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### **Reprocessing of medical devices in Germany**

Dear Ladies and Gentlemen,

It is a great pleasure to have been invited to speak at the inaugural forum of the EAMDR, which is, for the first time, seriously tackling the issue of medical device reprocessing. I thank you for the opportunity to make a contribution to the current debate on the possible creation of a legal European framework, a framework whose overall objective is of course to safeguard health. For this purpose, I would like to present Germany as an example of a country where the reprocessing of medical devices is legally regulated.

During my time in office as Minister for Health at the end of the 90s, a process was started to amend the existing laws governing medical devices. It was our aim to alter the legal situation in this respect, in order to provide the highest possible care for patients and, at the same time, make use of the latest technological progress. The result of this was a new framework, and the corresponding laws came into force in 2001. Today, I would like to present to you the central aspects of this framework, as well as the conclusions of our first evaluation, five years later. Finally, I would like to explain in a bit more detail why I would recommend the German approach as a positive example for potential regulation at a European level.

#### **THE ROLE OF THE MEDICAL DEVICE INDUSTRY IN GERMANY**

The main issue with medical devices is patient safety – this is the case for Germany, and for all other European countries. Medical devices are indispensable for treating patients, and we must therefore always make sure we keep up to date with the advances in technology. In Germany, the use and, where appropriate, the reprocessing of medical devices are regulated according to these principles.

The German sector for medical devices is highly developed – the German market is the third largest in the world, after the US and Japan, and it is by far the largest market in Europe. To the German government, the sector is therefore not only of interest for the sake of patients' safety, but also for economic reasons: given the scale of the costs involved, these are an important factor for the overall expenditure of the health care system. At the same time, the legal framework should ensure that German medical devices, with their high safety standards, remain globally competitive.

#### **POLITICAL CHALLENGES**

As you know, the range of medical devices goes from very simple to extremely complex (and therefore equally expensive) devices. For a while now, multiple-use devices have been re-used after simple sterilisation or inadequate cleaning. From the user's point of view, however, it is precisely in the case of those expensive, complex devices that reprocessing can offer the most potential savings. We in Germany considered that this reprocessing - without complying

to quality standards - presented a risk to patient safety. We consequently outlawed it, as did many other countries. Nonetheless, there was a concern that the high cost of the devices could lead to illegal reprocessing, which would put patient safety in extreme danger.

Then, in the 90s, we started to see companies who had developed new procedures for reprocessing. With the most modern reprocessing facilities and validated procedures, it was becoming possible to reprocess medical devices without putting patients or users at any increased risk.

For politicians, this presented an opportunity to achieve two objectives at the same time: on the one hand, to considerably increase patients' safety, and on the other, to make significant cost savings.

Before the opportunity could be exploited, however, it was first necessary to check and demonstrate that those offering the new procedures were making promises that they could keep. This required extensive testing procedures, which were developed together with the reprocessing companies and the relevant testing authorities.

## THE LEGAL FRAMEWORK IN GERMANY

Consequently, a comprehensive amendment of the existing legal framework was put into motion and concluded in 2001. The result was an amendment to the medical devices laws, and guidelines which provided legally binding recommendations for the hygienic reprocessing of medical devices.

Together they constitute an updated framework, that should both meet patients' safety requirements, and also provide the industry with opportunities for growth.

Allow me to go into the clauses currently in force in a bit more detail. The *medical device law* was amended to accommodate the following core principles:

- **Reprocessing is legally permitted**, if it is carried out according to the appropriate validated procedure. These procedures must ensure that reprocessing constitutes no risk for the safety or health of patients, users or third parties.
- With respect to reprocessing requirements, there must be **no distinction** between single and multiple use devices. The only distinction is that, where devices are labelled as "multiple use", it is up to the *manufacturer* to provide specifications for the appropriate reprocessing procedure. In the case of single use devices, it is the responsibility of the user or *reprocessor* to develop appropriate procedures and have them validated.
- The law clearly defines what reprocessing is, i.e. it includes the cleaning, disinfection, sterilisation, and all related steps in these procedures, as well as reinstating and testing technical and functional safety.
- During the reprocessing itself, the recommendations or guidelines of the **Robert Koch Institute** must be observed (I will go into these in a little more detail later on).
- In this context, it was also clarified that, if medical devices are reprocessed for third parties and exclusively returned to the same people they came from, we are *not* talking about "placing on the market". The reprocessing in this scenario is a closed loop, whereby the liability for the reprocessed device clearly lies with the reprocessor.
- Whoever reprocesses devices for third parties must - as a labelling requirement - indicate that he/she does so. The reprocessor is subject to official supervision.

- In Germany, it is the regional authorities who are responsible for the **supervision** of reprocessing single use devices. The regions or *Länder* should not only undertake **spot checks** based on samples, but should also determine the scope and depth of the supervision. The federal authorities are responsible for **determining and evaluating** the risks.

Supporting the legal structure, the guideline of the Robert Koch Institute acts as the second “pillar” of the German legal framework surrounding medical devices. The Institute is the central federal institution responsible for disease control and prevention. The guidelines were drawn up in cooperation with the Federal Institute for Drugs and Medical Devices, whose responsibility is to supervise the safety of drugs and medical devices. The guideline is legally binding. It contains detailed recommendations and references to European and international norms and standards, and defines the hygienic requirements of the reprocessing of medical devices. The central aspects of the guideline are as follows:

- **Validated procedures** must be used to make sure that each individual step is successfully executed and can be reproduced. At no point may there be any increased danger to the safety of patients, users or third parties. The validated procedures also define the parameters that are required to demonstrate that each individual step of the process is satisfactorily carried out.
- Reprocessors must implement a **Quality Management System** to guarantee a consistently high and transparent level of quality. These are to be monitored by the relevant authorities, and supervised and certified by accredited institutions.
- The user is responsible for the **risk assessment** of the medical devices or device groups, and should take into consideration the manufacturer’s specifications, existing norms and the reprocessor’s recommendations. Devices should then be classified into the following risk categories:
  - non-critical (contact with unbroken skin, e.g. ECG electrodes)
  - semi-critical (contact with mucal membranes or pathologically affected skin, e.g. flexible endoscope)
  - critical (contact with blood, body tissue etc, e.g. keyhole surgery trocar)
  - critical devices are subdivided into those without and those with enhanced requirements (critical C). The latter are subject to a further external quality control, i.e. a certification of their quality management systems, in order to guarantee a consistent and ongoing compliance with the requirements.
- Based on this risk categorisation, the reprocessor determines the appropriate procedures.
- The **personnel in charge of reprocessing** must have adequate qualifications, knowledge and experience – training requirements are laid down in the relevant annex of the guideline.

## THE SITUATION FIVE YEARS ON

Today, five years after this legal framework came into force, we can draw positive conclusions from the mid-way review: so far, more than six million single-use devices have been reprocessed without one single claim being reported. During this time, the testing authorities have constantly been improving, extending and intensifying their testing procedures.

Against this background, the German government was able to achieve several objectives simultaneously thanks to the change in the legislation:

- The safety and health risks to patients and users has been minimised, in as far as uncontrolled and illegal reprocessing is being stamped out
- Considerable savings have been achieved in the health care sector. For example: a new ablation catheter costs between €1,000 and €3,000 – reprocessing can save up to 50 percent of these costs. Small hospitals can save around €45,000 per year, larger ones up to several millions.
- Less hazardous medical waste is produced, as reprocessing provides substantial material savings in comparison to the resources necessary for the manufacture of new devices.
- Savings are made in natural resources such as energy, as reprocessing uses practically only water.
- The reprocessing industry could also further expand their technological capacities to the benefit of patients and users.

A study of 20,000 medical devices in the German reprocessing industry showed that, given the technology at that time, 16 percent of all devices labelled as ‘single use’ are reprocessible according to the RKI guideline with no increased risk to patients. With the development of new reprocessing processors, it can be assumed that this proportion will increase. With only one exception, all German university clinics make use of professional reprocessing services, as do 650 of Germany’s approx. 2,500 hospitals. Over 70% of German cardiologists use professionally reprocessed ‘single use’ devices.

I have already referred to this, but I would like to emphasise again: the reprocessors assume full liability for their services. In Germany, insurance companies are prepared to offer high liability limits to professional reprocessors, against claims for personal or material damages. This shows that the insurance sector considers the applied reprocessing procedures responsible and of acceptable risk, and do not view reprocessing as posing an appreciable risk. The end result after five years proves them right – so far not one damage claim has been reported.

## **THE LEGAL SITUATION IN EUROPE**

There is no unified legislation across Europe. Apart from Germany, some other countries also allow and regulate reprocessing, e.g. Denmark. In others, such as Greece, there are no regulations at all, and in yet others, like France, reprocessing is not recommended or even forbidden.

A common European legal framework would of course be more desirable than many individual national regulations. This is as true from the point of view of the patients and users, as it is from an economic perspective. On the one hand, this could mean that patients and users of *all* EU Member States could enjoy better healthcare, in that they would be protected from unprofessional reprocessing. On the other hand, the healthcare system could make considerable cost savings, and benefit the environment by reducing waste.

The current revision of the Medical Device Directive 93/42/EEC could provide an opportunity to shape a new framework, which would regulate the reprocessing of medical devices with these points in mind. As I am sure you are aware, the Commission's proposal has been passed to the European Parliament and Council, where the contents of the directive will further be discussed.

I hope that my presentation has awakened your interest in the German approach to the reprocessing of medical devices. German institutions and reprocessors are happy to answer any further questions you may have; which, as experts, I am sure you will. I myself am also glad to remain at your disposal for any information regarding the political procedures, although I am of course no expert on the technical side of reprocessing.

The experience of the last few years has shown that we have placed great trust not only in the German institutions, who monitor the reprocessing, but also in the reprocessors themselves, who have stood up to all of these examinations most convincingly. This is why I wanted to present the German experience to you today. I thank you for your interest, and for your attention.