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Commissioner Dalli delivers speech on Personalised Medicines

John DALLI, European Commissioner for Health and Consumer Policy, attends the 5th Golden Helix Pharmacogenomics Day Symposium

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5TH GOLDEN HELIX PHARMACOGENOMICS DAY ON PERSONALIZED MEDICINES

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UNIVERSITY OF MALTA

SPEECH

Ladies and Gentlemen,

I am honoured to have the privilege of opening the "5th Golden Helix Pharmacogenomics Day on Personalized Medicines".

Personalised medicines, which are incorporating the progress of genome-based knowledge into medical treatment, offer tremendous benefits for patients and our health care systems.

Since the ancient Greek physician Hippocrates formulated the first binding values for physicians, we have learned to diagnose and treat within the context of parameters, such as signs and symptoms as well as age, gender and weight, correlating these with risks and expected outcomes.

Now we share the dream of being able to prevent, diagnose, treat and care for health and disease on the basis of a comprehensive but complex set of personal objective information.

Personalised medicine has the potential to provide solutions that are better tailored to the individual patient than traditional "one-size-fits-all" medicinal products.

By immediately offering patients the medicine that is effective for them, trial-and-error can be limited or even avoided, and adverse reactions can be reduced.

While a few products are already on the market, we are still at the very early stages of translating research results into actual products.

A medicinal product might be authorised for the exclusive use by patients who have an over-expression of a given protein.

Products can also be authorised for a given disease, but limited in their use based on genomic factors, either alone or in combination with other factors.

Genomic information can also be used in the determination of the appropriate dosing of a medicine, or the selection of treatment sequences and duration.

These examples show that personalised medicine offers the possibility and promise of a wide range of uses.

They also highlight the importance of reliable determination and interpretation of the patient's genomic information.

Let us remain realistic and not forget that personalised medicines are not a universal panacea.

Nevertheless, personalised medicine based on genomic information is expected to offer clear public health benefits.

Their potential is largely unexplored. Considering the myriad of existing diseases – rare diseases alone account for 5000 to 8000 – the challenge ahead seems enormous.

Even the most common diseases might be very complex. And as diseases evolve, researchers might be faced with moving targets.

This complexity demands collaboration and partnerships between scientific areas; academia and industry; and between the pharmaceutical and diagnostics industries.

It is essential that the EU's role in innovation is augmented to make science deliver better for European patients.

Personalised medicine is already being taken into account in companies' business strategies. But much more remains to be done.

Both the diagnostics industry and the pharmaceutical industry have an important role to play as drivers of innovation.

There are also challenges for policy-makers. Let me mention just a few:

The current EU legal framework for pharmaceuticals, coupled with detailed scientific guidance documents, enables economic operators to bring safe, efficacious and quality medicines to the market. This applies equally in the field of personalised medicine.

But we will have to look into whether improvements are needed to make personalised medicine products more rapidly available to patients.

For example – does a defined or limited patient population pose additional challenges for conducting clinical trials?

It is clear that industry must have a framework which allows it to organise clinical trials in the EU, across borders, in an efficient manner.

This is an important aspect that I will be considering when preparing a revision of the Clinical Trials Directive next year.

The regulatory pathways for the placing on the market of medicinal products and of diagnostic medical devices are different because the nature of the products regulated is different.

But what we must ensure is that both pathways allow only safe products to be placed on the European market.

In this respect, next year's revision of the medical devices legislation is an opportunity to ensure that diagnostic medical devices used in the context of personalised medicine offer the appropriate level of safety and performance.

Furthermore, what can be done to ensure that medicinal products arising from innovation bring benefits to patients across Europe on an equal basis? The current health inequalities are ethically not acceptable, worrying and call for determined action. Economic aspects play an important role in this context. We hope that the costs for personalised medicine could be compensated by efficiency gains for public health budgets.

But even with possible efficiency gains, it will be a true challenge for companies, healthcare providers and policy makers to reconcile high prices with the growing demands of healthcare from an ageing population, and against the backdrop of economic and budgetary austerity.

Thorough macro and micro economic analysis will be necessary to reveal best practices, and to access how patient needs and health systems capacity can be met in pharmacogenomics.

Health Technology Assessment (HTA) offers one promising way forward by helping to direct the scarce budget of our healthcare system to those technologies – both products and services – which bring highest benefits to the patients and the efficiency of our healthcare.

The European Commission strongly encourages and supports Member States in their work on HTA. In a few days, we will launch the discussion with Member States on the future orientation of this cooperation. My personal view is that we should be ambitious in order to reduce duplication and waste of resources and to deliver highest benefits to our patients in all Member States.

If we want to encourage successful uptake of personalised medicine in Europe, we must ensure that HTA methods take into account the specificities of these technologies.

The potential benefits do not just relate to treatment and diagnostics, but also to the prevention of illness.

Genomic information might, for example, in the future help over-weight persons opt for a diet which is suitable for their genotype.

In parallel we must attack the root causes of health problems – such as poor living conditions or unhealthy lifestyles.

This goes much wider than technological innovation.

We need to explore innovation from research to market in a way that responds to the needs of Europeans, bringing tangible benefits for final users – be they patients, health providers or care professionals.

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Ladies and Gentlemen,

This conference is an important fact-finding forum.

It shows that there are a range of different aspects that have an impact on the future role of personalised medicine in fostering public health in Europe. It also shows that we stand only at the foot of the mountain.

Even if I cannot be with you for the entire event, I am very much interested in the outcome of your reflections. They provide important input for a report on the use of "Omics" technologies in pharmaceutical research and development, which I intend to present next year.

Your input is important, because you represent the key players towards making personalised medicine a fully integrated element of healthcare in Europe.

I look forward, with anticipation, to our future collaboration.

Thank you.