IHK Industrie- und Handelskammer Schwarzwald-Baar-Heuberg

MedicalMountains

Position paper

Statements and demands of the medical technology industry on the proposal for an EU medical devices regulation

Introduction

The European Commission plans to introduce a standardised regulation concerning medical devices. In September 2012 the EU Commission presented a proposal (2012/0266) to parliament. The new regulation aims to unify and standardise Directives 93/42/EEC and 90/385/EEC.

The proposal has caused a lot of commotion in the Tuttlingen area, the international centre of medical technology. If the regulation should pass as planned numerous manufacturers in the medical technology industry expect significant subsequent expenses and disadvantages, while smaller manufacturers may even face a threat to their existence. It can already be said that the regulation will have a significant influence on the health care market within the EU and beyond.

For this reason the regional cluster organisation MedicalMountains AG has called for various conferences and workshops of experts in medical technology between November 2012 and February 2013. Together they developed this position paper with statements and demands of medical technology manufacturers. The medical technology industry in the Tuttlingen area is one of the biggest driving forces in international medical technology. So it is natural that they have a great interest in making a mutual and substantial statement on this subject. It is their goal to inform the EU Commission about the potential of optimisation of the proposed regulation and the expected consequences for the pioneering medical technology industry. Our goal is to point out unclear issues and necessary corrections as well as to assist in making the necessary changes and adaptations of the proposal.

We explicitly identify with the goals, which are included in the new regulation such as, for instance, the achievement of maximum safety for patients, users and others. We are also for a standardised regulatory framework, which applies to all economic operators of the EEC alike. However, as a general rule, fast access to the market must still be guaranteed for innovative technologies in Europe.

In addition to important and positive aspects the presented proposal shows a proneness to hyperregulation, which cannot be in the interest of its authors. This includes the demand of elaborate and costly controls, which would pose a particular disadvantage to small- and medium-sized enterprises in medical technology. It should be remembered that the medical technology industry already currently has the highest standards in quality and safety, which are implemented conscientiously. Criminal intentions cannot be averted through tighter legislation, already available tools of sanctioning should be fully exploited instead.

With this position paper we would like to provide a first statement on the proposed regulation of the EU Commission. It should serve as a basis for constructive discussions with politicians and the EU Commission.

Overview of key demands

1. **Publications**: It should be clearly defined, which data entered into the EUDAMED are published and who will have access to these data. Additionally, a longer interval should be prescribed for on-going data validation. We suggest an interval of 5 years here with an appropriate timely reminder (Articles 25, 27).
2. **Unique device identification** (UDI): Nationally isolated solutions must be replaced by the EUDAMED database system (Articles 23 + 24, Annex V).
3. **Vigilance procedures:** National vigilance procedures must be terminated and replaced with the central procedure (Articles 61-66).
4. **Requirements for notified bodies:** It must be ensured that the notified bodies in countries outside of Europe audit in accordance with the same standards as in Europe and that the monitoring of non-European sites is subject to the same requirements as those within the EEC (Articles 28 + 29, Annex VI).
5. **Qualified person:** The "qualified person" should be introduced throughout the EU. The medical device consultant, who has been tried and tested in Germany, should also be included in the regulation (Article 13).
6. **Unannounced factory inspections and sampling:** Orders for unannounced audits and sampling should be made by national authorities. Furthermore, this procedure should only be possible, if there is a comprehensible reason (Article 42 Para. 10 and Article 67).
7. **Classification criteria, classification rules 6 and 7:** The word "special" must be included again in the first bullet point of Rule 6 and also in the first bullet point of Rule 7 of the regulation. Classification rule 19: It is absolutely imperative to define the classification of **nanomaterials** more specifically, so that only technically produced nanoparticles are considered and not those that are accidentally released (Annex VII).
8. **Control of certain conformity assessments:** The mechanism regarding the control of certain conformity assessments is rejected in general, since the current system is sufficient and works efficiently (Article 44).
9. **Implant card:** The kind of implants referred to must be defined more accurately. Only users (hospital, physician) can be obligated to hand out implant cards to the patient in the correct "language" (Article 16).
10. **Single-use devices:** It is positive that companies, which reprocess single-use devices will be considered manufacturers in the future. We think it is necessary for a higher patient safety to prohibit the reprocessing of certain single-use devices. (Article 15).
11. **Repair/maintenance** of medical devices: Only repairs should be allowed, which are performed and documented in accordance with the original manufacturer's specifications. A sufficient qualification and certification of the repairer is to be demanded. (Article 21).

Positive aspects

1. The proposal takes the form of a regulation that ensures that directly applicable, standardised rules and an equal quality level are achieved throughout Europe.
2. The CE process of the "New Approach" is left unchanged in its principles (Article 42). The maintenance of the proven system with its processes of conformity assessment and its further development to improve patient safety are positive.

Critical aspects

1. The central European database **EUDAMED** (Articles 25, 27) is to be expanded and contain standardised, **publicly accessible data** of medical devices.

   In general, a standardised database is welcomed as is the fact that the public also has access to certain information. However, access to particularly sensitive and confidential data must be limited, so that only authorities and the notified bodies have access to these data. The effort required to enter and maintain data should be of reasonable scope for the manufacturer. The database must be reliable and easy to operate.

   The economic operators should be obligated in Article 25 Para. 5 to confirm the entered data every two years. The device could otherwise be taken off the market due to a formal error. This demand is unreasonable. Company representatives recommend an interval of 5 years as well as mechanisms with a timely reminder.

   The database should be used as an obligatory tool for all operators. It must provide the option for manufacturers to create so called "free sales certificates" with the help of the system.

   In various articles of the proposed regulation the publication of certain data and documents is demanded, which include summaries of safety and clinical performance for class III devices, certificates (Article 45 Para. 4) and clinical investigations (Article 53, Article 27 Para. 2 d).

   The following must be pointed out here: In general, confidential and highly sensitive business data should not be publicly accessible. It should be clearly defined, which data are published and who will have access to these data. Confidential data must be protected. Additionally, it must be taken into consideration for the planned regulation that manufacturers themselves have a right to fully access data stored about them. This is not intended so far in Article 62.

2. In the future there will be a system of **unique device identification** (UDI) in the EU. The UDI should enable the distinctive identification of medical devices and facilitate their complete traceability. (Articles 23 + 24, Annex V).

A standardised coding system for medical devices is in general positive, also in combination with a central database of medical devices (EUDAMED). However, the central registration of devices will only be an advantage, if all national reports and/or registrations become no longer necessary at the same time. Italy's system should be mentioned here in particular: Italy currently operates its own coding system, which is incomplete and requires additional effort in device registration. Isolated national solutions must be replaced with the UDI and EUDAMED database system.

The traceability of devices is interrupted by the end user in many cases. A convincing approach in the regulation is missing here, for instance, regarding how the UDI is handled at the hospital.

In general, a standardised, regulated system across Europe, which is based on international guidelines, is welcomed.

3. Vigilance procedure (Articles 61-66): According to the proposal the **vigilance procedure** is to be standardised and centralised. At the same time national vigilance procedures have to be eliminated.

4. The planned regulation demands higher and especially standardised **requirements for notified bodies** (Articles 28 + 29, Annex VI). The notified bodies would need to be renotified after the introduction of the regulation and would then be subject to centralised control.

   It must be seen as a positive aspect that the notified bodies will be subject to the same criteria and requirements across the EU and the notified bodies themselves will also be controlled under a standardised system.

   It must be also ensured that the notified bodies in countries outside of Europe audit in accordance with the same standards as in Europe and that the monitoring of sites is subject to the same requirements as those within the EEC. If this is not ensured, European manufacturers would be at a disadvantage.

   It must also be checked beforehand and ensured by appropriate methods from the authorities that the notified bodies are able to fulfil their significantly extended tasks. This includes to ensure that all notified bodies are qualified to bridge the gap between being an economic operator and a quasi-authority.

5. The proposed regulation also demands that the manufacturers appoint a particular **qualified person**, who ensures that the manufacturer (Article 13) follows all legal provisions.

We support this approach. The qualified person must be appointed by the management and fulfil specified criteria. A basic requirement should be to have at least 5 years of experience in the medical technology industry as well as knowledge in conformity assessment and vigilance procedures. It should be made possible in any case to engage a qualified person from outside. Despite the engagement the responsibility, however, lies with the manufacturer.

Furthermore, the appointment of medical device consultants has proven its worth in Germany. We recommend introducing them in the whole EEC in addition to the "qualified person." This is an informed person, who provides, among others, the consultation and instructions to users. At the same time this person would be legally obligated to report knowledge about device defects and risks to the manufacturers in writing.

Due to the positive experiences we suggest to make the medical device consultant mandatory for manufacturers and other economic operators in the regulation.

6. According to the proposal, the notified bodies should make **unannounced inspections to the manufacturers' factories** and, if necessary, their suppliers and subcontractors (Article 42 Para. 10).

   If the regulation allows unannounced factory inspections, the extent and costs of regular audits are at least to be credited. Additional factory inspections pose an added strain on the manufacturers. We would like to point out that unannounced audits and sampling are only justified, if there is good cause.

   These unannounced factory inspections should only be made possible, if there is an imminent danger or if certain incidents were reported. These inspections should be appropriate in light of the device risk and only be ordered by the responsible authority.

   Furthermore, the proposed regulation of the EU Commission allows the taking of **samples** on the free market (Article 67).

   The type of audit to be performed must be exactly defined. Samples should only be taken, if there is an imminent danger or if there is a reasonable cause for suspicion. The national authority must be able to provide comprehensible reasons while maintaining a certain commensurability. The limit of the risk class should be clearly defined here. It is also not clearly defined what costs will incur for the manufacturers.

7. **Classification rules 6 and 7:** The word "special" must be included again in the first bullet point of Rule 6 and also in the first bullet point of Rule 7 of the German version of the regulation. Rule 7 contains a false translation, where the word "special" is missing in the German version. According to Rule 6, first bullet point, all devices not specifically intended for use on the heart would be classified as class III.

Classification rule 19: It is absolutely imperative to define the classification of **nanomaterials** more specifically, so that only technically produced nanoparticles are considered and not those that are accidentally released (Annex VII).

8. According to the proposed regulation an additional control mechanism (Article 44) will be installed in addition to the established CE procedure for class III devices.

   Coordination group: This mechanism is rejected in general, since the current system is sufficient and works efficiently.

   An additional control by the coordination group as described in the proposed regulation would unnecessarily extend the process of certain conformity assessments (60 + 30 days, possibly suspension of the period due to requests for additional information). Such a control mechanism would also question the competence of the notified bodies. Furthermore the benefit of such a coordination group sought has not yet been proven. A standardised and coordinated monitoring of the notified bodies and notifying authorities would be a more reasonable solution.

9. According to the proposed regulation manufacturers of an implantable device are supposed to deliver an **implant card** together with the device, which is to be given to the patient. This card should be comprehensible to laypersons (Article 16).

   The type of implants must be defined more precisely. The implant card should only apply to sterile packed implants. Screws and plates, for example, which are used to treat fractures, should not require an implant card.

   We consider this to be primarily the users' (hospital, physician) responsibility, since only they are in direct contact with and can specifically inform the patient about potential risks regarding the provision of one or more implants.

10. According to the proposed regulation companies, which reprocess **single-use devices**, will be regarded as manufacturers in the future and subject to all requirements of the regulation (Article 15).

    Since the reprocessing of invasive single-use devices in regard to the used materials and the design is not intended, another conformity assessment is required by the responsible manufacturer.

Hospitals, central sterilisers or external service providers are not familiar with all relevant properties of single-use devices. They are also not informed about technical changes, which have been made by the manufacturer in the meantime. Such changes, however, may have drastic effects on the result of reprocessing and subsequently on patient safety. For this reason third party reprocessing of single-use devices cannot be validated, because the technical, functional and especially hygienic safety of a reprocessed single-use product cannot be ascertained. We think it is necessary for a higher patient safety to prohibit the reprocessing of certain single-use devices.

11. The **repair or maintenance** of medical devices is not or insufficiently regulated in the proposed regulation (Article 21).

    Only repairs should be allowed, which are performed and documented in accordance with the original manufacturer's specifications. If such information is missing or if appropriate information of the manufacturers is ignored, the repairing company must accept full responsibility of a manufacturer in the future.

    Devices, which are not repaired in accordance with the specifications of the original manufacturer, may no longer fulfil the general requirements or the safety and performance requirements. This means that the repaired device came without an EC declaration of conformity.

12. In connection with the planned regulation, the EU Commission reserves the right to more than 50 delegated legal acts and implementing acts, which means that it could change many passages of the regulation without a parliamentary hearing after the regulation has passed. This element of uncertainty is not acceptable for the companies.

    Representatives of the medical device manufacturers should be involved in further consultations and decisions.

    No claim is made to completeness.

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