European patients' Forum conference
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The New European Union Health Strategy
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Ladies and Gentlemen,

I was privileged to participate in the official launch of the European Patients' Forum at the European Parliament one year ago and it is a real pleasure to be back with you today. The Commission services were very keen, after two years of hard work, to see the creation of the European Patient's Forum in order to give a strong voice to patients in several consultation processes.

As you may know, the EU health Forum was established in 2002 and includes some 10 specific European patient representative groups who have been active in pre-existing structures. The second EU Open Health Forum will take place on 8 November and will see the participation of many more patient organisations. Nevertheless, in EU consultation processes, it is often useful to be able to speak with one voice in order to be properly heard.

The European Patient Forum does not have always to be a "single voice", but a pan-European voice, and a strong one. I am very pleased with the excellent co-operation between my services and your Forum.

A new programme and new EU agencies

At the initiative of Markos Kyprianou, Commissioner in charge of health and consumer protection, the Commission adopted on 6 April 2005 a new health strategy for Europe, together with ambitious funding plans for health and consumer policies under the new financial perspectives (2007-2013).

I will focus on these proposals, made in response to a major public consultation exercise held last year under the title "enabling health for all", and to which you contributed last October. I will also address a couple of other concrete areas of work which concern directly patients and patient representation.

For example, last March, the European Medicines Agency (EMEA), established in London since 1995 celebrated its 10^{Th} anniversary. On 20th May the European Centre for Disease Prevention and Control (ECDC) became operational in Stockholm. These events marked an important step forward for health protection in the enlarged European Union.

These are effective mechanisms available to the European Union for transforming policy objectives into concrete activities which benefit more directly European citizens. This is also the case for the European Food Safety Authority (EFSA), officially inaugurated in Parma yesterday.

The new health strategy and the new health and consumers programme

The Commission strategy and programme proposal set out a number of ambitious targets for EU health and consumer policy, with a total budget of 1.2 billion € (0.96 billion for health) and a further 847 million to support EFSA and the ECDC, from 2007 until 2013.

The strategy and programme proposal bring health and consumer protection policies together under one single roof, in order to strengthen and expand European activities in both sectors and put forward concrete action to meet citizens' concerns.

Health policy and Consumer protection policy share many objectives, such as promoting health protection and citizens' information. The new programme aims to serve European citizens better by pursuing a set of common health and consumer protection objectives:

- protecting citizens from risks and threats;
- enabling citizens to make better choices about their health and consumer interests;
- mainstreaming health and consumer policy objectives across all EU policies.

The programme will build on the experience acquired with the two existing but separate Public Health and Consumer protection programmes, to develop their specific areas of work. As regards health, the new programme reinforces the three strands of the existing Public Health Programme, which aim to gather and disseminate health information, to monitor threats and to tackle key health determinants. In particular, information gathering, analysis and dissemination will be made in a user-friendly manner.

Some new aspects for future health projects

In addition, the new programme creates three new strands that respond to emerging health challenges and policy priorities:

- a new strand to create new capacities to deliver an efficient response to health threats at EU level,
- a second new strand on disease prevention so that urgent action to help reduce the burden of major diseases such as HIV or cancer can be taken forward,
- a third new strand to foster co-operation between health systems, and encourage national actors to work together across borders on a wide range of issues that interest this Forum in relation with patient mobility,
- bridging health inequalities and addressing ageing will be priority themes cutting across all action strands.

As you know, the legal basis of the current programme does not allow operating grants. However SANCO was able to support patients in different ways, by facilitating a number of meetings venues in Luxembourg or Brussels and support some travel costs.

The new strategy stresses the Commission's intention to co-operate more closely with civil society and to strengthen consultation mechanisms. It is our role to help civil society make its voice heard, not least the patient community. For this reason, article *3.2 b)* of our proposal would make it possible, for the first time, to support the operational costs of health NGOs pursuing European objectives.

These proposals were presented by Markos Kyprianou to the Health Council on 3 June and to the Environment and Health Committee in Parliament on 20 June, with a favourable reception in both institutions. Nevertheless, the difficult negotiations of the financial perspectives between Heads of States and Governments last week indicate that one has to be cautious in predicting the outcomes and that your organisation ought to be vigilant and particularly active to defend these opportunities.

A decade of dialogue with EMEA/ 5 years of orphan drugs policy

The EMEA has provided the European Union and its citizens with the best scientific assessments of the quality, safety and efficacy for 300 biotech or other novel products for human use. The EMEA also harmonises their conditions of use, and provides packaging leaflets and medical information in all Community languages.

Ten years ago, the EMEA initiated a new tradition of full transparency of its operation by publishing all its assessment reports and conducting a permanent dialogue with its stakeholders, including patient groups.

The EMEA also celebrates this year 5 years of orphan drug policy and decided so far on the merits of some 300 orphan medicinal products destined for rare diseases. The orphan medicinal products Regulation offers incentives to encourage the development and marketing of medicines to treat rare diseases. Further down the research cycle, 20 orphan medicinal products were granted an EU marketing authorisation.

In 2000, a Committee on Orphan Medicinal Products (COMP) was established in the European Medicines Agency, charged with reviewing designation applications to develop medicines for rare diseases. This was the first EU committee where patients are permanently represented by patient groups (Eurordis and the European Genetic Alliance).

A complex revision of the European pharmaceutical legislation took place last year to adjust to the challenges of the enlargement of the European Union. The EMEA road map to 2010 commits this agency to further develop its worldwide role as a public health regulatory authority and to provide for better protected and informed patients.

You will be contacted soon by the Commission to participate in a new European Pharmaceutical Forum which will address the challenges of drug information for patients.

The need for an European CDC

The EU must act to protect its people against major health threats. It must have in place the necessary instruments to fight disease outbreaks as and when they arise. Creating a small but effective European centre dedicated to supporting continent-wide disease surveillance and networking Member States' public health institutes soon emerged as the best option for achieving such reinforcement.

The formal proposal for a regulation establishing the ECDC was made by the Commission in July 2003 and adopted in April 2004 by Council and Parliament through a single reading. The Commission will this week finalise the representation of 3 NGOs in the Advisory Forum of the ECDC, including the European Patients' Forum.

Over the coming months, the Centre will aim to develop its network of surveillance linking existing disease-specific networks, such as on HIV/AIDS, Tuberculosis, antibiotic resistance and reference laboratories.

The Centre will also set up expert groups to assist Member States, the WHO and third countries, and dispatch investigation teams at their request. Another area of high sensitivity, is influenza – and in particular the possible emergence of a pandemic strain to which people have little or no resistance. The Commission is helping Member States to strengthen all aspects of their defences against influenza and update their preparedness plans. We will conduct an exercise this autumn to evaluate and test coordination between the plans.

After 3 years of successful operation with communicable diseases, Council and Parliament will be asked by the Commission to consider a possible extension of the role of the ECDC to all diseases were European added value can be demonstrated.

EU cooperation: High Level Group and EU Health Forum

In 2003 the Commission invited all EU Health Ministers, a representative of the European Parliament and 6 European NGOs representing civil society, including the European Patient's Forum, to engage in a high level reflection process on patient mobility and healthcare developments in the European Union.

The Commission has set out its response to the report of the reflection process in April 2004, making proposals on European cooperation to enable better use of resources; information for patients, professionals and providers; the European contribution to health objectives; and responding to enlargement through investment in health and health infrastructure.

These activities have been taken forward through the new High Level Group on health services and medical care established in July 2004. The High Level Group has agreed in principle to involve civil society participants in relevant working groups, and there is clearly a valuable contribution that organisations such as yours can make.

The High Level Group is focusing on certain areas:

- facilitating cooperation in cross-border care and providing better information to patients about their rights under European law;
- managing the impact of the movement of health professionals, including what this means for the country from which they leave;
- developing principles for European centres of reference for highly specialised care or expertise;
- putting in place a network to share efforts on the assessment of new health technologies and techniques, which we hope to get up and running this year;
- looking at how best to use information and communication technologies to share information and improve service provision;
- getting a better understanding of how Community policies impact on health systems;
- improving patient safety, to work together in minimising the harm to patients that can arise from healthcare interventions.

Patient safety issues in Europe

Improving patient safety in particular and quality in general is important for all health systems across the world. The EU Commission is keen to co-operate in this area with the World Alliance on Patient Safety, as well as with the Council of Europe.

Patient safety issues with regards to health products such as pharmaceuticals and medical devices are covered in principle by EU legislation, because the circulation of such products across Europe had clearly to be regulated.

When it comes to patient safety in hospitals and medical practice, EU action must fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. The primary level for action on patient safety must be within the Member States, because in practice quality and safety can only be assured by integrating them into local professional practice in consultation with patients and patient groups.

Having co-sponsored the EU Presidency Conference last April in Luxembourg, the Commission welcomes the call in the "Luxembourg Declaration on Patient Safety" for greater EU collaboration on these issues and developing structures for collaborating on these issues through the High Level Group on health services and medical care. A specific working group on patient safety, chaired by Sir Liam Donaldson will meet next week in London.

The High Level Group has agreed in principle to involve civil society participants in relevant working groups, and there is clearly a valuable contribution that your organisation can make.

Our EU Health Forum, with some 50 European representative NGOs in the Health sector, could also be invited to create a special working group on patient safety.

Rare diseases projects under the EU Public Health Programmes

In the former Community action programme on rare diseases, attention was given to improve knowledge about these 7000 diseases, affecting more than 7 million people across Europe. It supported 24 projects totalling 6.5 Mio €. The current public health programme 2003-2008 continues to support rare diseases projects.

The first priority EU action for the current public health programme was the continuation of some internationally recognised projects with a significant added value such as: ORPHANET, EURORDIS, EUROCAT and ENERCA.

The second priority has been to reinforce the visibility and the operational capacity of organisations and networks acting in the field of rare diseases, such as the organisation of a European Rare Diseases Conference under the Luxemburg's Presidency yesterday and today.

As a result of this conference, a "European Rare Disease White Book" providing best practices and recommendations to all Member States will be developed and disseminated to strengthen European cooperation.

Patients' involvement at EU level

The transformation of the patient from a passive recipient of treatment, to an increasingly active (and sometimes mobile) seeker of quality services is a driver of change in European health.

In recent years, many debates about European health issues ranging from pharmaceuticals to e-health, have confirmed that the patient must be at the centre of policymaking.

European citizens are taking an increasing interest in their health and well-being. Listening to and responding to the voice of patients becomes crucial for EU institutions.

People expect to be well-informed about health issues that concern them and their families. The Commission envisages to create progressively a EU Health Portal to provide them with validated sources of information and knowledge.

Greater collaboration at European level between patients and professionals or patients and industry can help improve choice, quality and effectiveness of medical and health care services.

Patient's organisations participation in the European Union Health Policy Forum has proved to be a valuable tool in advising and influencing not only DG SANCO, but also many other Commission departments,.

The European Patients' Forum has an important role in taking the European health agenda forward. My colleagues and I look forward to a continuing a fruitful co-operation with you.

NB More information can be found at: http://europa.eu.int/comm/health/index.html