

Date: Wednesday 6 October 2004
Venue: Committee Room 3, National Assembly for Wales
Title: Current European Issues

Purpose

1. This paper contains a list of EU documents, relevant to the Health and Social Services Committee, which have been deposited in the UK Parliament between 5 June and 5 September 2004. The paper also contains updates and information on the following items requested by the Committee at the meeting held on 23 June 2004:

- ◆ An action plan for a European e-Health Area
- ◆ Patient mobility between Member States

Action

2. Members are invited to:

- ◆ Consider whether they wish to give further scrutiny to the items identified as possibly significant for Health and Social Services (Annex A);
- ◆ Note the other EU documents of relevance to Health and Social Services (Annex B);
- ◆ Raise any issues in relation to the European e-Health Area action plan or the draft regulations for patient mobility between Member States (Annex C).

Background

3. The attached Annexes A and B contain details of EU documents deposited in the UK Parliament since 5 June 2004 that have been considered either to be of possible significance for Health and Social Services (Annex A), or appropriate to inform the Committee about (Annex B).

4. This is the fourth list provided to the Committee under the new arrangements for scrutinising EU documents agreed by Committee members at the meeting on 3 March 2004.

5. As promised at the meeting on 5 May 2004, this paper continues to include Annex C which relates to developments of those specific items identified by the Committee as being of interest, their relevance to Wales and any scope available to the Assembly Government to influence the proposals.

Members' Research and Committee Services

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ANNEX A

**Legislative and non-legislative items of interest to the HSSC committee deposited in the UK Parliament:
from 1 June 2004 to 5 September 2004**

MRS and EU Ref.	Title	Commentary	Link to document
MRS: 730 EU: 10491/04	<p>COM (2004) 416 final:</p> <p>Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee.</p> <ul style="list-style-type: none"> ◆ The European Environment and Health Action Plan 2004-2010 – Volume I/II 	<p>On 9 June 2004, the Commission launched an Action Plan (AP) for 2004-2010 aimed at reducing diseases caused by environmental pollution. This is the first of two volumes of the 2004-2010 Action Plan, and contains the key elements. This volume contains a summary of the AP on pp.5-6 together with actions and implementation plans related to links between, and issues around, health and the environment, development of monitoring processes, indicators and risk reduction measures.</p>	<p>http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=52004DC0416&model=guihett</p>
MRS: 728 EU: 10491/04 ADD1	<p>COM (2004) 416 final:</p> <p>Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee.</p> <ul style="list-style-type: none"> ◆ The European Environment and Health Action Plan 2004-2010 – Volume II 	<p>Volume II sets out key elements of the plan and explains how it will be implemented. Key aims are to target gaps in information on the links between pollutants and their effects on human health and disseminate the results of research examining the potential effects of pollutants on human health.</p> <p>The plan targets the following health concerns: asthma, allergies, neurodevelopmental disorders, cancer, and endocrine disruptors. Once information has been gathered, policy makers will decide how to act, either through the adoption of new or revised exposure limits or preventative measures to protect human health from any risks found during the information gathering stage. There are also proposals for awareness-raising actions on environment and factors linked to diseases.</p>	<p>http://www.europa.eu.int/cgi-bin/eur-lex/udl.pl?REQUEST=Seek-Deliver&COLLECTION=com&SERVICE=eurlex&LANGUAGE=en&DOCID=504PC0416&FORMAT=native</p>

Annex B

Documents to note for HSSC committee deposited in the UK Parliament: from 1 June 2004 to 5 September 2004

MRS and EU Ref.	Title	Commentary	Link to document
MRS: 729 EU: 10491/04ADD2	SEC (2004) 729 final: Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee. ♦ The European Environment & Health Action Plan 2004-2010 – Extended Impact Assessment	This paper is a staff working paper.	http://europa.eu.int/comm/secretariat_general/regdoc/liste.cfm?CL=en
MRS: 770 EU: 11068/04	COM (2004) 439 final: Proposal for a Council Decision authorising the placing on the market of foods and food ingredients derived from genetically modified maize line NK603 as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council	The Committee failed to deliver, by qualified majority, an opinion on the draft submitted by the Commission. However, in accordance with Article 46 of Regulation (EC) No 1829/2003 on genetically modified food and feed, the authorisation in case must be granted under the provisions of Regulation (EC) No 258/97. However, in doing so, it needs to take into account Regulation (EC) No 1829/2003.	http://www.wales.gov.uk/keypub/assemeuropeancomm2/content/euleg040705/11068-04.pdf
MRS: 829 EU: 11607/04	COM(2004) 487 final: Financial Perspectives 2007-2013	Budget policy document	http://www.wales.gov.uk/keypub/assemeuropeancomm2/content/euleg040719/11607-04.pdf

MRS: 906	COM(2004) 539 final: 27th Annual Activity Report of the Advisory Committee on Safety, Hygiene and Health Protection at Work – 2002	This Committee has a monitoring and advisory function only. Paragraph 4.3 informs that part of the mandate of the "Chemicals in the workplace" group has been extended with regard to the establishing of occupational exposure levels (Doc. No 2502/2/01).	http://europa.eu.int/eur-lex/en/com/rpt/2004/com2004_0539en01.pdf
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Items identified by the Committee

At the Committee meeting on 23 June 2004, two policy items were identified as being of possible interest:

- 1 An Action Plan for a European E-Health area: 2004-2010
- 2 Follow-up to the high-level reflection process on patient mobility and healthcare developments in the European Union

The paper also includes an update on one item identified at the meeting of 3 March 2004:

- 3 The establishment of a European Centre for Communicable Diseases

Scope for the Committee to influence policies

The Committee might like to consider monitoring the progress of E-Health actions and the development of any legislation on patient mobility and to which the Assembly Government may contribute.

1 E-Health Action Plan 2004- 2010

Background

The e-Health Action Plan 2004-2010 is a policy document that forms an integral part of the overall European Union strategy for health. It is expected that the NHS in Wales will, as a regional body of a Member State, need to be aware of expectations to contribute to key targets and actions.

Three key stages in the development of the e-Health Action Plan are:

- ◆ May 2000: EU Health Strategy
Aim - to integrate all EU health-related policies and concentrate resources without duplicating the work of the Member States or international organisations.¹
- ◆ May 2003: declaration at the first e-Health conference.
E-Health became an e-Europe 2005 policy priority. Targets included:
 - ◆ Building on the European health insurance card to create a European electronic health card.
 - ◆ Developing Health Information Networks to speed the flow of health information through the healthcare system.
 - ◆ Putting health services online such as information on healthy living and illness prevention, electronic health records, teleconsultation and e-reimbursement.²

¹ http://europa.eu.int/comm/health/ph_overview/strategy/health_strategy_en.htm

² http://europa.eu.int/information_society/europe/ehealth/conference/2003/doc/min_dec_22_may_03.pdf

- ◆ April 30, 2004: Adoption of the Action Plan by the European Commission.³

The Action Plan

- ◆ The Action Plan was the third element of the Commission's recent activities in the health area. It addresses the role of new technologies and new ways of delivering health care in improving access to quality and effectiveness of care. The Action Plan aims to make the most of new information and communication technologies in the health sector and to achieve better integration of a range of e-Health policies and activities.
- ◆ A table of agreed actions for Member States and the dates by which they should be achieved is given in Annex C (i). Actions have been listed thematically under the three main issues identified:
 - ◆ Addressing common challenges
 - ◆ Pilot actions: accelerating beneficial implementation
 - ◆ Working together and monitoring practices

Expected outcomes for 2010

- ◆ The European Union will be well placed to measure the impact of e-Health in terms of better access and better, more efficient, services as well as on the overall productivity of the healthcare sector.
- ◆ e-Health will have become commonplace for health professionals, patients and citizens; and e-Health will be adequately resourced within healthcare budgets, and contribute to boosting wider objectives, such as competitiveness, jobs and cohesion.

2 Patient Mobility between EU Members States

Background

The Committee identified the issue of patient mobility from the Commission Communication, and the focus of this item therefore will therefore be on section 2.1, entitled 'Rights and duties of patients'.

The Communication was produced following a meeting of the Health Council in June 2002 where three key needs were identified:

- ◆ A European framework to facilitate co-operation between Member States and shape developments arising from greater mobility of patients and the impact for healthcare systems.
- ◆ Discussions within in the High Level Group on Health Services and Medical Care to assist those responsible for health systems to work together at European level.

³http://europa.eu.int/information_society/europe/ehealth/conference/2003/doc/the_case_for_eHealth.pdf

- ◆ Clarification for citizens of the existing legal framework regarding access to healthcare and the reimbursement of the costs incurred in another Member State.

A number of key issues related to healthcare were identified and these were listed under four main headings:

- ◆ European co-operation to enable better use of resources (including 'Rights and duties of patients')
- ◆ Information
- ◆ European contribution to health objectives
- ◆ Responding to enlargement through investment in health and health infrastructure

Rights and duties of patients

This section of the document discusses the existing framework under which patients are currently entitled to healthcare in a Member State other than their own, and includes the legislation and other declarations which provide this framework:

- ◆ The European Charter of Fundamental Rights which states that:

“Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices.”
- ◆ Regulation 1408/71 on co-ordination of statutory social security schemes, i.e. the provision of health care during a temporary stay in a Member State.
- ◆ Clarification by the European Court of Justice of the conditions under which patients may be reimbursed for healthcare provided in another Member State than the Member State of affiliation of the patient.⁴
- ◆ A proposed Directive on services in the internal market.⁵

The Communication and the proposed Directive contain the following paragraphs on patient mobility:

- ◆ **Communication**

The current framework reflects the following general principles regarding patients' rights to treatment in another Member State:

- Any non-hospital care to which you are entitled in your own Member State you may also seek in any other Member State without prior authorisation,

⁴ See in particular the Kohll judgement, Case C-155/96 of 28.04.98, ECR 1998 p. I-1931; Smits et Peerbooms judgement, Case C-157/99 of 12.07.01, ECR 2001 p. I-05473 ; Vanbraekel judgement, Case C-368/98 of 12.07.01, ECR 2001 p. I-05363, Inizan judgement, Case C-56/01 of 23.10.03, not yet published; Leichtle judgement, Case 8/02 of 18.3.04, not yet published.

⁵ <http://europa.eu.int/cgi-bin/eur-lex/udl.pl?REQUEST=Service-Search&LANGUAGE=en&GUILANGUAGE=en&SERVICE=all&COLLECTION=com&DOCID=504PC0002>

and be reimbursed up to the level of reimbursement provided by your own system.

- Any hospital care to which you are entitled in your own Member State you may also seek in any other Member State provided you first have the authorisation of your own system. This authorisation must be given if your system cannot provide your care within a medically acceptable time limit, considering your condition. Again, you will be reimbursed up to at least the level of reimbursement provided by your own system.
- If you wish to seek treatment abroad, your health authorities can provide you with information on how you can seek authorisation for care in another Member State, the reimbursement levels that will apply and how you can appeal against decisions if you wish to.

◆ **The Directive**

The Directive states:

“In order to eliminate the obstacles to the free movement of services, the proposal provides for:

- the ***right of recipients to use services*** from other Member States without being hindered by restrictive measures imposed by their country or by discriminatory behaviour on the part of public authorities or private operators. In the case of patients, the proposal clarifies the circumstances in which a Member State may make reimbursement of the cost of health care provided in another Member State subject to authorisation.”

Next Steps

As set out in the Communication, the Commission has already taken, or will take action, on several aspects to improve certainty over the impact of the rights of citizens under European law to seek healthcare in other Member States and be reimbursed. These include:

- providing better and clearer information about those rights and what they mean in practice, as described above;
- providing better legal certainty as regards the authorisation regime for reimbursement of health care costs incurred in another Member State, in the light of the jurisprudence of the Court through the Commission proposal for a Directive on services in the internal market (COM(2004)2);
- improving the decision-making process through extending the application of health impact assessment to assess the impact on health services, as described under the section on better understanding the European contribution to healthcare objectives;
- simplifying the existing rules on the coordination of social security systems through the modernisation and simplification of Regulation 1408/71;
- facilitating mobility of citizens through simplification of procedures and the deployment of the European health insurance card as from 1 June 2004;
- improving information about patient mobility and healthcare developments, as set out in the section on information;

- and facilitating cooperation at European level by establishing High Level Group on Health Services and Medical Care, as described under the section on the European contribution to health objectives.

The Commission has invited Member States to:

- ◆ Act to raise awareness of these initiatives and to improve legal certainty concerning the right of patients within their system to benefit from medical treatment in another Member State.
- ◆ Determine the rules governing rights or duties of healthcare cover under their social security system, and the conditions on which benefits provided by their sickness insurance scheme are granted.⁶
- ◆ Review systems to see if clarification is required on benefits provided and the conditions for access to them.

The Commission will also explore further the possibility of reaching a common understanding on patients' rights at European level through the High Level Group on Health Services and Medical Care and the reflection process.

The proposed Directive on internal markets is now with the Council and discussions are taking place.

3 European Centre for Disease Prevention and Control

The new European Centre for Disease Prevention and Control (ECDC) opened in Stockholm on Monday 27 September 2004. It is expected to become operational in May 2005. The UK representative on the Centre's Management Board is Mr Gerard Hetherington, Head of Health Protection, Department of Health.⁷

The new EU agency is described as being able to provide:

“A structured and systematic approach to the control of communicable diseases and other serious health threats which affect European Union citizens. The ECDC will also mobilise and significantly reinforce the synergies between the existing national centres for disease control. It is due to start work in May 2005.”

The four main tasks of the Centre will be:

- ◆ Epidemiological surveillance and networking of laboratories
- ◆ Early Warning and Response
- ◆ Scientific opinions
- ◆ Technical Assistance and Communication⁸

⁶ EC rules on free movement require only that these conditions be neither discriminatory nor an obstacle to freedom of movement of persons, of services and of establishment.

⁷ http://europa.eu.int/comm/health/ph_overview/strategy/ecdc/ecdc_en.htm

⁸ http://europa.eu.int/comm/health/ph_overview/strategy/ecdc/main_task_ecdc_en.htm

Issues and Actions: e-Health Action Plan

Annex C (i)

Issue 1: Addressing common challenges	Date	Action by:
Each Member State is to develop a national or regional roadmap for e-Health. This should focus on deploying e-Health systems, setting targets for interoperability and the use of electronic health records, and address issues such as the reimbursement of e-Health services.	End 2005	Member States
Member States, in collaboration with the European Commission, should identify a common approach to patient identifiers. This should take account of best practices and developments in areas such as the European Health Insurance Card and identity management for European citizens.	End 2006	Member States, Commission
Member States, in collaboration with the European Commission, should identify and outline interoperability standards for health data messages and electronic health records, taking into account best practices and relevant standardisation efforts.	End 2006	Member States, Commission
A collaborative approach should be undertaken among Member States to supporting and boosting investment in e-Health.	End 2006	Member States
Member States should adopt conformity testing and accreditation schemes following successful best practices.	End 2007	Member States
Member States should support deployment of health information networks for e-Health based on fixed and wireless broadband and mobile infrastructures and Grid technologies.	2004-2008	Member States
<p>The European Commission, in collaboration with Member States, should undertake activities to:</p> <p>Set a baseline for a standardised European qualification for e-Health services in clinical and administrative settings.</p> <p>Provide framework for greater legal certainty of e-Health products and services liability within the context of existing product liability legislation.</p> <p>Improve information for patients, health insurance schemes and providers regarding the rules applying to the assumption of the costs of e-Health services.</p> <p>Promote e-Health with a view to reducing occupational accidents and illnesses as well as supporting preventive actions in the face of the emergence of new workplace risks.</p>	End 2009	Commission, Member States
Issue 2: Pilot actions: accelerating beneficial implementation		
Promoting the use of cards in the health care sector. Adoption of implementation of an electronic health insurance card by 2008.	2008	Commission, Member States
The majority of European health organisations and health regions (communities, counties, districts) should be able to provide online services such as teleconsultation (second medical opinion), e-prescription, e-referral, telemonitoring and telecare.	End 2008	Member States

Issue 3: Working together and monitoring practices		
Member States, in collaboration with the European Commission, should agree on an overall approach to benchmarking in order to assess the quantitative, including economic, and qualitative impacts of e-Health.	Start 2005	Member States, Commission
The European Commission, with contributions from Member States, should establish an effective way of disseminating best practices and supporting actions within the European e-Health area.	End 2005	Commission, Member States
An assessment of e-Health developments should be completed ahead of the second part of the World Summit to be held in Tunis.	2005	Commission, Member States
Member States with the support of the European Commission will organise special events such as high level conferences in order to disseminate best practices.	2004- 2008	Member States, Commission