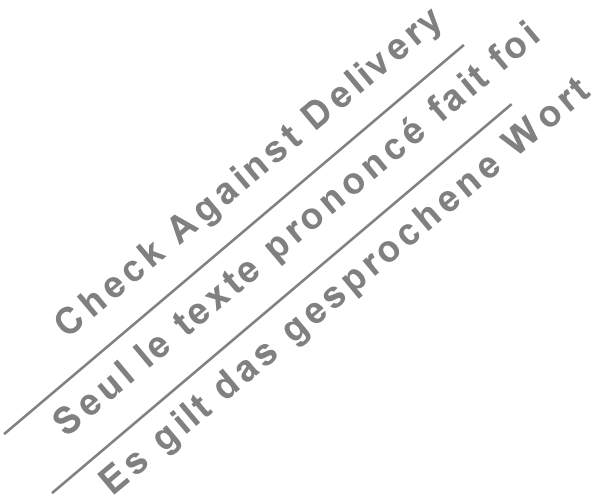
John Dalli

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

Commissioner Dalli delivers speech on "Clinical Trials Directive – Meeting Patients' Needs"



John DALLI, European Commissioner for Health and Consumer Policy, attends a joint event organised by the European Federation of Pharmaceutical Industries and Associations and the Roche Group

Brussels, Belgium, 07 March 2012

COMMISSIONER DALLI'S PARTICIPATION AT

THE JOINT EFPIA/ROCHE EVENT

ON

'THE REVISION OF THE CLINICAL TRIALS DIRECTIVE'

WEDNESDAY 7 MARCH 2012, 19:00-19:30 HRS

REPRESENTATION OF THE FREE STATE OF BAVARIA, BRUSSELS

SPEECH

"CLINICAL TRIALS DIRECTIVE – MEETING PATIENTS' NEEDS"

Dr Schlunk,

Dr Schwan,

Honourable Members of the European Parliament,

Ladies and Gentlemen,

It is a pleasure to be here this evening to discuss the important issue of the review of the Clinical Trials Directive.

This debate comes at a very good time – the Commission will come forward with a proposal to revise the Clinical Trials Directive later this year.

I would like to use this opportunity to:

- First, put the review of the Clinical Trials Directive in the wider policy perspective of the European Union; and

- Second, set out the key issues to be covered in the revision.

There has been a decline in clinical trials in the EU in recent years of about 15%. At the same time, costs for bureaucracy and resource requirements to handle paperwork have doubled, and delays have increased by 90%.

These trends worry me, as I am sure they worry you.

They worry me as Commissioner responsible for health. And they worry me as member of a Commission which is committed to building a Europe fit for the future, to stimulate growth and to contribute to job creation.

Clinical trials are 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. Today, clinical trials account for investments of over €20 billion per year in the EU.

It is therefore crucial to provide the right regulatory framework. This regulatory framework is provided by the Clinical Trials Directive.

As you know, this Directive has attracted much criticism – criticism voiced equally by patients, academic researchers and industry.

But let us be clear – the Clinical Trials Directive is not the only reason behind the decline in clinical research in the EU. There are many other factors not linked to regulation, with R&D commitment by industry, their cooperation with academic research, availability of venture capital as well as return on investment, just to name a few.

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

I am committed to putting forward a proposal to the European Parliament and to the Council that addresses the valid concerns that have been raised.

Allow me to outline the **key issues under consideration**.

First – the authorisation process. The Clinical Trials Directive introduced an obligatory authorisation process for all clinical trials.

This authorisation process was introduced for very good reasons. However, in many cases, the way this process has been designed in the Directive hinders the conduct of pan-European research projects.

Why? – because one clinical trial, with one sponsor responsible, one protocol and one set of results is submitted and assessed in too much isolation by each of the Member States where the clinical trial is conducted.

This leads to high costs, delays and incoherent research protocols. It increases costs without any added value. Today, even for small clinical trials, if they are multi-national, hundreds of thousands of pages of documentation have to be submitted to the relevant national authorities.

We therefore want to streamline the submission process and create a single submission portal. Information on one clinical trial should be submitted only once.

Regarding the assessment of a clinical trial application, clearly, there has to be a mechanism of co-operation between Member States. We are still working on the details of this. Let me, however, outline some policy aims:

I want an assessment system that is fast, 'slim', pragmatic, and not disproportionately expensive, complex or bureaucratic.

Therefore, I would not want to see a new, central bureaucracy developing for clinical trials. Instead, we need a collaborative, flexible approach.

We must keep in mind that each year sees the authorisation of approximately 4400 new clinical trials.

At any point in time, some 12 000 clinical trials are ongoing in Europe. Of these, 25% are multi-national, taking place typically in 3 to 5 Member States.

These figures show that a central bureaucracy would lead to uncompetitive timelines, and to inflexible and disproportionately expensive mechanisms.

This is critical in particular for academic research. There is broad agreement that the rules for clinical trials should, in principle, also apply to sponsors other than industry. However, we have to be aware of the limitations for these 'academic sponsors' in terms of resources, including financial resources.

I also want to see an assessment process for a clinical trial that is strictly separate from the 'scientific advice' for the development of a medicine.

Scientific advice gives guidance on what clinical data are desirable in a future marketing authorisation.

A clinical trial authorisation is something very different – it assesses whether the conduct of a clinical trial is acceptable in view of the risks and potential benefits for the patient.

Therefore, it is important to keep the body indicating, via early scientific advice, what data is desirable, separate from the one that determines what clinical trial is acceptable.

This is a critical point – the potential for conflicts of interest must be avoided.

I must also emphasise the importance of the subsidiarity principle. Ethical and intrinsically national or local issues should be assessed nationally.

This discussion is not one of the role of 'Ethics Committees' in the Member States. Member States should decide how the review process should be organised and who should be involved – provided that there is independence and a high level of expertise. And provided that timelines are sufficiently attractive for conducting clinical trials in the EU.

Therefore, we should define a catalogue of issues to be looked at in co-operation by Member States. And we should clearly define the issues on which Member States would assess the application individually.

A final word on the question of the legal form of the revised legislation – we want to adopt the revised legislation in the form of a Regulation.

Why? Because experience shows that co-operation amongst Member States is very difficult and costly if each Member State bases its work on 'similar, but different' transposing national laws.

However, even a Regulation is no guarantee against differing interpretations of the law. What matters is that the actual application of the law is done in co-operation by Member States in a fast and efficient way.

Let me also briefly address two other important issues – risk-adaptedness and global aspects.

A 'clinical trial' does not necessarily imply a high risk to the treatment of a patient.

There are many clinical trials where the additional risk for this trial subject is minimal. These are clinical trials with authorised medicines that may improve treatments with existing medicinal products, and which are often conducted by academics.

The details of this matter are technical and complex. We are currently screening the various regulatory requirements to see where, for this category of trials, we can cut red tape without compromising patient rights and safety, and data integrity.

As regards the global aspects of clinical trials, there are many claims that the globalisation of clinical trials leads to decreased patient protection in third countries.

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.

Ladies and Gentlemen,

This time we have to get it right.

The revision of the Directive is being prepared with the broadest possible involvement of stakeholders with a view to Europe becoming, once again, an attractive place for clinical trials of the highest standards.

I hope to gain the support of all those with an interest in revised rules to ensure both the reliability of data generated in trials and the protection of the health, safety, rights and well-being of patients.

Ultimately, it is the interest of patients that guides us in shaping a regulatory framework which strengthens health and research, while not compromising patient health and safety.

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