

# **Report on the reprocessing of medical devices in Germany**

**Basis:** Questionnaire sent by the Federal Ministry of Health,  
to authorities, federations, organisations, experts,  
others (Internet survey)

**Section 1:  
Report section –  
Analysis of the answers received  
and conclusions of the  
Federal Ministry of Health**

Bonn/Berlin, March 2008

**Published by the Federal Ministry of Health**  
[www.bmg.bund.de](http://www.bmg.bund.de)

Translated by Production sa/nv, La Hulpe, Belgium for the EAMDR in April 2008

<b>I. Foreword</b>	<b>6</b>
<b>1. Introduction and initial position</b>	<b>6</b>
1.1 Basic remarks	6
1.2 Explanation of the responsibilities in Germany	7
1.3 Situation in Europe	8
1.4 Preliminary remarks on the report	9
<b>2. Results of the survey in key words</b>	<b>10</b>
<b>II. Assessment and need for action from the point of view of the participants</b>	<b>12</b>
<b>1. Legal framework (Medical Device Act, Medical Device Operator Directive)</b>	<b>12</b>
1.1 Highest Federal States authorities for medical devices, Federal Ministry of Defence, ZLG, BfArM, RKI	12
▶ Assessment	12
▶ Need for action	12
1.2 Federations, organisations, experts and others	13
1.2.1 Manufacturers	13
▶ Assessment	13
▶ Need for action	13
1.2.2 Users and external processors	14
▶ Assessment	14
▶ Need for action	14
<b>2. RKI/BfArM recommendation</b>	<b>14</b>
2.1 Highest Federal States authorities for medical devices, Federal Ministry of Defence, ZLG, BfArM, RKI	14
▶ Assessment	14
▶ Need for action	15
2.2 Federations, organisations, experts and others	16
2.2.1 Manufacturers and notified bodies	16
▶ Assessment	16
▶ Need for action	16
2.2.2 Users and external reproprocessors	16
▶ Assessment	16
▶ Need for action	17
<b>3. Supervision – Reports of the federations, organisations, experts and others</b>	<b>18</b>
3.1 Staffing levels of the supervisory authorities	18
3.2 Expertise of the supervisory staff	18
3.3 Need for action	20
<b>4. Equipment and staffing, quality of the reprocessing - Report of the authorities</b>	<b>20</b>
4.1 Reprocessing in hospitals (primary care)	20
4.2 Reprocessing in the secondary care sector	21
4.3 External reproprocessors/service providers	22
4.4 Need for action	22
<b>III. Conclusions and measures</b>	<b>24</b>
<b>1. Preliminary remarks</b>	<b>24</b>
<b>2. Immediate measures</b>	<b>24</b>
2.1 Study into the quality of processed medical devices	24
2.2 Letter from the Federal Ministry of Health to healthcare federations and organisations	25
2.3 Addition of the topic of “Supervision” to the Federal Ministry of Health report for the 81st Health Minister Conference on July 2 <sup>nd</sup> and 3 <sup>rd</sup> 2008 in Plön	25
2.4 Mission entrusted to the Commission for hospital hygiene and prevention of infection at the RKI	26
<b>3. Short-term regulatory changes</b>	<b>26</b>

3.1 Compulsory quality management system (QM-System)	26
3.2 Quality management system requirements for reprocessors	26
<b>4. Further feasible options</b>	<b>27</b>
4.1 Make the RKI/BfArM recommendation binding	27
4.2 General ban on the reprocessing of so-called single use devices	28
4.3 Negative list of devices that may not be reprocessed	28
4.4 Obligatory authorisation for the reprocessing of particularly critical so-called single use devices	28
4.5 Laying down of additional labelling requirements	29
<b>5. Further procedures</b>	<b>29</b>
<b><i>Annex I</i></b>	<b>30</b>
1. Letter from the Federal Ministry of Health to federations, organisations, external reprocessors	30
2. Letter from the Federal Ministry of Health to the authorities	32

# I. Foreword

## ***1. Introduction and initial position***

### **1.1 Basic remarks**

Health policy is putting ever-increasing emphasis on preventative health protection, as the issues and problems involved are sensitive. Particular care needs to be taken when patients receive direct medical treatment. This clearly means that patients have not only a right to respect for general hygiene regulations (see among others the “Clean Hand Campaign”) but also to the use of medical devices that are in perfect working order - both in primary and secondary care. As medical devices contaminated with pathogens can be a source of infections in the event of a medical intervention, an adequate and appropriate reprocessing of these medical devices plays an essential role in day to day practice. That is why, along with decrees and bans, recommendations in the form of generally applicable requirements are also necessary, which put those concerned in a position to provide safe medical devices in all fields of medicine.

On this basis, with the Second Law on the Amendment of the Medical Devices Act (which entered into force on January 1<sup>st</sup> 2002) the Federal Government has recommended a whole range of amendments and additions to the Medical Device Act and the Medical Device Operator Directive as well as ordinances<sup>1</sup>. With these new regulations,

- the already existing strict requirements governing the reprocessing of medical devices should be made more precise and stringent,
- the reprocessing of so-called single use devices should not be prohibited, and
- with regard to the requirements governing reprocessing in the interest of preventative patient protection, no distinction should be made between multiple use devices and the so-called single use devices.

The German Bundestag (Parliament) and Bundesrat (Federal State Chamber) have unanimously passed this law across all parties and coalitions.

---

<sup>1</sup> A detailed description of the legal situation in Germany since the 1st of January 2002 can be found in annex II of this report (p. 35f.).

## 1.2 Explanation of the responsibilities in Germany

The federal construction of the Federal Republic of Germany means that even in the field of the reprocessing of medical devices, there are several jurisdictions, which means that responsibility is shared. The Federal level is responsible for the legislation and directives. The Länder (Federal States) enforce the Medical Device Act in accordance with Art. 83 of the Constitution and are therefore, by virtue of paragraph 26 of the Medical Device Act, also responsible for the supervision of the healthcare institutions and external reprocessors. The Federal Institute for Drugs and Medical Devices (BfArM) and the Robert-Koch Institute (RKI) are responsible as higher federal authorities for the scientific input (in this case in point the RKI/BfArM recommendation<sup>2</sup>). The local responsibility falls however in particular to the operators of medical devices, who request the reprocessing of medical devices, as well as the users, who, before each use, must assure themselves that the medical device complies with the regulations and is in correct working order. These players must comply not only with the legal provisions governing the medical devices in relation to their patients but also with the general liability provisions under civil and criminal law.

The last few years have shown that to comply with the existing regulations, effective supervision at Federal States level is essential. However, no nation-wide action plan exists to define the extent of this supervision.

During a meeting between the Federation and the Federal States on the **December 18th 2006** in Bonn on this topic, the following was unanimously recorded in the minutes:

- Supervision suffers from some fundamental and, in part, serious shortcomings, which is why there is an urgent need to take action. As far as possible, the supervision should be organised along uniform lines (see also on this subject the Health Minister Conference ruling of 29/30.06.2006); while respecting these criteria, specific priorities can also be set by the individual Federal States (adapted to the risk);
- Occasional supervision is not enough. Indeed, random, unannounced spot tests need to be accompanied by an incident-unrelated, systematic supervision that is adapted to the risk in order to effectively enforce respect for the relevant guidelines; the operators or those responsible for medical devices must expect to be supervised;
- The staffing situation in the Federal States is (almost) universally bad, however possibilities of improving the supervision must be found. The adequate staffing of the supervision authorities must be ensured in particular;

---

<sup>2</sup> Recommendation of the Commission for hospital hygiene and prevention of infection at the Robert Koch-Institute and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene requirements governing the reprocessing of medical devices" of 1.11.2001. The Commission members are appointed by the Federal Ministry of Health in conjunction with the highest Federal States health authorities. The representatives of the Federal Ministry of Health, of the highest Federal States health authorities and of the Robert Koch Institute take part in the meetings as advisors.

- The level of qualification of the supervisory officers must be as uniform as possible across the country (which implies support from training bodies through the federal authorities such as BfArM and RKI);
- Cooperation between the Federal States must be made more intensive. In doing so, new forms of cooperation (for example inspection federations across the Federal States) must be tested and the work on the content carried out to date within the framework of the Working Group on Medical Devices must be continued;
- There is currently no need to legislate.

### 1.3 Situation in Europe

DIRECTIVE 2007/47/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market was successfully concluded during the German presidency. In the negotiations of the presidency with the European Parliament, the reprocessing of medical devices was a central topic. A compromise was finally found covering several points.

a) Recital 7 was added:

*"(7) Particular care should be taken to ensure that the reprocessing of medical devices does not endanger patients' safety or health. It is therefore necessary to provide clarification on the definition of the term "single use", as well as to make provision for uniform labelling and instructions for use. Moreover, the Commission should engage in further analysis in order to see if additional measures are appropriate to ensure a high level of protection for patients. "*

b) A new point was added defining "single use device":

*" n) ,single-use device': a device intended to be used once only for a single patient. "*

c) In the Basic requirements in Annex I Section 13.f, the manufacturers of single use devices are now obliged to inform the users about possible risks known to them relating to the reprocessing of the devices.

d) A new article 12 a was also added:

*"Article 12 a*

*Reprocessing of medical devices*

*The Commission shall, no later than September 5<sup>th</sup> 2010, submit a report to the European Parliament and to the Council on the issue of the reprocessing of medical devices in the Community. In the light of the findings of this report, the Commission shall submit to the European Parliament and to the Council any additional proposal it may deem appropriate in order to ensure a high level of health protection".*

The Commission has started with the preliminary work and, at the end of 2007, sent a questionnaire to the Member States that the Federal Ministry of Health has answered. In the spring of 2008, on the basis of the analysed replies, a first catalogue of measures should be drawn up containing the possible measures envisaged by the European Commission.

#### **1.4 Preliminary remarks on the report**

The Federal Government believed that it would take a transitional period of around half a year after the entry into force of the new regulations on the reprocessing of medical devices on January 1<sup>st</sup> 2002 for all of the participants to be informed of the new rules through various media (seminars, publications, etc.) and for the responsible authorities of the Federal States to implement uniform guidelines relating to the organisation of supervision. After around 3 years, the Federal Ministry of Health was to submit a report on the results of the amendment to the legislation. However it quickly emerged that the transitional period would take much more time. In order to be able to judge whether the guidelines have been respected, a period of at least 5 years is necessary. Information campaigns on the theme of reprocessing, presenting the “new” regulations, were still being held in 2007. The Federal States also needed considerable more time to set up the framework conditions for uniform supervision within the relevant project groups (see below under 1.2.2). For example, in the “RKI/BfArM recommendation” project group, the draft “Recommendation on the supervision of the reprocessing of medical devices” was drawn up. The recommendation was passed by the Medical Device Working Group of the Federal States in a meeting held on March 12<sup>th</sup>-13<sup>th</sup> 2008 in Kiel. It will serve in future as a basis for the execution of the Medical Device Act.

This report is based on the feedback to a questionnaire that the Federal Ministry of Health sent out in January 2007 to the players concerned. Alongside the authorities (Federal States, Federal Ministry of Defence, the Central Authority of the Länder (Federal States) for Health Protection with Regard to Medicinal Products and Medical Devices (ZLG), the Federal Institute for Drugs and Medical Devices (BfArM) and the Robert Koch Institute (RKI), federations, organisations and external reproprocessors were also asked to answer questions on this matter. Furthermore, a Federal Ministry of Health press release reported on the questionnaire campaign and urged players to take part in the campaign. A total of **79** (some very comprehensive) positions were received by the Federal Ministry of Health, 20 from the aforementioned authorities. **Annex 1** contains not only a list of the authorities, organisations, federations, experts and others who replied to the Federal Ministry of Health questionnaire but also the actual letter sent out by the Federal Ministry of Health.

Analysing the questionnaires proved to be more difficult than expected, as most of the questions could not be answered with a simple “yes” or “no” but called for very specific answers. Some commented on matters not broached in the questions. That is why this report is a summary of the replies of the players concerned and also contains conclusions and proposals for measures. The summary of the replies reflects the trends that emerged from the views expressed. An analysis of the replies in figures, which is very difficult due to the extremely broad spectrum of the assessment of individual questions by the players concerned, have been put into diagrams to elaborate on the comments on the trend. The diagrams can be found in **Annex III** of this report.

To do justice to the summarised account of all of the respondents and, at the same time to ensure utmost transparency, the Federal Ministry of Health asked the participants (except for the Federal States<sup>3</sup>) whether they authorised the publication of their position.

All of the positions received whose publication was not expressly refused are included as annexes to the report. You are requested to respect the introductory remarks.

## ***2. Results of the survey in key words***

The results of the survey describe initial experiences with the application of the RKI/BfArM recommendation, which is already however triggering a majority of positive effects. However, it is too early as yet to make a final assessment of the existing regulations governing the reprocessing of medical devices, as the transposal process of the RKI/BfArM recommendation is still in progress and has only just begun in some areas of the secondary care sector. Also as far as supervision is concerned, very different approaches can still be observed at present.

The central findings of the survey to date, based on the majority opinion<sup>4</sup> are that:

- the legal framework governing the reprocessing of medical devices is generally sufficient;
- a far-reaching correction of the regulations governing the reprocessing of so-called single use devices leading to a complete ban is neither helpful, nor advisable for other reasons;
- in order to clarify the objectives, however, some adjustments should be made to the upcoming legislative bills;
- technical guidelines on the reprocessing procedures of critical medical devices should be made concrete;
- there are considerable discrepancies when it comes to awareness of the RKI/BfArM recommendation between primary and secondary care;
- the supervision of the reprocessing procedures in the healthcare institutions and by external reprocessors is starting to become of central importance;
- some of the supervisory authorities suffer from staffing shortages;

---

<sup>3</sup> The Federal States were asked by the Federal Ministry of Health to answer additional questions in relation to their practical experiences of supervision. In doing so, the Federal States provided facts that are regarded as confidential data and that are not intended to be divulged to the public.

<sup>4</sup> As not every individual opinion can be included here, and as, on the other hand, contradictory positions cannot be ignored, we refer to the annexes, which contain all of the positions received, as long as their publication was not refused.

- the participants must be made more aware of the importance of compliant reprocessing procedures to increase patient protection.

## **II. Assessment and need for action from the point of view of the participants**

### **1. Legal framework (Medical Device Act, Medical Device Operator Directive)**

#### **1.1 Highest Federal States authorities for medical devices, Federal Ministry of Defence, ZLG, BfArM, RKI**

##### **► Assessment**

In response to the question of whether the legal guidelines governing the reprocessing of medical devices are sufficient, the spectrum of answers ranges from a very short “yes” to a detailed description of the merits of the regulations in question as well as individual proposals on the extension of the regulations. Generally speaking, the existing legal provisions are considered to be sufficient. In principle, they offer a satisfactory basis in order to ensure a safe reprocessing of medical devices. However, several comments by the authorities reveal that, in the end, only a close supervision by the authorities with a higher budget guarantees the safe reprocessing of medical devices.

Most of the *authorities* believe that it is advisable and right that the legal provisions on the safe reprocessing of medical devices should not make a distinction between the reprocessing of multi use devices and so-called single use devices. From the point of view of patient protection, it is essential that medical devices are safely reprocessed. That is why a distinction, which could give the impression that multi use devices are reprocessed with less care, would be counterproductive in this respect.

Individual authorities of the Federal States touched on the issue of the so-called single use devices. Most of the Federal States believe that the existing rules, also with regard to the reprocessing of so-called single use devices, are generally sufficient. Due to the recurring press reports on partly badly reprocessed so-called single use devices, some individual demands were voiced for manufacturers of so-called single use devices to justify to the authorities the reasons for their classification as “single use devices” before they are brought onto the market.

Furthermore, the conditions under which a product may be classified as a so-called single use device should be laid down by law.

Some claimed that a general ban on the reprocessing of so-called single use devices could have the advantage of reducing the current supervisory costs for the authorities, thus allowing the authorities to cut down on their expenditure. Independently of this, the Federal States acknowledge the fundamental importance of supervision.

##### **► Need for action**

*From the point of view of the authorities* however there is less need to act to amend the legal provisions in the field of reprocessing of medical devices.

A suggestion was made to make compliance with the individual guidelines of the

RKI/BfArM recommendation legally binding. It should be ensured in particular that the reprocessing of medical devices with a “Critical C”<sup>5</sup> classification is only permitted when the reprocessor has implemented and complies with a quality management system that is audited by an independent and accredited body.

Other proposals to solve the issue of the current arbitrary labelling of the devices by the manufacturer as a single use or multi use device, call for a change in the European guidelines.

## **1.2 Federations, organisations, experts and others**

### **1.2.1 Manufacturers**

#### **► Assessment**

The *manufacturers* of medical devices believe that the legal provisions governing reprocessing are fundamentally sufficient. However, they point out that compliance with the RKI/BfArM recommendation should be made more legally binding. They also demand that the reprocessing of so-called single use devices be banned or governed by special rules.

The central argument in favour of a ban on the reprocessing of so-called single use devices is the assumption that a hospital or an external reprocessor is not in a situation to completely evaluate the safety and operation of the reprocessed devices. As the devices have been designed especially for single use, a reprocessing would also imply considerable risks. The problem, which was touched upon by many other respondents in this context, that it is currently only down to the manufacturer to declare its devices as so-called single use devices, and which can be in its own economic interest, is not broached by the manufacturers or manufacturing federations.

#### **► Need for action**

Although the *manufacturers* do not fundamentally question the legal provisions, they do see a need for action in relation to so-called single use devices.

Some for instance call for a ban on the reprocessing of so-called single use devices. Alternatively, it is suggested that the reprocessing of so-called single use devices should be put on an equal legal footing with the manufacturing procedure and that the reprocessors should follow a complete EC conformity assessment process (as is the case for new devices).

---

<sup>5</sup> The definition of “Critical C” under the RKI/BfArM recommendation: with particularly strict reprocessing requirements, thermolabile devices/devices that cannot be steam sterilised (example: balloon catheters), cfr. annex 11, p. 37/38

## 1.2.2 Users and external processors

### ► Assessment

The decision not to make a distinction between so-called single use and multi use devices as well as the question of the reprocessability of so-called single use devices on the basis of the RKI/BfArM recommendation prompted conflicting reactions.

Unlike the manufacturers of so-called single use devices, the organisations, in particular the *hospitals and the external reproprocessors* that carry out a reprocessing of medical devices believe that the legal provisions are sufficient. Several users expressed concern that the guidelines laid down by the manufacturer for the reprocessing of their multi use devices are not sufficient in order to guarantee a safe reprocessing. Other professional groups such as *dentists* for example believe that the legal provisions are too strict. They blame this mainly on the distinction made between the reprocessing of so-called single use or multi use devices by the legislator. It is presumed that the indiscriminate inclusion of the so-called single use devices in the regulation has meant that the legal guidelines governing the reprocessing of multi use products have been formulated more strictly than actually necessary. Those concerned find that it is now very difficult to comply with these guidelines. On this point, there are also references to the very different supervision practices of the responsible Federal States authorities.

Several users stressed that they are happy to fully refrain from the reprocessing of medical devices and, in the interests of the patients, only wanted to use so-called single use devices. However, the current refund and cost reimbursement system, especially in secondary care, is incompatible with this demand.

### ► Need for action

Most *users*, as well as the organisations that *carry out reprocessing*, do not see any acute need for action with regard to the legal provisions.

Nor are additional legal provisions deemed to be necessary to overcome the shortcomings observed in the reprocessing requirements for multi use devices. Action seems to be called for however in the field of market surveillance and to improve the formulation of individual device standards.

## 2. RKI/BfArM recommendation

### 2.1 Highest Federal States authorities for medical devices, Federal Ministry of Defence, ZLG, BfArM, RKI

#### ► Assessment

There is agreement in principle that a correct reprocessing of medical devices is possible by respecting the RKI/BfArM recommendation. At the same time, the authorities believe that improvements can be made on some points. This mainly results from discussions among the players about the practical enforcement of the recommendation. To avoid repeating ourselves, the reader is invited to refer to the

following section.

### ► **Need for action**

The most common views expressed by most of the *Federal States* (including the ZLG) can be summarised as following:

- The external certification of a reprocessing facility should be compulsory for the reprocessing of medical devices with a risk classification of “Critical C”.
- The concepts of validation (or suitable validated process) and qualification as well as requirements with regard to the correct operation of cleaning-disinfection equipment and sterilizers are to be defined.
- The relation between other recommendations of the Commission for hospital hygiene and infection prevention at the Robert Koch-Institute and the RKI/BfArM recommendation is to be clarified. Differences of content are to be avoided. Existing differences on reprocessing in the recommendation “Preventing infection in dentistry – hygiene requirements” require clarification.
- National guidelines are called for to govern staff qualifications and for the structural conditions and requirements for reprocessing units.
- Furthermore, for medical devices of the category "critical B"<sup>6</sup> " only mechanical cleaning/disinfection” should be encouraged.
- There are individual calls for the need to carry out a conformity assessment process for the reprocessing of so-called single use products. The introduction of a quality management system in accordance with DIN EN ISO 13484 for the reprocessing of critical medical devices is considered as useful.

The *higher federal authorities* emphasised the following aspects:

- The minimum demand is considered to be the legally binding regulation for reprocessors of medical devices with the risk classification “critical C” in relation to the certification obligation by a body notified by the ZLG.
- The legal relevance for further topical recommendations by the Commission for hospital hygiene and infection prevention should be clarified.

---

<sup>6</sup> Definition of "Critical B" according to the RKI/BfArM recommendation: medical devices with stringent reprocessing requirements, thermolabile products / steam sterilised at 134 °C (examples: Trokar for minimally invasive surgery and minimal surgical instruments), cfr. annex 11, p. 37/38

## **2.2 Federations, organisations, experts and others**

### **2.2.1 Manufacturers and notified bodies**

#### **► Assessment**

The RKI/BfArM recommendation is in principle considered to be sufficient for medical devices that are intended by the manufacturer for reuse. As with the authorities, at the same time it is considered that there is room for improvement. The reprocessing of so-called single use devices is generally rejected, in part the precision of the requirements for the reprocessing of these medical devices is considered to be necessary.

#### **► Need for action**

The positions submitted here can be resumed as follows:

- The area of application of the RKI/BfArM recommendation should be clearly determined i.e. the reprocessing of so-called single use devices is to be excluded. The reprocessing requirements should be put in concrete terms in view of the distinction made between the devices for certain device groups.
- More consideration for necessary procedures to ensure the functional and security properties is considered to be necessary.
- A change should be made to the conditions governing the reprocessing of medical devices with a risk classification of “Critical C” so that an “external certification” is necessary only when there is definitively no reprocessing instruction provided by the manufacturer.
- The joint guidelines of the German Society for Hospital Hygiene (DGKH), of the Germany Society for Sterile Supply (DGSV) and of the Working Group on Instrument Reprocessing (AKI) should be enclosed in an annex to the recommendation.

One *notified body* deems that the RKI/BfArM recommendation is sufficient for the reprocessing of reusable medical devices. The reprocessing of so-called single use products should however be combined with a procedure comparable with a conformity assessment on the basis of a risk analysis and risk management. For the validation of the procedure, the use of qualified test laboratories should be required.

### **2.2.2 Users and external reproprocessors**

#### **► Assessment**

As far as the users are concerned, the general attitude is that the RKI/BfArM recommendation is sufficiently concrete in its formulation and fulfils its requirement of appropriately and adequately reprocessing medical devices. However, possibilities for optimisation are also pinpointed in this respect.

## ► Need for action

The positions of the *doctor organisations* are listed below:

- A greater discrimination is required between the classification of medical devices with due consideration for topic-related requirements. Furthermore, a nationwide risk evaluation and classification of medical devices is demanded.
- The concept of validation should be defined.
- When defining the requirements with regard to the qualification of the staff, the already existing knowledge and experiences should be taken into consideration.
- Furthermore, reference is made to the need to clarify the position of the RKI/BfArM recommendation with regard to the recommendation "Preventing infection in dentistry – hygiene requirements".

The need for action that is considered to be necessary by the *Medical Societies* can be summarised as follows:

- To date, the RKI/BfArM recommendation has only been applied to hospitals, and not to doctors' surgeries, secondary care, etc. From this point of view, an extended, clear definition of the field of application is demanded, although consideration should also be given to the fact that the guidelines for outpatient surgery are insufficient.
- Cross references are necessary to other relevant recommendations of the Commission for hospital hygiene and infection prevention, clear guidelines for other medical specialties as well as an extended bibliography (here in concrete terms: inclusion of the recommendations of the DGSV).
- Individual comments call for a conformity assessment process for the reprocessing of so-called single use devices and supervision by notified bodies that is independent of the production classification.
- The reprocessing of medical devices that come under risk classification "Critical C" should generally be carried out by external reproprocessors in order to ensure the necessary material tests.
- The RKI/BfArM recommendation should be expanded by giving more details about the structural requirements and about the necessary staff training measures.

The demands of the *external reproprocessors* (including the German Interest Group on the Promotion of Quality in the Reprocessing of Medical Devices) are listed include:

- For the reprocessing of so-called single use devices, test laboratories with experience of manufacturing and with proven specialised competence should be used to ensure quality assurance. DIN EN ISO 14971 should be applied.
- In the event of external reprocessing, the quality management system should be generally certified by an accredited body.

- Improvement is demanded in the certification rules of the ZLG, e.g. should the medical devices to be reprocessed be listed on the certificate.
- Two reprocessors speak in favour of carrying out a conformity assessment procedure for the reprocessing of so-called single use products or the equal treatment of reprocessors with manufacturers.
- Furthermore, it is pointed out that the RKI/BfArM recommendation should be interpreted in the same way by the Federal States authorities and the ZLG.

Other repeated demands in the positions with regard to the different legal sources include:

- More precise formulations in order to reduce the room for interpretation;
- The drawing up of a list of so-called single use devices whose reprocessing is authorised (or unauthorised);
- Current assessment of the Creutzfeldt Jakob issue on the basis of the problems with alkaline cleaning.

### ***3. Supervision – Reports of the federations, organisations, experts and others***

#### **3.1 Staffing levels of the supervisory authorities**

The *German Medical Association* comes to the conclusion that the staffing levels vary considerably. It also emerges that the intensity of the perception of the supervisory tasks are vary significantly across the board.

The *German Hospital Federation* estimates that the staffing levels of each different Federal States are very different. Generally speaking, the authorities speak of understaffing. This is also expressed by the fact that there are significant shortcomings in the supervision of the secondary care sector.

*The German interest group for the promotion of quality in the reprocessing of medical devices* believes that the scope of the mission entrusted to the supervisory staff is too broad. This applies both to the specialist areas to be processed and to the number of organisations to be supervised.

#### **3.2 Expertise of the supervisory staff**

The *National Association of Statutory Health Insurance Physicians* points out that the expertise of the supervisory staff is the main problem raised by many of its members. It claims that while it is true that the expertise with regard to the purely formal guidelines cannot be criticised, in many cases persons from professions not connected to medicine are appointed to carry out the qualitative work of doctors such as the reprocessing of surgical instruments. That is why supervisory staff across Germany

should be given medical training as well as hygiene training. Furthermore inspections of the practices by the authorities, if applicable and at the request of doctors under contract, should also involve staff with the corresponding medical expertise of the associations of statutory health insurance physicians. It also appears important in this context that the supervisory authorities develop awareness of the different specialisations of the practises (spectrum of services) and make sensible and appropriate use of their powers of discretion with regard to the individual requirements. It is further pointed out that supervision within the meaning of advice and support is seen as useful. What is criticised is the sometimes very stringent procedures in some Federal States (namely North Rhine-Westphalia).

The *German Medical Association* makes the same assessment. It points out that the level of expertise varies considerably. While it is impossible to make a decisive assessment of the formal specialised qualification, there does not seem to be one specific qualification for this field of health /medical devices. It is pointed out that complaints are voiced by some Federal States about inappropriate visits by the persons entrusted with the supervision.

The *Federal Dentist Association* stresses that any kind of advisory competence comes under the responsibility of the dentist associations. The supervisory staff appointed by the authorities cannot be automatically regarded as universally competent in all specialisations. That is explained by the fact that the specific demands in dentistry call for a specific amount of expertise in order to appraise the situations that come up in the practices. It is recommended that the appropriate training is carried out. This would require cooperation with the relevant dentist association.

The *German Hospital Federation* also points to shortcomings in the expertise of the supervisory authorities. The individual assessments however cover a broad spectrum, ranging from “excellent expertise” to “insufficient staff expertise”. In principle, the expertise does exist but is more theoretical than practical. This leads in the case of the supervision of reprocessing in the daily clinical environment for example to demands that do not correspond to the practical situation, although no significant shortcomings are deplored. A further result is the varying interpretation of the RKI/BfArM recommendation and the different approach of individuals to supervision.

*The German interest group for the promotion of quality in the reprocessing of medical devices* comes to the conclusion that the supervisory staff does not always have reprocessing expertise. The contents of the training courses provided to supervisory staff in the individual Federal States differ considerably. Alongside the heavy workload that makes self-study impractical, there is a lack of suitable training possibilities for the supervisory staff.

In the view of the *expert Dr. Haindl*, in a federal system, where the responsibilities in the Federal States are partly still distributed among different departments, it is hardly possible to ensure sufficient qualification of the supervisory officers across the board. Not enough use is being made of independent experts, although this is provided for in the Medical Device Act.

### **3.3 Need for action**

Most believe that the staffing levels vary considerably between one Federal State and another. Generally, therefore there is a staffing shortage among the authorities. The expertise of the supervisory staff is also evaluated very differently. In particular, a lack of specific medical knowledge is criticised. Furthermore, the intensity of the perception of the supervisory tasks is not uniform across Germany. This assessment shows that also from the point of view of the *federations*, a further improvement in the quality of the supervision by the authorities is seen as an important step for the transposal of the RKI/BfArM recommendation. There are calls for training for the authority employees as well as for cooperation with the professional organisations.

Even the *authorities* themselves see a need for action with regard to the supervision of the reprocessing of medical devices. This has led to the setting up of the “RKI/BfArM recommendation” working group by the Medical Device Working Group of the Federal States (AGMP). This project group was commissioned by the AGMP in October to draw up guidelines for a uniform interpretation and supervision of reprocessing throughout Germany in line with the RKI/BfArM recommendation. The draft of the “Recommendation on the supervision of the reprocessing of medical devices” was submitted to the AGMP in March 2007. The draft, revised on the basis of the positions of the Federal States, is being discussed again during the 11th meeting of the AGMP in March 2008.

It is generally estimated that with the transposal of this recommendation by the supervisory authorities of the Federal States, an important step can be taken to improve the quality of supervision.

## **4. Equipment and staffing, quality of the reprocessing - Report of the authorities**

### **4.1 Reprocessing in hospitals (primary care)**

No general statement can be made about the equipment. In cases where the reprocessing is concentrated within a CSSD (Central Sterilisation Supply Department) or within hospitals operated by the same authority, the equipment is generally deemed to be “good” to “very good”. However there is still some room for improvement in the cleaning – disinfection equipment. CSSDs in new buildings are better equipped than in old buildings. However in the old buildings the trend points towards an improvement or renewal of the equipment. The problem is partly to do with space however. In this process, supervision by the authorities plays an important role.

In smaller hospitals, the equipment is often much worse. This is particularly true of outdated cleaning and disinfection equipment. In some establishments, the cleaning and disinfection is still carried out by hand. Obsolete sterilizers are still widely used that often cannot be validated. There is great room for improvement here.

Some complain of a shortage of space. Many of these smaller facilities have only just started renewing their equipment. This also has economic grounds. It is precisely on these grounds that some of the smaller hospitals have outsourced reprocessing to external service providers or that several hospitals have centralised the reprocessing

in one facility.

Staffing levels also differ considerably. In large hospitals, the required expertise is usually available. Especially in smaller facilities however there are still shortcomings with regard to the qualification of the staff. However, a continuous improvement can be observed in the qualification of staff.

Overall there is greater awareness of the need for reprocessing that complies with the regulations. Furthermore, in many hospitals management has carried out a “reevaluation” of the reprocessing needs of medical devices.

The quality of the reprocessing in the hospitals has improved considerably. Most of them are considered to be “good” to “very good”. However it is pointed out that this improvement was achieved in particular through the intensification of the supervision. A lot remains to be done however before the RKI/BfArM recommendation is completely transposed, especially in smaller hospitals.

## **4.2 Reprocessing in the secondary care sector**

In the *doctors’ surgeries*, the RKI/BfArM recommendation is hardly known and only implemented in very few cases. The medical associations of the Federal States have to date, unlike the dentist associations, carried out hardly any activities to publicise and implement the RKI/BfArM recommendation. In some Federal States however, the medical associations are starting to introduce the appropriate measures in cooperation with the supervision authorities.

The *equipment in the doctors’ surgeries* is generally still considered as insufficient. The cleaning and disinfection is carried out almost exclusively by hand. The sterilizers are often outdated and cannot be validated. A difficult problem is often caused by the shortage of space. An improvement in the equipment begins as a rule only after supervision by the authorities with the laying down of the appropriate measures. The replacement of obsolete sterilizers with modern sterilizers has (only just) begun.

In the outpatient surgical centres the situation reached is very different. More recent establishments usually have cleaning and disinfection equipment as well as modern sterilizers. In older establishments, the cleaning/disinfection work is often still carried out manually and the sterilizers are mostly outdated and cannot be validated. One of the reasons for the sluggish implementation of the RKI/BfArM recommendation is the high costs for new investments. An additional problem is often the shortage of space. Compared with the doctors’ surgeries, while a higher implementation rate has been reached, there is still a lot of catching up to be done in the field of outpatient surgical centres.

In the *dentists’ practices*, a higher degree of implementation of the RKI/BfArM recommendation has been reached than in the doctors’ surgeries. This is also brought about by the additional RKI recommendation on “Preventing infection in dentistry – hygiene requirements”. Furthermore, the relevant activities of the dentist associations of the Federal States play an important role in changing attitudes in this area. But here again there is a lot of catching up to be done.

*Staffing levels* in secondary care vary significantly. In the doctors' surgeries, the staffing levels are as a rule problematic. The lack of expertise among staff entrusted with the reprocessing of medical devices, is seen as the cause of this. Often the "receptionist" is also responsible for reprocessing. The RKI/BfArM recommendation is mostly unknown. Relevant actions by the medical associations of the Federal States have only become significant now.

In the *outpatient surgical centres*, the staffing levels are better than among doctors' surgeries but not yet satisfactory. However, here space shortage is often a problem.

In the *dentists' practices*, the staffing levels are considered to be better. Thanks to the additional RKI recommendation on "Preventing infection in dentistry - hygiene requirements" a strong awareness of the requirements for the reprocessing of medical devices has been achieved.

The quality of reprocessing in secondary care varies considerably. Generally speaking, it is considered to be "sufficient" to "satisfactory". Along with this there are also upward and downward deviations. Doctors' surgeries are those with the most "catching up" to do. This assessment is also true for the reprocessing in out-patient surgical centres. In the dentists' practices, the quality of the reprocessing is deemed to be higher than in the doctors' surgeries. What is problematic here however is the reprocessing of handpieces and anglepieces.

### **4.3 External reprocessors/service providers**

In the field of *external reprocessors* work started early with the transposal of the RKI/BfArM-recommendation. The equipment is generally "good" to "very good". In individual cases, however there is still room for improvement. One so-far unsolved problem with the reprocessing of medical devices of the risk classification "Critical C" is the question of the (voluntary) certification of the quality management system by an accredited body.

The staffing levels are very good. The staff has the specialised knowledge required by the /RKI/BfArM recommendation.

The quality of the reprocessing is mainly considered as "good" to "very good". It can be compared with the quality that well-equipped and well-staffed (large) hospitals reach.

### **4.4 Need for action**

The general picture that we gain is far from uniform. A general comment is also not possible, as the Federal States have a different approach both in terms of content and strategy. Most of the Federal States have started with the supervision of the hospitals. Others have chosen to focus on secondary care and one Federal State had only supervised the reprocessing of flexible gastroscopes.

The comments made about the equipment and staffing and the quality of the reprocessing are therefore to be considered from the point of view of a "trend

assessment". With the RKI/BfArM recommendation, a process has been launched, which in one sense is still in its early phase in many areas.

To summarise, it can however be observed that there is no sign that the existing legal foundations are insufficient for a reprocessing of medical devices in accordance with the regulations. However, it must be ensured that the existing legal provisions are known to all involved and also correspondingly respected. This means that the further improvement of supervision of the RKI/BfArM recommendation by the authorities must be given highest priority.

### **III. Conclusions and measures**

#### ***1. Preliminary remarks***

After analysing the positions received, the Federal Ministry of Health sees a need for action at various levels. First, it must be recorded that contradictory reports exist about the actual reprocessing quality in the health establishments. A nationwide representative study does not exist. That is why the BfArM should take over responsibility for this topic. Independently of this, there is no need for a drastic deviation from the legislative approach followed to date. A general, indiscriminate ban on the reprocessing of so-called single use products is not indicated. Small amendments to the Medical Device Operator Directive, which first and foremost serve as clarifications, are also useful. Preventative patient protection must however be mainly improved through other measures. A central role is played by heightening the awareness of the players involved for a reprocessing of medical devices in accordance with the regulations, as this is essential for patient safety. In this context, we should also point to the emphasised importance of supervision by the authorities of the Federal States, which cannot yet be described as optimal. As preparatory work is required for the further measures, below a chronological approach is suggested. The setting up of expert groups on certain points is necessary in order to be able to recommend scientifically valid and practical improvements.

#### ***2. Immediate measures***

##### **2.1 Study into the quality of processed medical devices**

The discussions in the past few months have shown that no data exist that put into question the quality of reprocessed medical devices in Germany. Of course there are individual reports on the quality of reprocessed so-called single use devices, which however are only based on occasional spot checks, partly commissioned by television magazines. Valid national data, which could justify the need for action in one or other direction, are not available. Many Federal States have therefore asked the Federal Ministry of Health to check whether, under the responsibility of the BfArM, a broad study into the quality of reprocessed medical devices could be carried out. As also the European Commission in the implementation of article 12 a of Directive 2007/47/EC of the European Parliament and of the Council amending Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market is very interested in receiving information on this topic from the Member States and therefore have requested the support of the “largest” Member States in particular, in December 2007, the Federal Ministry of Health entrusted the BfArM with the drafting of this kind of scientific study and its subsequent implementation. Preliminary work has already begun: a broad outline has been drawn up. When evaluating the reprocessing quality, the emphasis of the study should be put on

- the examination of the functionality of the reprocessing,
- cleaning controls,

- microscopic surface examinations,
- examinations of material changes, as well as
- examinations of protein residues.

The study also deals with the foundations for the checking of the functionality of the medical devices as this is seen as a central point for the operational fitness of the medical device. The final concept is currently being drawn up and subsequently the practical approaches will be determined with the participants (in particular the Federal States).

## **2.2 Letter from the Federal Ministry of Health to healthcare federations and organisations**

The importance of medical devices is constantly increasing in the field of patient care today. This also puts the spotlight on aspects such as patient safety related to the use of medical devices. Central topics for reasons of safety are not only technically reliable medical devices but also questions with regard to the reprocessing of these products. Alongside the general hygiene in the healthcare establishments, which has recently been the subject of a far-reaching communication campaign (among others via the “Clean Hand Campaign”) the reprocessing of medical devices is also of central importance.

The positions of the Federal States have unfortunately revealed that awareness and the degree of implementation of the regulations on the reprocessing of medical devices is anything but optimal. In a letter sent by the Federal Ministry of Health to the federations and organisations it is therefore important to underline the importance of these legal provisions for patient safety. Medical devices that are reprocessed in accordance with the regulations and in compliance with the accompanying hygiene requirements make it possible to not only avoid suffering to the patient but the health system can be spared avoidable subsequent costs.

## **2.3 Addition of the topic of “Supervision” to the Federal Ministry of Health report for the 81st Health Minister Conference on July 2<sup>nd</sup> and 3<sup>rd</sup> 2008 in Plön**

The positions received have made it clear that the role and importance of the supervision of all participants is considered as very important. In this respect however, vast discrepancies are still visible between the Federal States. As the transposal of the results of the discussion between the Federal level and the Federal States mentioned above under 1.1.2. is proving to be difficult, the Federal Ministry of Health will include the topic of this report with the emphasis on “importance of supervision” in its written report for the next health minister conference. As the political importance of supervision is very high, as the public reactions to the rotten meat scandal show, Federal Minister Ulla Schmidt will also tackle this point in her oral report.

## **2.4 Mission entrusted to the Commission for hospital hygiene and prevention of infection at the RKI**

Many positions praise the recommendation of the Commission for hospital hygiene and the prevention of infection at the Robert-Koch Institute and the Federal Institute for Drugs and Medical Devices with regard to the “hygiene requirements for the reprocessing of medical devices” (RKI/BfArM recommendation) as exemplary and useful. Nevertheless, several comments are made on the subject of the need for clarifications with regard to practical enforcement. Others call for the recommendation to be made recommendation as binding, for it to be adjusted to the progress in technology or for a specific section to be adopted on the reprocessing of so-called single use devices.

The Federal Ministry of Health will therefore ask the Commission for hospital hygiene and the prevention of infection at the RKI to examine the positions of the relevant players on the RKI/BfArM recommendation and by the end of 2008 to report on any need for action or to prepare a new version of the recommendation.

## **3. Short-term regulatory changes**

### **3.1 Compulsory quality management system (QM-System)**

Reprocessors of medical devices with the risk classification “Critical C” and of certain so-called single use devices, must in future demonstrate a QM system and have it certified by notified bodies accredited by the Central Authority of the Länder for Health Protection with Regard to Medicinal Products and Medical Devices (ZLG). This provision is already contained in the RKI/BfArM recommendation as a “strong recommendation”. The positions received make it clear that the participants have only partly implemented these.

### **3.2 Quality management system requirements for reprocessors**

This QM system must ensure in principle that within the framework of the reprocessing procedure of medical devices with a “critical C” risk classification, a single product test (100% test on the quality, safety and functionality) is carried out for each product. If this is not possible for certain devices during the reprocessing procedure, the functionality of the reprocessed devices is to be ensured through other measures. With the obligation to set up and certify this QM system, the processor must fulfil demands which are not only comparable with the requirements made on the manufactures of medical devices but that even exceed them in relation to the frequency of testing. This applies, for example, to the demand for a general obligation to certify the QM system and the individual testing of the functionality of the devices.

This comes with the obligation to draw up specially adjusted requirements for the QM system for the reprocessing of medical devices of the risk classification “Critical C”. These requirements are based on the manufacturer standards regarding the control of the individual processes and procedures. However, the specific characteristics of the reprocessing procedures with regard to process validation, the guaranteeing of the

product and material properties as well as functional safety must be taken into consideration.

To do so, two possibilities are available:

The DIN could be requested to draw up an applicable standard. As an alternative, the ZLG could be asked, together with RKI and BfArM to draw up a relevant “Good Manufacturing Practice” provision. This could be inspired by the ISO 13485 (QM-standard for medical device manufacturers). Here it must be clarified with the participants which path would be most useful.

The points set out under 2.1 and 2.2 could be implemented with the next amendment of the Medical Device Operator Directive. As the requirements made on the QM system are yet to be drawn up, this point can only enter into force at a later date.

#### **4. Further feasible options**

Below further feasible options are examined but need to be discussed in detail by the players concerned before a decision is taken.

##### **4.1 Make the RKI/BfArM recommendation binding**

With the demand to make the RKI/BfArM recommendation binding, a string of questions need to be answered. As the recommendation is drawn up in the form of a standard, several provisions use the construction “should” or “could”. That is why it is also possible to deviate from this recommendation if a viable reprocessing alternative can be proven.

If the RKI/BfArM recommendation is made binding, it would also be necessary to clarify which function would still be served by the further recommendations of the Commission for hospital hygiene and the prevention of infection such as, for example

- “preventing infection in dentistry – hygiene requirements” of April 10<sup>th</sup> 2006 or the
- "hygiene requirements for the reprocessing of flexible endoscopes and additional endoscopic instruments" of April 1<sup>st</sup> 2002.

It should also be remembered that according to the legal experts, the RKI/BfArM recommendation is already today virtually binding as no alternative proof exists. Some court rulings (among others the administrative high court of Nordrhein Westfalen of 9.11.2007 Az.: 13 B 1192/07 - 16 L 1008/07 Düsseldorf) confirm this impression.

## **4.2 General ban on the reprocessing of so-called single use devices**

Even if this is demanded by some, there is no convincing technical justification for such a ban. We do not have a Europe-wide binding directive for manufacturers laying down when such devices are to be labelled as single use devices that allows us to adopt this principle. That is why it is important to first await the investigations launched by the European Commission and the report that is to be completed by the end of 2010.

## **4.3 Negative list of devices that may not be reprocessed**

According to estimates by the authorities, today, compared to the past, only around 10% of the so-called single use devices are still reprocessed by external reprocessors. This is proof that many so-called single use devices cannot be safely reprocessed in accordance with the current process of technology. In order to prevent for example new reprocessors that are not yet established on the market from being able to advertise with the offer "we reprocess what others no longer reprocess", it could be useful to draw up such a list. The experiences of other Member States or other nations could also be used. A basis for this kind of approach is also offered by the "Instructions on the reuse of selected technical medical consumer goods" of July 27<sup>th</sup> 1981 by the Ministry for Health of the GDR.

## **4.4 Obligatory authorisation for the reprocessing of particularly critical so-called single use devices**

This would take the form of a virtual ban on the reprocessing of certain critical devices that can no longer be safely reprocessed according to the recent progress in technology and science. To avoid putting an obstacle in the way of innovation, as an exception from the rule, reprocessing would have to be made possible only via a special authorisation procedure. This could be implemented by making it compulsory for external reprocessors and sterilisation units in hospitals that reprocess so-called single use devices for third parties, to not only respect a quality management system (see above 2.1 and 2.2) but also to have an authorisation for this activity that is issued by an authority or an accredited private independent organisation. The authorising body would have to evaluate the submitted validation data also from the point of view of the functional safety of every individual device.

Through this state control a high degree of regulatory safety would be implemented. The reprocessing of certain critical so-called single use devices would in principle still be possible. However it would be limited to cases that have already been given an authorisation to carry out this procedure for that device.

Experiences and lists from the USA could be used for the evaluations. Through the authorisation procedure, technological openness would be ensured i.e. with the application procedure, devices that according to current knowledge cannot be safely reprocessed, could be reprocessed in future. With this procedure, Germany would be in a position to build up specialised competences, which can later be used as a reference for an EU regulation of reprocessing.

However, the expertise and any laboratory capacities that are necessary for this task must be built up or further developed (staffing and equipment costs). The costs for the authorisation would have to be paid by the applicants. This would then be passed on to the end customers and thus the health authority. Along with these points of view there are further questions as to the practical nature of this kind of approach which must first of all be answered by experts.

#### **4.5 Laying down of additional labelling requirements**

The law or a directive could contain minimum requirements for the labelling of reprocessed so-called single use devices (special serial numbers, maximum reprocessing cycles, reprocessing cycles carried out, addresses of the reproprocessors or, if relevant, safety information, etc.). The advantages would be a better information of users as well as a practical traceability of the devices. In the context of the avoidance of unnecessary bureaucracy, thought must however be given to the fact that labelling rules already exist in the provisions relating to product liability or other regulations. This also requires a debate at European level, probably also discussions with the USA, Japan and other leading export countries of medical devices in order to ensure a uniform labelling.

#### ***5. Further procedures***

The options presented in part III. can be transposed either immediately or be further discussed in a yet to be established procedure with the players concerned. In these discussions, the participants are naturally free to introduce further alternative actions.

## Annex I

### **1. Letter from the Federal Ministry of Health to federations, organisations, external reproprocessors**

Federation and organisations

(Distribution list)

Bonn, January 2007

#### **Report on the reprocessing of medical devices in Germany**

Dear Sir/Madam,

The reprocessing of medical devices is a difficult process that calls for stringent requirements in the interest of patient safety. On January 1<sup>st</sup> 2002, a whole range of amendments and additions to the Medical Device Act and to the Medical Device Operator Directive as well as ordinances entered into force. With these new rules, the guidelines for the reprocessing of medical devices for the purpose of preventative patient protection were made more stringent. Reference was also made within this context to the central importance of supervision of the reproprocessors by the responsible authorities.

Back in 2002 the Federal Ministry of Health announced its intention to draw up a report on the topic of "Experiences with the changed rules on the reprocessing of medical devices". It is now intended to present this report before the Parliamentary bodies by the end of 2007. The aim is to obtain honest feedback about the actual situation in Germany. To do so, the Federal Ministry of Health needs your cooperation.

I would therefore be grateful if you could send me your position, in particular to the questions below,

**by May 18<sup>th</sup> 2007.**

Naturally, further comments on matters that are not explicitly mentioned here are not only possible by expressly requested.

#### **I. Legal Framework including specialist recommendations:**

1. Do you agree with the **principle**, jointly decided by the Lower and Upper Houses of Parliament, in the interest of preventative patient protection, of strict guidelines for the reprocessing of all medical devices and thus without discrimination between so-called single use and multi use devices, in the light of the experiences of the last few years?
2. Current practice in Germany: Those who respect the strict guidelines of the "Recommendation of the Commission for hospital hygiene and infection prevention of the Robert Koch Institute and the Federal Institute for Drugs and Medical Devices with regard to the hygiene requirements in the reprocessing of

medical devices" (RKI/BfArM recommendation) are also authorised to reprocess so-called single use devices. Do you believe this to be right? If not, why not?

Independently of your answers to questions 1 and 2:

3. Do you consider the existing legal provisions governing the concrete requirements for the reprocessing of medical devices to be sufficient in order to allow the safe reprocessing of these medical devices? If not, where do you see concrete need for improvement?
4. Are the "Recommendations of the Commission for hospital hygiene and infection prevention at the Robert Koch Institute and the Federal Institute for Drugs and Medical Devices for hygiene during the reprocessing of medicinal products" (RKI/BfArM recommendation) concrete enough?

Do you believe that there is a need for more precision/additions to the following (examples) key points?

- Area of application
- Relation to further proposals of the Commission for hospital hygiene and infection prevention at the Robert Koch-Institute
- Do you see any other need for changes or additions to the RKI/BfArM recommendation?

## **II. Experiences in relation to supervision**

5. Do you believe that the staffing levels of the authorities for the supervision of the existing legal provisions are sufficient? Are there any shortcomings? If so, which?
6. How do you assess the expertise of the supervision staff? Do you see any room for improvement? If so, which?
7. How do you evaluate the qualitative improvements in reprocessing achieved thanks to the changes and additions to the Medical Device Act and Medical Device Operator Directive introduced in 2002?

Yours faithfully,

On behalf of

Dr. Schwerdtfeger

## **2. Letter from the Federal Ministry of Health to the authorities**

Highest Federal States authorities for medical devices

Federal Ministry of Defence

ZLG

BfArM

RKI

Bonn, January 2007

### **Report on the reprocessing of medical devices in Germany**

The reprocessing of medical devices is a difficult process that calls for stringent requirements in the interest of patient safety. On January 1<sup>st</sup> 2002, a whole range of amendments and additions to the Medical Device Act and to the Medical Device Operator Directive as well as ordinances entered into force. With these new rules, the guidelines for the reprocessing of medical devices for the purpose of preventative patient protection were made more stringent. Reference was also made within this context to the central importance of supervision of the reprocessors by the responsible authorities.

Back in 2002 the Federal Ministry of Health announced its intention to draw up a report on the topic of "Experiences with the changed rules on the reprocessing of medical devices". It is now intended to present this report before the Parliamentary bodies by the end of 2007. The aim is to obtain honest feedback about the actual situation in Germany. To do so, the Federal Ministry of Health needs your cooperation.

I would therefore be grateful if you could send me your position, in particular to the questions below,

**by May 18<sup>th</sup> 2007.**

Naturally, further comments on matters that are not explicitly mentioned here are not only possible by expressly requested.

I would also appreciate the participation of the authorities responsible for local supervision.

#### **I. Legal Framework including specialist recommendations:**

1. Do you agree with the **principle**, jointly decided by the Lower and Upper Houses of Parliament, in the interest of preventative patient protection, of strict guidelines for the reprocessing of all medical devices and thus without discrimination between so-called single use and multi use devices, in the light of the experiences of the last few years?

2. Current practice in Germany: Those who respect the strict guidelines of the "Recommendation of the Commission for hospital hygiene and infection prevention of the Robert Koch Institute and the Federal Institute for Drugs and Medical Devices with regard to the hygiene requirements in the reprocessing of medical devices" (RKI/BfArM recommendation) are also authorised to reprocess so-called single use devices. Do you believe this to be right? If not, why not?

Independently of your answers to questions 1 and 2:

3. Do you consider the existing legal provisions governing the concrete requirements for the reprocessing of medical devices to be sufficient in order to allow the safe reprocessing of these medical devices? If not, where do you see concrete need for improvement?
4. Are the "Recommendations of the Commission for hospital hygiene and infection prevention at the Robert Koch Institute and the Federal Institute for Drugs and Medical Devices for hygiene during the reprocessing of medicinal products" (RKI/BfArM recommendation) concrete enough?

Do you believe that there is a need for more precision/additions to the following (examples) key points?

- Area of application
- Relation to further proposals of the Commission for hospital hygiene and infection prevention at the Robert Koch-Institute
- Do you see any other need for changes or additions to the RKI/BfArM recommendation?

## **II. Experiences in relation to supervision**

5. To what extent are the corresponding regulations, in particular the RKI/BfArM recommendation known to the reprocessors and how are they implemented (difference between hospitals, doctors' surgeries and external reprocessors)?
6. How is the equipment and staffing levels of the processors evaluated (e.g. technical equipment and number and qualification of staff, organisational rules such as for example the allocation of responsibilities)?

Which shortcomings were noticed in particular?

7. How is the cooperation with the authorities of other affected areas evaluated (for example, the infection protection law, public health)?

Does this offer any possibilities of overcoming any personnel shortages?

8. How do you evaluate the qualitative improvements in reprocessing achieved thanks to the changes and additions to the Medical Device Act and Medical Device Operator Directive introduced in 2002?

### **III. Additional information requested by the Federal Ministry of Health**

Independently of the questions put to you in relation to the report for the attention of the health committee of the Lower House of Parliament, the Federal Ministry of Health is also interested in answers to the following questions:

1. Which problems have been observed within the framework of the supervision of the reprocessing of medical devices (e.g. badly reprocessed medical devices, possible causes?) What measures were implemented if any?
2. How do you generally evaluate the quality of the reprocessing of medical devices on the basis of the supervision results (differences between hospitals, doctors' surgeries and external reproprocessors)?

Yours faithfully,

On behalf of

Dr. Schwerdtfeger



### **About EAMDR:**

The European Association for Medical Device Reprocessing (EAMDR) was created in 2003. It represents and promotes the interests of associations and research institutes, companies, opinion leaders on hygiene and microbiology, as well as members of the medical device industry involved in the reprocessing of medical devices throughout Europe.

### **Contact information:**

- EAMDR · Avenue Louise 149/24 · 1050 Brussels · Belgium  
Tel.:+32 (0) 2 / 788 17 77 · Fax: +32 (0) 2 / 788 17 78 · e-mail: [info@eamdr.org](mailto:info@eamdr.org)
- EAMDR Administrative Office: Französische Str. 23 · 10117 Berlin · Germany  
Tel.:+49 (0) 30 / 80 90 64 66 · Fax: +49 (0) 30 / 80 90 64 65  
e-mail: [info@eamdr.org](mailto:info@eamdr.org)
- President: Robert Schrödel · Managing Director: Nikou Ghassemieh