In vitro diagnostic medical devices

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This Communication, together with the proposal to revise the legislation on medical devices and the proposal on in vitro diagnostic medical devices, constitute a response to the Council Conclusions on innovation in the medical device sector adopted on 6 June 2011 and to the European Parliament Resolution on defective silicone breast implants adopted in June 2012 . Both the Council and the European Parliament have pointed to the necessity of adapting the medical device legislation with the aim to achieve a suitable, robust, transparent and sustainable regulatory framework. Such framework should be central to fostering the development of safe, effective and innovative medical devices and in vitro diagnostic medical devices, for the benefit of European patients, consumers and healthcare professionals.

It is estimated that, in 2060, there will be twice as many Europeans aged 65 or over (152.6 million in 2060 compared to 87.5 million in 2010). An ageing population and changes in lifestyle will lead to an important evolution in disease patterns, with an increasing prevalence of chronic, and often multiple, diseases, such as cancer, diabetes, heart diseases, respiratory conditions, stroke, dementia and depression. In 2010, over one-third of Europe’s population was estimated to have developed at least one chronic disease.

In this evolving and challenging context, medical devices and in vitro diagnostic medical devices will be of increasing importance to public health and medical care.

The need for a safe, transparent and sustainable legislation: appropriate legislation is fundamental to ensuring health protection and effective innovation and will:

- give patients, consumers and healthcare professionals confidence in the devices they might use every day;
- allow industry to bring safe, effective and innovative products to market quickly and efficiently;
- increase the ability of innovative companies to attract investors, estimate costs and anticipate procedures.

The need to restore patients', consumers' and healthcare professionals' confidence: in an internal market of 32 participating countries, important differences in interpreting and applying the rules have emerged, thus undermining the legislation's main objectives — the safety of devices and their free circulation within the internal market. Moreover, there are regulatory gaps or uncertainties with regard to certain products. The regulatory system has also suffered from a **lack of transparency and shortcomings in its implementation**, in particular in the fields of market surveillance, vigilance and the functioning of notified bodies.

In addition, **recent serious incidents involving medical implants** (e.g. breast implants, metal-on-metal hip replacements) have put patient safety at risk and revealed further shortcomings of the current legislation, especially with regard to post-market controls.

The proposed Regulations will:

- amend and clarify the scope of the legislation, to take into account scientific and technological progress and respond to tomorrow's needs. It is extended to include, for example, implants for aesthetic purposes and clarified as regards genetic tests;

- strenghten the supervision of the notified bodies by the Member States, in order to ensure that all bodies have the necessary competence to carry out the pre-market assessment of devices;

- guarantee the independency and the quality of pre-market assessment of devices, by clarifying and enhancing the position and powers of notified bodies vis-à-vis the manufacturers (e.g. regular checks on manufacturers, including unannounced factory inspections) and by providing an appropriate level of intervention of public authorities;

- clarify the obligations and responsibilities of manufacturers, importers and distributors. This encompasses diagnostic services, internet sales and parallel trade;

- ensure transparency, in particular through an expanded European database on medical devices and in vitro diagnostic medical devices partially accessible to the public. It will provide patients, healthcare professionals and the public at large with comprehensive information on products available on the EU market, enabling them to make better informed decisions;

- increase devices traceability throughout the supply chain, by requiring that manufacturers, on a risk-based approach, fit their devices with a Unique Device Identifier (UDI). This will allow fast and effective measures in case of safety problems;

- reinforce the rules governing clinical evaluation throughout the life of medical devices and in vitro diagnostic medical devices, to ensure patient and consumer safety;

- strengthen the provisions governing market surveillance and vigilance, allowing better coordination between authorities to ensure rapid and consistent responses to safety issues;

- make the management of the system more robust through mechanisms of effective coordination between authorities, with scientific support by the Commission, in order to ensure a uniform and sustainable implementation of the future Regulations.

The medical device and the in vitro diagnostic medical devices sectors are estimated to comprise more than 500,000 products. They contribute substantially to the EU's balance of trade, employ more than 500,000 people in about 25,000 companies, 80 % of medical devices companies and 95% of in vitro diagnostic medical devices companies being small to medium-sized or micro enterprises. In 2009, they generated annual sales of around EUR 95 billion (EUR 85 billion for medical devices and EUR 10 billion for in vitro diagnostic medical devices) in the European (EU/EFTA) market. Last but not least, they are sectors that invest heavily in research and development, as about 6-8 % of medical devices annual sales and 10% of in vitro diagnostic medical devices annual sales are ploughed back into research each year, equivalent respectively to some EUR 6.5 billion and some EUR 1 billion, usually through collaboration with healthcare professionals and academia.

It is estimated that the **establishment of a central registration tool** would help reducing the administrative costs by up to EUR 157million. Also an **EU vigilance portal** with central reporting of serious incidents instead of multiple reporting is expected to bring about non negligible reductions in administrative costs.

Health is a clear determinant of economic growth. In this context, innovation in the medical device and in vitro diagnostic medical device areas occupies a central place in initiatives falling in the framework of the Europe 2020 Strategy, in particular under the **Innovation Union and the Digital Agenda for Europe flagship initiatives.**

The proposed Regulations have the objective of bringing these two aspects together and are an essential ‘push’ factor for fostering an EU of active and healthy citizens.