BEUC The European Consumer Organisation

The Consumer Voice in Europe

BEUC position on the forthcoming revision of the EU legislation on medical devices

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Summary

The recent PIP breast implants scandal and emerging technologies have challenged the current legislative framework and highlighted loopholes which put consumers' health at risk.

The forthcoming EU legislation on medical devices should focus on increasing patient safety and consumer confidence by:

- Increasing quality and safety standards;
- Strengthening pre-market assessment;
- Ensuring consistency among the notified bodies;
- Better regulating border line products, aesthetic products and self-testing devices;
- Reinforcing market surveillance;
- Providing consumers with better information;
- Improving transparency, coordination and enforcement;
- Designing a legal framework which meets the needs of tomorrow.

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1. Learn lessons and restore trust

Consumers use medical devices in their daily lives and this wide range of products contributes significantly to people's health and well-being.

The PIP breast implants fraud[1] and the metal on metal hip implants case[2] are just the most recent of a series of scandals affecting the medical devices sector over the last few years and they have clearly shown that the current rules are inadequate and that the whole system needs to be reviewed. Unfortunately these scandals also led to undermining consumer confidence in medical devices, including in the oversights of the competent authorities, and it is urgent to restore trust[3].

It is unacceptable that consumers are afforded a different level of protection depending on whether they have a hip replacement or diabetes. It is also difficult for consumers to understand why a device implanted in their body does not undergo the same thorough assessment as for example the pills they take for high blood pressure. All the more because if there is a problem with a medicine they can simply stop taking it while if there is a problem with a high risk device, such as an implant, they have to go for invasive and risky surgery to have it removed.

Watch this video to listen to the stories of five women who had an implanted device. They remind us that medical devices make hearts beat and allow people to walk but if they are not of high quality they can disrupt consumers' daily life. They also show that much more has to be done to guarantee safety and that consumers need to be better informed about the benefits and the risks of these products.

2. No access without safety

European consumers are often considered as the 'guinea pigs' for medical devices, especially in comparison with consumers in the United States, where many products used in Europe were never approved as they were considered dangerous and ineffective[4]. While in the US high risk devices are subject to a form of marketing authorisation and are assessed by the Food and Drug Administration on the basis of valid clinical trials to prove their safety and efficacy/effectiveness, in Europe they can enter the market after a CE certification given by private companies called "notified bodies" on the basis of limited evidence, often without significant studies in humans.

As in the US, the EU pre-market system should move from requiring performance data only, to requiring sound clinical data that prove safety, efficacy and effectiveness. European consumers cannot and should not involuntarily partake in what is effectively a large, uncontrolled experiment[5]. The current system is unethical and exposes consumers to unjustified risks.

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[1] http://europa.eu/rapid/pressReleasesAction.do?reference=IP/12/96&language=EN
[2] http://www.bmj.com/content/344/bmj.e1410?ga=w_ga_mpopular
[3] BEUC open letter to Commissioner Dalli, January 2012.
[4] Unsafe and ineffective devices approved in the EU that were not approved in the US, Food and Drug Administration, May 2012.
[5] Dispositifs médicaux: le patient sert de cobaye,Test-Achats, Test-Santé n. 106, Décembre 2011.

2.1 Pre-market authorisation for high risk devices

After a series of failures, the medical devices legislation is in need of radical change. It is necessary and possible to reinforce the pre-market system and put in place an approval process which avoids exposing consumers to both unnecessary risks and unnecessary delays. High risk devices such as pacemakers, breast implants and hip replacements require a more thorough assessment before they are used and for these products the Commission should consider the possibility of requiring a form of marketing authorisation similar to that foreseen for medicines.

The European Parliament[6] also called on the Commission "*to shift to a system of pre-market authorisation for certain categories of medical devices, including at least for medical devices of class IIb and III".*

2.2 More clinical data

For medical devices in most cases it is not feasible to perform the same kind of clinical trials as for medicines as it is not ethical for example to implant a fake hip or pacemaker, but it is indeed necessary to require manufacturers to perform clinical studies based on well-defined criteria and to submit more information on the risk/benefit balance and the clinical efficacy of their products. Clinical trials should be conducted according to high quality standards and should be registered within a central European Union register accessible to the general public like the one existing for medicines (www.clinicaltrialsregister.eu). Results of all clinical trials should be made publicly available.

For all devices companies should be required to submit more reliable and comprehensive clinical data proving that the product offers actual treatment benefit to consumers. The assessment should also concern the substances used and the potential carcinogenic, mutagenic or toxic risks.

Manufacturers should be required to conduct more thorough non-promotional, post-marketing studies to assess the long term safety of the device and the impact they have on people's daily lives.

2.3 An efficient evaluation system

The Commission should consider the possibility of centralising the evaluation of high risk devices at European level, for example by a dedicated scientific committee within the remit of the European Medicines Agency. The administrative burden and the costs associated with a form of EU pre-market authorisation would be out-weighted by increased safety, reduced recalls and expensive care following adverse events (e.g. implants), increased transparency and faster pricing and reimbursement procedures. At present, even if available on the market, many high risk devices are inaccessible to consumers because the health technology assessment and reimbursement bodies require additional safety and efficacy studies before approving the products for use in the national health care system. It would be more efficient to collect these data beforehand in a consistent manner also reducing inequalities among Member States.

[6] European Parliament resolution on defective silicone gel breast implants, 14 June 2012.

3. Improve the work of the notified bodies

3.1 More consistency

In theory medical devices are subject to the same legislation across the EU but we are concerned that the agreed common standards are not applied consistently by all the notified bodies. It is essential to improve the work of the notified bodies by increasing supervision by national authorities, ensuring that all notified bodies apply the same high-quality standards and also fulfil matching criteria of impartiality, competence and transparency.

The current system with more than 70 notified bodies allows companies to 'shop around' for the most flexible notified bodies. The number of notified bodies should be reduced and the criteria for accreditation should be strengthened, particularly with regard to the competences of the staff and to the transparency of internal procedures. National authorities should increase their supervision of the notified bodies and ensure that they are all in line with common, high quality, EU standards to ensure uniformity.

The legislation should be consistently implemented in all Member States. The current Medical Devices Expert Group should be given the power to oversee the application of the EU legislative framework, including how the national authorities designate and monitor their notified bodies.

3.2 More Transparency

The public health authorities should have at all time full access to all the data submitted by the applicant to the notified body for the assessment process and also to all vigilance information (see also point 6). The information on the basis of which the notified body grant the CE marking should be publicly available. In the US the Food and Drug Administration publishes on its web site information about the basis for the approval decisions and also the data on safety and effectiveness. This information is vital for consumers and also for health care professionals in order to make informed decisions.

3.3 A better classification system

More consistency and more transparency should also be ensured in the classification system. There is an increasing number of borderline products, and some, such as nasal sprays[7] or cranberry[8] whose classification as a medical device leave room for perplexity. In order to ensure consistency there should be a dedicated EU committee that provide recommendations on the classification and guarantee a coherent approach among EU member states. This would prevent confusion among consumers and ensure the same level of consumer protection across the EU.

[7] Médicament ou pas, Test Santé n..108, Test-Achats, April 2012.
[8] EU Food policy, Issue n.112, May 2012.

4. Better regulate the "jungle" of aesthetic products

According to our members it is urgent to better regulate the 'jungle' of aesthetic products. Substances such as dermal fillers can cause serious complications such as nerve damage, necrosis, cosmetic disfigurement and anaphylactic shock. Yet, in order to be placed on the EU market they only have to be tested in a reduced number of subjects and for a limited period of time[9].There are currently over 160 EU approved dermal fillers on the UK market alone, 80 in France and they can be administered by anyone from a dental hygienist to an aesthetician. It is sufficient to say that in the US there are currently 10 dermal fillers on the market, all of which have passed the controlled clinical testing for safety and effectiveness required for high-risk devices. In addition, many products are subject to long-term safety studies after marketing.

In a survey[10] conducted by the British Association of Aesthetic Plastic Surgeons (BAAPS), 2 in 5 plastic surgeons in the UK reported seeing patients in that year who had experienced complications with permanent facial fillers and almost a quarter reported having patients in that year who required surgery to correct the complications caused by permanent fillers. BAAPS members said one of the main reasons for complications from EU-approved dermal fillers was a lack of regulation which has allowed "unproven substances" to be used. Also the British Association of dermatologists is very concerned about the safety of these products and calls for significant changes to the legislation and to the classification system in order to safeguard patients[11].

5. Reinforce rules for self-testing devices

Consumers are increasingly taking their health into their own hands, with many preferring a quick trip to the pharmacy for self-diagnosis instead of a visit to the doctor. Self-testing health kits allow consumers to test themselves in the comfort and privacy of their home. BEUC supports the idea of monitoring your own health, but consumers should be provided with better information on what the tests will - and will not - be able to tell them. The UK consumer association *Which?* carried out an investigation[12] into self-testing health kits and identified a number of important problems, including lack of information, difficult language, false alarms, false reassurance and misleading names. Consumers should have clear information at the point of sale, as well as clear information about the results, what they mean, and contact information for medical professionals so they can follow up their results. In order to be approved for sale, a kit must show that it can identify the bio-marker. However, currently suppliers of the tests are not required to show they are effective in a domestic environment. Therefore, in the context of the forthcoming regulation on *in vitro* diagnostics (IVD) we ask the European Commission to reinforce the standard of clinical validity and introduce the concept of clinical utility.

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[9] Topical Report Injectable products to fill wrinkles, AFSSAPS, June 2011.
[10] Fillers Less Regulated than Tattooing and Acupuncture - Call to Make Them Prescription', British Medical Journal, July 2009.
[11] Press release on cosmetic injections, British Association of dermatologists, 2012.
[12] Self-Test Kit Campaign, WHICH, 2010.

5.1 Clinical validity

Clinical validity is the accuracy with which a test identifies a patient's status. Health kits are usually trialled by medical professionals, in hospitals, on patients who are already exhibiting symptoms. In that scenario the test is far more likely to be accurate than where a person is using the test at home. There are also some biomarkers which are far more accurate in indicating a disease than others. Also the Danish TeknologiRadet[13] recommended stringent rules for the testing and approval of self-testing, particularly in the selection of the test population and in the assessment of the risks of potential misuses and misinterpretation of the results.

5.2 Clinical utility

Clinical utility is the usefulness of the test to the patient. Even if a test is very accurate it could well be that the risks of it offering a false positive or false negative outweigh the benefits of using it. At best consumers might be worried or frightened unnecessarily. For example, tests for stomach ulcers measure the presence of particular bacteria, but only a minority of people with the bacteria actually get a stomach ulcer. However, at worst, a false-negative might stop people from getting medical help as early as possible. *Which?* interviewed a group of older men who disliked the idea of going to the doctor for a prostate cancer test. They said they would rely on a negative home test result rather than visit their GP. But the tests themselves are only one part of a diagnosis, and doctors will take other symptoms and lifestyle into account. High cholesterol, for example, is linked to an increased risk of coronary artery disease, but it can also be a symptom of an under active thyroid. A doctor can tell if that's the case while a test result can't.

We understand this might go beyond the remit of EU legislation and we think consumers should have the possibility to use these products if they want, but it is important to ensure that they offer some benefits and their use does not cause any harm (including the risks associated to misinterpretation and possible false results).

6. Better post-market surveillance

We are sure a more complete clinical evaluation in the pre-market phase will reduce the risks to which consumers are exposed but, as for medicines, no pre-market regulatory system can guarantee that all medical devices on the market are completely safe and effective. A robust surveillance system is therefore essential.

BEUC welcomes the measures announced by the Commission in February 2012[14] aimed at reinforcing market surveillance following the PIP breast implant scandal. We see both these and the forthcoming revision of the EU medical devices legislation as long overdue and necessary steps to try and ensure patient safety in the sector, but we encourage the Commission and the Member States to take bolder action in order to demonstrate to European consumers that their health is well protected.

[13] Teknologiradet report, October 2011.
[14] European Commission Press release, IP/12/96, 2 February 2012.

6.1 A central reporting system and more supervision

The current system is undoubtedly very weak: the significant differences in the number of reported accidents[15] among Member States (e.g. 229 in Germany, 108 in Ireland, 2 in Italy and 1 in Portugal and 1 in the Netherlands) indicate potential discrepancies in the level of supervision carried out at national level and show that the competent authorities lack a clear picture on the safety of products on the market.

We call for stronger and more coordinated market surveillance with a central reporting system which facilitates analysis of incidents and a rapid and a coherent EU response in case of safety concerns. The system should be based on a EU Portal based on the existing database Eudamed which should include also information on clinical investigations, CE certificates etc and most of all information on the medical devices available on the market. At present, competent authorities do not have complete information on the high risk devices used on the market (e.g. stents used in health care settings) and it is not possible to have a proper monitoring of health outcomes.

6.2 Improve traceability

Improving the traceability of products all along the supply chain is an essential step to facilitate market surveillance and combat counterfeiting. In this respect BEUC supports the introduction of a Unique Device Identifier for high risk devices as is currently under discussion in the Commission UDI working group. The traceability system should be efficient, guarantee consumers' privacy and facilitate recalls.

BEUC also supports the introduction of registries for implants in all Member States in order to generate clinical evidence useful for research and market surveillance purposes. The registries should comply with the EU data protection legislation and the introduction of patients' personal data should be subject to informed consent.

6.3 Encourage reporting of incidents and involve consumers

To ensure a proactive surveillance system, it is also essential to involve consumers in the reporting of incidents. Consumers are the end-users of these products and they can play an important role in detecting problems. Evidence on direct reporting in the pharmaceutical sector shows that consumer reporting has added value and contributes to increasing safety[16]. Also health-care professionals should be better informed about the notification system and should be encouraged to report.

6.4 Public access to safety information

Vigilance data should be made public following the same principles and format as the EU medicines safety portal www.adrreports.eu. In the US, side-effects and recalls must be reported to the Food and Drug Administration and they are publicly disclosed on its website. The information provided should be easily retrievable and understandable by a lay-person. Independent research bodies should have access to statistical data and additional scientific information to conduct independent analysis.

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[15] Vigilance Reports, European Commission, 2011. http://ec.europa.eu/health/medicaldevices/files/stats2011_en.pdf

[16] BEUC position on pharmacovigilance, X/86/2009.

7. Better information to consumers

They should receive unbiased information on the benefits and the risks of the product and clear instructions for use. Each medical device should have a summary of product characteristics which should be made publicly available. The information should be user tested and adapted to consumers' needs. For implants, as part of giving informed consent for surgery, consumers should be provided with a document on the specific product used, its characteristics, the Unique Identification number, the potential risks and also additional information on the post-operative follow up measures associated with the implant. The documents should be signed by both the surgeon and the patient. Consumers have the right to access information on adverse events reports for all devices on the market (see point 6.4).

8. Promotional activities

It is urgent to better regulate the advertising of medical devices by harmonising national legislation. We have observed unethical aggressive and misleading advertising, particularly for cosmetic surgery. All Member States should consider a ban on advertising of cosmetic surgery as it has already been done in some countries like Belgium and France. Consumers who choose to undergo cosmetic surgery should receive complete information on the potential risks of the procedure and on the quality of the devices used. For example, women who want to have breast implants should be informed about the fact that the implants require removal and replacement after a certain period of time depending on the individual case[17]. High ethical and transparency standards should be respected in the relationship between industry and healthcare professionals.

9. More coordination among Member States

It has been made clear in the PIP scandal that in case of reported problems, consumers are given different advice by competent health authorities depending on the country in which they live. Indeed, some Member States have only foreseen monitoring while others recommend removal. This generates a lot of confusion and anxiety. When safety concerns arise, the information and the preventive measures should be coherent across the EU in order to prevent inequalities.

In order to optimise resources and exploit synergies it would be productive to enhance cooperation and the exchange of best practices between Member States.

Where incidents occur, Member States should immediately inform the Commission and the other Member States of the measures taken and the risk management plans.

10. Better enforcement

The PIP fraud clearly showed that the current system where inspections at the manufacturer site are announced in advance is totally inadequate. The competent authorities should have the power to conduct announced inspections of

[17] Third generation implants have a rate of rupture of 10-15% after 10 years have elapsed.

manufacturers' sites as well as of notified bodies. National authorities should be provided with more resources to guarantee enforcement of legislation, including in that relation to products sold on the internet. National health authorities should make better use of their enforcement powers to minimise the damage caused by dangerous products which reach the market and be more proactive[18].

Severe penalties and dissuasive sanctions should be imposed on industry and other actors involved in the supply of medical devices deemed non-compliant.

As also acknowledged in the European Parliament resolution[4] adopted in June 2012, the PIP case and others provide further evidence of the need for a collective redress mechanism that help those who suffered harm to seek redress and compensation. Moreover, damages for defective medical devices can reach substantial amount of money thus manufacturers should be required to have liability insurance in order to place their products on the market. For instance, the Austrian consumer organization VKI is now bringing the proceedings against the insurance of the company PIP to claim compensation for victims because the company itself is insolvent.

11. Meeting the needs of tomorrow

The new legal framework should ensure medical devices are timely available and safe throughout their lifecycle. It should be risk-based, have sound evidence, be clear, predictable, self-sustaining and self-improving. It should be designed to meet future technological advances and the challenges posed by emerging technologies, such as nanotechnology and societal issues such as ageing populations.

Consumers should be involved in the research, development and evaluation process to ensure new products meet their needs and are more consumer-centred. It should reward innovation which has true added-value, improves safety and is cost-effective.

12. Conclusions

Increasingly sophisticated devices extend and improve the everyday life of millions of European consumers, but devices malfunctions have become "modern diseases" which will continue to occur. The revision of the EU legislation on medical devices is a unique opportunity to increase consumer protection, reduce risk and avoid costly recalls.

A proper pre-market assessment, a more coherent risk based classification system and better market surveillance are essential to guarantee that European consumers have timely access to innovative treatment without compromising safety.

Consumers have the right to receive more and better information on medical devices. Where problems occur consumers should receive proper follow up and have an adequate system to seek redress and compensation for the damages they suffer. The whole medical devices sector would benefit from more information sharing, more coordination and more transparency.

END

[18] Prothèses de hanche: que fait l'agence des médicaments?,Test-Achats, March 2012.