

John Dalli

Member of the European Commission, responsible for Health and Consumer Policy

Commissioner Dalli delivers speech on "The European Commission Strategy for the Pharmaceutical Sector"

*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 53rd Annual Meeting of the European Association of Full Line Wholesalers (GIRP)

Lisbon, Portugal, 04 June 2012

**53RD ANNUAL MEETING OF THE
EUROPEAN ASSOCIATION OF FULL LINE WHOLESALERS (GIRP)**

PORTUGAL - LISBON

MONDAY 4 JUNE 2012, 09:00HRS ONWARDS

KEYNOTE SPEECH

**THE EUROPEAN COMMISSION STRATEGY FOR THE
PHARMACEUTICAL SECTOR**

Ladies and Gentlemen,

The European Union is going through a challenging period: we are fighting a long and deep fiscal and economic crisis. At the same time, the ageing of our society puts additional strain on our healthcare systems, and health inequalities are widening.

An inspired vision for healthcare, as the title of our conference suggests, is indeed essential to meet these challenges.

As President Barroso has pointed out in his video-message, we are not yet out of the woods as regards the fiscal and economic crisis.

Today, we spend in Europe 10% of our GDP on healthcare –more than ever before.

In most EU Member States health expenditure has been growing faster than the overall economy for many years. That may reflect the growing importance of health, but this trend is unsustainable in the long run.

A key factor contributing towards pushing health expenditure upwards results from one of our most notable health achievements – increasing life expectancy.

But while many Europeans live active and healthy lives well into retirement, many do not.

- Half of Europe's 65 to 74 year olds report a health problem;
- An average of 20% of our lifespan is spent in ill health;
- Those over 65 are likely to be unwell for half of their remaining life.

Other factors contributing to increased healthcare expenditure include higher citizens' expectations and technological innovation.

We therefore face a double challenge: We need to contain costs, starting now, whilst building modern, responsive, and sustainable health systems fit for the future.

My personal vision on how to respond to these challenges builds on three key elements:

- First, sustainability and affordability. Our health systems must and can become more cost-effective. We can provide better care at lower cost. The key is to use the vast potential of innovation in products and services. Innovation is not just a cost driver. If used intelligently, it can bring down costs significantly.
- Second, availability and universal access. I am determined to fight the growing health inequalities in Europe. In a community build on common values, universal access to necessary healthcare is indispensable.
- Third, quality and safety. The healthcare that patients receive in the EU must be of the highest quality, and it must be safe. Safety is the minimum on which we cannot compromise.

Allow me in the following way to explain you some of my initiatives which contribute to implementing this vision and which are relevant for your sector.

Improving the sustainability of healthcare

There are many initiatives under way that aim at supporting Member States in their efforts to improve the sustainability of their healthcare systems:

- The Commission is cooperating with Member States to develop a common methodology for Health-Technology Assessments. This will help to focus public budget on the most innovative and beneficial technologies.

- The Commission is also building up capacities and knowledge in order to assist Member States, for example in the context of the European Semester. The country-specific recommendations that the Commission adopted last week, reflect the growing importance of healthcare in the overall economic and fiscal coordination in Europe.
- A further important initiative contributing to the sustainability is the European Innovation Partnership on active and healthy ageing.

Its ambitious general target is to increase the average healthy life span of European citizens by 2 years by 2020. Its core is to better exploit innovative ideas with a view to deliver better health and quality of life for Europeans at lower cost, while at the same time promoting competitiveness and growth.

We are just about to start with the operational phase of the Partnership and I can tell you that so far it has been a great success. Last week, the deadline for partners to submit "commitments" has expired. And the number and range of commitments that were actually submitted is impressive. I know that the European association of wholesalers also participates in some of the projects submitted, and I would like to thank you for your support.

As an example of potential activity, steps should be taken to make it easier for older people to adhere to medication and treatments.

Many people take several different medications for multiple chronic illnesses, which can further impact their health and their ability to follow their treatment as instructed.

Currently, only 79% of patients take their 'once daily' dose, while only 51% of patients required to take four actually do so.

I have chosen this example as I know that pharmaceutical wholesalers are particularly interested and active in this area. At first sight, this is perhaps surprising. You would expect a wholesaler just to do wholesale business – buy the medicine from the producer and sell it to the pharmacy.

But the reality has become much more complex, which I welcome as I believe that it is a reflection of the move towards innovation. Providing innovative solutions often requires changing the way we have been doing business in the past. If this leads to better service for the patients at lower cost, then it is precisely what we want to promote and advocate through the Innovation Partnership.

We will now analyse the numerous commitments that have been submitted in the six priority action areas of patient compliance, integrated care for chronic diseases, frailty, falls prevention, active and independent living at home, and age-friendly cities.

All commitments selected will then be taken forward in action groups with the objective to deliver first intermediate results by end of this year and more substantial results by end of next year. There is no time to lose to determine the best solutions and promote their rapid and broad market uptake!

Another important tool as regards the future sustainability of health systems is eHealth, which holds enormous potential to provide better care to more people, in a more efficient manner.

eHealth can make a difference in delivering high quality, safe healthcare to each and every European; while reducing medical errors and cutting costs.

This is why I am keen to support Member States to cooperate on eHealth and to encourage the uptake of interoperable eHealth solutions.

I have just brought together all Member States in a voluntary eHealth network, which met last month for the first time. The network will identify the minimum set of patients' data that needs to be on electronic record, to ensure safety and continuity of care across borders. The network is also working on common identification and authentication measures to ensure the transferability of data to the right people.

The network is supported by results of work undertaken by the more technical work of the eHealth Governance initiative.

Some Member States are paving the way in rolling out eHealth solutions.

For example, more and more Member States are using electronic prescriptions. I saw in Denmark last month how the pharmacies of several countries are using an interoperable system whereby ePrescriptions from different countries can be accessed and delivered. Such tools are needed to translate into reality the right for citizens in getting their prescribed medicines anywhere in the EU.

Availability and universal access

Next to improving the sustainability, improving the availability of healthcare including access to pharmaceuticals is one of my most important objectives.

The existing EU pharmaceutical legislation already includes requirements for the continued supply of medicines placed on the market. And through the 2010 pharmacovigilance legislation we have introduced some further flexibility, for example on the language regime, in order to facilitate a broader availability of medicines.

I am not confident though that this is enough. From my own experience as health minister in my country, I had to realize that after Malta's accession to the EU the number of medicines on the market decreased.

In order to get a deeper understanding of the underlying problems, I have therefore initiated a study. It shall analyse to which extent patients in the Member States, particularly in smaller ones, indeed face problems of availability. It shall also identify which factors lead to such problems of availability. And it shall analyse how, and to what extent, recent changes to EU pharmaceutical legislation and its implementation have served to alleviate such problems. I want to know, how we can best use the regulatory tools at our disposal in order to ensure optimal availability of medicinal products, in the interest of patients and public health.

Another important aspect in improving rapid access to medicines is the time needed for national decisions on pricing and reimbursement.

In March this year, my colleague Vice-President Antonio Tajani presented a proposal for revising the so-called "Transparency Directive". It aims to tackle delays in marketing medicines through an accelerated decision-making process.

It seeks to ensure a better functioning of the internal market and is expected to deliver benefits to various stakeholders:

- Patients should get faster access to medicines, both originators and generics.
- The pharmaceutical industry as a whole – both originators and generics manufacturers – should get a faster return on investments in research and development and operate in a legally predictable environment.
- Given the economic crisis, faster introduction of off-patent medicinal products could translate into significant savings for national budgets.

Quality and safety

Finally, let me turn to the crucial aspect of safety. I trust that we all agree that we need to strive for the highest level of safety.

We are working on this through the recent revisions of the pharmacovigilance legislation, but also through determined action against falsified medicines in particular in the legal supply chain.

We are currently working on implementation measures following adoption of the new Directive on falsified medicines, and notably the delegated act on the unique identifier to be placed on the outer packaging of medicinal products. This will provide verification that such products are authentic.

One of the main objectives of the delegated act will be to ensure the development of a system to be integrated into the existing structure of the supply chain. It has to provide a high level of security for patients whilst being cost-effective.

The Commission is also taking forward two other important acts related to the new rules for import of active substances and good manufacturing practices for active substances.

Furthermore, we are revising the good distribution practices, initially published in 1994. The main goal is to ensure the storage and the distribution of medicinal products under appropriate conditions, taking particular care to avoid unnecessary costs. I am aware of the strong concerns amongst many of you about the first draft published by EMA, but I can reassure you that we are currently revisiting the draft thoroughly taking into account the many comments we received. We need to ensure a safe distribution line, but we also must avoid red tape.

Ladies and Gentlemen,

I hope that I was able to sketch out the key challenges I see in the healthcare sector and which vision is underlying the actions the European Commission is taking to successfully respond to these challenges.

Pharmaceutical wholesalers are an important actor in this vision. I had the chance to visit a wholesaler in Belgium some time ago, and I was impressed by the quality, the speed and reliability of the service provided.

You help to ensuring that medicines reach the patients. You have a key role in guaranteeing that this supply is maintained and is given even in remote locations, in particular for those of you who are full-line wholesalers. And I very much welcome if you seek to explore new services, such as on patient compliance in the Innovation Partnership, which provides better assistance to the patients and helps to improve the sustainability of our healthcare systems.

I count on your active support as a key partner in this sector, and reconfirm my commitment to an ongoing dialogue with you.

Thank you.

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