UEMS News 2006 / 03 en

20 February 2006

European Union of Medical Specialists
Union Européenne des Médecins Spécialistes

The Newsletter of European Medical Specialists

European Parliament - February plenary session
Draft Directive on services in the internal market

From 13th to 16th February last, the European Parliament convened in Strasbourg and examined in first reading the Report of Ms. Evelyne Gebhardt on the proposed Directive on services in the internal market. After a series of lively debates, and again during the plenary session, the vote was cast in a heated atmosphere. The Report drafted by Ms. Gebhardt was finally adopted by 394 votes to 215 with 33 abstentions.

This new version of the text has dramatically modified the original proposal issued by the European Commission at the beginning of 2004. After passionate discussions, MEPs found common ground on the major issues at stake with a compromise eventually being achieved within the assembly.

As for the most important issue for the UEMS, MEPs agreed to remove all healthcare services from the scope of the Directive. The Executive of UEMS was particularly enthusiastic at the outcome when this vote was announced as the UEMS position, adopted at the Council Meeting of 12 March 2005, (UEMS 2005 / 13) had been fully endorsed by the decision-makers.

This EP decision will now be transmitted to the European Commission, which will issue its comments on the final report, before being sent to the Member States. The European Commissioner for Internal Market and Services, Charlie McCreevy has already announced that the Commission will keep most of the improvements made by the Parliament. It is also clear that the European Commission will not leave the health sector untouched and will return to this issue again in the coming months. The UEMS has already been in contact in order to closely collaborate with the Commission during the consultative and legislative processes. The next issues of the Newsletter will of course keep you fully informed of any further development with regard to this issue.

The Secretariat of UEMS holds the following texts at your disposal:

Report on the proposed Directive on services in the internal market

José Manuel Barroso, President of the European Commission, *"Speaking note on the Services Directive"*

> ***"If health services are excluded from the scope of the Directive, this does not take away from the necessity to address the increasing jurisprudence of the Court of Justice in regard to patient mobility. A separate proposal from the Commission addressing this issue will therefore be necessary."***
>
> **Charlie McCreevy**
> **European Commissioner for Internal Market and Services**
> ***(Strasbourg, 14.02.2006)***

Charlie McCreevy, European Commissioner for Internal Market and Services, *"Statements on the Services Directive"*

The meetings of the Board and Council will be held on Saturday 18th March 2006

Summary:

- Partnership initiated by the European Commission aims to reduce animal testing
- Infringement Proceedings against Luxembourg and the Czech Republic
- Concerns on EU law on clinical trials
- EU Report demonstrates positive impact of the 2004 enlargement
- Call for proposals 2006 under EU Public Health Programme

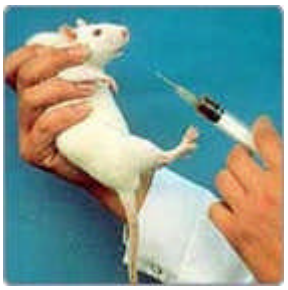
In this issue:

Partnership to reduce animal testing

The European Commission agreed a partnership with industry associations aimed at finding alternatives to animal testing.

The "European partnership to promote alternative approaches to animal testing" was agreed at a Conference held in Brussels in November 2005. An action programme was also established with concrete activities in order to reduce the estimated 10.7 million animals used for testing purposes in Europe each year. The "Three Rs Declaration" (Refining, Reducing, Replacing) was signed by the European Commission and industry associations in the pharmaceuticals, chemicals, cosmetics and biotechnology sectors. These include the European Chemical Industry Council (CEFIC), the European Crop Protection Association (ECPA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

For further information on this issue, please visit the following website: www.ecvam.jrc.it/index.htm.



Source: www.scenta.co.uk

Internal Market - Infringement proceedings

Czech Republic - Recognition of dental and medical qualifications

The Commission has decided to refer the Czech Republic to the Court of Justice over its partial communication of national measures implementing Directives 78/686/EEC and 93/16/EEC on the mutual recognition of the diplomas of practitioners of dentistry and doctors respectively.

Under the Treaty of Accession, the Czech Republic had to take all necessary measures to comply with these Directives by 1 May 2004 at the latest.

The Directives apply both to establishment and to the freedom to provide services on a temporary basis. To promote the freedom to provide services by the professionals in question, provision has been made for a simpler procedure than that required for establishment.

However, the Czech Republic has adopted and notified the Commission of various measures to implement the above Directives, but none to promote the temporary provision of services by professionals established in other Member States.

Luxembourg - Legal protection of biotechnological inventions

The Commission has decided, under Article 228 of the EC Treaty, to send a further reasoned opinion to Luxembourg, requesting it to comply immediately with a previous European Court of Justice judgement requiring it to write into national law Directive 98/44/EC on the legal protection of biotechnological inventions (Case C-450/03, 9 September 2004).

The Directive should have been written into national law by 30 July 2000. It aims to clarify certain principles of patent law applied to biotechnological inventions whilst ensuring that strict ethical rules are respected. Such clarifications have proved essential in order to exploit fully the medical, environmental and economic potential of biotechnology in line with high ethical standards. To date only two Member States have not implemented the Directive: Luxembourg and Latvia. Non-implementation creates trade barriers and hampers the Internal Market, putting the European biotechnology sector at a serious disadvantage.

Czech Republic requested to inform the Commission of measures taken with regard to the temporary provision of services by doctors and dentists

Luxembourg to comply with Directive on legal protection of biotechnological inventions

Concerns raised over impact of EU Directive on clinical trials

On the occasion of the 13th European Cancer Conference held in Paris on … last, concerns were raised that the recently introduced EU clinical trials directive will have a restrictive effect on the number of new cancer trials being carried out in Europe.

The Directive in question aims to harmonise legal provisions with regard to the establishment, conduct and reporting of clinical trials, implement good clinical practice and ensure patient safety. In a recent statement, the European Federation of Cancer Societies (FECS) though feared that "its mandatory implementation will be to the detriment of future non commercial trials as requirements, obligations and clinical costs associated with the new legislation continue to increase".

A comparative analysis was undertaken in eight EU Member States in order to investigate the impact o the directive, i.e. differences, obstacles, pitfalls in the conduct of future investigor-led multicentre trials in Europe. According to this study, only few Members States have added provisions for non-commercial trials when transposing the legislation and no common definitions exist across the EU.

"The conclusion is that the new legal framework for clinical trials renders the realisation of future pan-European multicentre studies much more difficult. There has been a failure to simplify the conduct of academic trials in the European trial space", the statement continues.

For further information on this issue, please visit the following website: www.fecs.be/emc.asp?page1d=10&Type=P.

"In paediatric oncology and cancers of very low incidence, the expected drop-down of available clinical trials will constitute a major challenge for all stakeholders, including patients and physicians as well as drug manufacturers and policy-makers."

Dr. Markus Hartmann European Consulting & Contracing in Oncology

Free movement of workers
Commission report unveils positive impact of EU enlargement

A European Commission report published recently showed that workers' mobility from the EU Member States in Central and Eastern Europe to the former EU15 had mostly positive effects and was in most countries quantitatively less important than foreseen.

Workers from the ten "new Member States" helped to relieve labour market shortages and contributed to better economic performance in Europe. Countries that did not apply restrictions after May 2004 (UK, Ireland and Sweden) experienced high economic growth, a drop of unemployment and a rise of employment. As to the 12 EU countries using transitional arrangements, where workers managed to obtain access legally, this contributed to a smooth integration into the labour market. However, evidence also suggested that some of these countries may also have faced undesirable side-effects, such as higher levels of undeclared work and bogus self-employed work. For the EU as a whole, flows of workers were rather limited.

The Commission's report, as required by the Accession Treaty, highlights statistics and experiences of labour flows from new to old EU Member States since enlargement in May 2004. It is designed to provide Member States with a factual basis when deciding on whether to continue with national labour markets restrictions on workers' movement.

The next step is for the Commission's report to be presented to the Council.

For further information, please visit the following website: http://europa.eu.int/comm/employment_social/emplweb/news/news_en.cfm?id=119.

See also UEMS News 2005 / 12 of 30.09.2006.

"This report clearly shows that the movement of free workers has not had disruptive effects on EU15 labour market. Quite the contrary individual countries and Europe as a whole has benefited from it."

Vladimír Špidla

European Commissioner for Employment, Social Affairs and Equal Opportunities

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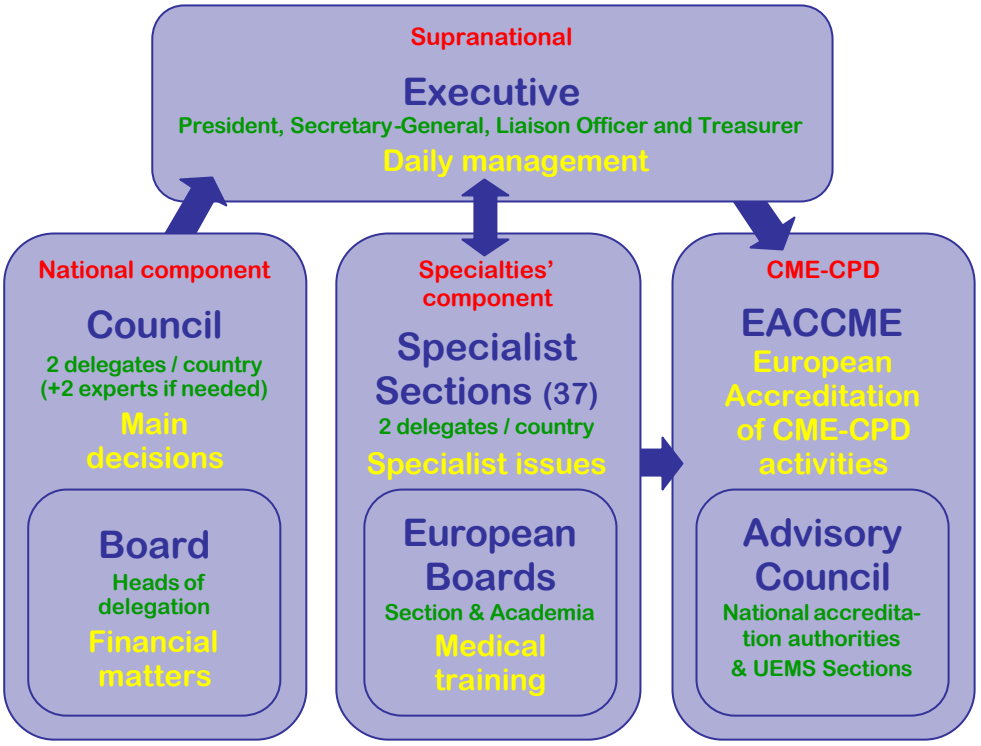

If you have any views with regard to the issues covered in this Newsletter, do not hesitate to contact the Secretariat of UEMS.

Call for proposals 2006

The European Commission is inviting public authorities, civil society organisations and health experts to put forward public health projects for EU co-funding. The call is open to participants from all 25 Member States, Bulgaria, Romania, Turkey, Iceland, Liechtenstein and Norway.
A budget of € 43 million has been set aside for the call.
To be eligible for Commission co-financing, projects must contribute to a high level of health protection.
The newly created Executive Agency for the Public Health Programme will be responsible for the management of this call.
The life-time of projects to be co-financed should not exceed three years.
For information on content and how to apply, see: http://europa.eu.int/comm/health/ph_programme/howtoapply/call_for_propal_en.htm.
For recall, an Information Day will be held on 22nd February 2006.
See UEMS News 2006 / 02.

Events

HealthGrid'06
Valencia (Spain), 7-9 June 2006
This event will aim to provide en open forum for the exchange and discussion of ideas, technologies, solutions and requirements that interest the Grid and Life-Sciences communities to foster the integration of Grids into Health.

Publications

Commission report on the functioning of the Transitional Arrangements set out in the 2003 Accession Treaty
(period 1 May 2004-30 April 2006)
http://europa.eu.int/comm/employment_social/news/2006/feb/report_en.pdf