The Commission launches a public consultation on medical devices

Within the framework of the “strategy for the simplification of the regulatory environment” launched following the adoption of the Strategy of Lisbon on March 24, 2000, the Commission has decided to modify the legislative measures framing medical devices.

It states that the legal framework on the matter “does not always offer a uniform level of protection of public health in the European Union” and that it is “too fragmented and difficult to follow and fraught with national variation”. According to the Commission, it should take into greater account not only developments in terms of technological advancements but also recognise the world environment in order to maintain European competitiveness. For this purpose, the Commission considers that “the Community regime needs to further converge on the ‘global model’”.

Continued on page 2

The EU prioritises “the fight against cancer”

The European Parliament (EP), the Commission and the Slovenian Presidency have decided to make cancer one of their priorities. In its program, the Slovenian Presidency had indicated cancer as one of the “major health challenges in Europe”.

“The Burden of Cancer: joining forces in Europe to prevent and fight this disease”

The European Commissioner in charge of health, Androulla Vassiliou (see UEMS News 2008/03), in her speech at the conference of the “European Patient Cancer Coalition” on April 7, 2008, affirmed that cancer currently represents one of the greatest burdens for the European economy. The European Parliament (EP) also devoted its attention to cancer with the adoption on 10th April of a resolution on the subject. Both the Commission and the EP insisted on the need to advance prevention and screening programmes. Indeed, a study by the World Health Organization shows that a third of cancers could be addressed by prevention. However, only 3% of the health budgets of the OECD countries are devoted to prevention, the remaining 97% being allocated to treatment and care. The two institutions also denounced the great inequalities existing in Europe in the incidence of cancer and the quality of its handling, particularly between new and old Member States. Members of the European Parliament (MEPs) also denounced “striking and unacceptable” differences in death rates which are allegedly primarily due to the “differences in the quality of treatment services of cancer, screening programmes, radiotherapy services and the availability of new anticancer drugs”. The European deputies and the Commissioner invited the Member States to combine their efforts in order to improve cancer control.

Continued on page 2
Care of older people in Europe

The British Medical Association Northern Ireland (BMA, NI) and the Irish Medical Organisation (IMO) have published a joint paper entitled “Care of older people”. This paper was released on 15th April 2008 at a reception with Members of the European Parliament in Brussels.

The BMA (NI) and IMO, while recognising the limited power of the EU in public health, “urges their respective governments, the leaders of the EU and other Member States to work together to address the long-term healthcare of older people through the formulation and implementation of coordinated policies and strategies”. Indeed, the BMA (NI) and IMO see the demographic evolution of an ageing population as a major challenge to the public health system in Ireland and in other Member States, and calls for a strong European leadership in this field. Both organisations advocate several propositions to meet this challenge: to develop strategies to reform and resource care systems; cross-border cooperation in healthcare programmes; a holistic approach to ageing and long-term care with the aim of embracing all aspects of an ageing population such as the economy, housing, transport and the environment, and; development of the use of e-health.

More information and full text on: http://www.bma.org.uk/ap.nsf/Content/elderlycareeurope

Public consultation on medical devices

Medical devices in figures:

Worldwide market
- approximately 187 billion Euros
- growth rate of around 5% - 6% per annum

European market
- 33% of the worldwide market
- approximately 6% of the health expenditure in Europe
- 435,000 employees in Europe in more than 11,000 companies.

Mr. Günter Verheugen, Vice President of the Commission in charge of enterprises and industry, has launched, in the name of the European commission, a public consultation in order to modernise and simplify public legislation on medical devices. This consultation requests the views of recipients on a number of issues: fields of application; harmonisation of the application of the legislation; regulatory simplification; protection of citizens; etc. All responses concerning this public consultation must be submitted by July 2, 2008 at the latest. For more information: http://ec.europa.eu/enterprise/medical_devices/consult_recast_2008_fr.htm.

Fight against cancer

A Communication of the Commission on a “cancer action plan” in 2009

Commissioner Vassiliou announced that the Commission will publish a communication presenting a “cancer action plan” for the European Community. This strategy should concentrate on a “number of important aspects of cancer control, such as prevention, early detection, diagnosis, treatment, rehabilitation and palliative care”. The Commission would also stress the need for supporting research on cancer.

Combating cancer in the enlarged EU

On its side, the resolution of the EP proposes a number of measures, particularly in order to address both those questions identified above and emphasising the problems of breast cancer. One of the most noteworthy proposals is the creation of a working group gathering members of the Commission, the Council and the Parliament in order to “collect and exchange best practice for prevention, screening and treatment”.

Many more deaths could be prevented in the EU each year by more consistent, extensive and effective cancer screening and a more effective sharing of best practice.

Liz Lynne, MEP (UK)
European Health Policy Forum

On 30th May, the European Commission (DG Health & Consumer - DG SANCO) convened a meeting of the European Health Policy Forum (EUHPF) in Brussels. This platform aims to bring together representative organisations involved in health matters at the European level, which includes the UEMS, and organises open discussions on issues currently under consideration within the relevant Commission services. These have included the implementation of the EU Health Strategy, through the initiatives on patient mobility, patient information and patient safety.

Stakeholders’ involvement

Under the chairmanship of Mr Robert Madelin, Director General in DG Sanco, the morning’s discussions focussed on the mandate and methodology of the Forum. This item has been under scrutiny for some time and will lead to enlarging the EUHPF membership and revising its working methods alongside implementation of the EU Health Strategy. One of the aims of this process is to encompass and involve all 27 Member States. In addition, the Members of the EUHPF discussed the organisation of the next meeting of the Open Health Forum to be held on 10th-11th December 2008 in Brussels. Proposed issues to be dealt with at that Conference includes: healthy lifestyles of young people, health impact of climate change, the use of new technologies

EU health-related issues

The review on current European issues included a series of topics ranging from the EU Health Strategy and initiatives related to telemedicine and the EU budget.

EU Health Strategy

Overall, a consensus was reached between the different institutions as to which items should be dealt within the broader framework of the Strategy. Current activities encompassed the following initiatives:
- The directive on cross-border care
- A recommendation on patient safety
- A green paper on health workforce
- A communication on inequalities

EU Budget Review

A position paper on the proposed EU budget was prepared by an ad hoc EUHPF working group. This document, which identified the disparities in allocating funding to health-related matters, was fully endorsed by the members of the Forum.

Telemedicine and ICT for chronic disease management

The European Commission (DG Information Society & Media - DG Infso) is currently working on a Recommendation on this issue. For this purpose a group of experts, on which the UEMS is represented through its Section of Radiology, was convened in order to analyse the obstacles to a concrete implementation of ICT tools. This reflection process will lead to the release of a Recommendation by the end of this year in order to propose relevant solutions and support the use of information technologies.

Patient Information and Safety

These issues will be dealt with in 2 separate Recommendations to be released at the end of 2008. Agreement by the EU Council and Parliament will be sought for early 2009.

Cross-border care and patient mobility

This long-awaited initiative aims to ensure the implementation of patient rights. As announced by the European Commissioner for Health Ms Androula Vassiliou, the proposed directive will be issued this month (See UEMS News 2008/03). The text was reported to be divided into 3 different pillars:
- Ensuring patient rights
- Making safe, high quality medical care available to all
- Fostering collaboration between national health systems

This proposal will be released within a broader “social package”, together with other pieces of legislation relating to social security.

For further information, please contact the Secretariat of the UEMS.
CALLS FOR TENDERS

**EMEA and FDA announce first joint biomarkers qualification**

The European Medicines Agency (EMEA) and the US Food and Drug Administration (FDA) have concluded the first joint qualification process for biomarkers. Following this initial experience, the EMEA is inviting comments by 30th June 2008 on draft guidance on the Agency’s new procedure for qualification of biomarkers via the Scientific Advice Working Party/CHMP.


**Methodology to assess Telemedicine Applications**

The European Commission (DG INFSO) is launching a call for tender on a study to provide accurate and up to date information on telemedicine applications in use in Europe, with a particular focus on cross border solutions. This study will also need to identify enablers and obstacles to the deployment of telemedicine applications and to provide an initial overview of national policies in telemedicine.


**Monitoring eHealth Strategies**

The European Commission (DG INFSO) is launching a call for tender on a study to monitor progress and to analyse trends in the development and implementation of national eHealth strategies versus the targets set by the eHealth action plan.


PUBLICATIONS

**Type 2 diabetes management**

The National Institute for Health and Clinical Excellence (NICE) has published an update of its five guidelines dealing with different aspects of the care of type 2 diabetes. These guidelines, which aim to provide resources for all health professionals dealing with type 2 diabetes, cover: monitoring of glucose, lipid and blood pressure levels; diabetes education programmes; dietary advice; the use of medications, detection and ongoing management.


**Euro Observer**

Published quarterly, Euro Observer is the health policy bulletin of the Observatory on Health Systems and Policies and provides information on health policy issues and health system reforms across Europe through review articles, case studies and commentaries. It also highlights forthcoming Observatory studies, reports and other research activities.

More information and full text: [http://www.euro.who.int/observatory/Publications/20020524_29](http://www.euro.who.int/observatory/Publications/20020524_29)