Health and Social Services Committee **HSS(2)-14-04(p.3)**

Date: **Wednesday 24 November 2004**
Venue: **Committee Rooms 3 & 4, 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 6 September and 5 November 2004.

Action

2. Members are invited to consider whether they wish to give further scrutiny to the legislative and non-legislative items considered to be of interest to Health and Social Services (Annex A)

Background

3. The attached Annex A contains details of EU documents deposited in the UK Parliament since 6 September 2004 that have been considered to be of interest to Health and Social Services.

4. Also contained in the Annex is a new section in which documents highlighted but deemed not to be relevant to the Committee are listed.

Members' Research and Committee Services

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Annex A

Legislative proposals of interest to the Health and Social Services Committee, deposited in the UK Parliament (from 6.09.04 to 8.11.04)

MRCS Ref.	Title	Link	Commentary and relevance to Wales	Opportunity and timescale for action
13880/04	COM(2004) 599 final Proposal for a Regulation of the European Parliament and of the Council on medicinal products of paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/83/EC and Regulation (EC) No. 726/2004	http://europa.eu.int/prelex/detail_dossier_real.cfm?CL=en&DosId=191868	The explanatory memorandum states that more than 50% of the medicines used to treat the children of Europe have not been tested and are not authorised for use in children. The purpose of this Regulation, which follows on from a Council Resolution of 14 December 2000, is to encourage the development of medicines for use in children and to ensure that those used to treat them are subject to high quality research and appropriately authorised. Also the Regulation seeks to ensure that children are not subjected to unnecessary clinical trials and that those carried out are in full compliance with the EU Clinical Trials Directive. This proposal meshes with, and builds on, 5 existing Community legislative texts which together provide a framework for the regulation of medicinal products.	The Committee may wish to find out whether the Medicines and Healthcare products Regulation Agency (MHRA) and DoH proposed *Strategy on Medicines for Children* published in July 2004 will take account of the EU proposal and other relevant EU legislation. http://medicines.mhra.gov.uk/ourwork/licensingmeds/children/paediatricstrategydoc.pdf The earliest this proposal is likely to become law is late 2006.

13489/04	COM(2004) 650 final – 2004/0237 (COD) Proposal for a Directive of the European Parliament and of the Council amending Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuffs.	http://europa.eu.int/prelex/detail_dossier_real.cfm?CL=en&DosId=191806	The Explanatory Memorandum states that amendments to these existing Directives have been prompted by recent technical and scientific developments, and the need to ensure a high level of protection of human health together with economic considerations. The action proposed for Directive 95/2/EC relates to a number of revisions of current authorisations which includes nitrates in meat products, additives in baby food, dietary food supplements and a range of additives relating to specific food products. Directive 94/35/EC seeks the authorisation of a new sweetener, erythritol, as a food additive.	For information – timescale not known.
12683/04	COM(2004) 607 final Proposal for a Directive of the European Parliament and of the Council amending Directive 2003/88/EC concerning certain aspects of the organisation of working time.	http://europa.eu.int/prelex/detail_dossier_real.cfm?CL=en&DosId=191740	The main changes contained in this proposal of two new additional definitions of working time is in response to the SIMAP and Jaeger rulings in the European Court of Justice on definitions of working time and rest periods. The rulings had a particular impact on the working time of doctors and other healthcare workers, and the intention of this proposal is to modify the impact of the original Directive 2003/88/EC. While the definitions of "working time" and “rest period” will remain unchanged, new definitions of “on-call time” and “inactive part of on-call time” will be added. Other changes proposed to specific articles in the Directive give additional clarification to the new definitions.	The Committee may wish to consider whether these proposals might provide enough flexibility to allay any concerns over the impact of the original Working Time Directive to the Health Service+ in Wales.

Non-legislative documents of interest to the Health and Social Services Committee, deposited in the UK Parliament (from 6.09.04 to 8.11.04)

MRCS Ref.	Title	Link	Commentary and relevance to Wales	Opportunity and timescale for action
13880/04 AD	SEC (2004) 1144 Commission Staff Working Paper – Proposal for a regulation of the European Parliament and of the Council on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/83/EC and Regulation (EC) No. 726/2004	http://europa.eu.int/prelex/detail_dossier_real.cfm?CL=en&DosId=191868	This is the working paper related to COM(2004) 599 final above.	Committee members with a particular interest in this topic may wish to see this.

Remaining legislative and non-legislative documents deposited in this subject area and not considered of interest

MRCS Ref.	Title
12164/04	COM 2004 534 Final Communication from the commission to the Council and the European Parliament on the Mid-term review of the Commission's legislative and work programme for 2004 http://europa.eu.int/eur-lex/en/com/cnc/2004/com2004_0534en01.pdf
12113/04	COM (2004) 575 Final Report from the Commission to the Council and the European Parliament on the experience of Member States with GMOs placed on the market under Directive 2001/18/EC and incorporating a specific report on the operation of parts B and C of the Directive. http://europa.eu.int/cgi-bin/eur-lex/udl.pl?REQUEST=Service-Search&LANGUAGE=en&GUILANGUAGE=en&SERVICE=all&COLLECTION=com&DOCID=504PC0575
12113/04 Add	SEC (2004) 1063 Commission Staff Working Paper – Annex to the report from the Commission to the Council and the European Parliament on the experience of member states with GMOs placed on the market under Directive 2001/18/EC and incorporating a specific report on the operation of parts B and C of the Directive. http://europa.eu.int/cgi-bin/eur-lex/udl.pl?REQUEST=Service-Search&LANGUAGE=en&GUILANGUAGE=en&SERVICE=all&COLLECTION=com&DOCID=504PC0575

Other Information

Public Consultation

Committee Members may wish to note the following public consultation currently being undertaken by the Food Standards Agency. This is a proposal for a European Directive on food supplements for sportsmen and women that are “intended to meet the expenditure of intense muscular effort”. The consultation period for this proposed Directive ends on 28 January 2005 http://www.food.gov.uk/foodindustry/Consultations/ukwideconsults/proposalfoodmuscle.