"The voice of SMEs in Europe"

Press Release

FOR IMMEDIATE ISSUE

Medical Devices Directive: is patient safety a priority for the Parliament?

- **"Statement of conformity" including all manufacturing sites must be provided to patients**

Brussels, 27 March 2007. UEAPME, the European craft and SME employers' organisation, called on the European Parliament to reinsert rules on patient information and safety ahead of the plenary vote on the revised "Medical Devices Directive" on Thursday. The compromise text seen by UEAPME could seriously endanger both the quantity and the quality of the information given to patients on important aspects such as safety conformity and manufacturers' details.

According to the Directive, all custom-made medical devices can be put into service and placed on the market if they meet a number of safety conditions and are accompanied by a statement of conformity. Both the original Commission proposal and the text approved earlier by the Parliament's Environment Committee stipulated that a copy of this statement must be provided to patients. Unfortunately, this clause could be deleted by the plenary vote on Thursday. UEAPME strongly criticised the last-minute amendments removing this very important passage, and called on MEPs to support patient information by rejecting them.

"European patients rely heavily on the functioning and quality of medical devices such as dental and other prostheses, orthopaedic footwear or hearing aids", said **Oliver Loebel**, UEAPME Director for Sectoral Policies and Coordinator of the UEAPME Healthcare Forum. *"It is unrealistic and irresponsible to limit the amount of information provided to patients on such devices. For instance, a dental prosthesis can be fitted in a patients' mouth for decades – it is a matter of common sense and a basic right for the patient to know where and by whom it was made, what materials were used and whether it complies with safety standards"*, he went on to explain.

UEAPME also insisted on the need to broaden the scope of the statement of conformity. According to the current Directive, the statement will only indicate one manufacturers' name, which is not necessarily the initial maker in case of imported medical devices. UEAPME invited the Parliament to maintain the position of the Environment Committee and clarify that all manufacturing sites must be explicitly mentioned if more than one company is involved in the process.

"Transparency, traceability and patient safety are high on the agenda of the EU, and the European Commission will soon publish its proposals on patient rights and information. We call on the European Parliament to follow the same line and vote in favour of transparency and safety", concluded Mr Loebel.

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EDITORS' NOTES: UEAPME is the employers' organisation representing crafts, trades and SMEs from the EU and accession countries at European level. UEAPME has 81 member organisations, which represent crafts and SMEs across Europe, covering over 11 million enterprises with 50 million employees. UEAPME is a European Social Partner.

The UEAPME Healthcare Forum brings together European representatives from almost 100.000 manufacturers of custom-made medical devices such as dental and other prostheses, orthopaedic footwear, hearing aids and spectacles. Participants include experts from European healthcare associations, national SME associations and NORMAPME. The Forum sends experts to the EU Medical Devices Expert Group that monitors the implementation of the Medical Devices Directive, and to the CEN Healthcare Forum in charge of European standardisation in this sector.

Further information: Oliver Loebel, Director for Sectoral Policies, Tel. +32 2 230 7599

Francesco Longu, Press and Communications Officer
Email: pressoffice@ueapme.com Web: www.ueapme.com/pressroom/