Karolina Sojka, Keywan Sohrabi, Volker Gross and Michael Scholtes*

Reflection of the Medical Device Regulation

A Review of Socioeconomic Impacts

https://doi.org/10.1515/cdbme-2023-1051

Abstract: The MDR states the objectives of the law in the preface. There you will find, among other things, a consideration of small and medium-sized enterprises as well as high health protection and an innovative effect. Therefore, the question arises to what extent these goals have been achieved so far or can be achieved in the foreseeable future. To this end, a systematic literature review was conducted to present the perspectives of various stakeholders in the healthcare sector. Critical situations certainly arise for certain manufacturers, Notified Bodies and certain patient groups. The adopted extension of the transitional periods could be helpful but will not solve all problems.

Keywords: Medical Device Regulation, Socioeconomic Impact

1 Introduction

1.1 Goals of the Medical Device Regulation

Since May 26, 2021, the EU Regulation 2017/745, referred to as the Medical Device Regulation (MDR for short), has become fully valid, replacing the previous European directives. The trigger for this legal revision was, among other things, scandals such as that of the breast implant manufacturer Poly Implant Prothèse. Among other things, patient protection was to be ensured by tightening up the regulations. In the preface of the MDR, the following objectives thus emerge: "*This Regulation aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health (...), and taking into account the small- and medium-sized enterprises (...)"* and *"ensures a high level of safety and health whilst supporting innovation.*" [1]

1.2 Scientific reflection of MDR's socioeconomic impacts

The question arises to what extent these self-declared goals of the MDR have already been achieved or can be achieved. Based on a systematic literature research, this review lays out the current and foreseeable impacts of the MDR on manufacturers, Notified Bodies, and physicians and their patients. Even though the MDR applies throughout Europe, this work focuses on the German medical device market.

2 Material and Methods

The process of conducting and selecting the literature is guided by Brocke [2]. Literature in English- and German-language was enclosed. The following literature databases were searched: EBSCO, Google Scholar, IEEE Xplore, PubMed, Springer Link, Thieme and WISO.

German and English search terms were used with all possible synonyms and Boolean links were created between reasonable combinations. Common abbreviations and written out terms as well as truncations were used. The search terms (more than 50 terms) include the following:

- "*medical device regulation AND challenge**",
- "*medical device regulation AND impact**",
- "*medical device regulation AND opinion**",
- "*medical device regulation AND reflection**",
- "*medical device regulation AND small and medium enterprises OR SME*",
- "*medical device regulation AND effect**",
- "*medical device regulation AND notified bod**",
- "*medical device regulation AND patient* care*".

A total of 197 sources were found, of which 50 sources were classified as relevant and evaluated, and 22 were included in this paper. The identified impact was structured by Notified Body, manufacturer and physicians with their patients.

***Corresponding author: Michael Scholtes:** Faculity of Health Sciences - University of Applied Sciences Giessen, Wiesenstraße 14, Giessen, Germany, e-mail: michael.scholtes@ges.thm.de
Karolina Sojka, Keywan Sohrabi, Volker Gross: Faculity of Health Sciences - University of Applied Sciences Giessen

3 Results

3.1 Impact on Notified Bodies

Medical device manufacturers - with medium or high-risk devices - are obliged to involve a Notified Body for the conformity assessment procedure. The new requirements of the MDR must be implemented and observed by the manufacturers. However, it is the Notified Bodies that must verify compliance with these requirements based on the Technical Documentation in order to issue a corresponding CE certificate.

BVMed CEO Dr. Marc Pierre Möll explained that a huge certification backlog is looming in the next few years due to scarce resources and that Notified Bodies will not be able to meet the challenges placed on them. [3] He also mentions the following possible solutions: "*Notified bodies must be notified more quickly*", "*sufficient resources must be available in the Notified Bodies*", "*all areas of expertise of the notified bodies must be covered*", and "*the duration of existing certificates for medical devices must be extended*."

Another approach comes from Dr. Max Singh, Global Director of TÜV Süd Product Service, in his opinion, the technical documentation must be better structured by the manufacturers [4]. In February 2023, the number of Notified Bodies across Europe under the MDR was 37, under the previous directive it was more than 50, the capacities are not enough yet [5].

In BVMed's May 18, 2022, press release, Dr. Marc-Pierre Möll and Dr. Martin Walger, executive directors of VDGH (Verband der Diagnostica-Industrie), explain that there are fewer Notified Bodies and fewer resources under the MDR and IVDR compared to the previous directives - while at the same time there are more products to be certified in a shorter period of time and more extensive testing and audits. [6]

By May 2022, only just under 1,000 of 25,000 required certificates had been issued [7]. So, by May 2024, about 24,000 certificates still need to be issued. However, since certification takes an average of 18 months, this quantity is not feasible. For applications submitted today, there is thus hardly any chance that they will be processed on time [8].

3.2 Impact on manufacturers

To meet the quality management requirements, 62 % of the companies have hired additional specialists. Approximately 68 % of the companies surveyed make additional use of external service providers, both of which also increase expenditure. [9]

Furthermore, 77 % of the companies, state that the duration of the review of the technical documentation for existing medical devices is very much prolonged. The delays are causing further revenue losses for some companies. In the foreseeable future, 74 % of companies expect to reduce their product portfolio or have already done so [10]. Due to the tightening, funds from research and development must be used for regulatory purposes [11]. As a result, innovation is suffering at 58 % of companies. For some medical device companies, a critical or even existence-threatening situation may arise. [12]

The German Medical Technology Association (BVMed) conducted an autumn survey of a total of 110 member-companies in 2021. This revealed that the biggest obstacle to the future development of medical devices is the MDR. Nearly 70 % of companies are calling for a simplified process of recertification for recognized and commonly used existing products. The new requirements emerging as a result of the MDR, represent the biggest obstacle related to medical device industry development for 87 % of companies. The required comprehensive clinical data is seen as critical by 77 % of BVMed companies. In particular, niche products that are manufactured for special patient groups and custom-made products, that are individually adapted for patients, are strongly affected [13]. According to the MDR, no simplifications apply in this regard [14]. [15]

In addition, difficulties in understanding the interpretation of the MDR are apparent. Currently, there are about 100 guiding documents to clarify the MDR's deficiencies and ambiguities texts and to present it in a more comprehensible way [16].

For 35 % of the companies, the situation is critical, as the lack of data means that the clinical evaluation by the Notified Bodies is classified as inadequate. This has a negative impact on the conformity assessment procedure in terms of time and money. In addition, clinical studies are also required for numerous existing products, e.g. due to a higher classification [17]. Of the companies surveyed, 30 % will need to conduct clinical studies for their products over the next five years in order to survive in the marketplace. Of these, 48 % face additional complications due to negative evaluations by ethics committees or a lack of investigators to conduct clinical trials [18]. [19]

A survey of 18 e-health start-ups by Hagen and Lauer in August 2017 found that most of them (72 %) are engaged in developing medical app applications. Start-ups identified the biggest hurdles as certification costs (44 %), certification duration (67 %), and reimbursement (72 %). [20]

In Switzerland, medical devices become around twelve percent more expensive on average. Additionally, two-thirds of Swiss manufacturers stated that they will have to reduce their product portfolio - by an average of 13 %. [21]

3.3 Impact on physicians and their patients

The situation described for manufacturers also affects medical professionals and their patients. There will be treatment difficulties in the near future for certain patient groups with rare diseases or physical disabilities [22]. This will severely limit the treatment options for these patient groups. [19, 23-25]

4 Discussion and Perspective

The shortage of skilled workers is further exacerbating the situation. The increased costs are difficult to compensate, especially for SMEs, and niche products in particular are disappearing from the market; on the patient side, this particularly affects children and patients with rare diseases. Innovations have been cut back, as funds have been diverted from research and development to the conversion of technical documentation. The situation is summarized in Fig. 1. Thus, the goal of the MDR *"(...) taking into account the small- and medium-sized enterprises (...)*" as well as "*(...) whilst supporting innovation*" is missed. The goal of "*(...) ensures a high level of safety and health (...)*" does not seem to be achieved by the reduction of products either. According to Prof. Gassner, the goals of the new MDR have also not been achieved: "*In the end, a minus balance of life years is achieved*". [13]

In addition, many companies plan to carry out marketing and initial registration outside Europe, so that fewer products will be available on the European market [19, 26]. The danger that Europe will distance itself further from the USA and China in medical technology is great [24].

A small ray of hope was the proposal adopted by the Commission on January 06, 2023, which, among other things, provides for an extension of the original transitional provisions, according to which: "*For medical devices for which a certificate or a declaration of conformity was issued before May 26, 2021, the period for transition to the new rules [of the MDR] will be extended from May 26, 2024, to December 31, 2027, for higher-risk devices, and to December 31, 2028, for medium- and lower-risk devices.*" [27]

In an urgent procedure, the EU Parliament has approved the EU Commission's proposals in February 2023. However, many strategic and business decisions have already been made and may not be reversible, so the consequences of the MDR will not be completely reversed by this extension.

Furthermore, the authors question whether this extension constitutes a distortion of competition. Since companies that may have taken care of the changeover to MDR too late could now have an advantage. Companies for which the changeover

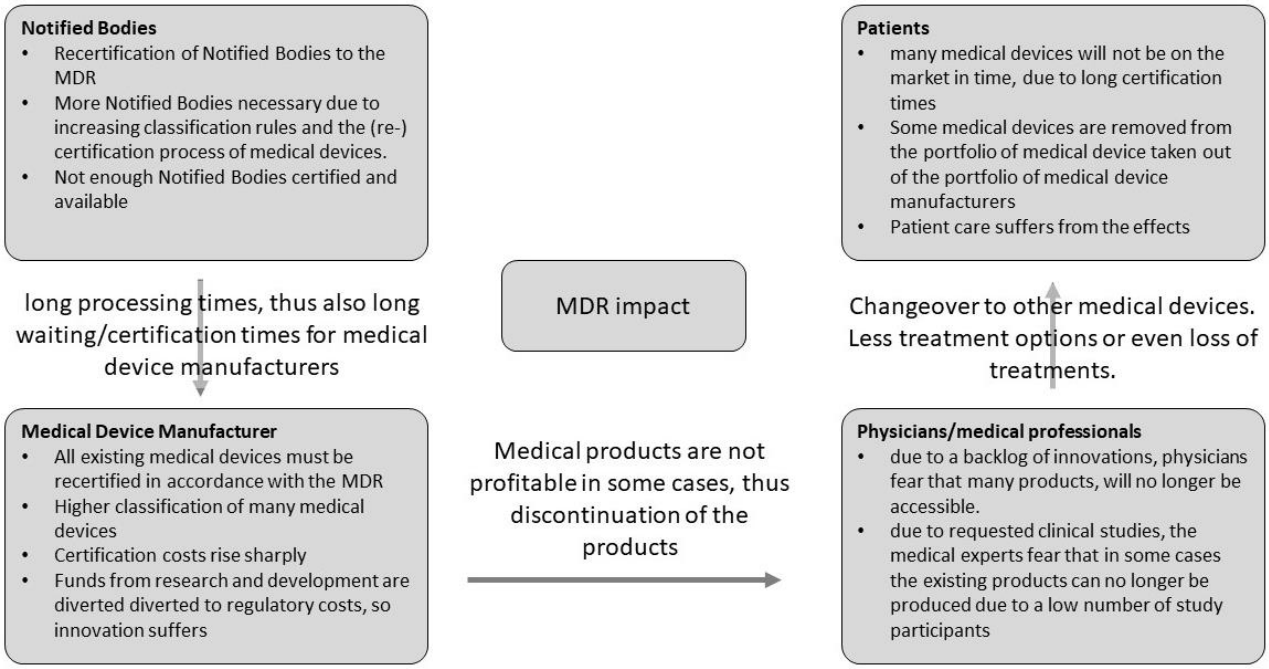

Figure 1: Impact of MDR on various players in the healthcare system and their interdependencies.

is not profitable may not benefit from the extension because they have not submitted an application to a Notified Body.

Author Statement

Research funding: The author state no funding involved. Conflict of interest: Authors state no conflict of interest. Informed consent: Informed consent has been obtained from all individuals included in this study. Ethical approval: The research related to human use complies with all the relevant national regulations, institutional policies and was performed in accordance with the tenets of the Helsinki Declaration, and has been approved by the authors' institutional review board or equivalent committee.

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