



FEPPD
Press Release

FOR IMMEDIATE ISSUE

Is patient safety a priority for the Parliament?

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

Brussels, 28 March 2007. FEPPD, representing independent dental technicians and laboratory owners 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 FEPPD 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. FEPPD strongly criticised the last-minute amendments removing this very important passage, and called on MEPs to support patient information by rejecting them.

*“The recent change has weakened the proposal to almost irrelevant. **Should be available** is unlikely to achieve the aim to make the whole process transparent with the patient. European patients rely heavily on the functioning and quality of medical dental devices”,* said Jürgen Schwichtenberg, President of FEPPD. *“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.

Custom-made medical devices rely on a professional to manufacture the correct appliance out of safe, state of the art materials and techniques to manufacture appliances, which are fit for purpose. Transparency from manufacturer through the prescriber to the patient is the only way to ensure informed choice and traceability.

FEPPD 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. FEPPD 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.

Patient safety, transparency and traceability 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 .

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FEPPD The European and international organization of independent dental technicians and laboratory owners (FEPPD), is representing +/- 40.000 dental laboratories and 210.000 dental technicians.

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