John Dalli

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

Commissioner Dalli delivers speech on rare diseases and orphan products

John DALLI, European Commissioner for Health and Consumer Policy, attends the 6th European Conference on Rare Diseases and Orphan Products

Brussels, Belgium, 24 May 2012
Ladies and Gentlemen,

I am delighted to be here with you today to speak about European Commission action on rare diseases.

First, I would like to express my gratitude to EURORDIS and to the Danish Health & Medicines Authority for bringing us together in this conference co-sponsored by the European Union Health Programme.

I would also like to thank each and every one of you for being here; and in particular for your dedication to the rare diseases' cause.

We all share a common objective: to improve the lives of over 30 million Europeans who suffer from a rare disease.

Today and tomorrow you will have the opportunity to exchange views about projects – some supported by the European Commission - and to discuss how to develop
initiatives that benefit in particular patients suffering from rare diseases.

You will also listen to their testimonials which illustrate the difficulties people living with rare diseases face. Isolation and uncertainty are often at the heart of the problem. It can take years before patients with rare diseases get a proper diagnosis and appropriate treatment.

Even once the rare disease is identified, the nearest health centre able to provide treatment for such condition may be far away, even in another country.

And that is assuming that there has been enough research on the condition and that treatment even exists.

This fragmentation of knowledge about rare diseases, and the small numbers of patients affected by a single disease makes it indispensable to work across borders.

I believe European co-operation on rare diseases can make a difference; the difference between marginalisation and proper care for millions of people.

The work and commitment of your European and national organisations is very important in this regard.

Our work in the European Commission is to help bring together the scarce knowledge and resources fragmented across individual European Union countries and maximise synergies and results.

And this is exactly what the European Commission has been doing in the past few years.

The 2008 Commission Communication on rare diseases put forward a co-operation system between the Commission, Member States and various stakeholders.
This paved the way for a Council Recommendation on rare diseases in 2009, to a number of joint actions under the EU Health Programme, and to the creation in 2010 of the EU Committee of Experts on Rare Diseases.

In the Council Recommendation I just mentioned, Member States have committed themselves to adopting national plans or strategies for rare diseases by the end of 2013.

The Commission has developed technical assistance and training tools to help Member States create these national plans: the EUROPLAN project and the 2012 Joint Action.

The idea is that Member States shape their own national rare diseases plan adapted to their reality, following common guidelines.

I am confident that most Member States will adopt national plans on rare diseases in due time despite the difficult economic climate. The European Commission will report on progress made next year.

Ladies and Gentlemen,

Easy access to information about rare diseases for both patients and health professionals is indispensable for good quality care.

I believe we all agree that one of the best sources of information on rare diseases is the "Orphanet" database supported by the EU Health Programme.
Orphanet has become the world reference for gathering and disseminating knowledge on rare diseases and related issues; and a useful tool to assist health professionals in the correct diagnosis of rare diseases. I am pleased that Orphanet continues to grow.

Information is, however, just the start.

Let's now think about treatment. People with a rare disease will need access to a highly specialised health centre, and to the right medicines. Our action addresses these two aspects.

We are working on a system for establishing European Reference Networks - some of which will certainly bring together highly specialised centres on rare diseases - under the Directive on patients’ rights in cross-border healthcare adopted last year.

Such Networks will comprise already existing centres with a high level of expertise, which would need to fulfil specific criteria to ensure quality and safety of the care provided. The Commission is currently working with the Member States in developing such criteria, with a view to adopting them in 2013.

Thanks to such networks, patients would have easier access to the expertise of the best centres in the European Union. Also thanks to the networks, Member States would be able to co-operate in the development of diagnosis and treatment capacity of rare diseases.

We are not starting from scratch. Since 2004, the European Commission has already supported 11 pilot European Reference Networks for different rare diseases including rare cancers.
Last December, when the Commission adopted the Health Programme Work Plan for 2012, we have set aside 4.5 million euros to help finance additional networks and rare diseases registries. Proposals are currently being evaluated.

As regards medicines, we have created specific incentives for pharmaceutical companies to develop new medicines for rare diseases in the framework of the Regulation on "orphan medicines".

Our aim is to encourage the development and marketing of medicines to treat, prevent or diagnose rare diseases. It goes without saying, to understand rare diseases and develop medicines to treat and cure them, you need research.

And this is why the EU has supported rare diseases research for over 20 years. Since 2008 - under the seventh Framework Programme for Research alone – the Commission has allocated over 300 million euros to research on rare diseases.

Research on rare diseases can also serve as models to better understand more common conditions. Rare disease research can further help the development of models for personalised medicine.

For such research purposes, the Commission supports the development of rare diseases registers, some of which are part of the reference networks I mentioned earlier.

Our action on Research does not stop at European borders.
The European Union is part of the International Rare Disease Research Consortium launched last year, an ambitious initiative to pool resources to accelerate research on rare diseases.

The Consortium brings together the European Union, the United States and other countries, to mobilise the rare disease research community around the world towards achieving an ambitious objective: to deliver 200 new therapies for rare diseases, and diagnostic tools for most rare diseases by 2020.

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Ladies and Gentlemen,

The European Commission's objective in the years to come remains to improve the conditions for patients to obtain appropriate and timely diagnosis, information and care.

This is why action on rare diseases features prominently in the European Commission proposal for the new Health Programme and the new Research Programme for 2014 onwards.

I have proposed that the future Health Programme finances action on rare diseases, in particular exchange of information, rare diseases registries and European Reference Networks. These proposals are currently being debated in the European Parliament and the Council and I very much count on your support to ensure their adoption.

Much has already been achieved and more still needs to be done. It is clear that, if we are to make inroads, we will have to work in tandem and maximise the value added of our actions.
This gathering here today is witness to the importance and commitment we all share to deal with rare diseases.

I wish you all a fruitful conference.

Thank you.