



**Department of
Health & Children**
AN ROINN SLÁINTE AGUS LEANAÍ

**REPORT OF THE
DEPARTMENT OF HEALTH AND CHILDREN
TO THE OIREACHTAS**

**Under Section 2 (5) of the European Union (Scrutiny) Act,
2002**

For the period from July to December 2008

INTRODUCTION

Under the terms of the European Union (Scrutiny) Act 2002, Ministers submit reports to the Oireachtas every six months on developments at European Union level in their area of responsibility. This report summarises the key legislative and policy developments during the second six months of 2008. France held the Presidency of the European Union during this period. Information on the French Presidency can be accessed at:

<http://www.eu2008.fr>

This report has two parts. The first part sets out the principal developments in the policy areas which fall within the responsibility of the Department at EU level. The second part provides an update on the EU legislative proposals for which information notes were submitted to the Oireachtas Joint Committee on European Scrutiny under the European Union (Scrutiny) Act, 2002 during the period from July to December, 2008.

Part 1

Summary Report of developments in EU policy in the area of Public Health

1. Review of the French Presidency

France assumed the rotating six-month Presidency of the EU on 1 July 2008. The five main themes identified by the Presidency in the area of health were:-

- health security and pandemic preparedness;
- Alzheimer's disease and healthy ageing;
- European health policies at the service of the patient (the theme under which the proposed Directive on patients' rights in cross-border healthcare, rare diseases, health security and quality and antibiotic resistance were examined);
- health determinants (with particular regard to tobacco) and
- the safety and effectiveness of medicines.

Alzheimer's disease and healthy ageing was the subject of a Presidency Conference which took place in Paris in October, 2008.

A conference on the overall theme of European Health Policy at the Service of Patients took place in October, 2008. See Point 4 below for further information on the "Europe for Patients" initiative.

The French Presidency prepared and co-ordinated the EU negotiation position in respect of the Conference of the Parties to the Framework Convention on Tobacco Control (FCTC) which met in South Africa in November, 2008.

The Pharmaceutical Forum held its final meeting in Brussels in October, 2008. The Presidency also brought forward various proposals in the pharmaceutical area i.e. information to patients, variations regulations and a review of pharmaceutical legislation.

The Presidency also organised a conference in Cairo in Egypt in November, 2008 in conjunction with the European Commission and the Ministry of Health in Egypt on cooperation in health issues in the Mediterranean area (Euromed).

2. Proposed Directive on the application of patients' rights in cross-border healthcare

In July, 2008 the Commission (DG SANCO) presented a proposal for a Directive on the application of patients' rights in cross-border healthcare. The proposal is aimed at guaranteeing safe, high-quality healthcare for all patients; helping patients make use of their rights to cross-border healthcare and promoting cooperation between health systems. The purpose in particular, is to codify the case law of the Court of Justice of the European Communities (ECJ) on reimbursement for cross-border healthcare.

The proposed Directive was discussed in depth by the Council Working Group on Public Health during the period July-December, 2008 and Ministers had a first opportunity to comment on the proposal at the EPSCO Council in December, 2008.

The position of most Member States, including Ireland, is that, while the opportunity to finally consider a proposal from the Commission on this issue is welcome, there are concerns regarding the scope of the draft directive and significant changes to key provisions of the Directive are required to achieve greater clarity and compatibility with Member States responsibilities.

The French Presidency drafted a compromise proposal reflecting the outcome of the discussions in the Working Group. The Presidency's compromise proposal was supported by almost all delegations, a large majority of whom regarded it as an improvement on the initial proposal. It was considered that it could form the basis for future discussions. Discussions on the Directive are ongoing under the Czech Presidency.

The European Parliament's Committee on Environment, Public Health and Food Safety (ENVI) is also examining the proposal as part of the co-decision process.

3. EU Health Strategy – “Together for Health – A Strategic Approach for the EU, 2008-2013”

The new Health Strategy “Together for Health: A Strategic Approach for the EU 2008-2013” was adopted on 23 October, 2007. Council Conclusions were adopted in December, 2007.

The Strategy focuses on four principles and three strategic themes for improving health in the EU. The principles include taking a value-driven approach, recognising

the links between health and economic prosperity, integrating health in all policies, and strengthening the EU's voice in global health. The strategic themes include Fostering Good Health in an Ageing Europe, Protecting Citizens from Health Threats, and Dynamic Health Systems and New Technologies.

Conclusions agreeing implementation mechanisms for the Strategy were adopted by Health Ministers at the EPSCO Council in June, 2008.

Under the Council Conclusions, a new mandate was given to the Working Party on Public Health at Senior Level to discuss major common strategic issues in health and to identify priorities, objectives and actions within the strategic framework, including the timeframe for implementation and monitoring of progress. The first meeting of this Working Party under its revised terms of reference took place in December, 2008. Ireland was represented by officials from the Department of Health and Children.

4. Europe for Patients

This campaign, which was launched by Commissioner Vassiliou on 30th September 2008, highlights the different health policy initiatives the Commission intends to adopt in the coming months.

All the initiatives have a common goal – better healthcare for all in Europe.

Areas included in the campaign

The initiatives address areas such as patient safety, rare diseases, organ donation and transplantation, cancer screening, health workforce, flu and childhood vaccination and antibiotic use.

(A) Cross Border Healthcare

As set out above, the Commission adopted a proposal on 2 July, 2008 for a legal instrument which will provide more clarity about the possibilities of seeking healthcare in another Member State.

The proposal will also make clear who is responsible for quality and safety of care in cross-border settings. It will strengthen co-operation in different areas such as networks of centres of reference for specialist care.

Initiative: Directive on the application of patients' rights in cross border healthcare.

(B) Rare Diseases

The Commission published a Communication on Rare Diseases with the objective of setting out an overall Community strategy to support Member States in ensuring effective and efficient recognition, prevention, diagnosis, treatment, care and research for rare diseases in Europe. Patients will benefit from the sharing of scarce resources that currently exist in individual Member States. This will be followed by a Council recommendation under the Czech Presidency.

Initiative: Commission Communication published in November 2008 and Council recommendations on European action in the field of rare diseases.

(C) Health Workforce

Progress on improving and providing better access to healthcare for all cannot be made without a workforce of sufficient capacity and skills. The Green Paper raises the general issues and problems facing the workforce in health in the EU, suggests ways in which these issues might be addressed and poses a series of questions on which views are invited.

Initiative: Green Paper on the European Workforce for Health launched on 10 December, 2008.

(D) Patient Safety

The Commission will put forward a Communication and a proposal for a Council Recommendation on patient safety and quality of health services, addressing general, system and patient safety issues and specific measures to prevent and control healthcare-associated infections (HAIs).

Initiative: Commission Communication and Council recommendation on patient safety and quality of health services, including the prevention and control of healthcare associated infections.

(E) Organ Donation and Transplantation

The Commission plans to propose a combination of initiatives in this area. Firstly in an initiative related to basic safety and quality principles and measures in relation to procurement and donation of human organs. Secondly the Commission also intends to propose an Action Plan with 10 priority actions to meet the challenges of organ donation and transplantation in the EU, through a mechanism which strengthens coordination between Member States.

Initiative: - proposal for a directive on setting standards of quality and safety of human organs intended for human transplantation.

Action Plan on Organ Donation and transplantation (2009-2015)

(F) Cancer Screening

The Cancer Screening Recommendation of 2003 invites the Commission to report on the implementation of cancer screening programmes, to consider the extent to which the proposed measures are working effectively and to consider the need for further action. The first such report has recently been published.

Initiative: Report on the implementation of the Cancer Screening Recommendation of 2003.

(G) Cancer Platform

The Commission aims to support the Member States in their efforts to tackle cancer by providing a framework for identifying and sharing information, capacity and expertise in cancer prevention and control and by engaging relevant stakeholders across the European Union.

Initiative: Action against cancer; European Platform

(H) Flu Vaccination

Current vaccination production capacity is not deemed to be sufficient to meet the demands of the Community in the event of a pandemic. The objective of the European Commission would be to increase the use of seasonal influenza vaccine, thus contributing to increasing manufacturing capacity.

Initiative: Commission proposal for a Council Recommendation on seasonal flu vaccination.

(I) Prudent Use of Antibiotics

The Council Recommendation 2002/77/EC on the prudent use of antimicrobial agents in human medicine requests Member States and EEA countries to put in place specific strategies on prudent use of antimicrobial agents including measures in relation to surveillance of antimicrobial resistance and use, control and preventive measures, education and training and research and to report to the Commission on its implementation.

Initiative: 2nd report from the Commission on the implementation of the Council Recommendation

European Antibiotic Awareness Day – 18 November 2008. First such event - to become an annual event - managed by European Centre for Disease Control.

(J) Mental Health

The Mental Health Pact agreed in the June 2008 High Level Conference will be followed by a series of thematic conferences focusing on the pact priorities and by further action highlighting EU added value in this area.

Initiative: First Thematic Conference in 2009

(K) Childhood Vaccination

This initiative aims to establish a “transit” immunisation schedule to facilitate a smooth transition from one national immunisation schedule to another and to seek a firm political commitment from Member States to step up efforts at increasing and maintaining a very high childhood vaccination coverage for priority diseases.

Initiative: Council recommendation on cross border aspects of childhood immunisation

5. Informal Meeting of Health Ministers

The Minister for Health and Children, Mary Harney T.D., attended the Informal meeting of Health Ministers which took place in Angers, France on 8 and 9 September, 2008. The meeting focused on public health security, one of the priorities set by the French Presidency in the health field. The Commissioner for Health, Ms A. Vassiliou presented her initiative on the health of children and young people.

6. Employment, Social Policy, Health and Consumer Affairs Council

The **Employment, Social Policy, Health and Consumer Affairs Council** was held in Brussels on 16 and 17 December, 2008. Health issues were dealt with on 16 December. Ms Máire Hocht T.D., Minister for Older People attended the Council on that date. The Council adopted conclusions in two areas as follows:-

- Health Security
- Combating neuro-degenerative diseases (in particular Alzheimer's disease)

The Council held a public debate on the proposal for a **Directive on patients' rights in cross-border healthcare** on the basis of a progress report prepared by the Presidency. All delegations wanted all of the Court of Justice jurisprudence in this area to be codified in the Directive. The majority of delegations recommended that the Regulation on the co-ordination of social security systems (1408/71) should be supplemented by the Directive on cross-border healthcare and that a "third method" of reimbursement should be avoided.

Ministers requested that, in order that equal access to healthcare would not be compromised, Member States should be able to make the use of cross-border healthcare subject to prior authorisation or to apply a gatekeeper principle. Delegations also wanted the Member State of Treatment to be responsible for giving patients information on the quality and safety of healthcare provided in that country.

All delegations agreed that the Presidency's compromise proposal formed a good basis for future work. However the Commission representative entered reservations on the approach selected by the Presidency in relation to the quality and safety of healthcare (Article 5) and prior authorisation (Article 8).

In its conclusions on the debate, the Presidency supported the idea of a balance between the rights of patients and of Member States and identified outstanding issues, including the management of incoming patient flows and the definition of healthcare.

There was a first exchange of views on the **proposal for a Council Recommendation on European action in the field of rare diseases**.

Those delegations which took the floor, including Ireland, congratulated the Commission on its initiative. The Ministers agreed that the particular nature of rare diseases made this an area in which Europe could bring substantial added value.

Information in relation to 12 other issues was noted under **Any Other Business** including:-

- Council Working Party at Senior Level which will work on the implementation of the EU Health Strategy;
- The proposed Regulation on the provision of food information to consumers;

- The proposed Directive on variations to the terms of authorisations for medicinal products
- Organ donation and transplantation
- The proposed Recommendation on the safety of patients and the quality of health services including the prevention and control of nosocomial infections;
- The Commission's Green Paper on Health Professions
- Proposed new legislation in the pharmaceutical area.
- eHealth

Information on all of the Councils can be accessed at:

<http://www.consilium.europa.eu>

7. Second Programme of Community Action in the Field of Health (2008-2013)

2008 is the first year of the **Second Programme of Community Action in the Field of Health** (2008-2013) which was agreed during 2007. This follows on from the First Programme of Community Action in the Field of Public Health (2003-2008) which financed over 300 projects and other actions.

The objectives of the Programme are:

- To improve citizens' health security;
- To promote health, including the reduction of health inequalities;
- To generate and disseminate health information and knowledge.

42 projects, 10 proposals for operating grants, 2 for joint actions and 11 for financial contributions to the costs associated with conferences were accepted under the 2008 work programme.

More information on the Programme can be found on the European Commission's Health and Consumer Protection Directorate General website:-

http://ec.europa.eu/health/ph_programme/pgm2008_2013_en.htm

8. Presidency of the Czech Republic

The three main themes identified by the incoming Czech Presidency in the **Health area** are antibiotic resistance, eHealth and the financial sustainability of healthcare systems. The Presidency will host Conferences on these three themes.

The growing resistance of bacteria to antibiotics and the loss of their effectiveness for treating infections is a global problem. The Czech Presidency will examine the steps necessary to prevent a further rise in antibiotic resistance through, for example, the rational use of antibiotics and taking measures to prevent the spread of multi-resistant microbes. A Ministerial level conference entitled "The microbial threat to patient safety in Europe" will be held from the 15th to 16th April 2009. The Presidency's work in this area will contribute to discussions in Council on the Commission's expected initiative of a Communication and Council Recommendation on patient safety and quality of health services.

The Czech Presidency will also focus on the issue of digital integration of healthcare services and the interoperability of information systems in healthcare (eHealth). A two-day Conference is planned for the 19th and 20th of February 2009 entitled “Innovations for Health - eHealth for Individuals, Society and Economy”.

The third priority for the Czech Presidency is the financial sustainability of healthcare systems. The aim is to generally increase awareness of some aspects of population aging, in particular about financial sustainability of healthcare systems and to increase cooperation between member states in the area. A two-day conference at expert level with ministerial participation is planned for the 11th and 12th of May 2009.

Negotiations under the Czech Presidency will continue on the draft directive on patients’ rights in cross-border healthcare.

The Czech Presidency will commence negotiations on the recently published proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation.

Examination of the Commission’s recently launched pharmaceutical package, which provides for legislative proposals in the areas of information to patients, pharmacovigilance and counterfeit medicines, will commence under the Czech Presidency.

Discussions on the draft Council Recommendation on rare diseases will continue under the Czech Presidency.

The Czech Presidency will also continue work on the regulation on provision of food information to consumers (labelling) and the proposal for a Regulation on Novel Foods.

Part 2

**Summary of draft EU legislative proposals submitted by the
Department of Health and Children for review by the Oireachtas**

1 July – 31 December 2008

Commission proposal number	Proposal	Date Reviewed Decision of the Sub-Committee	Update
COM(2008) 437	Proposal for a COUNCIL DECISION on the signature and conclusion of the Agreement between the European Community and the Government of the People's Republic of China on drug precursors and substances frequently used in the illicit manufacture of narcotic drugs or psychotropic substances	23/09/08 Proposal was noted with no further scrutiny.	This Decision was formally adopted by Council on 13/11/08.
COM (2008) 414	Proposal for a Directive of the European Parliament and of the Council on the Application of Patients' Rights in Cross-border Healthcare	23/09/09 It was agreed that the proposal warranted further scrutiny and that it should be forwarded to the Joint Committee on Health and Children and the Joint Committee on Social and Family Affairs for written observations.	This proposal was the subject of detailed discussions in the Council Working Party on Public Health during the French Presidency. Discussions are ongoing under the Czech Presidency. The European Parliament's Committee on Environment, Public Health and Food Safety (ENVI) has also been examining the proposal as part of the co-decision process.

Com (2008) 726	Proposal for a COUNCIL RECOMMENDATION on a European action in the field of rare diseases	13/01/09 It was agreed that the proposal required no further scrutiny and it was forwarded to the Joint Committee on Health and Children for information.	This proposal was initially discussed at the EPSCO (Health) Council in December, 2008. Discussions are ongoing in the Council Working Party on Public Health with a view to having the text ready for adoption at the EPSCO (Health) Council in June, 2009.
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