Health & Social Services Committee

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Date: Wednesday 1 February 2006
Venue: Committee Room 3 & 4, National Assembly for Wales
Title: European Issues - Update

Purpose

This paper provides information about the proposal for a Paediatric Medicines Regulation and amendments to existing related legislation, and updates on items selected from the 2005 Work Programme and the Mental Health Green 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

Background

A Paediatric Medicines Regulation and amendments to two existing Regulations and one Directive have been proposed by the European Commission on the basis that around 50% of the medicines given to newborn babies or to adolescents have never been tested for their impact on these age groups. According to the EC, it is common practice that doctors prescribe to babies and children smaller or less frequent doses of medicines intended for adults, even though their organs absorb or eliminate medicines differently. The rationale for the proposed actions is to reduce the risk of unwanted side effects from medicines administered to babies and children.
The Regulation is subject to co-decision, which means that the European Parliament and the Council will have to reach a joint agreement on it,

Progress

6 September 2005 - The First Reading took place in the European Parliament with MEPs supporting the report drafted by the Environment, Public Health and Food Safety Committee, which included:

- a six-month extension of a patent/supplementary protection certificate (SPC);
- an increase of exclusive commercial rights of 'orphan drugs', intended to treat rare illnesses, from 10 to 12 years (if invented specifically for children);
- establishment of a Medicines Investigation for the Children of Europe (MICE) fund, a special EU

programme for research into medicines for children;
- establishment of a network of researchers and research centres under the supervision of the European Medicines Agency to avoid duplication of research and tests on children;
- establishment of a Paediatric Committee as the 'cornerstone' of the European paediatric R&D system.

The ENVI Committee also agreed on the need to carry out an impact assessment and thus review the new Regulation six years after its entry into force to determine the law's effectiveness in producing better medicines for children. The review would include an economic assessment to ensure that industry rewards are commensurate with investments.

9 December 2005 - The Council reached political agreement on the Regulation, agreeing with the European Parliament on the key points. However, there remain some differences and the dossier has now been transferred to the Parliament for 2nd reading. A Commission Regulation will also follow, detailing the required implementing provisions. Further provisions may be put forward by the Commission as guidelines.

Further information

http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/1559&format=HTML&aged=0&language=EN&guiLanguage=en

Western Mail Press article Children's doses 'a guessing game' , 7 September 2005 http://icwales.icnetwork.co.uk/0100news/health/tm_objectid=15939242&method=full&siteid=50082&headline=-doctors-can-only-guess--what-quantity-of-medicine-to-give-to-a-child--name_page.html#story_continue

Influenza and Other Pandemic Plans

23 and 24 November 2005 - A Europe-wide simulation exercise that tested the ability of the EU and its member states to respond to an influenza pandemic was held. Although the official assessment of the exercise will not be delivered by the European Centre of Disease prevention and Control (ECDC) until February 2006, one reported issue that emerged was how to regulate information flows in the event of a public health crisis.

29 November 2005 - the European Commission adopted two Communications on how to respond to public health emergencies, one of which focuses specifically on pandemic influenza preparedness and updates the Commission’s plan (published in March 2004). In particular, this paper sets out a proposed EU response for each phase of a flu pandemic and clarifies the responsibilities of the member states, the Commission and the EU agencies. Updates are in line with the revised World Health Organisation definitions of pandemic phases and the opening of the European Centre of Disease prevention and Control (ECDC). The key message to emerge from the two Commission Communications is the need to:

"extend emergency planning beyond the health sector to include aspects such as civil protection, transport, communications, emergency services, investment in laboratories, and international relations".

9 December 2005 - Flu preparedness was an agenda item at a meeting of the EU Health Council of Member States' Health Ministers. A summary of the discussion is at: http://www.dh.gov.uk/PublicationsAndStatistics/PressReleases/PressReleasesNotices/fs/en?CONTENT_ID=4124360&chk=cKjrzq

12 December 2005 - a second meeting of Member States' Chief Veterinary and Medical Officers was held in Brussels. The report of the meeting is at: http://europa.eu.int/comm/health/ph_threats/com/Influenza/influenza_key10_en.pdf

Services Directive

The Council is awaiting the European Parliament's First Reading of the Directive, which is scheduled for 14 February 2006.
Meanwhile, at its meeting on 22 November 2005, the Parliament's Internal Market Committee amended the Directive to remove public and private healthcare from its scope. However, it will be for the Council to reach a political agreement following the First Reading after which it will return to Parliament for a Second Reading.

Green Paper on Mental Health

The Green paper on mental health was published on 14 October 2005 and responses to the consultation are sought by 31 May 2006.

At its meeting of 23 November 2005, this Committee agreed to submit a response. This will be considered at a future meeting.

9 December 2005 - this was a further item on the agenda of the EU Health Council meeting. The summary of discussions reports that:
The Council gave a clear supportive steer to the Commission on their recent green paper on mental health. Mental ill health is an important part of Europe's public health agenda. The consultation on the green paper concludes at the end of May, but the initial remarks from Health Ministers showed that the Commission has developed an extremely important contribution to this vital area for all Health Ministers.

Green Paper on Nutrition

The Green paper, which is entitled "Promoting healthy diets and physical activity: a European dimension for the prevention of overweight, obesity and chronic diseases" was published on 8 December 2005. On the same date, it was adopted by the Commission and transmitted to the Council and European Parliament. There are potentially a number of areas of questioning to which Welsh experiences may

provide a contribution.

Working Time Directive

December 2005 - At the last meeting of the Social Policy and Employment Committee under the UK presidency, efforts by the UK to gain agreement among ministers on the opt-out clause failed despite a UK change of stance. The UK has now revised its position on opting out of the maximum 48 hour working week to the exception rather than rule.

Action for Subject Committee

This is a paper to note.
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3 January 2006