



European Association of Hospital Pharmacists

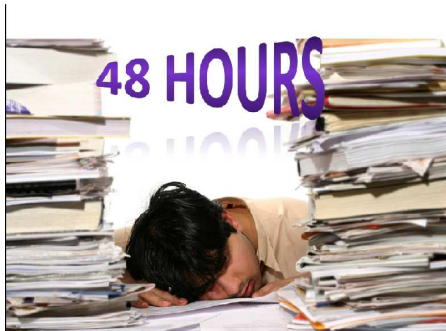


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EAHP wishes all its readers a very happy and healthy year 2009

I. European Parliament votes against the European Working Time Directive

Source: the EurActiv



The European Parliament (EP) on 17 December voted by 421 votes against versus 273 in favour (absolute majority) to scrap national opt-outs to the Working Time Directive and enforce an EU-wide maximum working week of 48 hours. The EP main positions are:

- end of the opt-out: the majority of Members of the European Parliament is in favour of a phase-out of the “opt out” option.
- any period of on-call time, including inactive time, must count as working time. Many governments and the European Commission favour the concept of "active" on-call time (a period during which the worker must be available at the workplace in order to work when required by the employer) and "inactive" on-call time (a period when the worker is on call but is not required by his employer to work).

The debate over EU rules on working hours has been provoking controversy and entrenched political polarisation in the EU since the first Directive was adopted in 1993. The latest round of votes and negotiations is no exception.

Those opposing the opt-out argue that it will lead to social dumping and will harm health and safety at work, as well as people's ability to reconcile work and family life. In the opposing camp, those favouring the opt-out argue that it increases flexibility in labour markets, particularly in difficult economic times. Business federations, in particular, have long argued that the opt-out is an important tool for companies to deal with fluctuations in demand.

Open Europe, a London-based think tank, estimates that ending the opt-out could cost the UK economy between £47.74 billion and £66.45 billion by 2020.

It is expected that UK Prime Minister Gordon Brown will not back down on the opt-out issue, despite the intriguing fact that a majority of Labour MEPs voted against their prime minister in yesterday's vote.

The Directive will now go to a conciliation committee, the 'last-chance saloon' of Council-Parliament negotiations. The Parliament enters negotiations from a position of strength. There are no guarantees a compromise will be found. In effect, this means that should the conciliation process fail, the current Directive with its present opt-outs will remain in place.

The issue is expected to be addressed by a conciliation committee in early 2009.

II. Patient Safety high on the European Commission's agenda



On 15 December 2008, the European Commission adopted a communication “on patient safety, including the prevention and control of healthcare-associated infections”, and a proposal for a Council Recommendation with specific actions that Member States can take, either individually, collectively or with the Commission, to improve the safety of patients.

The most common types of adverse events in healthcare are: healthcare associated infections (HCAI); incorrect or delayed diagnoses; surgical errors; and medication related errors. Most efforts to improve patient safety at Member State and EU levels have so far focussed on specific causes, for example, minimising the risk from medicinal products, medical devices or antimicrobial resistance. However, most adverse events are caused by a combination of factors which together result in harm to the patients.

Although the problem of patient safety is primarily the responsibility of Member States, the EU can encourage cooperation between Member States and support their actions in areas where EU intervention can have an added value.

This initiative intends to foster political commitment by Member States to make patient safety a priority in national public health objectives and to create a framework to stimulate policy development.

The EU sees it has a role to play in:

- collecting comparable and aggregate data at Community level, hence achieving economies of scale,
- disseminating best practice among the Member States to establish efficient and transparent patient safety programmes, structures and policies,
- facilitating mutual learning among Member States by developing a common “language” or “taxonomy” for patient safety and common indicators,
- providing political weight and visibility to patient safety.

The Commission Communication recommends a comprehensive approach to improving patient safety. Member States are encouraged to put in place and improve strategies to prevent and control adverse events in all healthcare settings. The primary focus is on addressing systemic and organisational failures responsible for most harm to patients.

Key recommendations for Member States include, for example:

- establishing or strengthening reporting and learning systems
- embedding patient safety in the education and training of healthcare workers
- involving patients in the development of safety measures and
- providing patients with relevant information on health risks and safety issues.

Member States are also encouraged to share best practice and expertise in this field. The Commission will work with Member States to develop common definitions and indicators for patient safety.

It is interesting to note that the Member States are advised to set up or improve comprehensive blame-free reporting and learning systems so that the extent and type and causes of adverse events are captured to enable resources to be efficiently channelled into developing solutions and interventions which can then be shared at the EU level. Such reporting on adverse events should be done in a constructive, rather than a punitive or repressive, manner so that healthcare providers feel confident that they can report without fear of negative consequences.

Regarding healthcare associated infections (HCAI), the Member States are recommended to:

- implement prevention and control measures to support the containment of HCAs
- enhance infection prevention and control at the level of healthcare institutions
- establish or strengthen active surveillance systems
- foster education and training of healthcare workers on infection and control
- improve the information given to patients and
- support research.

The communication:

http://ec.europa.eu/health/ph_systems/docs/patient_com2008_en.pdf

Proposal for a Council Recommendation:

http://ec.europa.eu/health/ph_systems/docs/patient_rec2008_en.pdf

III. No consensus on the Patients Rights to Cross Border healthcare found yet

Source: EurActiv and various



Despite some progress, EU health ministers meeting on 16 December 2008 in Brussels remained divided over the draft directive regarding the application of patients' rights to treatment in other Member States (see EUM, [issue 21](#))

The draft Directive adopted by the Commission on 3 July 2008 aims to improve cooperation between Member States and to provide legal certainty over patients' right to seek healthcare in another Member State.

Ministers focused their discussion on the first three chapters of the draft Directive. They reached general consensus on improving legal recourse for cross-border patients by codifying all the European Court of Justice's (ECJ) case law on the subject and linking it to a Regulation on the coordination of social security systems. Several ECJ rulings confirm that the EU Treaty gives individual patients the right to seek healthcare in other Member

States and be reimbursed for it at home, but uncertainty remains over how to apply the principles of that jurisprudence more generally.

The remaining stumbling blocks are the definition of “hospital” and “non-hospital” care and “specialised” care, as well as securing the principle of prior authorisation for care reimbursement.

Plans to ensure that patients are provided with adequate information was also discussed, with Member States expressing their preference for a provision allowing "informed choices" and enhanced cooperation between countries.

Small Member States, like Cyprus, reiterated that the Directive would put some health systems under strain, especially for long-term care. There has been much speculation as to whether the proposals will be considered at all or simply “thrown out” by the Council.

Several health NGOs also expressed their concern particularly in relation to fundamental principles around quality of care and patient safety. They called for the Directive to explicitly uphold the Council’s commitment to the values of universality, access to good quality care, equity, and solidarity. They also asked for the Directive to recognise the Commission’s role in taking the lead in ensuring the collection and availability of accurate information on key quality indicators across the EU. Finally, where prior authorisation for hospital care is adopted, NGOs say authorisation processes should be swift, transparent and underpinned by clear information for patients.

The European Data Protection Supervisor (EDSP) transmitted also his opinion on the draft Directive to the Council, in the view of the December Council discussions. While expressing his support for the initiative, EDPS called for better coordination of the European Commission healthcare initiatives with regard to data protection (ex. the forthcoming Directive on human organs donation and transplantation, the Recommendation on the interoperability of electronic health records, the Communication on Telemedicines). He suggested the Directive should feature a clear definition of “health data” which should include medical data, as well as administrative and financial data related to health. Lastly, he strongly recommended the introduction of a specific article on data protection, which should describe the responsibilities of the Member States of affiliation and treatment and identify main areas for future development.

The draft Directive will be likely discussed by ministers at the Employment, Social Affairs, Health and Consumer Affairs Council of 8-9 June 2009, under the Czech EU Presidency, after the European Parliament has issued its own opinion in spring 2009.

The draft Directive:

http://ec.europa.eu/health/ph_overview/co_operation/healthcare/docs/COM_en.pdf

IV. EU pharmaceutical package finally released



No information to patient on prescription drug in general printed press

On 10th of December 2008, the European Commission (EC) finally adopted a Communication and three legislative proposals forming the so called pharmaceutical package. The release of the European Commission pharmaceutical package (see EUM 23 and 24, [October](#) and [November 2008](#)) announced for 26th of November 2008 had been postponed several times.

Although the final proposals include major changes from their first drafts, controversies remain particularly on the provision of information to patients and on repackaging prescription drugs.

Regarding the former: the proposal on Information to Patients (ITP) allows pharmaceutical companies to publish information in health-related printed media (no more in all printed media), including health supplements, despite the fact that “advertorials” are known to be more influential than outright advertising. Article 100b gives pharmaceutical companies the possibility to present “the summary of product characteristics, labelling and the patient information leaflet of the medicinal product...in a different way” than is currently permitted under EU regulations. This is a redundant public health measure given that this information is already available on the European Medicines Agency (EMA) website for centrally approved products and on some national regulatory agencies websites for other products. The only real rationale for a change in the law is the commercial benefit of expanding the marketing reach for pharmaceutical companies operating in Europe.

Concerning fighting counterfeit, the plan to ban repackaging prescription drugs was removed from the original proposal on fighting counterfeit medicines - this favours parallel trade but raises concerns from the pharmaceutical industry. Parallel traders take advantage of the different prices of medicines between EU member states, buying up stocks in low priced countries and selling them on - at a discount - in countries where the price is higher. That practice requires the drugs to be repackaged to comply with the requirements of the destination country – for example the inclusion of a patient package insert in the correct language.

Commissioner for Trade and Industry Günter Verheugen seemed to favour a ban in recent months. But the parallel traders won a reprieve because of the impact on their businesses and the cost-savings afforded to EU healthcare systems through the use of parallel-traded medicines.

Groups such as the European Federation of Pharmaceutical Industry Associations (EFPIA) have argued that repackaging provides a weak link in the supply chain to allow the entry of counterfeit medicines, and had argued for a ban as part of a basket of anti-counterfeiting measures in the package.

The package:

http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/pharmpack_en.htm

V. European Commission releases a green paper on the European workforce for health



Employing pharmacists

On 10 December 2008, the European Commission (DG SANCO) released the green paper on the European workforce for health.

The paper will start a debate on the availability, mobility, financing and maximising the potential for health workforce in Europe.

This debate has been sparked by several factors, one being the movement of qualified professionals from east to west and from developing to developed countries (so called “brain drain”). Other factors include the ageing population, the increasing need for care as well as the raising retirement age and shortage of younger healthcare professionals.

Through the green paper, the Commission is asking stakeholders for their opinions and views on how to address the issues around European health workforce as well as posing the questions, is European level intervention needed?

The Commission’s consultation is open on the DG SANCO website:

http://ec.europa.eu/health/ph_systems/docs/workforce_gp_en.pdf.

The closing date for submission is 31 March 2009.

EAHP members are highly encouraged to answer this consultation to ensure that the potential shortage in hospital pharmacists is taken into account in the overall reflection the Commission is conducting on recruiting and retaining healthcare professionals.

VI. Limitations to pharmacy licences justified, says advocate general

Source: EuropeanVoice



A preliminary legal opinion delivered by the European Court of Justice (ECJ) on 16 December 2008 found that Member States can place limits on who may operate pharmacies in the EU, with the Advocate-general arguing that the EU's top court should uphold restrictions on pharmacy licences.

Yves Bot, the advocate-general, said that in his view German and Italian laws that prevent retail chains from operating pharmacies are justified. Bot argued that owners need to be qualified pharmacists and that the need to “protect public health” was more important than normal rules on the “freedom of establishment”.

The opinion, which serves as a form of external advice to the ECJ judges who will make the final ruling, is a setback for a number of larger European retail chains that hope to expand into the pharmacy businesses in countries where there are currently restrictions on who can own and

operate pharmacies. There are restrictions in roughly half of the 27-member EU, including some of its largest members: Germany, France, Italy and Spain.

This opinion is not binding but the ECJ, which will rule on the matter in early 2009, tend to uphold the advocate-general's opinion in a majority of the cases. Yves Bot was also the advocate general in the Case of European Commission vs. Federal Republic of Germany, C-141/2007 that advocated in favour of leaving the German law allowing German hospital to be serviced only by one external pharmacy as it was (see EUM 19, <http://www.eahp.eu/EAHP-EU-Monitor/Patient-safety-justifies-limitations-to-freedom-of-movements-of-goods-and-trade>)

VII. Czech Republic EU presidency priorities for health



On 1st of January 2009, the Czech Republic took over the rotating EU presidency for six months.

The Czech Republic is said to be Euro sceptic and observers seem to think that the health agenda will not be push forward under that presidency, as it was the case under its immediate predecessor, the French presidency.

The Czech Republic motto is “Europe without with barriers” and will focus on the competitiveness of Europe. In the field of health, the presidency has three priorities:

1. antibiotic resistance

The World Health Organisation and the e European Centre for Disease Prevention and Control recommended to the EU Member States to implement national programmes to control and prevent antimicrobial resistance, which is caused by excessive use of antibiotics and solved by measures preventing the spread of multi-resistant microbes.

Drawing on EU-funded health care projects, the Czech Republic will concentrate in particular on the draft standards for hospital antibiotic programmes aiming to reduce the danger of antibiotic resistance and nosocomial infections in order to enhance patients' safety and health care quality. Another goal is to recommend suitable models of support and funding of national antibiotic programmes by national governments and healthcare payers, especially health insurance companies.

A conference on the matter of microbial threat to patient safety is planned to take place in April 2009 (exact date and location to be précised)

2. financial sustainability of health systems

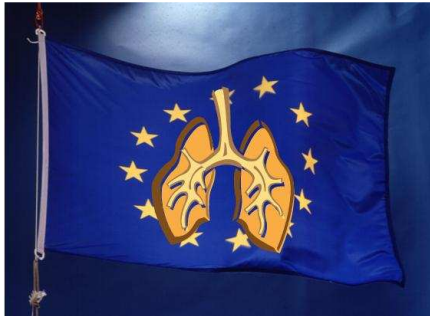
Together with the French and the Swedish Presidencies, the Czech Republic will concentrate on the financial impact of demographic changes and on the need for innovation, aiming to maintain a high quality of health service provision and to ensure access to these services. It will try to find more effective instruments to ensure the financial sustainability of the health systems. The goal of this priority is to promote the sharing of experience and exchange of information and to enhance communication among the Member States, which influence each other more and more in this area as a result of the free movement of persons, goods and services, while retaining their sovereignty. A conference on the subject is planned for May 2009 (exact date and location to be announced).

3. electronic integration of health services and the interoperability of information systems in the health sector (e-Health).

EAHP will closely monitor the progress made by the Czech Republic presidency in the above mentioned fields and will suggest actions or reflections when and where needed.

VIII. Commission adopts a Directive and an action plan for European organ donation

Source: European Commission



On 8 December 2008, the European Commission adopted important safety and quality measures for organ donation and a 10 point action plan to work with Member States on strengthening organ donation and transplantation systems in Europe. There are currently 56,000 patients waiting for a suitable organ donor in the EU. It is estimated that every day 12 people die while waiting for transplantation.

The Directive and Action Plan address three key challenges: (i) improving the quality and safety of organs across Europe, (ii) increasing organ availability and (iii) making transplant systems more efficient and accessible.

The Directive provides a legal framework for organ donation and transplantation in the European Union. In every Member State a national competent authority will be created or designated to ensure compliance with EU quality and safety standards. These standards include establishing a traceability system of human organs and a reporting system of serious adverse events and reactions. To facilitate exchange of human organs, data collection on specific organ characteristics will be standardised. Finally, national quality programmes will ensure continuous monitoring of performance and result in improved processes and learning. The goal of this Directive is to minimise the risk for the organ transplant recipient, to improve and optimise the allocation of organs across the European Union and to provide the transplant surgeon with the necessary information to make the best choice.

Ten point Action Plan

The Action Plan is a 6 year (2009-2015) plan with 10 priority actions addressing the 3 key challenges in organ donation and transplantation in Europe. The Action Plan aims to stimulate joint actions and facilitate coordination with Member States. This will be achieved through different mechanism such as exchanging good practice or creating EU wide agreements on specific topics. For example, one priority area is improving the knowledge and communication skills of health professionals and patient support groups on organ donation. A second key area is the exchange of experiences on the use of Transplant Donor Coordinators to increase the number of available organs.

The Directive and 10 action plan:

http://ec.europa.eu/health/ph_threats/human_substance/organs_en.htm

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Comments and suggestions are welcome: ed@eahp.eu

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