



EP Hearing

Minister of Health Cyprus

Dear Chairman, Honourable Members of the European Parliament,

I am greatly honoured to be able to appear before you today and present the program and objectives of the Cyprus Presidency of the European Council in the field of health. I look forward to an open discussion with the Members of the European Parliament on how to move forward the European Union's agenda in this field.

The Lisbon Treaty has undoubtedly introduced a more active European Acquis process. The European Parliament has now extended its powers as a legislative body, with the addition of about 40 new sectors under the scope of the co-decision procedure and has an important role in issues related to the Multiannual Financial Framework. Simultaneously, these extended powers brought to the forefront more responsibilities towards the citizens, the National parliaments and the European Union.

The Cyprus Presidency warmly welcomes these alternations and is looking forward to the establishment of an interactive communication and cooperation with Parliament in a range of public health issues that will enable the realization of a Better Health for all European citizens.

During the upcoming six months we aim to continue on the overarching priorities set up by the Trio Presidency in the framework of its eighteen months program with a focus on three main action lines:

1. non – communicable diseases and healthy ageing
2. diseases without borders and
3. Innovation and best practices

Six months is a short period of time to achieve miracles, but I am confident that if we work together in a spirit of a constructive dialogue and mutual understanding we can make the difference.

Allow me now to begin by presenting to you the program and the objectives of our Presidency in the area of health.

Our program will focus on four major action lines:

1. **Cross Border Health Threats in the EU and its neighbouring countries with a Focus on Communicable Diseases**
2. **Organ Donation and Transplantation and**
3. **Healthy Ageing across the Lifecycle**
4. **Innovative approaches in Healthcare**

Our first priority on “**Cross Border Health Threats in the EU and its neighbouring countries with focus on Communicable Diseases**” arises from the recent experience on H1N1 influenza and e-Coli outbreaks, which identified the need for further coordinated actions not only within the EU but also with neighboring countries. The importance of this area has already been identified both by the European and the International Community and consequent actions towards that direction have already been

initiated. The most recent discussion of the Commission's proposal on "Cross border threats to health", certainly creates an opportunity for a legal framework to be established, in close collaboration with the European Parliament.

For this purpose, an expert level conference was organised in Cyprus last week. The Conference brought together various stakeholders from the EU and its neighbouring countries of the East Mediterranean and North Africa and initiated relevant discussions on the contemporary issues of building capacity in relation to prevention, surveillance, early warning and effective control of communicable diseases. Emphasis was also attached on underlining the need for coordinated actions between the EU Member States and their neighbouring countries in the areas of prevention and control of communicable diseases. The conference's conclusions will be presented at the Informal Health Council, to be held in Nicosia, tomorrow.

Our second action line is "**Organ Donation and Transplantation**", as an ultimate action of altruism and social

solidarity, that can only bring benefit to all European citizens in need. Bearing in mind the great number of patients benefiting from a compatible donor, the economic effectiveness of transplantation, as well as the large number of patients on waiting lists for a compatible transplant, it is now the time for further coordinated actions in raising awareness on the issue.

Working into this direction, our Presidency, will prepare and promote adoption of respective Council Conclusions, which will call for further action in the area of organ donation and transplantation, especially in light of the forthcoming mid-term evaluation of the action plan on Organ Donation and Transplantation 2009-2013.

Our third action line is “**Healthy Ageing across the Lifecycle**”, an area which identifies the importance of disease prevention and health promotion in every stage of life and across the lifecycle in order to ensure healthy ageing. Especially, under the current economic framework and the trend towards an ageing of population, establishing a healthy ageing process from the early

stages of life can assure a productive population, minimize the demand for healthcare services related mainly to chronic diseases and as a direct consequence limit the cost of health care and promote more growth and productivity.

This priority will be the focus of discussion during a High Level Presidency Conference on Healthy Ageing across the Lifecycle. This conference aims at bringing together stakeholders from various areas of the health sector to discuss existing evidence and best practices, and agreeing on the way forwards. The outcome of the conference will constitute the basis for preparing council conclusions on healthy ageing as a continuous process throughout the lifecycle that will identify the current trends, underline the importance of health as an interdisciplinary and multidisciplinary approach and call for further action.

Our last but not least heading is “**Innovative Approaches in Healthcare**”. In line with the Europe 2020 strategy agreed on March 2010 calling for Innovation Union we think that a Health care

system can function as an Ecosystem for Open Innovation that can bring together players from different sectors and create synergies. The current drive for more innovation is forcing us to look outside the conventional tool kit. Open innovation is a new concept currently being tested by the European Commission in the form of Joint Technology Platforms in certain areas of research. Our key objective is to promote health care in a multidisciplinary and intersectoral approach. Companies developing Innovative drugs, companies with interest in application of IT in the health care sector in innovative ways, companies manufacturing food for children, academics and experts in personalized medicine will be some of the key participants to this conference that will take place in Larnaca in October.

Allow me now to move into the presentation on the legislative files that comprise the working programme of our Presidency in the area of health. Before proceeding with my presentation, I would like to underline that the overarching principle that will guide our approach both within the respective WP and with parliament will be

one of mutual respect. I should however emphasize that the scale and effectiveness of any action line, particularly in relation to the Health for Growth Program, are intricately linked to the extent of financial support. Miracles cannot be achieved through a program with a proposed budget of 446 m Euros over a period of seven years.

1. The Proposal for a Regulation on establishing a Health for Growth Programme, in the field of health for the period 2014-2020. This is an instrument of vital importance in implementing the Community's policy objectives in health. The discussions in the Council under the Danish Presidency have proceeded into a great extent and a partial general agreement on the file was obtained during the EPSCO Council on June 22nd. The Cyprus Presidency is looking forward to a close collaboration with the European Parliament in obtaining a full agreement on the context of the Proposal and adopting the file on a "partial" 1st Reading agreement, pending the agreement on the budget of the Multiannual Financial Framework. I am mindful of the many amendments proposed by

parliament and in particular those focusing on potential health inequalities as a corollary to the financial crisis. Indeed I share those concerns and hope that the ensuing annual work programs are formulated in such a way to take account of the extraordinary circumstances that millions of European citizens will find themselves embroiled with negative implications on health.

2. The Proposal for a Decision of the European Parliament and of the Council on serious cross-border threats to health. This highly debated file relates to the protection of European citizens from a wide range of health threats such as biological, chemical or environmental in nature and makes provisions for more effective monitoring and coordinated response in the event of a crisis. It also addresses various key aspects of health security including preparedness, early alerting and reporting, surveillance and response to health threats such as those posed by communicable diseases.

The results of the discussions which were initiated in the WP of the Council by the previous Presidency allows the Cyprus Presidency to proceed further on the file and to discuss and negotiate further with the European Parliament. I foresee that lengthy discussions will take place both within the Council and between the Council and the Parliament. But we are committed and ready to carry out this task in the most positive manner bearing in mind what happened in the past when serious epidemics troubled Europe and making sure that whatever we decide fully and effectively sub serves the scope of better and more uniform actions across Europe.

3. In the area of Pharmaceuticals, **the Proposal on the Revision of the Directive 2001/20/EC on Clinical Trials**. This is related to the revision on the requirements for conducting Clinical Trials on humans, aiming at the discovery or verification of the actions of one or more medicinal products, focusing at improving the harmonization of assessment and authorization of Clinical Trials. The Commission is expected to bring forward a proposal for a

Regulation during the Cyprus Presidency and we expect to move the dossier forward and hopefully reach an agreement on its context at Council level.

4. The **Proposal for a Directive 89/105/EEC relating to transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems**__aims to simplify the procedures and replace the Directive 89/105/EEC. The previous directive is considered that that no longer reflects the complexity of pricing and reimbursement procedures within the MS. The new Directive in no way is affecting the national policies related to pricing and organization of social insurance systems, except to the extent considered necessary to ensure transparency.

The discussion of the proposal at the Working Group on Pharmaceuticals and Medical Devices has been initiated by the Danish Presidency and it will be continued during the Cyprus Presidency. The work will also proceed into this direction at the level of the European Parliament, where again strong collaboration

is required, and an orientation debate will be presented during the EPSCO Council in December 2012.

5. The **revision of the regulatory framework on Medical Devices**, which consists of the revision of the Proposals for Directive on medical devices and repealing Directives 90/385/EEC and 93/42/EEC (LA) and of the Proposal for a Directive concerning in vitro diagnostic medical devices and repealing Directive 98/79/EC, aims to protect the health and safety of EU citizens and ensuring the proper functioning of the single market.

The recent incidents with breast implants and large Metal-on-Metal hip replacements, revealed the need for increased coordination between the Member States in order to guarantee patient safety. Our Presidency will initiate discussions in Council WP and we will do our best in negotiating the greatest acceptance among the MS, within the given timeline.

It is worth mentioning that our aim is to continue the work on the implementation of the existing **Action Plan on Medical Devices** , for enabling the functioning of the notified bodies, the cooperation, coordination and communication between MS and the traceability, for guaranteeing patient safety under the forthcoming discussions on the revision of the regulatory framework.

6. The proposal **for a regulation on food intended for infants and young children and on food for special medical purposes** aims to replace, clarify and simplify the current legal framework for food with particular nutritional uses.

The Cyprus Presidency will try to find the middle ground regarding the differences between the European parliament, the Council and the Commission in order to conclude on the file, preferable on an early 2nd reading stage.

7. The proposal on the Breakfast Directive (**Coffee, Jam, Milk, Cocoa, Chocolate**) aims to align the existing Commission

implementing powers in the 5 Directives to the differentiation between delegated and implementing powers of the Commission introduced by Articles 290 and 291 of the Treaty on the Functioning of the European Union and to confer additional delegated powers on the Commission.

The Danish Presidency initiated discussions in the Council and the Cyprus Presidency will exert every effort in moving forward or even conclude on the file.

Chairman, Honourable Members,

This was in general the health program for the Cyprus Presidency. We are mindful of the task ahead and the sensitivities on some of the issues. Where there is a will there is a way forward. We rely heavily on our collaboration with Parliament and the Council can and should move forward on all health policy issues for the benefit of the European Citizens.

In deliberating on the issues highlighted above we cannot oversee the general environment that is prevailing across Europe. The economic crisis is leading to demographic changes and puts severe pressure on the healthcare systems of all Member States. So in the absence of financial resources, this is the time to be creative.

Events unfolding around us every day are shaking the societal and economic fabric of Europe in an unprecedented manner. Indeed one might say that Europe has reached its most testing time point after World War II. Just like at war times when solidarity is a natural human reaction in the quest of survival, at times of peace the reaction should be no different. I hope that we all rise to the occasion and manifest the European solidarity that we all rhetorically espouse to.

Dr Stavros Malas, Minister of Health Cyprus