BEUC The European Consumer Organisation

The Consumer Voice in Europe

BEUC position on the Regulations on medical devices

Contact: **Ilaria Passarani – health@beuc.eu**

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BUREAU EUROPÉEN DES UNIONS DE CONSOMMATEURS AISBL | DER EUROPÄISCHE VERBRAUCHERVERBAND
Rue d'Arlon 80, B-1040 Brussels • Tel. +32 (0)2 743 15 90 • Fax +32 (0)2 740 28 02 • consumers@beuc.eu • www.beuc.eu
EC register for interest representatives: identification number 9505781573-45

Summary

Consumers use medical devices in their daily lives and this wide range of products contributes significantly to people's health and well-being.
The Commission proposals represent an important step in strengthening the market surveillance system, but additional measures are needed to ensure speedy access to safer and innovative devices for consumers, namely:

- All medical devices on the market must have a positive benefit/risk ratio and bring therapeutic benefit to patients;
- Manufacturers should be required to produce more and better clinical data and whenever possible conduct randomized controlled trials to demonstrate that a medical device is safe and effective before being placed on the market;
- Bring more clarity with regard to clinical evidence;
- Authorisation of a clinical investigation should be subject to the opinion of an independent ethics committee;
- All clinical investigations should be registered and all results made public;
- A centralised pre-market assessment should be established for a limited number of high risk devices and be entrusted to a new medical devices committee within EMA;
- Special precaution is needed for medical devices containing hazardous chemicals and nanoparticles;
- The functioning of notified bodies must be improved with a view to promoting specialisation and excellence;
- Increase transparency of notified bodies' fees;
- Apply a consistent risk-based approach for the classification of all devices;
- Set up a multidisciplinary expert group with binding power for a consistent classification of borderline products across the EU;
- Introduce stricter safety standards for the reprocessing of devices;
- Provide consumers with high quality, complete, understandable and user tested information for all devices;
- Provide consumers with adequate counselling for certain *in vitro* devices such as DNA testing;
- Ensure that the Eudamed and the Vigilance database are transparent;
- Guarantee the meaningful involvement of consumers in market surveillance and clarify the means for consumers to report incidents;
- Encourage the reporting of user errors;
- Require manufacturers to have a liability insurance;
- Reinforce the coordination and exchange of information between Member States;
- Provide the competent authorities with adequate resources to ensure proper enforcement.

1. Learn lessons and restore trust[1]

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

It is therefore essential for consumers to have a regulatory framework in place that guarantees that the devices are safe and effective.

The PIP breast implants fraud[2] and the metal on metal hip implants case[3] are just the most recent in a series of scandals affecting the medical devices sector in recent years and they have clearly shown that the current rules are inadequate and that the system requires comprehensive review. Unfortunately, these scandals also led to consumer confidence in medical devices and in the supervision of competent authorities being undermined. That trust must be urgently restored[4].

It is unacceptable that consumers are afforded a different level of protection depending whether they have a hip replacement or diabetes[5]. It is also difficult for consumers to understand why a device implanted in their body does not undergo the same thorough assessment as the pills they take for headache for example. 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 must pursue 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 not of high quality they can disrupt consumers' daily lives. They also show that much more has to be done to guarantee safety and that consumers need to be better informed as to the benefits and the risks of these products.

2. No access without safety

2.1 Benefits should outweigh risks

The existing legislation and the Commission proposal refer to "acceptable risks" (Annex I, par.1 and 5) while we strongly believe that in order to enter the market a medical device should have a clear positive benefit/risk ratio. The benefit for the patients and their health should outweigh the foreseeable risks.

For the same reason, when assessing a medical device, in addition to its safety, it is essential to measure its clinical efficacy and not only its performance *(Article*

[1] This is the BEUC position on the European Commission proposals for a regulation on medical devices http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf and on the Commission proposal for a regulation on *in vitro* diagnostics medical devices http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_541_en.pdf. This paper is based on the views already expressed by BEUC in 2012 (X/2012/058). This position paper may be updated in the course of the legislative process as necessary.

[2] http://europa.eu/rapid/pressReleasesAction.do?reference=IP/12/96&language=EN

[3] http://www.bmj.com/content/344/bmj.e1410?ga=w_ga_mpopular

[4] BEUC open letter to Commissioner Dalli, January 2012.

[5] D. Cohen, How safe are metal on metal hip implants? British Medical Journal, 2012. DOI: 10.1136/bmj.e1410.

49). Before being marketed, a medical device should demonstrate its efficacy in improving consumers' health and not only that it works as intended by the manufacturer. A demonstration of clinical efficacy does not equal a demonstration of performance. 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 while in the US the manufacturers must show that the laser incises heart tissue and also treats the arrhythmia[6]. Medical devices are not and should not be considered as any other product and should not be assessed in isolation, but rather in a wider healthcare context taking into account the needs and any ailment of the patient.

2.2 More and better clinical data

European consumers are often considered as 'guinea pigs' for medical devices, especially in comparison to consumers in the United States7. Many products used in Europe were never approved in the US as they were considered dangerous and ineffective8. 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 effectiveness, in Europe they can enter the market after a CE certification by private companies called "notified bodies" on the basis of limited evidence and often without significant studies in humans[9,10].
The small number of clinical medical device investigations conducted so far mostly involved only few patients, with no control group and short observation periods. In addition, in many cases manufacturers chose to submit only existing scientific literature rather than going through a full assessment by the Notified Bodies.

European consumers should not be involuntarily partaking in what is effectively a large, uncontrolled experiment[11]. The current system is unethical and exposes consumers to unjustified risks. Manufacturers should be required to produce more and better clinical data while conducting randomized controlled trials whenever possible to demonstrate that a medical device is safe and effective before being placed on the market. The new device should at least demonstrate an effect comparable to the existing standard treatment whenever it exists and ideally demonstrate an added value compared to existing similar devices. The Commission proposal introduces additional requirements for conducting clinical investigations, but more clarity is needed on the clinical requirements, including the scope of the relevant provisions and the concept of 'equivalence of data'. The definition of

[6] Cohen D. and Billingsley M. 'Europeans are left to their own devices' BMJ 2011;342:d2748.
[7] It is worth noting that only one in five of the 8.500 medical devices companies in Europe have approached the US market. In addition, more devices of a particular type are often marketed in Europe compared to the US, e.g. 28 drug eluting stents are CE marketed while only five obtained FDA approval.
[8] Unsafe and ineffective devices approved in the EU that were not approved in the US, Food and Drug Administration, May 2012.
[9] D. Kramer et. Al, Regulation of Medical devices in the United States and European Union, New England Journal of Medicine, March 2012.
10 D. Zuckerman et al., Public health implications of differences in US and European Union regulatory policies for breast implants, Reproductive Health Matters, 2012.
[11] Dispositifs médicaux: le patient sert de cobaye, Test-Achats, Test-Santé n. 106, Décembre 2011.

equivalence should be clarified and the appropriateness of a shorter development cycle assessed on a case by case basis. In the US, the so-called '510k procedure' used for fast tracked approval of devices with incremental changes is under the spotlight because the American National Institute of Health considers it inadequate to ensure consumer safety[12].

2.3 Clinical investigations should be subject to the opinion of an independent ethics committee

In *Recital 47*, the European Commission indicates that clinical investigations should be conducted in line with the Helsinki Declaration on Ethical Principles for Medical Research involving Human Subjects. However, as in the proposal for clinical trials in the pharmaceutical sector, the Commission excluded any reference to ethical committees. As with the regulation on clinical trials, BEUC believes the authorisation to conduct a clinical investigation can only be granted if an independent ethics committee expresses a positive opinion. The ethics committee should evaluate the study protocol on the basis of the medical justification, the suitability of the investigator and the informed consent form. The ethics committee shall ensure that the rights, safety and well-being of the participating subjects are protected. The ethics committee shall be independent from the researcher and the sponsor and free from any undue influence.

2.4 Results of clinical investigations should be made public

BEUC welcomes the Commission proposal to require the registration of clinical investigations before they start *(Article 52*) but it is equally important that all the results of all the clinical investigations (both positive and negative) are made public through the electronic system.It should also be ensured that, when a clinical investigation is terminated early, information on the reasoning is made public and provided to all Member States so sponsors conducting similar clinical investigations can be informed. This will enable more transparency and avoid several studies being run in parallel.

In our view, the electronic system on clinical investigation should be fully interoperable with the database being established in the context of the regulation on clinical trials and should be built on the basis of the experience already gained with the EudraCT database hosted by the European Medicines Agency. Stakeholders should be involved in the definition of the public interface of the Register to ensure it is user-friendly and the information is presented in a comprehensible manner.

BEUC welcomes the involvement of patients in the assessment of the application for a clinical investigation, but the wording of *Article 51* remains vague as to the specifics of involvement, including the resources and the training necessary to contribute meaningfully.

[12] Medical devices and public health, The FDA 510(k) Clearance Process at 35 Years, National Institute of Medicine, 2011.

2.5 A centralised pre-market assessment for high risk devices

In order to address the widely acknowledged weakness of the current conformity assessment procedure, the Commission has introduced a number of positive measures to improve the work of the notified bodies and make it consistent across the EU (e.g. designation, oversight by the competent authorities etc).

All these measures are to be welcome, but the main unaddressed problem remains that most Notified Bodies have neither the 'in-house' qualified staff, the competences nor the qualifications to evaluate the clinical data as is required in the Commission proposal. Nor do they have sufficient expertise to check the quality of clinical evaluations they could potentially commission to external subcontractors.

Regardless, it should be noted that while in the US the FDA has the institutional mandate to protect and promote public health, Notified Bodies do not have the mandate to protect public health, but rather are just service providers to the manufacturer. They assess medical devices in isolation as a mere product without taking into account the disease or the patient journey.

To fill this major gap, recognising that an independent assessment by experts from the competent authorities for high risk devices is needed, the Commission proposed the creation of a Medical Devices Coordinating Group (MDCG) to review the clinical evidence submitted by the manufacturer for the conformity assessment procedure. BEUC does not consider the scrutiny procedure as proposed in *Article 44* an appropriate solution because it would affect only very few products and the opinion of the (MDCG) would not be binding. Therefore it would not have any added value and it would not improve patient safety.

In addition it would create significant administrative burden and generate high costs without any benefit so it would be nor effective nor efficient. In addition the resources foreseen in the budget for the operation of the MDCG are probably not even sufficient to adequately perform the assigned tasks.

Since the beginning of the debate on the legislative revision, BEUC suggested that the Commission should have at least considered the possibility of centralising the evaluation of high risk devices at European level. We regret that, despite the European Parliament Resolution of June 2012[13] and calls for a shift to more thorough pre-market approval by many academics and leading experts, this option was not given due consideration in the Commission's Impact Assessment[14]. Also the European Parliament's appraisal[15] of the Commission's Impact Assessment noted that the option was not carefully considered and was not substantiated with sufficient data.

In the current economic climate, such a change is politically difficult but the administrative burden and the costs associated with a form of centralised EU pre-market approval would be out-weighted by increased safety, reduced recalls and less expensive care following adverse events, increased transparency and faster pricing and reimbursement procedures. The centralised approval should cover at

[13] European Parliament Resolution on PIP breast implants, June 2012.
[14] http://ec.europa.eu/health/medical-devices/files/revision_docs/revision_ia_part1_en.pdf
[15] http://www.europarl.europa.eu/committees/it/envi/studiesdownload.html?languageDocument=EN&file=85330

least a limited number of devices listed in Class III such as implants and devices incorporating a substance considered a medicinal product, intended to administer a medicinal product, or utilising non-viable tissues or cells.

The centralised approval procedure could be under the remit of the European Medicines Agency (EMA) in order to benefit from the existing structures, experience, expertise and well-established transparency and conflict of interest rules of EMA. In addition it would mirror the structure of the FDA and of 19 national authorities who are responsible both for medicines and medical devices. According to the Commission Impact Assessment14 the resources needed for a MDCG run by the European Commission and one run by EMA are almost the same.

2.6 No unnecessary delays

A sound system of approval for high-risk medical devices should make sure that patients receive devices which improve their lives without subjecting them to unnecessary risks and it should provide access to important therapies without unnecessary delay.

Because it takes time to produce sound evidence that a device is beneficial and that its benefits outweigh its risks, requiring evidence of safety and effectiveness and providing early access sometimes conflict. This tension raises questions of the value to patients and society as whether producing evidence of safety and efficacy as a prerequisite to marketing constitutes an "unnecessary delay".

Devices like the withdrawn AAA stents for aneurysms, the cardiac constraint devices for heart failure and the CoSTAR stent to open heart vessels cost the lives of European patients without providing any health benefits. Others like the Trilucent breast implant, the elbow implant, and the RoboDoc for hip surgery inflicted serious injuries and required expensive additional surgery to repair the damage they caused8. In many cases, the dangers of these EU-approved devices were not discovered until the manufacturers had to conduct the clinical studies needed to support the US application for approval. These scientifically robust studies revealed that the testing used to show the technical performance of the devices did not accurately predict whether they would provide a benefit to patients in actual use and that patients who received the devices were injured at higher rates than those patients receiving more established treatments.

BEUC considers it 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.

Industry funded research[16] indicates that in the US patients have to wait longer to have their devices in comparison to Europe. But peer reviewed research[17] published in the New England Journal of Medicine shows with real-life examples that the time it takes to bring innovative high risk devices to patients in the US is similar to or is in some cases even shorter than in main European markets.

It is important to consider the fact that the CE marking approval does not coincide with patients' access. At present in Europe, even if available on the market, many

[16] EU Medical Device Approval Safety Assessment, A comparative analysis of medical device recalls 2005-2009, Boston Consulting Group, January 2011.

[17] Patient Access to Medical Devices — A Comparison of U.S. and European Review Processes, New England Journal of Medicine, Vol. 367 No. 6, August 2012.

high risk devices are inaccessible to consumers - or at least to most as some devices could be available to wealthy patients paying out of their own pocket - because the health technology assessment and reimbursement bodies require additional safety and efficacy studies before approving the products for use in the national healthcare system. It would be more efficient to collect this data beforehand in a consistent manner also reducing health inequalities.

2.7 Special precaution for hazardous chemicals and nanomaterials

The use of certain medical devices may expose consumers to hazardous chemicals and special precaution is needed especially for vulnerable patients such as patients with a weak immune system, children and pregnant women.

BEUC calls for endocrine disrupting chemicals (EDCs), including some phthalates often used in medical devices, and substances which are carcinogenic, mutagenic and reprotoxic (CMRs) to be phased out unless no safer alternatives are available.

If hazardous chemicals are used, manufacturers should provide justification for their use and they should provide sound evidence to demonstrate that the clinical benefits outweigh the risks associated with the use of the hazardous substances. Where no safer alternatives exist, the industry should be pushed to come forward with more innovative solutions and place more efforts in funding research for safer alternatives.

Special precaution is also needed for medical devices containing nanomaterials and especially those with nanoparticles that can be released in the human body as there is still scientific uncertainty about the potential risks.

With regards to nanomaterials, our key concern is in fact the lack of adequate mechanisms and measurement methods to evaluate the effect of these materials on people's health, especially considering that some medical devices remain inside the body for many years. More research should be carried out to define methods to better study the effect of nanoparticles on human health.

The mandatory labelling of products where nanoparticles can be released in the body is positive, even if in many situations (e.g. in hospital) only the health professional and not the patient will have the information that the device used or implanted contains nano-material.

3. More competent and efficient Notified bodies

It is widely acknowledged that the current system of notified bodies is extremely weak. Companies can shop around for the most flexible ones to have a fast and cheap approval process[18]. At present, there are significant disparities in how the notified bodies across the EU function, in terms of their qualifications, internal procedures, impartiality etc. Their work has little or no transparency in relation to their activities, methods, data used for assessment or the qualifications of staff.

The Commission proposal introduces many provisions aimed at improving the work of the notified bodies, including monitoring by the competent authorities, the

[18] 'Faulty medical implants investigation: How the scandal was uncovered', October 2012. http://www.telegraph.co.uk/health/9626913/Faulty-medical-implants-investigation-How-the-scandal-was-uncovered.html

training of staff and the regular audits but additional measures should be included to make sure that notified bodies are fit for the job and do not unethically compete, at the expense of patients.

To this end, the fee system (*Article 40*) should be more transparent and fees should be made publicly available to allow comparison. Due attention should be paid also to the subcontractors of the notified bodies which should be subject to the same standards of quality, competence and transparency. Notified bodies should be required to make publicly available the names of subcontractors and the precise tasks for which they have been awarded a contract, while they should provide the competent authorities with full information as to the terms of the subcontract and the qualifications of the contractor.

In order to make the notified bodies more efficient it is important to improve the exchange of information between them and to promote specialisation for the assessment of specific devices in order to gain knowledge, exploit economies of scale and move toward excellence for the benefit of patients.

4. Borderline products: need for more clarity and consistency

BEUC welcomes the extension of the scope of the Regulation to aesthetic products (implants for aesthetic purposes, non-corrective contact lenses etc.) and devices containing non-viable human tissues (Article 1) as a necessary step to bring some legal clarity. We also welcome the clarifications on medical software (Article 2). Despite the improvement of the legal definition, in practice the demarcation between medical devices and other products such as medicinal products, biocides, food or cosmetics is not always clear. As the regulatory status of a product is the competence of Member States, divergent interpretations with respect to "borderline" cases can lead to a product being considered a medical device in one or several Member States while, in others it is considered a pharmaceutical or something else. This is particularly the case for some ingested products (e.g. antacid) and products containing substances administered to the human body for which the principal mode of action is often not scientifically clearly determinable. The difficulty in determining whether the principal mode of action is metabolic, pharmacological, immunological or not, is likely to increase with the development of new combination products (e.g. medicines-device).

The Commission proposes to upgrade all devices with substances intended to be ingested, inhaled or administered rectally or vaginally and absorbed by or dispersed in the human body to the classification 'Class III'. We agree that these products must meet the relevant requirements from the Medicinal Products Directive 2001/83/EC, but the automatic classification as risk class III *(Rule 21)* should be made more consistent with the rest of the classification system.

For all borderline products the classification should not reflect commercial strategies (e.g. circumvent the food legislation on health claims or the ban on advertising of prescription-only medicines) and it should not be left to the manufacturer. The sole criteria should be the safety profile of the product.

BEUC calls for the introduction of a multi-disciplinary expert group tasked with giving binding opinions on the classification of borderline products intended to

penetrate the body, either through an orifice or through the surface of the body.
This possibility already exists in some legislation such as the Active Implants Directive, the Regulation on Biocides and the Regulation on Advanced Therapy Medicinal Products. This would increase safety and reduce inequalities in terms of consumer protection. It would significantly improve the functioning of the Single Market at limited additional cost. Moreover the number of products to be assessed would decrease over time because of legal clarity and because many products bear the same characteristics.
The Council, in its Conclusions from June 2011, also called for the setting up of "*a simple and rapid mechanism…for accelerated adoption of binding and consistent decisions…on the determination of products…in order to address the growing number of 'borderline' cases between medical devices and other products subject to different regulatory frameworks".*

5. Higher safety standards for the reprocessing

The existing legislation as well as the Commission proposal explicitly refer to "reprocessing of single use devices", but in our view the wording is inconsistent. By definition, a device labelled as single use should not be reprocessed.
The status of single use or reusable device should be defined exclusively on the basis of safety considerations rather than of economic interests and should be decided on the basis of sound scientific evidence. Reprocessing of devices that pose risks to consumers' health should not be allowed. For example, the Scientific Committee on Emerging and Newly Identified Health Risks (SCHENIR)[19] identified several potential hazards (e.g. infections, potential contamination with agents causing transmissible spongiform encephalopathies, etc) associated with the reprocessing of the so called "devices for critical use" which are used in invasive medical procedures.
All those who reprocess medical devices should be subject to strict safety standards and follow specific guidelines. They should be considered liable if problems occur and all obligations of the manufacturer should apply to them.

6. Self-testing devices: better information for consumers

Consumers are increasingly taking their health into their own hands, with many preferring a quick trip to the pharmacy after 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[20] into self-testing health kits and identified a number of important problems, including a 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

[19] The Safety of Reprocessed Medical Devices Marketed for Single-Use, SCHENIR, 2010. http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_027.pdf
[20] Self-Test Kit Campaign, WHICH, 2010.

medical professionals so they can follow up their results.
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 unnecessarily worried or frightened. At worst a false-negative might stop people from getting medical help as early as possible. For example, high cholesterol 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 is the case while a test result cannot. We believe 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).

Overall BEUC welcomes the proposal for a Regulation on *in vitro* diagnostic medical devices which is identical on many issues (e.g. supervision of the notified bodies, post-market surveillance, traceability etc.) to the proposals for a Regulation on medical devices. For this regulation we propose the same improvements to pre-market assessment, the notified bodies, the ethical approval for clinical investigations etc. as listed in the points above and we hope that throughout the legislative process coherency and consistency among the two texts will be maintained.
With regard to elements specific to IVD BEUC supports the proposed classification system (A-D), but suggests clarifying the distinction between self-testing and near patient testing by healthcare professionals. We also recommend extending the scope of the Regulation to the so-called "lifestyle tests" and nutrigenetic tests due to the potential impact on individuals' health.
For DNA testing, appropriate advice should be foreseen to help consumers understand the implications of the test before it is performed.

7. High quality information empowers consumers and increases safety

In order to make informed choices and take a more active role in managing their own health, consumers want more and better information about the devices they use or are implanted in their bodies. High quality information is essential to empower consumers and increase patient safety.
Consumers should receive unbiased information on the benefits and the risks of medical devices and clear instructions for their use. *Annex I* (*point 19*) provides a detailed list of the information that should be provided on the label and in the instructions for use of the device. As for medicines, BEUC recommends that the information provided is user-tested to ensure it is understandable and meets consumers' needs.
Moreover BEUC welcomes the Commission proposal to make public a summary of product characteristics (*Article 26*) in layman's language. Ideally this information should also be user-tested and adapted to consumers' needs.

7.1 More information in the implant card

BEUC welcomes the introduction of the implant card (*Article 16*), but we suggest the addition of some further elements and to specify that the card should be

part of giving informed consent before the surgery. People implanted with a device have the right to be informed about the main characteristic of the device (e.g. materials used), the potential adverse effects, a warning of the potential health risks and associated post-operative follow-up measures. The implant card should be signed by both the patient and the surgeon responsible for the intervention. The introduction of this information in the implant card has also been requested by the European Parliament in its resolution on the PIP breast implant of 14 June, 2012 (2012/2621(RSP)).
The requirement of information on post-operative measures and the signatures directly affect the delivery of care and might fall outside the competences of the EU as set in Article 168 of the Treaty. If so, they could be added as recommendations for Member States.

7.2 An efficient and transparent database

BEUC welcomes that the Commission proposal expands the list of information to be included in the European Databank as introduced in *Article 27* (the existing Eudamed) and most of all that key information will be accessible to the public. The database contains useful information and contributes to greater transparency and public trust in the medical devices sector. Patients' groups and consumers' organisations should be consulted in the definition of the database's access policy as well as the layout of the information to ensure it is user-friendly.
The database should also include the report of safety and clinical information, including a summary as defined in *Article 26* (see *point 2*) and also reader-friendly information about the development, assessment and monitoring of medical devices. In this context, it is worth stressing that only some few patients and even healthcare professionals are aware of the process by which medical devices are evaluated (see also *point 1*).

8. Better post-market surveillance

We are sure a more complete clinical evaluation process at the pre-market phase will reduce the risks to which consumers are exposed, but as for medicines, no pre-market regulatory system can guarantee all medical devices on the market are completely safe and effective. Therefore a robust surveillance system is essential.
BEUC welcomes the measures proposed by the Commission to reinforce market surveillance, including unannounced inspections, better coordination and exchange of information between national competent authorities.
The new EU pharmacovigilance legislation extended the definition of adverse drug reaction to medication error. Healthcare professionals and users play a crucial role in relation to the safety of the device and it is equally relevant to gather all information on problems associated with the use of the device in order to improve clinical practice, the design of devices, the training of healthcare professionals and instructions for use.

8.1 Public disclosure of vigilance data

BEUC welcomes the establishment of an EU Portal for the reporting of incidents.

The Commission indicates that an adequate level of access should be granted to the general public, but we hope that this provision can be further clarified in order for the access to information to be meaningful. In particular the information should be complete and it should be easily retrievable and understandable by a layperson. Independent research bodies should have access to statistical data and additional scientific information to conduct independent analysis.

8.2 Encourage the reporting of incidents and involve consumers

BEUC welcomes the introduction of the possibility for consumers to directly report incidents to competent authorities. Consumer involvement is vital to ensure a proactive surveillance system. 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[21]. The instructions for use should include a reference to the importance of reporting and Member States should launch awareness campaigns to encourage reporting from healthcare professionals and the general public. The means of reporting should be better defined and decided with the involvement of patients' groups and consumers' organisations.

8.3 Improve traceability

Improving the traceability of products all along the supply chain is an essential step in facilitating market surveillance and combatting counterfeiting. As such, BEUC supports the introduction of a Unique Device Identifier for high-risk devices on a risk based approach as proposed in *Articles 23-25* of the Regulation.

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 EU data protection legislation and the introduction of patients' personal data should be subject to informed consent.

8.4 More coordination among Member States

It was shown in the PIP scandal that where problems are reported consumers are given different advice by competent health authorities depending on the country in which they live. In this case, some Member States only foresaw monitoring, while others recommended 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 further enhance cooperation and the exchange of best practices between Member States.

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

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

8.5 Better enforcement

National authorities should be provided with more resources to guarantee enforcement of legislation, including in relation to products sold on the internet. National health authorities should make better use of their enforcement powers to be more proactive and minimise the damage caused by dangerous products which reach the market[22].

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 judicial collective redress mechanism to help those who suffered harm seek redress and compensation.

Moreover, damages for defective medical devices can reach substantial amounts 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 organisation VKI is now bringing proceedings against PIP's insurance company to claim compensation for victims because the company itself is insolvent.

9. Conclusions

Increasingly sophisticated devices improve the everyday lives of millions of European consumers, but devices malfunctioning have become "modern diseases" which 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.

Proper pre-market assessment, a more coherent, risk-based classification system and better market surveillance are essential to guarantee 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 redress system to compensate for the damage they have suffered. The entire medical devices sector would benefit from increased information sharing, more coordination and more transparency.

END

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