John Dalli

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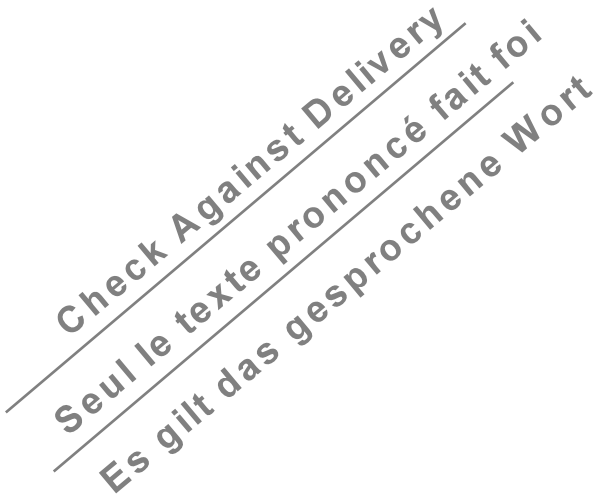
Commissioner Dalli delivers speech on "New regulatory developments in the EU on food and medical products"



John DALLI, European Commissioner for Health and Consumer Policy, addresses the European American Business Council

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"NEW REGULATORY DEVELOPMENTS IN THE EU ON FOOD AND MEDICAL PRODUCTS"

Ladies and Gentlemen,

I am very pleased to have the opportunity to address the European American Business Council here in Washington.

I believe it is important to maintain good relations and sound dialogue between the EU and US – not least because we share the same values, and also have to face many common problems.

That said, we are not "joined at the hip". We must appreciate that differences in orientation and perspectives across the Atlantic will inevitably arise – and that this should not automatically trigger alarm.

Let me start with a challenging question that I have often asked myself over the past months.

As regulators, what is our primary task – to guarantee safety, or to unleash innovation?

Is this a question that unites our mindsets across the Atlantic, or does it provide us fertile ground for strife?

Taking a simplistic view, safety and innovation lie at opposite poles of the pendulum's swing.

Safety is guaranteed through trial after trial – it provides us with a comfort zone that is difficult to move away from. It is the realm that most resists change and innovation.

Innovation, on the other hand, is often perceived as a process reflecting high risk – something that may have unknown consequences and hidden costs manifested only after repeated use.

It is within the limits of these two opposites, that a regulator has the responsibility to find the answers. It is along this continuum that we must plant our vision and plot the course.

Doing nothing is not an option. Doing nothing serves neither the principle of safety nor the principle of innovation.

At what point then, do we find the grounding balance of the pendulum?

For me the answer lies in a formula based on "risk/benefit" analysis. How high are the benefits and how high is the risk. This is against the backdrop of having firm and sound science.

It also however necessitates an understanding of the societies in which we operate and the contexts in which they are ready to accept a level of risk.

One cannot, for example compare the risk/benefit analysis in pharmaceuticals to that in food. Clearly, although both authorizations are based on science, popular scrutiny and preference will dictate very different outcomes.

This is why I believe that the answer lies in the pursuit of an agenda driven by the concept of "responsible innovation".

It is not innovation for its own sake, but rather innovation which has at its core the guarantee of safety based on a sound risk/benefit analysis.

It is also, however, a notion that will only succeed if we can bring our societies along with us to better understand and trust the systems we establish as regulators.

Let me turn to practical examples and give you an update on recent regulatory developments in Europe and our current activities in the areas of medical products and food.

In the area of health, we follow a patient-focused approach that requires health systems to be able to make intelligent choices about the best available treatment for all citizens.

We need the right medicines and medical devices. We also need the right conditions to make them safe, easily accessible and affordable.

There has been some debate of late about which regulatory system – the EU or the US – ensures a higher level of protection for patients.

I do not believe that this kind of debate is helpful since I firmly believe that both the US and the EU regulatory systems secure a high level of patient safety, albeit via different paths.

In Europe, **medical devices** may only be placed on the market after appropriate checks; which ensure that the device is safe, and that any possible remaining risks are acceptable, when weighed against the benefits to the patient.

The demonstration of the safety and the performance of a medical device, as well as the acceptability of a "benefit to risk ratio", must be based on clinical data.

EU law explicitly requires that the manufacturer performs a clinical investigation, in particular for implantable medical devices, unless reliance on existing data can be justified. This is a rigorous and robust system.

On both sides of the Atlantic, assessments are taking place on how to improve our respective regulatory systems; in pursuit of higher standards and better performance.

I believe that this is an opportunity to answer the question I asked at the beginning, and to see the extent to which we can come to similar conclusions on where to drop our anchor.

Indeed, technological developments along with ever-increasing globalisation, call for enhanced co-operation at international level – in particular between US and European regulators.

The EU regulatory framework on medical devices has brought about positive results over the last 20 years.

We are currently updating our system, to ensure:

- that the rules are adapted to current and future technical and scientific progress;
- that the rules are effectively enforced across the EU: and
- that we have the necessary instruments in place for transparent, sustainable and efficient management of the system.

My objective is to strengthen safety and to reinforce Europe's position at the forefront of innovation in medical technology.

With a view to enhancing co-operation at international level, I welcome the initiative to transform the "Global Harmonization Task Force" into a truly global forum for medical devices regulation.

This should provide a platform for regulators – with appropriate involvement of the regulated industry, and health stakeholders - to develop harmonised regulations and co-ordinate their implementation.

Turning now to the area of **pharmaceuticals**, last December the EU adopted new legislation on **pharmacovigilance** which will beef up and modernise the relevant rules through strengthened transparency, communication, patient involvement and efficiency which all provide for greater patient safety.

The core of the new European rules will be safety feature to identify and thus authenticate a medicine. This is an approach which I understand is shared in the US.

Throughout the entire supply chain it will be possible to identify a package, check its authenticity and trace it back.

On active pharmaceutical ingredients, the law strengthens inspections and international co-operation. The Commission will now work closer together with international partners, to achieve an effective system of inspection and enforcement.

Finally – an important point regarding online pharmacies. As in the US, the responsibilities for regulation lie at different levels of governance.

In the EU, the competence to regulate pharmacies, including online pharmacies, lies with the Member States. However, by means of an official logo, the new law will make it easier to identify legally-operating online pharmacies; and to distinguish them from bogus sellers.

All these points regularly feature on the agenda of the US-EU dialogues – in particular regarding inspections. Co-operation in this area, such as joint inspections, helps to address common challenges and may also facilitate a more efficient distribution of resources in the long run.

It will assist us to build understanding of common risks and common challenges so that we can cross these bridges together in our pursuit to deliver our agenda for responsible innovation.

Allow me now to focus on two additional issues.

The first is **clinical trials.** Medical research makes a crucial contribution to improving public health.

It is therefore of great concern that the number of clinical trials in the EU has fallen in recent years. I understand similar trends prevail in the US.

We have to answer a common question as to why this is happening – is it lack of trust in the safety of our systems or our inability to provide a framework that delivers on responsible innovation ?

My aim is to revise the EU legal framework for clinical trials to maintain the attractiveness of Europe for leading clinical research. At the same time, we have to retain our high level of protection of patients' safety and reliability of data generated in clinical trials.

I am planning to put forward a proposal next year, which provides for fast, efficient and pragmatic procedures.

Let me now say a few words about our food and nutrition framework which often can also lead to differences of views across the Atlantic.

At the start of my mandate, I had made a very clear statement: I do not want to tell people what to eat; but I want them to know what they are eating.

For me empowering the consumer is key. Armed with accurate and reliable information presented on food labels will help people make healthier choices.

The EU has just adopted new legislation, laying down basic labelling requirements including the introduction of mandatory nutrition labelling on most processed foods.

I know that this has been a requirement in the United States for many years; and that the US framework is also coming up for revision. I hope that the recent developments in the EU can contribute to future considerations here.

We also need to ensure that all information provided to consumers can be trusted. And this is where nutrition and health claims come in.

In most cases, people perceive foods bearing claims as better products, which bring benefits.

Therefore, across the EU, all health and nutrition claims must be reliable and backed by scientific evidence.

The European Food Safety Authority has assessed the evidence submitted to substantiate claims related to the reduction of a risk factor of a disease and to nutrient function.

So far, from the new claims submitted for approval, 18 claims have been authorised and 65 have been rejected. Plus, the Commission expects to propose a list of permitted "functional" health claims before the end of this year.

The establishment of the list is an important landmark for the implementation of the nutrition and health claims Regulation.

This European approach to controlling health claims has no precedent anywhere else in the world – and I know that, in this regard, the eyes of the world are upon us.

True – it has been a bigger task than we anticipated, but everybody has gained valuable experience from the process and I am ready to co-operate fully with the United States if they chose to go down this path.

Another area which goes to the core of the responsible innovation agenda is GMOs.

Since the start of my mandate, I have sought to set a framework that builds trust in the science-based process whilst allowing for flexibility and freedom for MS to make choices about what they farm on their territory.

Here again, I find that keeping open a channel of communication both with our societies and also at an official level across the Atlantic can help us bridge difference and better understand the approaches where we can work together.

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Ladies and Gentlemen,

I have spoken about the main developments in European legislation as they relate to an agenda based on responsible innovation.

Let me stress once again, that Europe attaches great importance to our co-operation with the United States in the areas I listed above, but also on the responsible innovation agenda as a whole.

I believe we have much to learn from each other for our mutual benefit and that of our people.

Thank you.