BEUC The European Consumer Organisation

The Consumer Voice in Europe

REVISION OF EU LEGISLATION ON MEDICAL DEVICES

Letter sent to Commissioner John Dalli

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Dear Commissioner Dalli,

As you are well aware, consumers use medical devices in their everyday lives and this wide range of products contributes significantly to the health and well-being of consumers.

Following BEUC's participation in the exploratory process on medical devices and in the context of the revision of the EU's medical devices legislation, we write you now to share our analysis of the main elements to be considered in the forthcoming legislative work.

The new legislation should focus on increasing patient safety and consumer confidence by:

1. ***Reconsidering the classification system***
   European consumers are often labelled as the 'guinea pigs' for medical devices, especially in comparison to consumers in the United States. The European Commission should address this concern and demonstrate to European consumers that their health is well protected. In this respect, we encourage the Commission to improve the risk based classification system with specific consideration to new and 'border-line' products. According to our members it is also urgent to better regulate the "jungle" of aesthetic products and self-testing devices.

2. ***Strengthening pre-market monitoring***
   Some high-risk products such as pacemakers, breast implants and hip replacements require a more thorough assessment before they are being used and for these we invite the Commission to consider the possibility of requiring a form of marketing authorisation similar to that foreseen for medicines. For other products, it is essential to improve the work of the notified bodies by increasing oversight by national authorities, ensuring that all notified bodies apply the same high-quality standards and also fulfill matching criteria of impartiality, competence and transparency. Companies should be required to submit more reliable and comprehensive clinical data on the safety, quality and the efficacy of their products.

3. ***Reinforcing post-market surveillance***
   We call for stronger and more efficient market surveillance with a central reporting system which facilitates the analysis of incidents and a rapid, coherent EU response in case of safety concerns.

   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.

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Health-care professionals should be better informed about the notification system and should be encouraged to report.

The recent scandal of PIP breast implants showed that an EU database is also needed. At present, competent authorities don't have a comprehensive picture of the products used on the market and of the potential risks to which consumers are exposed. Improving the traceability of products all along the supply chain is an essential step to facilitate market surveillance and combat counterfeiting. The system should be efficient and guarantee consumers' privacy.

4. ***Providing consumers with better information***

Consumers have the right to receive better information on the medical devices they buy, those implanted in their bodies and those used in hospital for their treatment. They should receive unbiased information on the benefits and the risks of the product and clear instructions for use. The information should be user tested and adapted to consumers' needs. It is also urgent to better regulate the advertising of medical devices by harmonising national legislation. High ethical and transparency standards should be respected in the relationship between industry and health-care professionals.

5. ***Improving coordination and enforcement***

The new legislation should be consistently implemented in all Member States. The current Medical Devices Expert Group or another EU body should be given the powers to oversee the application of the EU legislative framework, including how the national authorities designate and monitor their notified bodies. In order to optimise resources and exploit synergies it is productive to enhance the cooperation and the exchange of best practices between Member States.

The national authorities should be provided with more resources and inspection powers to guarantee enforcement of the legislation, including for products sold on the internet.

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

An efficient mechanism should be put in place to help consumers to seek redress and compensation when incidents occur.

6. ***Meeting the needs of tomorrow***

   The new legal framework should be designed to fit future technological advances and meet the challenges posed by emerging technologies such as nanotechnology and societal issues such as the ageing of the population.

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

Following the public attention generated by the breast implants scandal we urge the European Commission to show strong commitment towards improving quality and safety in this sector and to speed up the adoption of the new legislation.

We are committed to being a constructive partner throughout the legislative process and we remain at your disposal and that of your services, should you wish to discuss this further.

Yours sincerely,

Monique Goyens
Director General

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