SPEECH OF THE COMMISSIONER NEVEN MIMICA

"A NEW EU REGULATORY FRAMEWORK FOR MEDICAL DEVICES ENSURING SAFETY AND INNOVATION"

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Ladies and Gentlemen,

It is a great pleasure to participate at today's Breakfast Policy Briefing.

Medical devices play a crucial role in healthcare and contribute to improving the sustainability of health systems.

Scientific progress, demographic changes and ageing of European society have been **transforming healthcare delivery** models significantly in recent decades.

In this context, **the medical device sector has an important role to play**.

Prevention, early diagnosis, monitoring and treatment of disease, all of which involve medical devices, are increasingly important.

This is reinforced by Europe's **ageing population** and the increasing prevalence of **chronic diseases**. In addition, the **pressure on healthcare budgets** is mounting whereas **the number of healthcare professionals is declining**.

In this evolving and challenging context, **safe and innovative medical devices** and ***in vitro* diagnostic medical devices** will be increasingly important. They have the **potential** to **keep people healthy and active,** enhance the quality of their life and to allow disease prevention or early diagnosis. They can also make the **healthcare sector more sustainable**. They shift care from hospital to home thus preventing or reducing hospitalisation and healthcare costs. For example, modern telemedicine allows patients to have regular check-ups from home, instead of visiting a doctor or going to a hospital.

Innovation in medical devices and *in vitro* diagnostic medical devices has gained pace in recent years.

Scientific and technological progress is creating **new opportunities for improving healthcare.** It could even culminate in a revolution in the way healthcare services are delivered.

Revised legislation that creates the right conditions for safe and innovative medical devices is essential.

The **European Commission's proposals** on medical devices reflect the rapid pace of scientific progress, as well as the need to preserve the highest level of patient safety. They aim to **strike a balance between the need to foster innovation** in this important sector **and to safeguard patients' safety**. Innovation and safety are the two sides of the same coin. They are **our dual and mutually complementary objectives.**

The **co-legislators,** the European Parliament and the Member States in the Council, have been discussing these proposals since October 2012. In this negotiating process some very **good and constructive proposals** have been made. For instance, on reinforcing the designation and monitoring **criteria for notified bodies**.

However, **certain amendments** adopted by the Parliament **require more careful consideration**. This includes, for example, the modalities for application and the outcome of the **scrutiny procedure**.

My position is very clear: the **scrutiny procedure is an important and proportionate** tool in the pre-market phase. It allows regulatory authorities to have a second look at the notified body's conformity assessment. It also informs national authorities, at an early stage, of high-risk devices coming on the market.

While the procedure proposed by the Parliament has similarities with the initial Commission proposal, some elements require further consideration, including, the **exclusion of** combination products and some surgically invasive high-risk devices, **criteria to trigger the assessment procedure** and the binding nature of the **final outcome of the procedure**.

In the **Council**, the Presidency proposed that **national authorities review** the clinical assessments performed by notified bodies. The **aim of this procedure** is to check that the assessment was conducted appropriately.

In my view, the principle of such clinical assessments could be considered. However, since this would be ***a posteriori* control**, it can only be complementary to the pre-market controls of high-risk devices.

The issue of **reprocessing of single-use devices is another** important issue on which we have different views.

The highest and most homogeneous level of protection of health and safety has been the Commission's guiding principle for the reprocessing of single-use devices.

It allows the **practice of reprocessing** to develop further **under clear and safe conditions** leading to potential savings for healthcare systems.

The Commission is open to other proposals as long as they respect the above-mentioned principle, are manageable and enforceable and do not delay the market access of devices.

However, the **EP amendments on reprocessing** are not in line with these objectives, because they consider all medical devices as reusable and suitable for reprocessing, except when they are placed on a list of single-use devices.

Another issue where positions differ concerns the Parliament proposal for designating **Special Notified Bodies** by the **European Medicines Agency**. In this respect, the **practical and financial implications** of the involvement of the European Medicines Agency need to be carefully analysed and assessed.

The **Presidency compromise text on notified bodies** was discussed by the Ministers at the EPSCO Council on 20 June. Member States warned against the overly complex and detailed provisions proposed. They believe that this would make the system overly rigid and increase administrative burden.

On the other hand, during the negotiating process some very good and constructive proposals were made.

I would be **open to reinforcing** the Commission proposal so as to protect consumers and patients and to allow them to take informed decisions. In particular regarding the Parliament amendments on the **informed consent and counselling in the field of genetic testing**. The context of use is very important in this sensitive area but at the same time we need to ensure the full **respect of the subsidiarity principle**.

Proposals have also been made to introduce provisions on **the role of ethics committees and the protection of minors and incapacitated subjects** in the context of clinical investigations and clinical performance studies. The **inclusion of such requirements is indeed important** and I would **support it,** in line with the Regulation on clinical trials.

Ladies and Gentlemen,

I can assure you that the Commission continues to place **high priority on these proposals**. The rapporteurs of the two files in the European Parliament worked with great intensity towards early adoption of the two regulations. As a result of their efforts, Parliament voted on amendments last October and confirmed its first reading position in April of this year.

Unfortunately, **progress in the Council has been very slow** despite many days of meetings and the valuable efforts of the successive Presidencies.

I hope that we will reach **political agreement under the Italian Presidency** by the end of the year.

Breakthrough progress on the most difficult issues **over the coming six months** will be decisive for the rapid adoption of the future Regulations. A well-balanced compromise will reinforce trust in and the credibility of the EU regulatory system.

Further delays would be prejudicial, not only to patient safety, but also to innovation. Swift access to innovative and life-saving technology is an important aspect of public health.

At the same time, an uncertain and unpredictable legislative framework does not create a favourable environment for investment.

Ladies and Gentlemen,

I have just **returned from China** where I discussed the **Chinese revised regulatory framework for medical devices** and the effect of its implementation on the market access for the European medical devices.

When we have in mind that the **EU and China** together, represent over a **quarter of the world's population**, it is easy to recognise the **enormous potential** of this cooperation for the **mutual benefit of our consumers and economies**.

Convergences of regulatory frameworks play a great role in that respect. **We all know that fragmented rules result in fragmented markets** which, in turn, do not create benefits for consumers. This is the reason why the Union is currently investing significant efforts into negotiations on the **Transatlantic Trade and Investment Partnership with the US**. The outcome of these discussions will have a direct impact on consumers and patients.

For medical devices, I believe that the **mutual recognition of quality management system audits** can be beneficial for patients and companies on both sides of the Atlantic. But the basis should be **global standards** under the International Medical Device Regulators Forum, and not the standards of a single jurisdiction.

Discussions are also ongoing on the **harmonisation of regulated product submission** to facilitate market access, and on **Unique Device Identification** to ensure future international traceability. There is clear **potential benefit** of having global rules. But these objectives must be achieved without compromising the protection of public health and without taking over the rules of one jurisdiction.

Policy makers and negotiators should ensure that **citizens and consumers support** the TTIP negotiations. With this aim, the Commission has launched a **public consultation** on investment protection and Investor-State Dispute Resolution. This issue has raised many concerns, which we must consider carefully.

To achieve a positive final outcome, negotiators should strive towards **maximum transparency towards civil society**.

Let me conclude by expressing my confidence that the new legislative framework on medical devices and in vitro diagnostic medical devices will successfully respond to the challenges our healthcare systems are confronted with.

Our ambition is to establish a clear, transparent and sustainable framework and a framework that strengthens the safety of devices placed on the market. And a framework that is flexible enough to reap the benefits that innovation can bring for patients and for the competitiveness of the industry. That is why an early adoption of this package is in the best interest of all.

Thank you for your attention.