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COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Safe, effective and innovative medical devices and in vitro diagnostic medical devices for the benefit of patients, consumers and healthcare professionals

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Safe, effective and innovative medical devices and in vitro diagnostic medical devices for the benefit of patients, consumers and healthcare professionals

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1. INTRODUCTION

This Communication, together with the two proposed Regulations to revise the European Union legislation on medical devices[1] and *in vitro* diagnostic medical devices[2], constitutes a response to the Council Conclusions on innovation in the medical device sector adopted on 6 June 2011[3] and to the European Parliament Resolution on defective silicone breast implants adopted on 14 June 2012[4]. Both the Council and the European Parliament have pointed to the necessity to adapt the medical device legislation to the needs of tomorrow 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.

Health is indeed central to people's lives. It is ranked among the top priorities and concerns of European citizens. The right of access to safe products and quality healthcare services is also one of the most fundamental rights.

Demographic and societal changes, coupled with scientific progress, have been transforming healthcare delivery models and the innovation process significantly in recent decades. This will certainly continue to be the case.

The needs, roles, knowledge and expectations of patients, consumers and healthcare professionals have evolved considerably. 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)[5]. 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[6].

These changes come at a time of constantly increasing pressure on healthcare budgets, exacerbated by the recent global economic and financial crisis, and a steady decline in the number of healthcare professionals[7].

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.

It is therefore essential to create the right conditions for safe, effective and innovative medical devices and *in vitro* diagnostic medical devices to deploy within a secured and well-functioning internal market, while duly taking into account the peculiarities of each of these

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1 Medical devices include products such as sticking plasters, contact lenses, dental filling materials, x-ray machines, pacemakers, breast implants or hip replacements.

2 *In vitro* diagnostic medical devices include products such as devices used to ensure the safety of blood transfusion (*e.g.* blood grouping), detect infectious diseases (*e.g.* HIV), monitor diseases (*e.g.* diabetes) and perform blood chemistry (*e.g.* cholesterol measurement)

3 OJ C 202, 8.7.2011, p. 7

4 P7_TA(2012)0262

5 European Economy report - The 2012 Ageing Report: Underlying Assumptions and Projection Methodologies to be found at: http://ec.europa.eu/economy_finance/publications/european_economy/2011/pdf/ee-2011-4_en.pdf

6 The future of healthcare in Europe — A report from the Economist Intelligence Unit.

7 Green Paper on the European Workforce for Health, COM(2008) 725 final, 10.12.2008.

sectors in their respective Regulation. These are a prerequisite to ensuring the highest level of health protection that patients, consumers and healthcare professionals are entitled to expect. They are also vital to meet future demographic, societal and scientific challenges, improve European industry competitiveness, and thus achieve the smart, sustainable and inclusive growth that is so central to Europe 2020 Strategy.

2. THE NEED FOR A SAFE, TRANSPARENT AND SUSTAINABLE LEGISLATION

2.1. The legislation — a foundation for safe, effective and innovative medical devices and *in vitro* diagnostic medical devices

Appropriate legislation is fundamental to ensuring the highest level of health protection and effective innovation. It is also necessary for the good functioning of the internal market, which represents a major source of growth and jobs, and the effectiveness of European Union's external trade.

Appropriate legislation shall:

- 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.

Over the last 20 years, the medical device and the *in vitro* diagnostic medical device Directives have, overall, provided for safe, reliable and high-performing products in the European Union. They have ensured the flexibility needed to take account of the diversity of devices and their short life-cycle, and have proven to be favourable frameworks for innovation and small to medium-sized enterprises.

This practice needs to be maintained and developed further.

Translating discoveries and inventions into safe, effective and innovative devices that can reach patients, consumers and healthcare professionals in a timely manner is of the utmost importance, first of all for public health, but also for economic growth, the development of these sectors, their competitiveness and the jobs they create.

2.2. The need to restore patients', consumers' and healthcare professionals' confidence

Confidence and innovation must remain complementary and mutually supporting aspects of the promotion of public health.

Science evolves quickly in the areas of medical devices and *in vitro* diagnostic medical devices. In an internal market of 32 participating countries[8] that are subject to constant technological and scientific progress, 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

[8] EU Member States, EFTA countries and Turkey

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 have, without doubt, badly damaged the confidence of patients, consumers and healthcare professionals in the safety of the devices on which they may rely every day. These incidents have revealed further shortcomings of the current legislation, especially with regard to post-market controls.

This calls for determined action.

2.3. The necessity to adapt to a global market

The medical device and the *in vitro* diagnostic medical device markets have also become increasingly globalised. The European Union has, in the two last decades, encouraged regulatory convergence with its major trading partners (*i.e.* the United States, Canada, Australia and Japan) within the Global Harmonization Task Force[9] (GHTF), with the aim of ensuring the safety and the quality of devices, promoting technological innovation and facilitating international trade. The results of this international cooperation are being implemented not only in the participating jurisdictions, but also by many other countries that use the GHTF regulatory model as a blueprint for their national regulations. International cooperation will be strengthened further in the new International Medical Device Regulators Forum[10], with a view to continue developing efficient and effective regulatory models for medical devices and *in vitro* diagnostic medical devices that protect and maximise public health and safety while being responsive to innovation. To the extent possible, guidance developed for medical devices and *in vitro* diagnostic medical devices at international level have been taken into account in the proposed Regulations, in particular in the fields of traceability, safety and performance requirements, risk classification and clinical evaluation This will contribute to promote the global convergence of regulations, ensure a high level of safety protection worldwide and facilitate international trade. In addition the proposed Regulations encourage the regulatory cooperation between European regulators and their counterparts outside the European Union.

2.4. Towards a safer, more transparent and sustainable legislation

Strengthening the legislation is a prerequisite for the European Union capacity to continue to ensure a high level of health protection, restore the confidence of patients, consumers and healthcare professionals, and foster innovation and competitiveness.

In particular, the proposed Regulations foresee:

- to 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;

- to 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;

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9 http://www.ghtf.org/

10 http://www.imdrf.org/

- to 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;

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

- to 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;

- to 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;

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

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

- to 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.

3. A CONTRIBUTION TO THE OBJECTIVES OF THE EUROPE 2020 STRATEGY

3.1. The medical device and *in vitro* diagnostic medical devices sectors —key drivers for the European Union's economic growth

The medical device and the *in vitro* diagnostic medical devices sectors are estimated to comprise more than 500,000 products, covering a wide range of devices from simple bandages to the most sophisticated life-supporting devices. Medical devices and *in vitro* diagnostic medical devices play a crucial and complementary role in the diagnosis, prevention monitoring and treatment of diseases, the safety of the blood used in transfusions, and the improvement of the quality of life of people suffering from disabilities.

The medical device and *in vitro* diagnostic medical device sectors are characterised by a high degree of innovation, both incremental — once a device reaches the market, improvements may follow within 18 to 24 months — and breakthrough innovation.

The European Union has solid assets in the medical device and *in vitro* diagnostic medical devices fields and, without doubt, considerable potential to deliver growth. Not only the European Union has the largest market and some of the biggest companies in the world, but it also has an expanding ecosystem of innovative small to medium-sized enterprises, and even

micro enterprises, which are the innovators of the future. The medical device and *in vitro* diagnostic medical devices sectors have already proven to be key drivers of European economic growth. They contribute substantially to European Union's balance of trade, employs 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[11], the main markets being Germany (EUR 21 billion for medical devices and EUR 2.17 billion for *in vitro* diagnostic medical devices), France (EUR 17 billion for medical devices and EUR 1.7 billion for *in vitro* diagnostic medical devices) and the United-Kingdom (EUR 11 billion for medical devices and EUR 0.7 billion for *in vitro* diagnostic medical devices). 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, in order to better identify and respond to emerging medical needs.

Innovation in medical devices and *in vitro* diagnostic medical devices has gained pace in recent years. Scientific and technological progress, such as progress in drug-device combination products, tissue engineering, information and communication technologies (ICT), nano-science, personalised medicine and genetics, are creating new opportunities for improving healthcare and could culminate in a revolution in how healthcare services are delivered.

This innovation is central to the promotion of the smart, sustainable and inclusive growth which the European Union is determined to achieve through the Europe 2020 Strategy.

Safe and innovative devices have the potential to:

- keep people healthy and active for longer, by, for example, offering solutions for disease prevention or early diagnosis; this has a positive impact on productivity and competitiveness;

- make the healthcare sector more sustainable, as they can, for instance, help in preventing or reducing hospitalisation;

- improve skills and create jobs, since the healthcare sector employs one in ten of the most qualified workers in the European Union.

With the proposed legislation, the Commission aims also at maintaining the competitiveness and innovation capacities of the medical device industry by further harmonising the rules governing the medical device and the *in vitro* diagnostic medical device sectors and the enforcement practices in the Member States. In particular, it is estimated that the establishment of a central registration tool would help reducing the administrative costs by up to EUR 157mio. 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.

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[11] World Bank, EDMA, Espicom and Eucomed calculations, 2009

3.2. Medical devices and *in vitro* diagnostic medical devices support smart growth

3.2.1. Digital Agenda for Europe[12]

Progress in medical devices, in *in vitro* diagnostic medical devices and in information and communication technology (ICT) made it possible to radically transform the way healthcare services are delivered and to identify potential solutions to the demographic, societal and scientific challenges the European Union is facing.

In particular, over the last few years, e-Health technologies — many of which are medical devices or *in vitro* diagnostic medical devices — have created new possibilities for remote diagnosis, monitoring or treating patients and reducing hospitalisation, thus saving time and money for patients, healthcare providers and social security systems. Such innovations may offer the chance to make healthcare systems more efficient, thus providing equitable access to healthcare for millions of European citizens. These objectives are critical given the increasing incidence of chronic diseases, an ageing population and a shrinking healthcare workforce.

E-Health provides important opportunities to improve overall healthcare delivery. However, to reap these benefits, e-Health still presents challenges that the European Union is determined to tackle through, in particular, the Digital Agenda for Europe, the e-Health Action Plan[13] and the Directive on the application of patients' rights in cross-border healthcare[14]. This is necessary to achieve interoperable e-Health services in the European Union, to the benefit of patients (*e.g.* safety of treatments received and delivery of care at the point of need), healthcare professionals (*e.g.* improved quality and safety of care and up-to-date patient status information) and industry (*e.g.* opening up competition, reducing development costs).

3.2.2. Innovation Union[15]

Due to European Union's ageing population and strong competitive pressures from globalisation, future economic growth and jobs will increasingly have to come from innovation, be they related to products, services, processes, organisation or business models.

The Innovation Union initiative and its European Innovation Partnerships, in particular the Partnership on Active and Healthy Ageing, place great emphasis on the potential role of medical devices and *in vitro* diagnostic medical devices. By providing innovative solutions for prevention, early diagnosis, monitoring and assistance for independent living, devices may indeed have a crucial role to play in improving the health, mobility, independence and thus quality of life of citizens, in particular the elderly.

3.3. Medical devices and *in vitro* diagnostic medical devices support sustainable growth

Globally, medical devices and *in vitro* diagnostic medical devices represented less than 5% of Member States' healthcare spending in 2011 (*e.g.* 3% in Germany, 4% in the United-Kingdom, 5% in Sweden)[16], and offer alternatives to systematic or long-term hospitalisation, such as early diagnostic, minimally invasive surgical devices or home-use devices. In doing

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12 COM(2010) 245 final/2
13 COM(2004) 356 final
14 OJ L 88, 4.4.2011, p.45
15 COM(2010) 546 final
16 Espicom Health-care Intelligence — Medical Market Forecasts to 2011

so, medical devices support the long-term sustainability and efficiency of healthcare systems and have a positive impact on the productivity and competitiveness of the European Union's economy.

Medical devices and *in vitro* diagnostic medical devices are often an integral part of modern hospital services, and the strong link between a device and the surrounding environment often makes it difficult to correctly measure the added value of introducing an innovative device. The European Union supports projects aimed at improving health technology assessment methodologies for devices through the Seventh Framework Programme of the European Community for research, technological development and demonstration activities[17]. Improved methodologies will make it easier for health decision-makers to identify which new devices can contribute to efficiency gains and improved services. The establishment of a voluntary European Health Technology Assessment (HTA) network in 2013 will additionally enable easier sharing of HTA knowledge concerning devices and other health technologies among Member States.

3.4. Medical devices and *in vitro* diagnostic medical devices support inclusive growth

As the medical device and *in vitro* diagnostic medical devices sectors are comprised primarily of small to medium-sized and micro enterprises, they are major providers of jobs, especially highly skilled jobs in research and manufacturing, contributing directly to the Europe 2020 Strategy's aim to deliver high levels of employment.

Innovative solutions, for instance in the form of telemedicine or assisting technologies, offer great potential for improving access to medical services, combating health inequalities and social exclusion, and enabling more people suffering from diseases or disabilities to live independently and take an active part in society.

4. CONCLUSION

Safe, effective and innovative medical devices and *in vitro* diagnostic medical devices can certainly bring important benefits to the health of European citizens. They are also crucial in helping the European Union to meet current and upcoming demographic, societal and scientific challenges.

Health is also 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 on medical devices and on *in vitro* diagnostic medical devices have the objective of bringing these two aspects together under two safe, transparent and sustainable set of rules, built on a long-term vision. They will allow the European Union to continue to ensure a high level of health protection and counteract emerging doubts and decreased confidence of patients, consumers and healthcare professionals in medical devices and *in vitro* diagnostic medical devices, while at the same time fostering innovation and competitiveness of these two sectors.

The proposed legislation is an essential 'push' factor for fostering a European Union of active and healthy citizens where patients, consumers and healthcare professionals can reap the

[17] OJ L412, 30.12.2006, p1

benefits of safe, effective and innovative medical devices and *in vitro* diagnostic medical devices.