



HEALTHCARE FORUM¹

COMMENTS
of the
UEAPME NORMAPME Healthcare Forum
regarding the
Proposal for a Directive amending Council Directive 93/42/EEC of 14
June 1993 concerning medical devices

General comments

- The UEAPME NORMAPME Healthcare Forum has taken note of the draft amended Directive.
- Whilst member businesses have always expressed their overall satisfaction with directive 93/42/EEC, certain clauses had lead to problems for custom made devices (CMD) manufacturers and seriously jeopardised patient safety.
- It is noted with satisfaction that the draft revised directive proposes a number of amendments to remedy the situation.
- As outlined below, certain provisions still need adaptation to ensure patient safety and a level playing field for small manufacturers.

Specific comments:

Article 1, paragraph 2, (i) point (a) Definition of “medical device”

The UEAPME NORMAPME Healthcare Forum welcomes the definition’s extension to include modern IT tools (software) and integrate new market and technological developments. Manufacturers of custom-made devices are also increasingly using software to recognise or supervise special handicaps. Electronic audio tests are just one example.

Article 1, paragraph 6 (deleted)

The deletion of article 1 (6) clearly finds our support. Especially ear moulds produced by hearing aid manufacturers for ear and noise protection serve as disease prevention. At the same time, they serve as a means of relief for handicaps in the sense of article 1. By removing article 1 (6), current uncertainties could be overcome.

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.

Article 4 (2), second intent

The UEAPME NORMAPME Healthcare Forum strongly supports the amendment requiring the statement to be passed on to the patient. This will clearly improve transparency and patient safety. Patients will know the name and address of the manufacturer and, in line with Annex VIII, have a detailed description of the device and information relating to its use and storage. This enables the system of traceability and, by this means, significantly improves patient safety.

Current situation

The current situation has led to numerous problems. In some EU countries, the advice given by Competent Authorities requires manufacturers or agents to pass on the statement to the prescriber and not the final user, the patient. Since CMD are not CE marked, patients are not given any information about the manufacturer, the CMD, and whether the device meets the essential requirements of the directive.

UEAPME has information highlighting the rapid increase in CMD coming from outside the EU. This work is often placed on the market by persons who have not even registered with a Competent Authorities in their country. This has led to the following situation:

- Agents are ignoring the MDD believing nobody bothers to enforce it;
- EU manufacturers work at an economic disadvantage to non-EU because they have to comply with the relevant directives;
- Patient's health is at risk because materials may be used that don't meet the essential requirements. The manufacturer himself is the only person who is able to document the manufacturing process (use of CE marked components, instructions for use). No other member of the supply chain is able to provide this, and should therefore not be allowed to issue statements of conformity;
- Patients are not provided with any information about their CMD.

Article 11, point (6)

Urgent action needs to be taken to put in place regular inspections of CMD manufacturers, as they already exist for other medical device manufacturers. All surveillance activities should be managed by the competent authorities. Ireland has clearly demonstrated that it is possible to run such a system effectively. This is the only way to allow an effective and harmonised application of the MDD in all Member States (and hence guarantee quality and patient safety) and, at the same time, avoid excessive administrative burdens or extra costs for CMD manufacturers. It should be recalled that most of them are micro-businesses.

Commission proposal	UEAPME NORMAPME
<p>6. In the case of custom-made devices, the manufacturer shall follow the procedure referred to in Annex VIII and draw up the statement set out in that Annex before placing each device on the market.</p> <p>Member States may require that the manufacturer shall submit to the competent authority a list of such devices which have been put into service in their territory.</p>	<p>6. In the case of custom-made devices, the manufacturer shall follow the procedure referred to in Annex VIII and draw up the statement set out in that Annex before placing each device on the market.</p> <p>Member States may require that the manufacturer shall submit to the competent authority a list of such devices which have been put into service in their territory.</p> <p><i>Member States will take measures so as to ensure that the manufacturer is periodically controlled by the competent authorities. The intervals shall not exceed five years.</i></p>

Justification of this proposal

- According to directive 93/42/EC, custom-made medical devices (CMD: dental prostheses, spectacles, orthopaedic footwear, orthopaedic prostheses, audioprotheses etc.) are class I and class II products, but are only subject to a declaration of conformity from the manufacturer (art. 11). CE marking is not required (art. 17).

- While compliance of all other medical devices is checked by notified bodies, a derogation applies to CMD. In their case, competent authorities should verify the compliance of manufacturers with the Directive's requirements.
- However, practical experience shows an alarming situation. Statistically, a German dental laboratory is only checked by its Competent Authority once every 125 years. Although the figures are somewhat less dramatic for the UK with one check every 25 years, the situation clearly demonstrates the failure of the conformity assessment scheme for CMD. The rigour of the compliance check differs considerably throughout the EU and is non-existent for laboratories outside the EU.
- This lack of regular consistent checks leads to a number of dangerous consequences:

Product quality:

The increasing financial pressure from health insurance systems bears the risk of a shift from quality to the lowest price. The absence of compliance checks facilitates and encourages this development.

Patient safety:

The increased pressure on prices along with the lack of compliance checks jeopardises patients' safety. Particular risks arise from the use of cheaper, but more hazardous materials. As regards dental prostheses, hazards arise from devices using alloys, which contain beryllium, nickel, polymers or cadmium.

Additional negative effects can be found in the fields of the suitability of CMD for the patient and the durability of the product.

Unfair competition:

The current system disadvantages the manufacturers who bear the cost of complete compliance with the directive's requirements. Furthermore, it allows an uncontrolled influx of imports which, in a number of cases, are known to fail to comply with the legislation. Consequently, tens of thousands of highly qualified jobs in the EU have already disappeared over the past few years and this process is far from over.

Article 14

The UEAPME NORMAPME Healthcare Forum had repeatedly invited the European Commission to work towards the inclusion of CMD in the Eudamed database. However, a new Article 14 (4) of the initial draft revised directive was explicitly excluding CMD. It is clearly welcomed that this initial amendment does not appear in the draft revised directive.

The UEAPME NORMAPME Healthcare Forum wishes to emphasise the importance of allowing the patient to access certain information he is entitled to have. This must also include CMD. Health-related information is amongst the most frequently asked questions. For the benefit of the patient, both healthcare services and health-related information need to be on his / her disposal. Transparency will increase safety levels and reduce health risks for the patient.

Workable solutions for CMD already available

We insist on the fact that databases based on harmonised nomenclatures for CMD already exist and could be easily used for a European system. As a matter of example, Italy is using such a database including all CMD manufacturers and types of CMD manufactured. This document is published and can also be consulted on the internet by all interested parties.

Sweden has also introduced a system including CMD.

INTERBOR - the International Association of Orthotists and Prosthetists - has developed a complete nomenclature on the basis of all relevant ISO and CEN standards and WHO guidelines. This nomenclature could thus easily be adjusted to the Global Medical Device Nomenclature.

Why is the exclusion of CMD dangerous?

The CMD market is a multibillion Euro market with increasingly global dimensions. Most devices are used over a very long period of time. Dental prostheses, for example, are permanently fitted within the oral cavity, some are implanted into teeth and bone and may be in use for a lifetime.

As already outlined above, for reasons of health and safety, the patient should be able to verify whether his CMD was made by an authorised manufacturer. If this is not possible and, in addition, the CMD manufacturers are not properly checked, then the Directive's basic objective to ensure consumer and patient protection, becomes an empty phrase. To exempt such a large part of devices from the database means that political decision makers accept to potentially putting the consumer at risk.

The UEAPME NORMAPME Healthcare Forum invites the European Commission to launch a real dialogue with the CMD manufacturers with a view to integrating CMD in the Eudamed database.

Article 20, paragraph (2)

The new paragraph (2), lifting confidentiality from certain information, responds to a demand of the UEAPME NORMAPME Healthcare Forum. It will significantly extend patients' rights, as they will be enabled to find out if the manufacturer or agent is registered with their Competent Authority.

However, in the case of CMD, the system will only work if two conditions are met:

- The amended Article 4 (2), second intent is approved. In other words, the patient will really receive the statement and, hence, know the name of the manufacturer / agent.
- With article 20 referring to Eudamed, CMD must not be excluded from that database.

Annex I, Section 13.3, point (b)

This point refers to an "internationally recognised generic medical device nomenclature". However, such a nomenclature does not exist for CMD today. Moreover, CMD manufacturers are not involved in the works of the European Commission's Global Harmonisation Task Force. It would therefore be impossible for CMD manufacturers to comply with these provisions.

As already outlined above, independent nomenclatures already exist for certain CMD such as orthotic and prosthetic devices: They are based on all relevant ISO and CEN standards and WHO ICF guidelines and can therefore be easily integrated in the Global Medical Device Nomenclature. The following phrase should be added to point (b):

Commission proposal	UEAPME NORMAPME
“(b) the details strictly necessary for the user to identify the device and the contents of the packaging including the respective code of an internationally recognized generic medical device nomenclature;”	(b) the details strictly necessary for the user to identify the device and the contents of the packaging including the respective code of an internationally recognized generic medical device nomenclature. <i>The European Commission shall ensure that all medical devices are integrated in this nomenclature.</i>

Annex VIII, Section 2.1.

As already outlined above, the patient should have the right to know who produced his / her CMD. The new requirement to indicate “the name and address of the manufacturer and any additional manufacturing site” on the statement is therefore to be strongly welcomed. As outlined in the amended article 4 (2), the statement must be passed on to the patient. Otherwise, there would be no tangible improvements for the patient.

It is also strongly recommended, that the invoice be delivered to the patient along with the statement, as it is already required in a number of Member States. Again, this would increase transparency as the patient would know the original cost of the CMD. In practice this will help control overall costs to be borne by the patient and / or the health insurance system (see also comments on annex VIII, section 2.1.). Equivalent systems should be recognised.

Example:

In Austria, patients are regularly informed by their health insurance company as to the cost of medical services and devices it has paid for them.

Commission proposal	UEAPME NORMAPME
2.1. for custom-made devices: <ul style="list-style-type: none">• <u>the name and address of the manufacturer and any additional manufacturing site,</u>• data allowing identification of the device in question,• a statement that the device is intended for exclusive use by a particular patient, together with the name of the patient,• the name of the medical practitioner or other authorized person who made out the prescription and, where applicable, the name of the clinic concerned,• the particular features of the device as specified in the relevant medical prescription,• a statement that the device in question conforms to the essential requirements set out in Annex I and, where applicable, indicating which essential requirements have not been fully met, together with the grounds;	2.1. for custom-made devices: <ul style="list-style-type: none">• <u>the name and address of the manufacturer and any additional manufacturing site,</u>• data allowing identification of the device in question, including the price,• a statement that the device is intended for exclusive use by a particular patient, together with the name of the patient,• the name of the medical practitioner or other authorized person who made out the prescription and, where applicable, the name of the clinic concerned,• the particular features of the device as specified in the relevant medical prescription,• a statement that the device in question conforms to the essential requirements set out in Annex I and, where applicable, indicating which essential requirements have not been fully met, together with the grounds;

Annex VIII, Section 2.1. (German version)

The German version of annex VIII, point 2.1, forth point, is in contradiction with Article 1 (d) of the directive. This article states: “*Die oben genannte Verordnung (for a custom-made device) kann auch von jeder anderen Person ausgestellt werden, die aufgrund ihrer beruflichen Qualifikation dazu befugt ist.*”

However, annex VIII, point 2.1, forth point, speaks only of prescriptions made out by medical practitioners (*ärztliche Verordnung*). This ambiguity should be removed in line with the other language versions by using the term applied in article 1d (“*schriftliche Verordnung*”).

Commission proposal	UEAPME NORMAPME
2.1. bei Sonderanfertigungen: ... — die spezifischen Merkmale des Produkts, die sich aus der betreffenden ärztlichen Verordnung ergeben; — die Versicherung, daß das betreffende Produkt den in Anhang I genannten grundlegenden Anforderungen entspricht, und gegebenenfalls die Angabe der grundlegenden Anforderungen, die nicht vollständig eingehalten worden sind, mit Angabe der Gründe.	2.1. bei Sonderanfertigungen: ... — die spezifischen Merkmale des Produkts, die sich aus der betreffenden schriftlichen Verordnung ergeben; — die Versicherung, daß das betreffende Produkt den in Anhang I genannten grundlegenden Anforderungen entspricht, und gegebenenfalls die Angabe der grundlegenden Anforderungen, die nicht vollständig eingehalten worden sind, mit Angabe der Gründe.

Alternatively, the forth point of annex VIII (2.1) could be extended in accordance with article 1 (d):

Commission proposal	UEAPME NORMAPME
2.1. bei Sonderanfertigungen: ... — die spezifischen Merkmale des Produkts, die sich aus der betreffenden ärztlichen Verordnung ergeben; — die Versicherung, dass das betreffende Produkt den in Anhang I genannten grundlegenden Anforderungen entspricht, und	2.1. bei Sonderanfertigungen: ... — die spezifischen Merkmale des Produkts, die sich aus der betreffenden ärztlichen Verordnung ergeben. Diese Verordnung kann auch von jeder anderen Person ausgestellt werden, die aufgrund ihrer beruflichen Qualifikation dazu befugt ist.

gegebenenfalls die Angabe der grundlegenden Anforderungen, die nicht vollständig eingehalten worden sind, mit Angabe der Gründe.	— die Versicherung, dass das betreffende Produkt den in Anhang I genannten grundlegenden Anforderungen entspricht, und gegebenenfalls die Angabe der grundlegenden Anforderungen, die nicht vollständig eingehalten worden sind, mit Angabe der Gründe.
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Annex VIII, Section 4.

The amended provision is likely to lead to significantly higher burdens for CMD manufacturers. Today, they have to keep all relevant information for at least five years. The new proposal extends this requirement to the “intended lifetime of the product”, which can easily go beyond 10 years. Keeping records over such a long period takes up a lot of additional space and is therefore very onerous, particularly for small businesses. None of the UEAPME NORMAPME Healthcare Forum was able to report cases demonstrating the necessity to keep records over a period above five years. On the other hand, it is difficult to exactly determine the “intended lifetime of the product as defined by the manufacturer”, as it strongly depends on the intensity of use. The manufacturer offers a guarantee, which is usually considerably below five years. The intended lifetime may lead to confusion at national level, as health insurance companies may use this to determine the period in which a patient could receive (or be refused) refund for a new device.

Hence, the UEAPME NORMAPME Healthcare Forum proposes that the five-year period should be maintained.

Commission proposal	UEAPME NORMAPME
Par. (d) Section 4: The information contained in the declarations concerned by this Annex should be kept for a period at least <i>equivalent to the intended lifetime of the product as defined by the manufacturer but not less than</i> five years from the date of manufacture.”	Par. (d) Section 4: The information contained in the declarations concerned by this Annex should be kept for a period <i>of</i> at least five years from the date of manufacture.”

Annex VIII, Section 5. (new)

The UEAPME NORMAPME Healthcare Forum can, in principle, agree to the post market surveillance system for CMD introduced in this section. Without any doubt, the system will help decrease risks for the patient.

Still such a system will require a significant administrative effort from the manufacturers’ side. Again, costs are likely to be relatively higher for small enterprises. The Forum therefore calls on the legislator to avoid unnecessary red tape and keep the system as simple as possible.

The implementation of post market surveillance systems should be controlled as part of the regular checks proposed under article 11 (6) (see above). 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.

Brussels, 13th March 2006