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Council Still Disagreeing on Working Time Directive

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The Employment Council meeting in Luxembourg on 2 June 2005 has been unable to reach agreement on the draft working time directive (see IM, issue 2/2005), and no vote was taken on the proposal. The proposal put to ministers was already an attempt at a compromise on the controversial opt-out clause. The Commission's proposed middle way, put forward at the beginning of June, involved the continuation of the opt-out for three years after implementation of the directive, i.e. until 2012. This, however, was still not acceptable to the UK, which regards the opt-out as crucial to economic competitiveness. The regulation currently in force will therefore remain in place and the matter is likely to carry on into 2006.

Commission Consults Public to Improve Medical Devices Legislation

The European Commission recently invited the public to comment on its draft proposal to amend the rules on medical devices and on active implantable medical devices. Medical devices comprise any instrument, appliance, software, etc. used for the purpose of disease prevention (e.g. vaccinedelivery devices), screening (e.g. mammography for breast cancer), diagnosis (e.g. ultrasound system) or treatment or alleviation of disease. The European Community's involvement concerns mainly the regulatory framework for market access, international trade relations and regulatory convergence, and the competitiveness of industry.

At present, medical devices are regulated under three main Directives covering, respectively, active implantable medical devices, medical devices and in vitro diagnostic medical devices. Due to technical differences between the three directives, the Commission has decided against a merger of the directives.

Better regulation should be achieved through regulatory clarifications to ensure consistency of interpretation and implementation. For example, the proposed amendments are intended to improve:

• clinical evaluation, through clarification of the requirements,

• post market surveillance, to increase transparency for the general public,

• consistency between the medical devices and the active implantable medical devices directives,

• the decision-making process, by allowing binding decisions in case of conflicting national interpretations on whether or not a product is a medical device.

In a next step, the Commission will evaluate the comments it has received and prepare a legislative proposal.

European E-Health Conference – Tormso (Norway) 23-24 May

Health ministers and IT experts from across Europe met in the Norwegian town of Tromso on 23 and 24 May to debate how the potential of 'eHealth' could be realised. The event also encompassed an exhibition of best practices in healthcare drawn from across Europe. Some examples of presented success stories from European research in eHealth included:

Advance in the State of the Art in Magnetic Resonance Imaging

The EU research project 'AMIT' has delivered prototypes of an 'electron spin measurement system (ESR)' which considerably advances the state of the art in magnetic resonance imaging (MRI) for keyhole surgery. Such minimally invasive surgical techniques require a means of 'seeing' inside the patient so that the surgical instrument used can be placed very precisely and reliably. The project has already led to a small spin-off company – 'Neagen Oy' - being set up in Finland, to market the technology. More information is at: http://dbs.cordis. lu/fep-

cgi/srchidadb?ACTION=D&CALLER= PROJ_ IST&QM_EP_RCN_A=58082.

Czech Republic - The Picture Archiving and Communication System

All major hospitals and healthcare institutions in the Czech Republic can use services provided by Regional (formerly Metropolitan) Picture Archiving and Communication System operated by Masaryk University. These include the consultation of images (x-ray, ultrasound, mammography etc.), a fast and accessible electronic storage system, and broadband communication facilities for consultation between radiologists (to obtain a second opinion or image diagnosis by specialists from a distant hospital etc.)

More information is at: www.telemedicinabrno.cz

Denmark - Health Data Network

Denmark's Health Portal now enables all citizens that have a recognised digital signature (OCES) to review their own health data (i.e. their complete electronic medical file) and to communicate with their own doctor (e.g. for appointment booking). Equally, healthcare professionals can search for information on their patients using the Health Portal. Similar networks exist in Norway and Sweden and the next step is to create a cross-national Baltic Health Network (BHN), using EU funding. Two hospital networks from Lithuania and Estonia will also be connected. The objective of BHN is to remove the technical barrier for collaboration between health professionals and, when operational in August 2005, the BHN will be the only cross-national health network in Europe.

More information is at: www.cfst.dk

Later this year the Commission will launch an EU Public Health Portal. The Portal will provide a 'one stop shop' for health information produced by the EU and EU agencies and be a gateway to websites of national and regional health authorities and civil society groups in the health field.

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