European Social Insurance Platform, The Association Internationale de la Mutualité, International Society of Drug Bulletins, Medicines in Europe Forum are non for profit organizations. We are working for a medical devices regulation which will protect medical devices' users and patients.

Medical devices: True or false?

Episode 1: Marketing authorisation for high-risk medical devices will increase patient safety.

1. The PIP breast implant scandal is one isolated case of dysfunction in the medical devices certification procedure. [FALSE]

   FACT: There have been numerous scandals involving faulty medical devices. Already many people have been harmed because hip implants (e. g. ADEPT, ASR) or stent grafts to repair aortic aneurysms have been recalled or because defibrillator leads (e. g. Spring fidelis, Riata) have had to be prophylactically removed from the heart due to high failure rates.[1]

2. The PIP breast implant incident was due to a fraud, not to lack of safety. [FALSE]

   FACT: If a marketing authorisation had been requested like in the US, these breast implants would not have been used. Indeed, poor quality of the membrane was responsible for the burst.[2] The scandal also raised the problem of a lack of post-market monitoring by notified bodies of high-risk medical devices.

3. The negative consequences of these scandals affect the whole of society. [TRUE]

   FACT: Medical device scandals threaten the reputation of European medical devices industry and undermine Europe's competitiveness. Victims suffer a lot from defective or insufficiently evaluated medical devices.[3] And costs for replacement of defective medical devices and expenses related to renewed surgical interventions are particularly high for the health care systems.[4]

Safer – Healthier – Better – Stronger for patients means ...

... Complete revision of the medical devices legislation establishing a marketing authorisation procedure

Sources: [1]*D. Cohen, « Out of joint – The story of the ASR », BMJ, 2011, n°342 and Meier, Berry (2012): Hip Implants U.S. Rejected Was Sold Overseas, New York Times*
[2]*Scientific Committee on Emerging and Newly Identified Health Risks, The Safety of PIP Silicone Breast Implants, 1st February 2012, p. 9, 23, 27*
[3]*BEUC Medical Devices testimonies http://www.beuc.org/Content/Default.asp?PageID=2141*
[4]*Les prothèses mammaires implantables PIP - État des lieux, ANSM, Avril 2013.*

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Medical devices: True or false?

Episode 2: A marketing authorisation procedure for high-risk medical devices will support access to real innovations.

1. Today in Europe, people have access to life-saving medical devices several years earlier than in other parts of the world. [FALSE]

FACT: In the US, the Pre-market Approval for class III medical devices takes less than one year and it avoids that unsafe and ineffective devices are approved in the US.[1, 2]

2. The marketing authorisation is a barrier to innovation. [FALSE]

FACT: In the United States, such a marketing authorisation exists and they are still the leader in medical devices innovation[3] and the leading competitor, holding in excess of 40 % of the world medical device market despite the high approval requirements.

Safer – Healthier – Better – Stronger for patients means ...

... a marketing authorisation procedure for high-risk medical devices

... a safe and high-quality system

Sources: [1]*Improvements in Device Review Results of CDRH's Plan of Action for Premarket Review of Devices, Food and Drug Administration, November 2012, p. 18*
[2]*Unsafe and ineffective devices approved in the EU that were not approved in the US, Food and Drug Administration, May 2012.*
[3]*http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/default.htm*

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Medical devices: True or false?

Episode 3: High-quality clinical investigations are essential for high-risk medical devices.

1. The European certification system is as safe as the centralised approval system in the US. [FALSE]

   FACT: **US law requires proof of safety and efficacy of high-risk medical devices. Several high-risk devices that were approved in the EU on the basis of limited scientific data are later found to be dangerous or ineffective.**

2. High-quality clinical studies are not needed for medical devices that are similar with those already on the market. [FALSE]

   FACT: **No car manufacturer would use a new brake system which is only similar to an existing one and without having tested it under real conditions.**

3. Establishing a system of marketing authorisation for high-risk medical devices within the European Medicines Agency (EMA) is unrealistic. [FALSE]

   FACT: **High-risk medical devices represent only less than 2 % of the overall medical devices.[1]**

Safer – Healthier – Better – Stronger for patients means …

Safety, efficacy and positive risk-benefit balance must be proven by high-quality clinical investigations before high-risk medical devices are authorised.

Source: [1]*DIMDI-Database as of 26 January 2012 – see answer of the German Federal Government «Fehlende Patientensicherheit bei Medizinprodukten» German Bundestag Drucksache, 6 February 2012.*

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Medical devices: True or false?

Episode 4: Strengthening the rights of patients harmed.

1. Patients harmed by medical devices do not need access to product information considered "commercially confidential" by the manufacturer. [FALSE]

FACT: **Precisely because patients harmed do not have access to all relevant product information, they often fail to pursue their claims. Therefore, they must be given the right to demand all relevant information held by the manufacturer, the national and European authorities, as well as the notified bodies.**

2. Patients' rights in case of harm are sufficiently protected. [FALSE]

FACT: **Today, according to the current Product Liability Directive[1], the onus of providing proof of damage, defect and the causal relationship between defect and damage lies with the patient. Without access to relevant product information this is almost an insurmountable barrier in pursuit of patients' claim. If there is a suitable level of probability that harm could be linked to product failure then the onus should be on the manufacturer to prove otherwise (shift the current burden of proof).**

3. Manufacturers of medical devices are already responsible for damage caused by faulty products and patients harmed often obtain compensation. [FALSE]

FACT: **The current Product Liability Directive does not foresee any measures to assure financial security. The risk of damage and the risk of a manufacturer's insolvency are both placed on the injured party and the payers liable for the cost of treatment. Manufacturers should therefore be legally obliged to take out civil liability insurance with an adequate minimum cover so that claims can be made by damaged parties directly against the insurer on an EU-wide basis. Insurance coverage would be obligatory as is the case for motor insurance.**

Safer – Healthier – Better – Stronger for patients means ...

... strengthened rights to information for patients harmed

... easing the burden of proof for patients harmed

... EU-wide compulsory civil liability insurance for manufacturers of medical devices

Source: *[1]Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products*

About ESIP - European Social Insurance Platform

ESIP represents a strategic alliance of over 40 statutory social security organisations in 15 EU Member States, Croatia 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.

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Note: ESIP members support this position in so far as the subject matter lies within their field of competence.

About AIM - Association Internationale de la Mutualité

The International Association of Mutual benefit societies (AIM), created in 1950, brings together 48 national federations of autonomous health insurance and social protection bodies in 27 countries mainly in Europe, all operating according to the principles of solidarity and not-for-profit orientation. The members of AIM mainly provide coverage against sickness to more than 230 million people in the world, either by participating directly in the management of compulsory health insurance, or by providing voluntary health insurance or by delivering directly health care and social services through own facilities.

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About MiEF - Medicine in Europe

MiEF was launched in March 2002 and 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.

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About ISDB - International Society of Drug Bulletins

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.
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