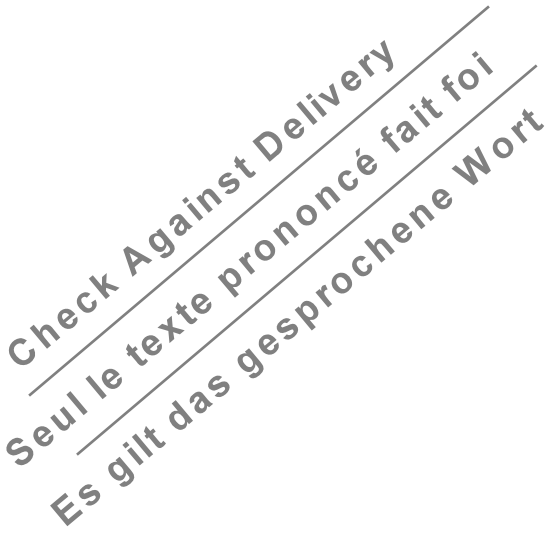
John Dalli

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

Commissioner Dalli delivers speech on US-EU Health



John DALLI, European Commissioner for Health and Consumer Policy, attends a lunch meeting with the European American Business Council (EABC)

Washington, USA, 27 June 2012

LUNCH MEETING WITH THE EUROPEAN AMERICAN BUSINESS COUNCIL (EABC)

WEDNESDAY 27 JUNE 2012 12.30-14.00HRS

SPEECH

Ladies and Gentlemen,

It is a pleasure for me to address this lunch meeting of the European American Business Council. I would like to take this opportunity to speak to you about a number of issues of common interest.

US-EU eHealth

Let me start with eHealth.

eHealth has great potential to deliver better healthcare, to more people, in a more cost-effective manner. It can also improve the use of health data for research and planning.

With the current economic challenges as a backdrop, there is not doubt that we need to redesign healthcare for the future. In this regard, I firmly believe eHealth must be an integral part of our health reforms to ensure long-term sustainability.

The USA and Europe have in common that our health systems are diverse.

In Europe, each Member State is responsible for its own health system – therefore to reap the benefits of eHealth solutions we need to ensure good cooperation to help us address the same challenges in a coordinated manner.

This year, I have established a new eHeatlh network bringing together all European Union Member States to co-operate in three priority areas:

First, the Network will identify the minimum set of patients' data to be exchanged cross-border to ensure safety and continuity of medical treatment and care, at home or abroad.

This is of tremendous importance in cases of emergency care, and is also instrumental in facilitating planned care across borders.

Issues such as semantics and technical interoperability will be addressed by the Network. We trust we can build on the work done by the project epSOS which I am aware is closely co-operating with the US administration to make progress globally on interoperability.

Second – the Network will work on common identification and authentication measures to ensure transferability of data in cross-border healthcare as a precondition for secure electronic health services.

Third – the Network will develop methods to enable the use of medical information for public health and medical research.

Another important issue concerns the protection of personal health data. Ensuring the safety of personal data is essential. However, the legislation protecting citizens in this field may at the same time limit solutions to improve healthcare.

The European Commission has proposed a new Regulation on data protection earlier this year, which seeks to enable easier secondary use of data, at national level and across borders, for the benefit of public health and research, whilst respecting the fundamental rights of citizens.

In many ways, what we are trying to achieve is parallel to the US HITECH act, which aims at balancing the need to respect privacy in the doctor–patient relationship with that of allowing the research community access to the wealth of data from electronic health records.

This is an area where we need to work together to ensure that the protection of health data is properly safeguarded, including when transferred via electronic systems.

In this context, let me recall the 2010 Memorandum of Understanding between the EU and the US on eHealth.

The Memorandum points directly to a key element needed if eHealth services are to provide better integrated health services – interoperability.

Through the Memorandum, the US and Europe are committed to working together to develop and increase the uptake of internationally recognised standards for electronic health records.

Europe and the US have some of the most advanced R&D enterprises in the world in ICT for Health. Using common interoperability standards would benefit not just health research; it would also serve as an incentive for these enterprises to develop new ICT tools which can become an integral part of the interaction between the patient and the health services.

Medicinal products – Clinical Trials

In September last year, I shared with you one of my core objectives – a patient-focused system in order to ensure the best available treatment for all citizens in the European Union.

To this end, the EU regulatory framework on medicinal products fosters innovation. In this context, the question of what would be required, in terms of regulation, to make Europe more attractive for clinical research has prompted the revision of the Clinical Trials Directive.

Clinical trials are of course crucial for the development of new medicines, and equally to improve and refine treatments with existing medicines.

Clinical trials are also a key contributor to growth and jobs in the area of public health. Clinical trials mean research and investment, including inward investment from outside the Union.

It is therefore crucial to provide the right regulatory framework.

The number of clinical trials performed in Europe declined by 25% between 2007 and 2011. But let me be clear – the Clinical Trials legislation was not the only reason behind the decline in clinical research in the EU.

There are many other factors not linked to regulation – R&D commitment by industry, its cooperation with academic research, availability of venture capital as well as return on investment, to name just a few.

But as regards the regulatory framework, we can and we will do better.

I am committed to putting forward a legislative proposal with the aim of strengthening knowledge and innovation in clinical research.

The future procedure for the authorisation of clinical trials will need to be fast, efficient and pragmatic.

Each year sees the authorisation of approximately 4000 new clinical trials, and at any point in time some 12 000 clinical trials are ongoing in Europe. Of these, 25% are multi-national.

We must always keep in mind that clinical trials are important not only for Europe. However, we do not want to see clinical trials referred to in the EU – for example in a marketing authorisation application – disregarding the rules on the protection of patients.

To ensure against this, our current legislation already includes the 'equivalence rule'. For the results of a clinical trial to be accepted, the regulatory framework in a third country must be equivalent to that of the EU as regards the protection of patients.

While there are important jurisdictional limits, we have to think of ways to ensure that this is properly enforced.

Availability and universal access

Last year, I mentioned to this forum the need for the right conditions to make medicines easily accessible and affordable, especially in these times where the financial and economic crisis provokes significant constraints on public health budgets. But whatever the financial situation, patient safety must always come first.

Together with fostering innovation, 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.

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 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; and

- Faster introduction of off-patent medicinal products could translate into significant savings for national budgets.

Medical Devices

Before I close, let me say just a few words about medical devices, where the Commission plans to present proposals for new EU regulations later this year.

These will seek to enhance the level of safety of medical devices; provide a framework that is supportive for innovation; and make the regulatory system more transparent.

More specifically:

- The scope of the regulatory framework will be better defined;

- The control of notified bodies will be reinforced;

- The requirements concerning clinical evidence will be strengthened and clarified;

- Improvements will be made in the areas of vigilance and market surveillance; and

- Requirements regarding traceability will be introduced.

In the short term, however, in response to the recent PIP breast implants scandal, I have asked Member States to contribute to a joint plan for immediate action on the basis of the current rules.

This plan will tighten up controls; provide a better guarantee of the safety of medical technology; and help rebuild patient confidence.

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Ladies and Gentlemen,

Let me finish with a few words on EU participation at international level. In an ever more global and integrated environment, international harmonisation is essential.

In this context, I am pleased to note the ongoing developments in the framework of the International Conference on Harmonisation.

During the most recent meeting of this conference (which took place earlier this month in Japan) important discussions took place on governance and the re-definition of the respective roles of regulators and industry.

This is a pre-requisite for reinforcing the legitimacy of the International Conference and paving the way for more in-depth reform.

One of the major objectives of this reform is to increase the international outreach of the Conference through the progressive involvement of the regulatory authorities of other countries, and notably Brazil, Russia, China and India, following the pattern recently established by the newly-formed International Medical Device Regulators Forum.

Finally, I would like to thank the European American Business Council for its kind invitation, and all of you for your attention.

Thank you.