



HEALTHCARE FORUM¹

POSITION
of the
UEAPME NORMAPME Healthcare Forum
regarding the suggestion to modify the Commission proposal relating to
ANNEX VIII of
Proposal for a Directive amending Council Directive 93/42/EEC of 14
June 1993 concerning medical devices

CONTEXT:

- On 13 March 2006, the UEAPME NORMAPME Healthcare Forum submitted detailed comments on the above draft directive with a particular focus on custom-made devices. At a number of meetings with the Commission services concerned, the Forum clearly opposed to the introduction of a compulsory quality management system for custom-made devices manufacturers.
- On 1 June 06, the European Commission requested FEPPD's comments on the idea to modify to Commission proposal relating to ANNEX VIII 2.1. In fact, the Commission enquires about our acceptance of to remove the intend “-name and address of the manufacturer and any additional manufacturing site” and put a new obligation in section 3 requiring to indicate on the statement the name of the person, who put the product on the market.
- FEPPD transmitted this question to the UEAPME NORMAPME Healthcare Forum to be able to give the European Commission a wider view on this matter.

POSITION:

- The UEAPME NORMAPME Healthcare Forum **strongly opposes** this proposal and presses the European Commission to maintain the wording of the draft revised directive 93/42. The reasons for you position are already outlined in our position paper dated 13 March 06 and can be summarised as follows:

¹ The UEAPME NORMAPME Healthcare Forum brings together European representatives from almost 100,000 manufacturers and dealers of custom-made medical devices (CMMD) from all EU Member States and beyond. The overwhelming majority of these manufacturers are small enterprises.

- The aim of directive 93/42 clearly is highest **patient safety**. If the Commission and the European legislators want to take this goal seriously, they must ensure the **respect of the directive by all supply chain members** as well as **highest transparency** and **traceability** in the supply chain. The European Union and national governments must respect the patient's right to receive accurate information so that he\she can make informed choices regarding their treatment.
- The agent who puts the custom made device (CMD) on the market does not know whether the CMD supplier is really the manufacturer or what parts / components were provided by other subcontractors. Unless all manufacturing sites are indicated on the Statement, traceability is not possible. However, traceability is one of the directive's major goals.
- The agent who puts the CMD on the market does not know how exactly the device was manufactured and what components / materials were used. Only the manufacturer disposes of this information. In the case of an emergency, it is therefore indispensable to have direct access to the manufacturer.
- The patient should have the right to know whether the CMD manufacturer is registered and therefore likely to comply with the directive's requirements. The UEAPME NORMAPME Healthcare Forum has therefore welcomed the revised article 20 (2) lifting confidentiality from certain information. However, if the manufacturers' name is not indicated on the Statement, the patient will be unable to verify. Who should have an interest to withhold this information from the patient?
- The draft revised directive includes a new section 5 in Annex VIII introducing a post market surveillance system. The UEAPME NORMAPME Healthcare Forum can, in principle, agree to this proposal although it will increase the administrative burden particularly for small enterprises. We believe this system will help decrease risks for the patient. The implementation of post market surveillance systems should be controlled as part of the regular checks proposed under article 11 (6). It must be stressed once again that, unless such regular checks are carried out, major parts of this directive (including the post market surveillance system) are unlikely to be equally applied in all Member States and internationally (for imports). This would not only negatively affect patient safety but also distort competition to the detriment of those manufacturers who comply with all the rules.
In other words, what is the purpose of this new section 5, if one does not even know who the manufacturer is? How can public authorities proceed with checks of CMD manufacturers if the system remains opaque? Again, who should have an interest in maintaining opacity?
- The Commission proposal is **simple and effective**. Additional administrative burdens are negligible. **ALL additional efforts lie with the CMD manufacturer, as he has to issue the Statement**. The UEAPME NORMAPME Healthcare Forum as the representative of this group of enterprises accept this additional responsibility for the sake of patient safety.

CONCLUSION:

- The UEAPME NORMAPME Healthcare Forum urges the European Commission to maintain the wording of the draft revised directive.
- The **Statement must be passed on to the patient and must include the name and address of the manufacturer and any additional manufacturing site**.

Brussels, 9th June 2006