



Uachtaránacht na hÉireann ar
Chomhairle an Aontais Eorpaigh
Irish Presidency of the Council
of the European Union
eu2013.ie

Speech for Minister Reilly

Presentation to the ENVI Committee of the European Parliament

23rd January 2013

Ireland's Presidency : Health Priorities

Chairman, Honourable Members of the European Parliament

I am very honoured to address you today to present the Irish Presidency programme in the field of health.

2013 marks the 40th anniversary of Ireland's accession to the then European Economic Community. For those of us who were around in 1973 it is fascinating to think back to the economic, political, and social landscape we lived in – both at home, and across Europe. Since that time our membership of the European Union has brought a great many benefits to Irish citizens both in economic and social terms.

We face different challenges now, none more so than the current economic situation.

For that reason, the Irish Presidency Programme will aim to progress proposals that will best deliver what Europe needs – *stability, jobs and growth*.

Notwithstanding the economic situation:

- we strive to improve the health and wellbeing of our citizens;
- we strive to ensure that there are systems that support and improve efficiency and effectiveness in the delivery of healthcare to our citizens.

While each Member State grapples with its own realities in the area of health, the importance of working together to share ideas, to share information and best practice and where appropriate to enact legislation cannot be underestimated.

The role of the European Parliament and the role of the Members of the Parliament has never been more important. As directly elected representatives of the citizens of the EU your role as co-legislators is crucial to ensure that their interests are represented. The Irish Presidency recognises the importance of engaging with the European Parliament. By working together at Council and with you in the European Parliament, we work to better the lives of our citizens now and into the future.

In Council, I am working closely with our TRIO partners – Lithuania and Greece and I look forward to fruitful discussions later today with my Lithuanian counterpart, Health Minister Dr Andriukaitis.

Progressing the legislative agenda is the cornerstone of Ireland's presidency programme.

The Irish Presidency will use its resources to prioritise making solid progress on a number of key legislative dossiers in health – proposals on tobacco products, cross-border health threats, clinical trials, medical devices and health for growth.

Tobacco

Smoking is one of the greatest threats to people's health and approximately 700,000 EU citizens die every year from tobacco related illnesses. Millions more have to live with the burden of chronic illness caused by tobacco consumption. The cost to individuals and their families in terms of the loss of healthy life years, the loss of family members and the distress caused is incalculable. And the great tragedy is that this is avoidable. We must do everything we can to help smokers to stop smoking and to prevent young people from starting to smoke.

In addition to the human cost of this level of preventable illness there is a major economic cost. Treating patients with tobacco related illnesses is a massive but avoidable cost to the health budget. Tobacco consumption also

has wider negative implications for the economy – absenteeism from the workplace, loss in productivity and early retirement.

EU Health Ministers are particularly concerned to ensure that tobacco products lose their attractiveness to children and young people. In Ireland we have evidence that 78% of smokers started smoking before they reached the age of 18, when they were minorsCHILDREN. Once a cohort of children is addicted they will struggle to beat the addiction for many years, if indeed, ever at all. We have a duty of care to our children. Ultimately 1 in 2 smokers will die from a tobacco related illness.

This clearly demonstrates that tobacco control measures taken to date have failed to protect the most vulnerable. The tobacco industry would love to create the impression that we are anti-smoker. But we are not, we are anti-smoking. We want to protect the health of the European population and we will do everything we can to assist the smoker who is after all our fellow citizen.

The Tobacco Products legislation is the main priority for the Irish Presidency, and I am personally committed to making as much progress as possible. Last August, I and nine other EU health ministers wrote to the Commission requesting that the proposal be published before the end of 2012. I was delighted that the Commission was able to publish the Tobacco Products proposal on the 19 December.

I know that the negotiations on Tobacco Products will be difficult. In the past, the tobacco industry has shown how very influential it can be, and its willingness to deploy its resources to frustrate the passage of progressive legislation. I believe that we as co-legislators, Council and Parliament, must put the health of citizens first and work for the early adoption of this proposal. I will return to this Committee next month, with Commissioner Borg, for the hearings on the Tobacco Products proposal. I look forward to working constructively with the members of this Committee and particularly the recently appointed Rapporteur, Linda McAvan to ensure that this very important piece of public health legislation is adopted as soon as possible.

On the wider issue of tobacco control you will be aware that Ireland was a pioneer in the protection of workers' health by introducing a ban on smoking in the workplace. When European Health Ministers meet in Dublin in early March we will have an opportunity to review progress in this area and discuss what more needs to be done to ensure a healthier, smoke free environment, for the citizens of Europe.

Ladies and gentlemen of the Parliament let us be honest – if this product was being placed on the market today – knowing what we know of it – it would never be legalised.

Health for Growth

This proposed Public Health programme will run from 2014-2020. It builds on the current Health Programme, which runs until the end of this year. In

comparison to the current programme the focus will be on a smaller number of concrete actions that offer clear EU added-value.

The general objectives of the programme are to encourage innovation in health care and increase the sustainability of health systems, to improve the health of EU citizens and protect them from cross-border threats.

I welcome the progress that has been achieved to date in the negotiations between Council and Parliament and I note that there is agreement on many aspects of the proposal. However, there are three outstanding issues, two of them of a more horizontal nature - the budget for the programme and the question of either delegated or implementing acts for adoption of annual work programmes. The other unresolved issue is the co-financing mechanism for joint actions.

The Irish Presidency is fully committed to concluding agreement on the proposal and is looking forward to working constructively with Parliament. The Presidency will remain in close contact with the Rapporteur - Madame Grossetête. The next trilogue should take place when the outcome of negotiations on the Multiannual Financial Framework are known. I hope that agreement can be reached in a timely manner to allow for the implementation of the new programme from the start of 2014.

Serious Cross Border Health Threats

Recent years have brought a number of significant cross-border health threats

such as the H1N1 outbreak, avian flu and SARS. To a certain extent we have been lucky that the impact of these pandemics was not as severe as expected. We must not lose sight of the need to be prepared and to ensure that all our citizens have equal access to vaccines and anti-virals. The current proposal on “Serious Cross Border Health Threats” represents another important step in building our defences against these threats.

The Irish Presidency is committed to negotiating a first reading agreement with the European Parliament and the Commission and looks forward a fruitful cooperation with Rapporteur Pargneaux. This legislative Decision is an important public health measure and in particular it will provide a legal basis for the joint procurement of vaccines and other medical counter measures to protect citizens from pandemics. The Decision should also strengthen the preparation and coordination among Member States to deal with Serious Cross Border Health Threats.

I expect trilogues with Parliament to commence in coming weeks. I know that there are some issues yet to be resolved including the extent of powers to be delegated to the Commission in establishing rules for coordination of preparedness and response planning. The Irish Presidency is confident, however, that these can be solved in a mutually satisfactory manner in order to adopt the Decision as soon as possible. In this respect the Irish Presidency is counting on your cooperation and of course that of the Commission.

Clinical Trials

Access to new and innovative medicines is important for our citizens. Clinical trials are essential to providing such new medicines for patients and to verify the safety and limitations of existing products. We are acutely aware of the importance of the proposed Regulation concerning clinical trials on medicinal products for human use which is designed to strengthen patient safety and to address the fall in clinical trial applications in Europe.

The facility to carry out safe clinical trials in Europe is critical to maintaining a strong pharmaceutical industry in Europe, by reducing the administrative burden and costs on sponsors.

Ireland aims to make significant progress on the proposal. I will be meeting with the Rapporteur – Glenis Willmott, later today and look forward to a positive exchange of views. I note with satisfaction that most Member States share the view that this proposal is of high importance and both Parliament and Council are interested in reaching an early agreement.

Medical Devices

The Presidency is also committed to making progress on two proposals for regulations on Medical Devices and *In-Vitro* Diagnostic Medical Devices which were published by the Commission in September 2012. The aim of the proposed regulations is to provide an improved legislative framework for the manufacture and placing on the market of both medical devices and *in vitro* diagnostic medical devices.

I understand the genuine concerns of citizens and politicians as a result of the PIP breast implant scandal. We must first and foremost ensure that medical devices are safe for use. Citizens need reassurance on the safety of medical

devices while at the same time we must ensure Europe's medical device industry can continue to bring innovative products to market in a timely manner.

The role of medical devices in healthcare is essential to save lives and improve the quality of life for citizens. Improvements in medical technology can also boost the EU's global competitiveness and create jobs, while reducing healthcare costs and enhancing the quality and efficiency of healthcare.

The proposals will establish a framework to coordinate the regulation of medical devices and they also provide for enhanced oversight of pre-market conformity assessments and greater clinical evaluation. The proposals are complex but I believe it is possible to make good progress during the Irish Presidency. I met the Rapporteur, Dagmar Roth-Behrendt yesterday evening for an initial discussion and the also Shadow Rapporteur Mairead McGuinness and I have arranged to meet the Rapportuer on the In Vitro proposal , Dr Peter Liese, later today.

Transparency Directive

(Transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems)

The Irish Presidency has closely followed the discussions in the European Parliament on the Transparency Directive and is well aware of the outcome of the recent vote in the ENVI Committee.

I would like to express my appreciation for the willingness of the Rapporteur , Dr Parvanova, to engage so positively with the previous Presidencies regarding Member States' concerns on this proposal.

The Irish Presidency has noted the reluctance among some of the Members in the Council to continue the examination of the proposal. The Presidency can only enter into negotiations with the other Institutions if it has the support from a qualified majority in the Council to do so.

It is my intention to explore the support in the Council for continued negotiations using the outcome of the Parliament's plenary vote next month as a starting point for elaborating a Council position that could obtain a sufficient support for starting negotiations with the other Institutions.

Other aspects of the Programme

Reflecting the importance of *research and innovation*, the Presidency will host a high level eHealth Conference and co-host with DG Innovation & Research a Conference on the future of brain research – both of which will take place in Dublin in May.

The eHealth high level conference will take place on 13, 14th and 15th May, 2013 in parallel with the World of Health IT Conference and Exhibition. The high level theme of this year's event will be "eHealth: delivering Innovative healthcare and well-being."

The second conference is a high-level expert conference co-hosted with DG Research and Innovation on the future of brain research. *'Healthy Brain: Healthy Europe - a new Horizon for brain research and healthcare'* It will take place on 27th and 28th May 2013 to mark the *'EU Month of the Brain'*.

We will also host an informal meeting of Health Ministers on 4th and 5th March in Dublin. Discussion will include issues pertaining to the *health and wellbeing* agenda. The agenda will also include items on smoke free environment, patient safety and children with complex developmental needs including autism.

I thank you all for your kind attention. I very much welcome this opportunity to brief you on the priorities of the Irish Presidency in the health area and, indeed, to answer your questions. As I stated, we are prioritising the legislative agenda, I believe that given where we are in the political cycle and the importance to European citizens of the legislative proposals before us, this is the appropriate use of our resources.

The range of measures that we as co-legislators are working on are extremely important both for the health of citizens and to support innovation and research in Europe. I look forward to working with you in a constructive manner to progress the health agenda.

Go raibh maith agaibh - Thank you.