomised controlled trials (RCTs). The Commission's proposal does little to improve the lack of clarity of the current provisions in this respect.
- To improve the rights of patients harmed, provisions need to be made to 1) oblige manufacturers to take out liability insurance, 2) give patients and payers the right to relevant information in order to prepare a claim for compensation, and 3) reverse the burden of proof.

About Us

	AIM. The Association Internationale de la Mutualité (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 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: aim.secretariat@aim-mutual.org
	ESIP. The European Social Insurance Platform (ESIP) represents a strategic alliance of over 40 statutory social security organisations in 15 EU Member States and Switzerland. ESIP's mission is to preserve high profile social security for Europe, to reinforce solidarity based social insurance systems, and to maintain European social protection quality. Note: *ESIP members support this position in so far as the subject matter lies within their field of competence.* More info: www.esip.org. Contact: esip@esip.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 pharmaceutical industry. Currently ISDB has around 80 members in 41 countries around the world. More info: www.isdbweb.org. Contact: press@isdbweb.org.
	MiEF. Medicines in Europe Forum, launched in March 2002, covers 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. Such a grouping is unique in the history of the EU, and it certainly reflects the important stakes and expectations regarding European medicines policy. Admittedly, medicines are no simple consumer goods, and the Union represents an opportunity for European citizens when it comes to guarantees of efficacy, safety and pricing. Contact: Pierre Chirac (pierrechirac@aol.com).