Editorial

The current issue of the UEMS Newsletter presents an overview of EU issues currently at stake at the European level.

A particular focus was given on the demonstration led in Strasbourg by the Federation of Salaried Doctors (FEMS) together with other European Medical Organisations in the framework of the EP vote on the revision of the European Working Time Directive.

This issue will also be covered in the next issues as further discussions are underway in the conciliation procedure.

In this issue

Organ Donation Directive & Action Plan 3

Commission Report on Cancer Screening 4

Internal Market Proceedings 4

EC COM on Healthcare-associated infections 5

SHARE releases 2nd wave of results 5

Venues & Publications 6

MEPs confirm their vote on working time

The debate surrounding the European Working Time Directive is set to continue in 2009, as the European Parliament’s last plenary session reiterated its position from the first reading, thereby opposing the common position adopted by the EU Council in June (See UEMS News 2008/07)

The Parliament’s plenary session of December 2008 restated the MEPs position on the Commission proposal of revision of the working time directive. The report drafted by the Spanish Socialist MEP Cercas was approved by an absolute majority of 421 votes in favour, 273 against and 11 abstentions. By adopting this report, the Parliament confirmed its disagreement with the Council, leaving, therefore, the final decision up to the Conciliation Committee. This long negotiation process, started in 2004, will, hence, continue in 2009.

At the heart of the argument: the opt-out clause and on-call time

This outcome was expected, given the earlier discussions in the EP’s Committee on Employment and Social Affairs and the massive mobilisation of opinion, notably from doctors, in favour of the Cercas report. Divergences with the Council are focused on two main issues: the opt-out clause and the definition of on-call time.

Directive on Patient Mobility 1st Discussions

Following the launch of the Commission’s draft Directive on Patients’ Rights in Cross-Border Healthcare on July 2008 (See UEMS News 2008/03; 2008/05; 2008/06) both the European Parliament and the Council have recently started debating its content.

After the several European Court of Justice (ECJ) rulings on cross-border healthcare affairs and the exclusion of healthcare from the Services Directive (2006/123/EC), the EU has, with this initiative, the opportunity to put in place a specific instrument, which will ensure European citizens further legal certainty as to their rights when moving to get treatment within the EU.

Draft EP Report

The British Conservative MEP, John Bowis, when presenting his draft report at the European Parliament’s Committee on Environment, Health and Food Safety, proposed several changes to the Commission’s initiative:

• The scope of the application of the directive should be limited to the use of healthcare abroad and to its cross-border provision. According to the EP rapporteur, both the permanent and temporary presence of healthcare providers should, hence, be excluded from it;
• The provisions relating to information to patients and professionals were also completed, including notably “information on
Indeed, the EP’s decision ruled that the opt-out possibility should lapse within three years after the entry into force of the revised directive, forcing the EU Member States that have applied the opt-out to gradually correct this practice and conform with this directive. MEPs also decided that any period of on-call time should count as working time, contrary to the Council’s common position, which ruled inactive on-call time as being outside of regular working hours. Other major decisions included the establishment of a reference period of twelve months for the calculation of the weekly limit of 48 working hours. The Parliament also decided that compensatory rest periods, should be granted directly after periods of time spent on duty. Regarding the situation of workers bounded by more than one contract, MEPs stipulated that working time should be calculated through the sum of periods of time worked under each contract.

Doctors’ demonstration in Strasbourg

In order to support the EP rapporteur’s position, two days of demonstrations had been organised outside the European Parliament, in Strasbourg, on the eve of the EP vote. Around 10,000 demonstrators from European doctors associations and major trade unions mobilised in Strasbourg, stressing the need to reinforce workers’ health and safety’s rights. The objective was to bring to the attention of the European authorities the specific concerns of the medical profession, particularly in regards to the safety of healthcare workers and their patients. Members of the European Federation of Salaried Doctors (FEMS) supported by other medical organisations (EMOs) participated actively in the protest activities. Meetings were also held with MEPs from all political groups, together with demonstrations, alerting the European deputies about their strong concerns on compensatory rest and the definition of on call time. Prior to that demonstration, the Presidents of different EMOs met with the EP rapporteur and other influential MEPs in order to get the message from the medical profession through. Another set of long debates will now start.

After the massive support for his report, the EP rapporteur, Alejandro Cercas, sees few chances that this process could go backwards. This voting opens the way for a new set of long discussions in the Conciliation Committee, the last stage of the Council-Parliament negotiations, under the co-decision procedure. The Commission already ensured its support in getting a satisfactory agreement from its two sister institutions. The Czech Presidency also seems to want the issue solved before the next EP’s elections. However, in the current context, analysts have already predicted a long debate probably leading to important concessions from both sides.

The UEMS welcomes the adoption of the Cercas Report and is thankful to its sister EMOs for their efforts and commitment to achieving this outcome.

EMOs Joint Press Release

The European Medical Organisations welcome the vote of European Parliament on the Cercas Report on the amendment of Directive 2003/88/EC and express their gratitude to the MEPs who have taken the specific concerns of the medical profession into account. The 2 million physicians, represented by 400 delegates from all over Europe, who gathered in front of the European Parliament 15 December to demonstrate their determination to defend their rights and working conditions, thank the MEPs for their support and the understanding that the main concern of physicians is the safety of their patients. Therefore, European Medical Organisations mainly claim that:

- time spent on call by doctors has to be considered part of their working hours;
- compensatory rest is to be taken following periods of time spent on duty. The medical profession celebrates the victory of democracy of the European Institutions and congratulate the European Parliament for having rectified the wrong move taken by the Council. The European Medical Organisations remain vigilant during the conciliation phase but trust that Parliament will reinforce its stand.

The UEMS welcomes the adoption of the Cercas report and is thankful to its sister EMOs, most particularly to FEMS and its President Dr. Claude Wetzel, for their efforts and commitment to achieving this outcome in the interest of European doctors and their patients.
Directive on Patient Mobility 1st Discussions

Still a long way to go
This draft directive will be now discussed under the current Czech EU Presidency, after the European Parliament’s opinion, which should be issued in Spring 2009. Given the sensitivity of the topic, the new elections to the European Parliament and a new upcoming Commission, it will probably take some time to conclude the debate.

As a matter of fact, the UEMS, being committed to ensuring the highest quality of health to European citizens, supports any attempt to guarantee such a high degree of quality and safety to any citizen being treated within the EU. The UEMS is though concerned with what was reported from the discussions within the EP and the European Council that the ambition of the original text is watered down. Therefore, the UEMS calls on EU decision-makers to keep in mind the necessity to prevent any distortion in EU national health systems, in regards to their quality, accessibility and safety by specialists trained to the highest quality.

Organ Donation Directive & Action Plan

After the directives on blood, tissues and cells, the European Commission has now launched a Directive and an Action Plan on organ donation and transplantation aiming to improve the quality and safety of organ donation across Europe, to increase organ availability and to make transplant systems more efficient and accessible in the Union.

In line with the previous EC Communication and EP Resolutions on this topic (See UEMS News 2008/03), this initiative provides for the establishment of a national competent authority in every Member State, which will be responsible for keeping compliance with EU quality and safety standards. The draft in question also proposes a traceability system of human organs, as well as a reporting system of adverse events and reactions. Further to the legal framework of the draft Directive, the Commission also set a 10 point Action Plan aiming to strengthening coordination between Member States on organ donation and transplantation procedures.
Given the increasing ageing population it is, therefore, urgent to optimize the use of cancer screening, notably of breast, cervical and colorectal cancer. The EC Report in question shows that most Member States have acted on the Recommendation and plan increased further action to complete its implementation.

Sections related to the training of health professionals and equal access for vulnerable social economic groups report very high levels of compliance (around 91%) with the Council’s 2003 Recommendation. Also registration and management of screening data demonstrate high level of implementation (82%). On the other hand, measures related to regular monitoring of screening programmes seem to be having more problems to be put in place, with only 55% of the Member States attaining the expected result.

Other measures showing an intermediate level of compliance with the Council Recommendation includes the establishment of a set of technical, ethical and legal standards which should follow the implementation of screening programmes (only 67%). According to this report, less than half of the population is still not yet covered by any screening programme and only half of those examinations respect the stipulations in the Recommendation.

In order to reverse this situation, the Commission intends to launch this year a partnership for action against cancer, with an aim to provide a framework for identifying and sharing information, capacity and expertise in cancer prevention and control.

---

**Internal Market Proceedings**

**Freedom of Establishment for Pharmacies**

The European Commission has sent a reasoned opinion to Italy, requesting revision of its legislation related to pharmacies, which is deemed to be incompatible with Article 43 of the EC Treaty on freedom of establishment. The current legislation puts considerable restrictions to pharmacists wanting to establish themselves in Italy. Allegedly, it forbids individual pharmacists from having more than one authorization to open a pharmacy and restricts the maximum number of pharmacies that may be owned by groups of pharmacists to four, which, moreover, must be located in the same province where the group has its registered place of business. This situation was therefore considered unacceptable by the EU authorities, as it was seen as going far beyond that necessary to achieve health protection, as claimed by the Italian authorities. If no suitable change occurs within two months, the Commission may take the matter to the European Court of Justice.

**Professional Qualifications**

Estonia, Lithuania, Latvia and the Netherlands have been brought by the European Commission, to the European Court of Justice, for not having, promptly, announced their measures to transpose the Directive 2005/36/EC on the recognition of professional qualifications into State law. This directive aims to simplify the system of recognition of qualifications and thereby ease mobility within the internal market for qualified people moving to another Member State either to provide a service or to settle there permanently. The late transposition of this directive was, consequently, seen as harmful to the European labour market, which led the Commission to undertake measures against the referred countries.
Internal Market Proceedings

Reimbursements

Portugal and France were objects of an action brought by the European Commission, before the European Court of Justice, for requesting prior authorization of the reimbursement of non-hospital treatment received in another Member State, contrary to Article 49 of the EC Treaty. By demanding this authorization, the Commission believes Portugal and France are restricting patients’ rights and has, thus, decided to bring actions against these two Member States, before the Court. The Commission has also sent a reasoned opinion to Spain for having, likewise limited approval of reimbursement to prior authorization, even without having a proper system for issuing such authorizations. Also related to the same issues, Luxembourg was also subject of a reasoned opinion, by the Commission, for not having reimbursed their nationals for the costs of medical tests carried out in another Member State, which is deemed to be incompatible with the already mentioned Article 49 of the Treaty.

EC Communication on Patient Safety & Healthcare-Associated Infections

Healthcare-associated infections were recently at the centre of attention as the European Commission adopted a new Communication aiming to diminish the number of patients (an estimated 4.1 million) that annually suffer harm from the medical treatment they receive. According to the Commission, the increasing mobility of patients in Europe is leading to worrying situations of healthcare-associated infections, notably as microbes become more resistant and tend to spread faster throughout the continent. The Commission, hence, took measures to try to halt this situation. After a public consultation launched in 2005, it recently adopted a Communication and a proposal for a Council Recommendation on patient safety, including the prevention and control of healthcare-associated infections. In this document, the Commission notably suggests that the training of healthcare professionals include diseases caught during treatment as well as providing more information to patients on the risks of such diseases. These proposals also call for better prevention, control and reporting systems. According to the European Centre for Disease Prevention and Control (ECDC) preventative measures could lead to a 20-30% reduction of healthcare-associated infections. Recent reports from the ECDC unveiled that such infections were the most common type of problem associated with hospital care, followed by respiratory infections, surgical site infections and blood infections.

SHARE Releases Second Wave of Results

As a consequence of the ageing population in Europe, the European Commission under its Research Framework Programmes, has requested a survey intended to provide more data to researchers and policy makers in the field of public health, economics and social sciences, so that the ageing process can be dealt with appropriately in the fields of pension, healthcare and labour market policies. Data on life circumstances of around 35 000 Europeans aged 50 and over, in 15 countries (Sweden, Denmark, Germany, Netherlands, France, Italy, Spain, Greece, Belgium, Austria, Switzerland, Israel, Poland, the Czech Republic and Ireland), were collected and analyzed, leading to some unexpected conclusions: women live longer especially in South of Europe, but men are less sick, especially in the North; Northern European people eat less; the demise of the family is a myth; consumption inequality is much lower than financial inequality; there is a strong relation between health behavior and socioeconomic status. Having the highest proportion of older citizens of any continent worldwide, Europe has to be prepared to face this new challenge. The results released by SHARE will, definitely, be relevant to helping the EU deal with this complex issue.
VENUES

The 17th European Psychiatry Association Congress
24th - 28th January 2009 - Lisbon, Portugal
More Information on http://www2.kenes.com/epa/Pages/home.aspx

The 18th IOF Advanced Training Course on Osteoporosis
3rd - 5th February 2009 - Lyon, France

International Meeting on Emerging Diseases and Surveillance
13th - 16th February 2009 - Vienna, Austria

eHealth 2009 — “eHealth for Individuals, Society and Economy”
18th - 20th February 2009 - Prague, Czech Republic

International Conference on Rare Diseases and Orphan Drugs
23rd - 25th February 2009 - Rome, Italy

European Awareness Day on Rare Diseases
26th February 2009

2nd International Conference on Innovative Approaches in Head and Neck Oncology
26th - 28th February 2009 - Barcelona, Spain
More Information http://www.estro-events.org/ESTROevents/Pages/ICHNO.aspx

PUBLICATIONS

The 4th edition of the Journal of Continuing Education in the Health Professions has been released
More information on http://www.jcehp.com/

The European Agency for Safety and Health at Work published its 2007 Annual Report

CE Mesure, the Journal of Outcomes Measurements in Continuing Healthcare Education, has recently issued its December edition
More information on http://www.cemeasure.com/