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Position Paper

of the German Hospital Federation, Berlin

and

the National Associations of Social Health Insurance Funds

**Federal Association of Local Health Insurance Funds(AOK), Bonn
Federal Association of Company-based Health Insurance Funds (BKK), Essen
Federal Association of Guild Health Insurance Funds (IKK), Bergisch-Gladbach
Maritime Health Insurance Fund, Hamburg
National Association of Agricultural Workers Health Insurance Funds, Kassel
National Miners Insurance Fund, Bochum
Federation of Salaried Employees Health Insurance Funds (VdAK), Siegburg
Federation of Workers' Alternative Health Insurance Funds (AEV), Siegburg**

on the EU Commission Proposal COM(2005) 681

**for the Amendment of Directive 93/42/EEC
on Medical Devices**

I. Comments on the legislative scope of the Directive with respect to the reprocessing of medical devices

Council Directive 93/42/EEC on medical devices is currently undergoing review. In May 2005, a draft proposal for amending this Directive was published for public comment on the homepage of the European Commission. The official COM proposal for the revision of the medical device directive, COM(2005) 681, has since been published.

The proposed directive has re-kindled the controversy surrounding the processing of so-called "single use" medical devices. The controversy revolves around two main issues:

- Should the reprocessing of so-called "single use" medical devices be made subject to more detailed regulation at the EU level?
- Should the reprocessing of so-called "single use" medical devices be prohibited at the EU level?

The medical device reprocessing industry calls for more detailed regulation of medical device reprocessing in the amendment of Directive 93/42/EEC, while the medical device manufacturers demand a general prohibition on the reprocessing of medical devices.

The German Hospital Federation and the national associations of social health insurance funds reject both demands.

- Neither Directive 93/42/EEC nor the draft amendments to this Directive contain detailed requirements for the reprocessing of medical devices. However, the Directive does specify the essential safety requirements that a manufacturer must fulfill in order to place a medical device on the market. These requirements can also include specifications on the appropriate reprocessing methods. In addition, manufacturers must perform additional conformity assessment procedures for sterile medical devices as part of the quality insurance for their products and their production processes.
- The German Hospital Federation and the national associations of the social health insurance funds are of the opinion, like the European Commission, that a more detailed regulation regarding the reprocessing of so-called "single use" medical devices goes beyond the scope of the EU directives. Rather, it is a regulatory responsibility of the Member States alone. In 2004, then Director-General Enterprise of the European Commission, Mr. Jean-Paul Mingasson, confirmed this position and emphasized that the Commission neither planned to develop detailed requirements for the reprocessing of medical devices nor sought legal responsibility at European level. The European Commission in the current discussion confirmed this position.
- There is no need for the EU to seek regulatory authority for the reprocessing of medical devices on the grounds of patient safety. National requirements already ensure that there is no increased risk to patients. The reprocessing of medical devices is regulated in Germany by the Medical Devices Act, the Medical Devices User Ordinance and in the recommendations on the "Hygienic Requirements for

the Reprocessing of Medical Devices” of the Commission for Hospital Hygiene and Infectious Disease Prevention of the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices. In principle, a medical device cannot be placed on the market, operated or used if there are reasonable grounds to assume that it poses a threat to the safety and health of patients, users or third parties. This requirement is supplemented by the recommendation of the RKI, which places very strict requirements on reprocessing; risk assessment and the classification of medical devices prior to reprocessing are at the heart of the recommendation.

- Neither the EU Directive nor national norms make a distinction between single use and multiple use medical devices. The decision to declare a medical device as single use or multiple use is made by the manufacturer alone. However, the declaration that a medical device is “single use“ does not mean that reprocessing and re-use is prohibited. With this term, the manufacturer is merely declaring that the possibility of reprocessing has not been tested and that manufacturers’ liability for a product applies only to its first use.

In this context it must be possible for users / operators to evaluate the suitability of single use medical devices for reprocessing purposes. In the interest of patient protection, the legal requirements define a tight framework in this respect. In principle, however, they leave the issue of reprocessing under the responsibility of users / operators.

The reprocessing of so-called single use products would be prohibited only if this term were included as part of the definition of the intended purpose of the medical device, because the user is required to apply the device in accordance with its intended purpose. The concept of intended purpose and the related legal requirements are part of the definition of a medical device as specified in the EU Directive. According to the definition in this Directive, the intended purpose of a medical device is related to its function or main effect (diagnosis, prevention, monitoring, treatment or alleviation of disease / injury).

Manufacturers define the intended purpose of their products. However, they must observe the conditions specified in the EU Directive for defining the intended purpose. Since the number of uses of a medical device is not part of the definition under EU law, the German Ministry for Health, the national associations of social health insurers and the German Hospital Federation are of the opinion that the manufacturers’ designation as “single use product” does not constitute a definition of intended purpose in the sense of the EU Directive but merely a descriptive definition by the manufacturer. Medical device manufacturers advocate the opposite view. Accordingly, the amendment should serve to clarify the point that manufacturers’ information on the number of uses is not part of the intended purpose and therefore not binding for users.

- In addition to patient safety, which is indisputably the central issue and is not to be compromised by reprocessing, economic and ecological effects should also be taken into consideration. The reprocessing of medical devices results in a reduction of acquisition and disposal costs and in a stock reduction. This helps alleviate the burden of steadily increasing cost pressures in the health care sector. The reduction of waste, the overall decrease in the utilisation of raw

materials and primary energy as well as the reduced production of materials that are harmful to the environment provide an additional effect for the protection of our environment. The Member States must remain able to decide whether they would like to make use of these options.

- The national laws on reprocessing differ across Europe and the reprocessing of so-called single use medical devices is prohibited in some Member States. However, it cannot be the European Union`s task to create a uniform approach to these issues in all Member States, especially in light of the fact that the different national approaches have no effect on the EU internal market. The subsidiarity principle is therefore applicable in this context.

In its revision of Directive 93/42/EEC, we therefore call on the European Commission to clarify that

1. the frequency of use of a medical device is not an element of its “intended purpose” and that
2. detailed regulations on the reprocessing of medical devices remain a competency of national lawmakers.

II. Comments on the proposed amendments to the definition of a medical device and the software necessary for its application

Directive 93/42/EEC, Article 1, no. 2(a) defines a medical device as “any instrument, apparatus, appliance, material or other article, whether used alone or in combination, *including the software necessary for its proper application* intended by the manufacturer to be used for human beings ...”.

The proposal for an amendment to the Directive would define hospital software as a medical device in principle, and not only when it is applied to ensure the proper functioning of a medical device.

The current definition of medical devices already makes it difficult to delineate between the software of a medical device and the software of other hospital equipment – the proposal for a new definition would make this distinction even more difficult. It is often difficult to define where a medical device ends.

- Is the telephone line used for teleradiology a medical device?
- Is a Picture Archiving and Communication System (PACS) a medical device when it is used to provide images for the evaluation of the progress of a disease?
- Is a Hospital Information System (HIS) a medical device?

The German Hospital Federation and the national associations of the social health insurance funds have a critical view of the planned extension of the definition of medical devices. The change would result in considerable difficulties in its practical implementation: every minimal change in system performance, each upgrading would require a re-classification and conformity assessment. The costs and the demands on working time and re-organization would be unmanageable.

In the view of the German Hospital Federation and the national associations of the social health insurance funds, the concept of software as a component of a medical device must not be made more general. Instead, it should be given a narrower definition in order to permit the clear distinction between medical devices and products that are not medical devices.

The same applies for the delineation of the concept of “medical device” itself. The definition must ensure that aggregates, which provide operating materials for medical devices (e.g. air compressors) are not classified as medical devices under the Directive.

We call upon the European Commission to provide a definition of medical devices that allows for the clear distinction between medical device software and software that is not classified as a medical device. The same applies to the distinction between medical devices and other operating equipment.

III. Demands of the German Hospital Federation and the National Associations of the Social Health Insurance Funds with Respect to the Amendment of Directive 93/42/EEC on Medical Devices

- No detailed regulations on the reprocessing of medical devices in Directive 93/42/EEC on medical devices:
→ Continuation of national responsibility for regulation.
- Clarification that the frequency of use is not part of the definition of intended use.
- Users / operators must be allowed to judge whether the products they are responsible for can be reprocessed.
- The definition of clear criteria to distinguish medical devices – and its software – from other operating resources.