John Dalli

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Commissioner Dalli delivers speech on "Healthy and Active Ageing through improved access to affordable generic medicines"

John DALLI, European Commissioner for Health and Consumer Policy, attends the 18th European Generic Medicines Association (EGA) Annual Conference

Portomaso, St. Julians, Malta, 15 June 2012

COMMISSIONER DALLI'S PARTICIPATION AT THE

18th European Generic Medicines Association (EGA) Annual Conference:

"HEALTHY AND ACTIVE AGEING THROUGH IMPROVED ACCESS TO AFFORDABLE GENERIC MEDICINES"

FRIDAY 15TH JUNE 2012, 09.00HRS

Conference Centre Hilton Malta Hotel

SPEECH

Ladies and Gentlemen,

It is a pleasure for me to address your annual conference for many reasons:

- The topic of your annual conference brings together several key aspects of my vision for a European health policy, including ageing, improved availability, and sustainability.

- Generic medicines have an important role to play in finding the necessary responses to these challenges.

- And generic industry makes a significant contribution to the Maltese economy.

Allow me to first set out the context of the future of health systems before turning to some issues of particular interest to the generic medicines sector.

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Ladies and Gentlemen,

In Europe, people are living longer and longer. This is a great success. At the same time, many of the years gained are not lived in good health. This gap is evening widening at the moment.

The progressive shift towards an older population has deep and far-reaching implications across all key policy areas, affecting the fundamental dynamics of economic, political and social systems.

Health – and in particular health systems and their sustainability – is an area where these effects will be amongst the most apparent.

Indeed, it is the very success of health policies over recent decades that has led to the marked upturn in life expectancy across the European Union.

But for decades, in almost all European economies, expenditure on health has absorbed – and continues to absorb – an ever increasing proportion of GDP.

Public spending on health care accounts for more than 7% of GDP already. According to current forecasts, this could further increase to up to 10% in the next decades.

Combined with long-term care, governments could spend by 2020 almost one third more on healthcare and long-term care than is the case today.

But whilst the challenges are indeed significant, there is considerable scope for new opportunities – opportunities for new ideas, new projects, new products, and new partnerships.

We must avoid the negative attitude of thinking about health as essentially a cost – a burden.

Instead we should think of health as a long-term investment with a significant and attractive rate of return.

We must keep in mind that:

- Health is not just one of our most important immaterial values as all those know who suffer from diseases.

- At the same time, health is one of the major economic sectors of every EU Member State.

- Health contributes to economic growth by fostering a healthier workforce and as a major employer of highly qualified workers.

- The health sector also drives demand for medical goods, for research, and for innovation.

The ongoing economic crisis puts pressure on health budgets as much as on other public sector budgets. It forces us to re-examine our basic approach to healthcare delivery.

Efficiency gains are urgently required to ensure the future sustainability of health systems. This is not about spending less, but rather about spending better.

The broad aim must be to deliver high quality healthcare to all, making our "health euros" go as far as possible.

Let me put this into the context of the Europe 2020 strategy which aims to achieve a smart, sustainable and inclusive European economy, which can emerge from the current crisis fitter, keener and stronger.

This calls for stronger co-ordination of economic and fiscal policies across the Member States.

Part of the EU response to this challenge is the European Semester – a new form of more effective economic governance, which strengthens the focus on achieving the Europe 2020 goals.

Member States are required to submit National Reform Programmes to show their contribution to the overall strategy objectives.

Health systems have an important role to play in this process. Indeed, all Member States cited health as a major topic with direct relevance to the Europe 2020 targets.

Beyond the European Semester activities, the Commission is also pursuing financial assistance programmes for specific countries suffering particular difficulties.

In such cases, Member States have agreed a list of targets and activities aimed at securing the sustainability of their health systems.

Both Greece and Portugal have set a ceiling for their public expenditure on pharmaceuticals. In addition, they agreed on a strategy for increasing the use of generics, in particular through by prescribing only the active substance and by imposing the principle of generic substitution on pharmacists.

Another measure, being used in Greece, requires generic medicines to account for 40% of the medicines prescribed by public hospitals, to be achieved through compulsory participation in a centralised tender procedure for medicines.

These joint procurements aim to reduce the costs for public hospitals and will help towards achieving the goal of a 35% prescription rate for generics in the general health system.

One key tool to improve the sustainability of healthcare spending is Health Technology Assessment. It is crucial if we want to focus healthcare spending on those technologies that bring the highest benefit for the patients.

HTA can look into the use of medicines, medical devices, surgical procedures, preventive measures – comparing the new technology with existing alternatives.

This gives health decision-makers a sounder basis for taking decisions on the use of innovative treatments, taking into account the full range of relevant factors.

Next year will see the establishment of a permanent voluntary HTA network in Europe, following years of HTA projects financed by the EU. Based on the European HTA methodology that we are currently developing together with the Member States, it should enable Member States to use HTA as a strategic tool when developing their health services.

This is particularly relevant for smaller countries like Malta, which have limited resources to develop HTA capacities in isolation.

Working in partnership is an important means of fostering smart and innovative solutions to turn the challenge of ageing into fertile opportunities, and healthcare expenses into sound forward-looking investments.

This is precisely what the "European Innovation Partnership on Active and Healthy Ageing" is aiming at. It shall encourage active collaboration across the widest possible range of health stakeholders.

The Partnership aims to encourage, foster and enhance Europe's innovation potential for tackling the challenges of demographic change associated with ageing. Its long-term goal is to increase, by 2020, the average healthy life-span of European citizens by two years.

Stakeholders across the entire innovation chain – from both the public and private sectors – have been invited to join the Partnership and to contribute to the process through making firm commitments. And the response has been overwhelming: In total, we received 261 commitments, spread very well over the six priority areas: 35 commitments for adherence, 32 for falls prevention, 51 for functional decline, 67 for integrated care, 41 for independent living at home, and 35 for age-friendly cities. In addition, we received 54 candidate reference sites.

I very much appreciate that the European Generics Association also participates in a commitment led by the Italian Medicines Agency on adherence. Ensuring that patients are taking their prescribed medicines and are following recommend treatments is a prerequisite in improving quality and sustainability of care.

Work under the Partnership will seek to build a holistic framework to help patients to use more effectively their medications and to reduce adverse outcomes.

Such a framework should draw on innovative adherence tools and reminders to help keep patients on track.

This approach needs, however, to be broadly based – involving patients and the entire healthcare team (including physicians, nurses and pharmacists).

We will now screen all the submissions and then set up Action Groups in each of the priority areas. Our aim is to deliver first concrete results from the commitments by end of next year.

If we want to improve patients' access to high-quality and affordable medication, including generics, we also have to get the regulatory framework right.

Our legal framework for medicinal products aims to protect public health and to ensure the free movement of medicinal products so that they can be made available to citizens right across the European Union.

The European system offers routes for the authorisation of medicinal products – at EU level with a centralised procedure, or at Member State level – before they can be placed on the EU market.

All medicinal products, including generics, are placed on the EU market following an in-depth assessment of their quality, efficacy and safety.

A generic company which obtains a marketing authorisation under the centralised procedure can market the generic product across the entire EU. This clearly shows the added value of the centralised procedure.

At present, the Commission is pursuing a number of initiatives to enhance the quality, efficacy and safety of all categories of medicinal products – generics included.

Under the new pharmacovigilance legislation, there will be a stronger focus on the risk of a medicinal product, which will reduce the burden for all known active substances. This risk-focussed spirit of the legislation will now have to be translated correctly when applying the new rules.

We are also working on various measures to implement the new Directive against falsified medicines.

The new Directive sets up the general rule that prescription medicines shall bear the safety feature while non-prescription medicines shall not. Generics subject to prescription are in principle included in the scope of the safety feature. Potential exceptions to the general rule can only be in compliance with the requirements already set in the Directive by the co-legislators.

In this context, I would mention in particular 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.

Overall, one of the main objectives of the delegated act will be to ensure the development of a system which can be integrated into the existing structure of the supply chain. It has to satisfy the twin aims of a high level of security for patients, whilst being cost-effective.

We are also taking forward two other important acts related to the new rules for the import of active substances. As of July next year, import of active substances into the EU will only be allowed if either the third country has been listed by the Commission as being EU equivalent or if the individual consignment is accompanied by a confirmation by the competent authority.

I am fully aware that parts of industry, including some of your members, are worried that key third countries such as India or China will not be ready in time to comply with these rules and that this could lead to supply shortages. Let me reassure you that we are very sensitive to this aspect and determined to avoid shortages.

In order to achieve compliance, we need to closely cooperate with the third countries. The EU has taken the initiative to work with our key partners. But I also call upon industry that is relying on active ingredients produced in those countries and imported into the EU to join our efforts with third countries.

Let me know turn to the issue of biosimilars. Biosimilars have a very promising potential as they provide more affordable access to highly-innovative biological medicines.

In the past, the EU had a leading role on biosimilars. We were the first to set up a comprehensive regulatory framework in 2005, which was followed by many countries world-wide. This may have contributed to the fact that the EU is also a leading industrial base for the development of biosimilars. I believe we can be proud of this and should eagerly defend this role.

What we have seen in the recent past, is that the development of biosimilars has become an increasingly global business. I believe that this is a natural and positive trend.

I realize however that the application of the EU rules on biosimilars do not fully match this trend. So far, the authorisation of biosimilars in the EU is based on the comparison of a medicinal product with a reference product authorised in the EU. We have consistently interpreted our legislation in a way that requires data provided in the marketing authorisation dossier to be established with batches sourced from the EU.

I recognise that such an interpretation obliges applicants to repeat all clinical studies with batches sourced from various continents. Such a system has helped in the past to ensure reliable comparability. In the meantime however other countries have set up rules on biosimilars which are similar to ours.

This allows us to reconsider our approach in the EU. In fact, I am able to inform you that after careful analysis of the scientific and regulatory elements, the European Commission will revise its interpretation. We will accept that a biosimilar application contains clinical data with reference products that are not sourced from the EU. I am also able to inform you that this change of interpretation is possible on the basis of the existing legislation. It hence could be applied without awaiting a lengthy legislative process.

Obviously, this requires appropriate conditions to ensure that the different reference products in the EU and outside are comparable. These details are currently under further discussion by our experts, keeping uppermost in our minds, of course, the overriding need to ensure the same high level of public health protection.

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Ladies and Gentlemen,

Let me conclude by saying, once again, that I fully recognise the important role that the generic medicines sector has to play not only now, but in the future in relation to the challenges to be met in achieving high-quality and sustainable health systems in Europe.

We will continue to pursue an approach to pharmaceuticals which ensures, first and foremost, the safety of European patients; which fosters innovation and excellence; and which contributes to reaching optimum performance of European health services and systems.

Thank you.

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