



“The voice of SMEs in Europe”

Press Release

FOR IMMEDIATE RELEASE

UEAPME wants regular third party audits for manufacturers of custom-made medical devices

Brussels, 07th July 2003. The European SMEs association’s –UEAPME- Healthcare Forum, deplores the European Commission’s failure to present solutions concerning the lack of consistent controls on manufacturers of custom made medical devices in its recently published Communication on medical devices. UEAPME’s Healthcare Forum, which unites small and medium-sized manufacturers of external custom-made medical devices, calls for more independent and systematic controls of EU and non-EU manufacturers.

The current absence of regular controls in Member States allows an uncontrolled influx of low quality imports that jeopardises product quality and the image of the entire custom made medical devices industry. Furthermore, the lack of control represents a potential risk for the customers who are not aware if the devices they are using abide with elementary safety rules. “The main victims of this system are the patients, who have medical devices fitted and are given no knowledge of where the device was manufactured or if it conforms to the medical devices directive” said **Jan Ebbink**, chairman of the Healthcare Forum.

A survey conducted by FEPPD, the European association of dental technicians, raises some alarming findings. A UK dental laboratory is only likely to be inspected by its competent authority once every 25 years. Their German counterparts have to wait up to 125 years to see their inspectors. A similar survey by INTERBOR, the international association of prosthetists and orthotists confirmed these results.

The Healthcare Forum had proposed the application of rules that are similar or close to those applied to other medical devices to custom-made devices. The Healthcare Forum, therefore urges the Commission to either oblige Member States to guarantee annual inspections of all manufacturers by competent authorities, or move towards a system of conformity assessment by notified bodies on the basis of adapted quality assurance systems.

The European Database on Medical Devices - EUDAMED - must include custom-made medical device manufacturers and be publicly accessible to allow patients to verify whether the supplier and his medical device are properly registered. "Patient protection is the primary goal of the medical devices directives. This must also apply to custom-made devices", Ebbink concluded.

***** End *****

Note to editors: For further information, please contact Oliver Loebel on tel +32 2 230 7599

Raphael Anspach, Press officer
Tel: +32 2 230 7599/ Fax: +32 2230 7861
Email: pressoffice@ueapme.com
Web: www.ueapme.com/pressroom