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Commissioner Dalli delivers speech at the Eucomed MedTech Forum: Driving Innovation in European Healthcare

*Check Against Delivery
Seul le texte prononcé fait foi
Es gilt das gesprochene Wort*

John DALLI, European Commissioner for Health and Consumer Policy, attends the Eucomed MedTech Forum 2011

Brussels, Belgium, 12 October 2011

COMMISSIONER DALLI AT THE EUCOMED MEDTECH FORUM
BRUSSELS (MEETING CENTRE, RUE MONT DES ARTS)

WEDNESDAY 12 OCTOBER 2011, 15:00-16:00 HRS

SPEECH

Ladies and Gentlemen,

It is a pleasure to be here today, and to reflect together on the role of medical devices for the ageing society, the increasing pressures on national healthcare budgets; and the right regulatory future for your sector.

Let me be very clear: To me, health is an investment. And it is a good, sustainable investment.

In fact, health can contribute substantially to most of the objectives established within the framework of the Europe 2020 Strategy.

- It contributes to increasing employment. The health and social sector itself is a major employer, accounting for 10% of the European workforce. Furthermore, healthy people are more likely to join the workforce and to stay there longer.
- Health also contributes to Research and Development. Sectors such as pharmaceuticals and medical devices are highly innovative.
- Health contributes to education targets: University degree rates are markedly higher in the health and social work sector compared to the economy as a whole.

- And health contributes to the reduction of poverty. Unhealthy people are often poor and vice versa. Adequate public health coverage, by contrast, serves as an effective safeguard against poverty.

Nevertheless, drawing upon my past experience as a finance minister, I am the first to acknowledge that **health takes up a significant share of public spending**. . In fact, expenditure on healthcare has risen steadily ever since governments took responsibility for the universal provision of healthcare. This is because expenditure on health is driven by a complex set of interrelated supply and demand factors, such as the size and structure of the population, the health status of the population, or the emergence of new technologies, just to name a few.

One key driver is obviously **demographic development**. According to a projection exercise carried out by the Commission, ageing could be responsible for an increase in total healthcare spending of between 1.5 and 2 percentage points of GDP by 2060.

It is a commonly held belief that average healthcare expenditure is linked to the age of an individual, with the demand for healthcare depending ultimately on the health status and functional ability of a person. In other words, **age** is often used **as an indicator of the health** status of a person.

But this connection is not only too simplistic, it even sends the wrong political message. We must not content ourselves with the equation that old age means poor health. Instead, we need to add better life to our years! This would mean a better quality of life. In fact, increases in expenditure could be reduced by two thirds if future projected gains in life expectancy are spent in good health.

To sever the link between old age and ill health, we must work towards healthy ageing. The "European Innovation Partnership on Active and Healthy Ageing" aims to enhance Europe's innovation potential for tackling the challenges of demographic change associated with ageing – harnessing both the public and private sectors.

By bringing together all actors across the entire innovation chain – from the public and private sectors, and at EU, national and regional levels – the Partnership's overall objective is to increase the average healthy lifespan of Europeans by 2 years by 2020.

It aims to deliver:

- Better health and quality of life, in particular for older Europeans;
- More efficient and sustainable health systems; and
- Greater EU competitiveness and growth.

It seeks to translate innovative ideas into tangible products and services that really respond to the needs of older Europeans.

To succeed, we need close co-operation across different policies spanning public health, research and industry. We need strong commitment from all partners at all levels.

Three specific focus areas have been identified based on intensive consultation with stakeholders:

- Innovation in awareness, prevention and early diagnosis;
- Innovation in care and cure;
- Innovation in environments for active and independent living.

An additional priority theme on horizontal aspects having a cross-cutting nature has also been agreed upon, thus shifting the focus onto issues related to funding, framework conditions and evidence, while ensuring coherence and complementarity across the thematic groups.

A limited number of priority action areas have been selected in these three areas by the partnership's Steering Group. These priority areas/themes should:

- make the greatest contribution to the objectives of the partnership;
- benefit from the partnership approach;
- contribute to overcoming key bottlenecks and barriers; and
- facilitate innovation in an area where European industry has, or may, develop a competitive advantage.

The health and medical technology industry plays an important role in the defined action areas – for instance, regarding the enabled personal guidance systems or in integrated care. In the latter area, actions take place regarding the remote monitoring of patients with a chronic disease.

I am aware that EucoMed have sent in some actions in the area of integrated care.

One such action concerns remote monitoring for cardiac devices to improve early detection of clinically relevant events regardless of the geographical location of the patient.

As well as reducing morbidity and mortality and improving the quality of life of patients with chronic cardiac conditions, this action might also improve access to care and bridge the gap in hospital, ambulatory and community care management for cardiac conditions.

As a result of such innovations, patients can become "co-producers" of their own health; receive more tailor-made healthcare; and stay at home, thus living actively and independently for a longer period of time.

This leads me to another important driver of health cost growth – progress in **medical technology**.

Science is constantly providing us with new and more effective devices for taking care of our health. But this improvement usually comes at a price.

The impact of technology depends to a considerable degree on the legal and institutional framework for the provision and financing of healthcare, which differs widely across the European Union.

The good news is that we now have tools to assess and promote more effective use of technology. Health Technology Assessment aims to inform the formulation of safe, effective, health policies that are patient-focused and seek to achieve best value.

I firmly believe that smart investment in health – coupled with smart innovation in health – provide the keys to the more efficient healthcare systems of the future.

At the same time, innovation must look beyond traditional "products" and include the whole healthcare chain – from hospitals, carers and health insurers, to health systems themselves. It must explore solutions for more efficient patient pathways in healthcare.

In addition, innovative solutions could be promoted to increase effectiveness in the health sector. Smart investment can trigger efficiency gains that help secure the quality and sustainability of health systems.

In this respect, we are exploring innovative ways to deliver better healthcare to more people on a smaller budget. Our main and ultimate goal is clearly to ensure people have equitable access to high quality healthcare services. And we must do this against the backdrop of economic fragility and uncertainty.

We must rise to the challenge of creating efficient and effective health systems, and maintain their operation at the highest level of quality and safety.

In June, the European Ministers for Health invited the Commission, with the Member States, to start a reflection process aimed at identifying effective ways of investing in health, so as to pursue modern, responsive and sustainable health systems.

In order to accompany and support such a move towards innovative medical devices we need an appropriate regulatory environment that ensures the safety of products and allows innovation to the benefit of patients.

Over the past 20 years, the three European medical devices Directives that define this regulatory framework have brought about positive results in terms of safety; support of innovation; rapid access of new devices to the market; and cost-efficiency.

But this should not induce complacency. We cannot afford to stand still. Technological development and the constant march of globalisation are major challenges to which the regulations need to respond.

The revision of the regulatory framework for medical devices is a very important initiative of the Commission – and I plan to present proposals for new EU regulations next year.

In revising our regulatory system, we want to keep the positive aspects whilst remedying identified weaknesses and addressing future challenges:

First, we need to ensure that the rules are adapted to technical and scientific progress:

- This will require adaptations to the scope of the devices regulations, for example:
 - The regulatory gap between tissue-engineered products falling under the pharmaceuticals legislation and the Tissues and Cells legislation should be filled;
 - Implantable or invasive products used for aesthetic purposes which are similar to medical devices should be subject to the same requirements as devices;
 - The practice of reprocessing single-use devices needs to be addressed to ensure a high level of protection of patients and public health;
 - It should also be clarified that genetic tests that provide information about the predisposition of a person to a medical condition or a disease fall under the regulations on in-vitro-diagnostics;

- Existing rules will need to be reviewed to ensure that developments of the sector are duly taken into account during the "benefit/risk" analysis – for example, the interoperability and compatibility between devices and their environment; and the assessment of nano-material in devices.

Second, we need to ensure that the rules are effectively enforced across the EU:

- This means, in particular, that the oversight of Notified Bodies – a cornerstone of the European approach to device regulation – is conducted rigorously and in accordance with the same high standards across the EU; and
- That necessary corrective action to safety issues occurring in the post-market phase are taken in a timely and consistent manner throughout the EU.

Third, we have to ensure that the necessary instruments are in place for the transparent, sustainable and efficient management of the system:

- For example, I consider it necessary that we have a single registration of devices placed on the EU market and a system that will allow their traceability through the supply chain;
- For "borderline" cases, I envisage proposing a mechanism to determine the regulatory status of a product at EU level with the involvement of all relevant sectors;
- We also need more structured access to external clinical and scientific expertise that will allow for the provision of expert advice in the pre- and post-market phase to manufacturers, Notified Bodies, competent authorities and the Commission;

- From the management aspect, we need enhanced co-ordination between national authorities that lives up to the principles of the internal market and allows burden-sharing, thus avoiding duplication of work;
- We cannot leave the Member States alone with this task. The administrative, technical and scientific support for the enhanced coordination must be provided at EU level. Whether this is done by a future "European Agency for Health Products", that would integrate the current EMA and a new department for medical devices, or by the Commission itself is a question of efficient organisation rather than of substance.

To the extent possible, guidance developed by the **Global Harmonization Task Force** (GHTF) will be taken into account during the revision of the EU directives. In particular, I am thinking of the adoption of the GHTF classification system for *in vitro* diagnostic medical devices as well as the requirements for clinical evidence for IVDs.

My objective is to further improve the protection of our patients' health and safety and to reinforce Europe's position at the forefront of innovation in medical technology.

I should say here that this is not a response to comparisons which have been made between the EU and the US systems. Actually, there is no evidence that one regulatory system is 'safer' than the other.

On both sides of the Atlantic, assessments are taking place on how our respective regulatory systems can be further improved.

This is, of course, a laudable and logical way to proceed – in pursuit of higher standards and better performance.

But this is not a reason to pit one system against the other. This is not a point-scoring exercise.

Rather, the challenges we are facing and growing globalisation call for **enhancing co-operation at international level**. I therefore welcome the initiative to transform the Global Harmonization Task Force for medical devices into a truly global forum for medical device regulation.

This should provide a platform for regulators to develop harmonised regulations and co-ordinate their implementation. The device industry and other stakeholders (such as healthcare professionals) should of course participate in this process.

May I suggest that you become actively involved in shaping the regulatory framework, both at European and at international level.

It is important to demonstrate to policy makers and other stakeholders the benefits that your products bring to society.

We all grow older and can become sick at any moment. Sooner or later, almost everyone will benefit from innovative devices.

In March of this year, together with the Hungarian EU Presidency, I chaired a high-level conference focused on innovation in the medical devices sector. This was followed up by Conclusions adopted by the Council of the EU.

I very much appreciated the exchange of views among senior representatives of patient organisations, healthcare professionals, industry, insurers, social security and regulatory authorities.

Let me finish by saying that I strongly suggest we continue this fruitful dialogue with a second high-level conference in 2012.

I am open to receiving suggestions for topics that could be discussed.

Thank you.

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