

John Dalli

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

Commissioner Dalli delivers speech on "Personalised Medicine: New Perspectives for Patients in Europe"

*Check Against Delivery
Seul le texte prononcé fait foi
Es gilt das gesprochene Wort*

John DALLI, European Commissioner for Health and Consumer Policy, attends a meeting of the European Alliance for Personalised Medicine at the European Parliament

Brussels, Belgium, 18 September 2012

**COMMISSIONER DALLI'S PARTICIPATION AT THE
EUROPEAN ALLIANCE FOR PERSONALISED MEDICINE
"PERSONALISED MEDICINE: NEW PERSPECTIVES FOR PATIENTS IN
EUROPE"**

**TUESDAY, 18 SEPTEMBER 2012, 17:45-19:00HRS
JAN2 QA, EUROPEAN PARLIAMENT, RUE WIERTZ 60**

SPEECH

Chairman, [Minister], Honourable Members of Parliament,
Ladies and Gentlemen,

I am very pleased to be here today to speak about personalised medicine and the recent Commission proposal on clinical trials.

Personalised medicine offer tremendous opportunities for better care and raise high expectations. If we are able to target the right patients for a medication, we reduce non-responders and side effects, avoiding much suffering and in addition waste of money.

These products are not a far-distant dream. They are already a reality, with a number already authorised in the European Union.

But much remains to be done to exploit the potential of personalised medicine to the full.

Indeed, a great deal of research and development is necessary. Efforts by the pharmaceutical and the medical devices industries need to be stepped up, and collaborations and partnerships between academia and industry enhanced.

The EU legal framework for pharmaceuticals enables industry to bring safe, efficacious and quality medicines to the market.

The framework has recently been complemented by a rigorous set of rules on pharmacovigilance, which of course applies equally to '*omics*' based products.

Personalised medicine relies on close inter-linkage between pharmaceutical and medical device aspects.

Indeed, the prescription of such medicines depends on the results of screening of the patient's genomic or other 'omic' - information, usually done by *in vitro* diagnostic medical devices – or companion diagnostics.

It is therefore essential to ensure that only safe and well-performing *in vitro* diagnostic medical devices are placed on the EU market. In this context, the Commission plans to adopt next week a proposal to revise the European regulatory framework of *in vitro* diagnostic medical devices.

This proposal will not only strengthen the safety and performance requirements applicable to companion diagnostics, but also bring the clarity and legal certainty necessary to pave the way for innovation in this field.

It will also foster better collaboration between the pharmaceutical and the device sectors.

But let me add a word of caution here. Personalised medicines clearly have a great potential. But these are critical economic issues which could negatively affect the availability.

With unit costs predicted by some to be prohibitively high for many, the possibility of a widening impact on health inequalities is a worrying prospect – and something we need to bear in mind.

Care must be taken to ensure that the maximum number of people can reap the full benefits. My vision is to reduce the inequalities in peoples' access to healthcare and medicines!

Another important aspect is the uptake of new medicinal products by healthcare systems.

The ageing population across European societies exerts growing healthcare demands in difficult economic circumstances.

Whilst we hope that the potentially high costs of personalised medicine could be compensated by efficiency gains for public health budgets, such hopes might not be enough.

Health Technology Assessment (HTA) offers a way forward – especially if effective co-operation between Member States can be established and maintained.

Through European HTA co-operation we want to facilitate the effective re-use of information from one Member State to another, thereby reducing duplication of work both for the Member States and the European health industry.

"*Omic*s" technologies can play an important role not only in treatment and diagnostics but also in prevention of illness.

But successful prevention goes far beyond technological innovation. The root causes of many health problems – such as poor living conditions or unhealthy lifestyles – must continue to demand attention and action.

The European Innovation Partnership on Healthy and Active Ageing is focusing on disease prevention and health promotion, integrated care and active and independent living for older persons.

Although the Partnership has not put forward any specific initiative in the area of personalised medicine, its concept is a significant driver for innovation and important in relation to healthy ageing.

Progress is being made in the area of personalised medicines in relation to health problems such as Alzheimer's disease, hypertension and cardiovascular diseases, and in classifying groups of patients according to their susceptibility to a particular disease or their response to treatment.

These disease areas mirror some of the priority actions identified in the Partnership – such as chronic diseases, cognitive impairment and adherence to treatment.

Overall, innovation and progress in the area of personalised medicine is an important element towards leading Europeans to age in better health, and to receiving better healthcare tailored to their needs.

But the path to healthy ageing for all is not going to be easy. This goes far beyond treating or curing specific diseases. It is a life-long endeavour; it requires sustained investment; it certainly carries risks; and we stand only at the foot of the mountain.

I am confident that the Commission's recent proposal on clinical trials will also contribute to the development of personalised medicines.

Before I finish – a few words on clinical trials.

The key objective of the proposed revision is to strengthen knowledge and innovation in clinical research, thereby ensuring that the EU remains an attractive place for medical research.

The revision aims to respond to the decline of clinical trials in the EU in recent years by seeking to reduce unnecessary bureaucracy for industry and academia, and to facilitate multi-national clinical trials.

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

They 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 essential to provide the right regulatory framework.

The main issues under consideration relate to the authorisation process, where we want to simplify and streamline procedures and facilitate the application for multinational trials.

This last point is critical for personalised medicines which – because of small patient populations – often require cross-border clinical trials. Only multinational clinical trials can reach recruitment targets and thus produce robust and reliable results.

Our proposal would introduce a risk-adapted procedure, in order to avoid unnecessary regulatory burdens. Furthermore, it would increase transparency for clinical trials conducted in Europe as well as in third countries.

I am confident that our proposal will gain the support of all those interested in restoring Europe's reputation as an attractive place for clinical trials, while ensuring both the reliability of data generated in trials and the protection of the health, safety, rights and well-being of patients.

To conclude, let me thank the organisers to bring together tonight key stakeholders to reflect on how to move forward with personalised medicines. I believe they must become an important element of healthcare in Europe. Such has been done already, but significant challenges remain to be tackled. The Commission will contribute to the necessary ongoing discussion with a report on personalised medicine next year, in addition to the initiatives I have just outlined. I count on your continued cooperation.

Thank you for your attention.