Impact of Medical Device Regulation on Developing Health Behavior Change Support Systems

Eunice Eno Yaa Frimponmaa Agyei [0000-0002-2011-0659], Sami Pohjolainen [0000-0002-4429-4245], and Harri Oinas-Kukkonen [0000-0002-1442-0562]

University of Oulu, OASIS, Pentti Kaiteran katu 1, 90570, Oulu, Finland
eunice.agyei@oulu.fi

Abstract. The enforcement of the Medical Devices Regulation (MDR) began in the European Union (EU) in May 2021. Under MDR, software and information systems may be considered as medical devices. Behaviour Change Support Systems (BCSS) are information and communication technologies aimed at helping their users to achieve behaviour change targets. Designers, developers, and researchers of health BCSS (hBCSS) need to understand the impact of this new regulation on the development of such systems as the regulation influences both design and development in a variety of ways. Furthermore, myriads of health BCSS have been developed previously in the medical, fitness, and wellbeing domains, and a substantial number of them may require qualification, classification, or reclassification as medical devices under the new regulation. However, the regulation process is complex and requires knowledge and expertise which many manufacturers do not have in-house. Depending on the context and classification, the costs may suddenly ramp up and become too much for smaller developers, and thus they should be carefully assessed. In this paper, we discuss the regulation from the point of view of hBCSS developers. We look at the regulatory process and highlight key issues for developers of hBCSS. Particular attention is given to the classification and design requirements most likely to pose immediate challenges to developers. In addition, we discuss the costs associated with MDR which are difficult to estimate without previous experience.

Keywords: Medical Device Regulation, MDR, Medical Device Software, Software Development, Persuasive Systems Design, PSD, Health Behaviour Change Support Systems, BCSS, hBCSS.

1 Introduction

There is a myriad of medical devices, including software and information systems, in the EU and the number is expected to increase rapidly to include more and more devices that perform invasive and critical functions [1]. More than 90 000 digital health apps were released in 2020 and an estimated 350 000 are already available to consumers [2]. Many of these apps are marketed for fitness and wellbeing, but an increasing number are targeted at specific diseases such as cardiovascular disease, diabetes, and mental health [2]. While an increasing number of new medical devices, including

apps, have influenced the new regulation, it was a few cases involving implants that prompted the European Commission (EC) to take immediate action to start revising the regulation in 2012 [1, 3] although the medical industry lobbied against it [4]. The weaknesses of the Medical Device Directive (MDD) regulation [5], which was operational at the time, were apparent [6] as it was too generic and lacked detailed information on its requirements. Also, some privately owned Notified Bodies who were charged with the responsibility of evaluating device safety and reliability and for issuing compliance certificates were more interested in attracting business than in the safety and reliability of the devices even to the extent that safety in some situations was compromised [4]. A closer examination of Notified Bodies was initially prompted by a few notable cases, such as the fake hip replacement case [7], fraudulent breast implant scandal [8], and failures with transvaginal meshes [9].

Medical Device Regulation (MDR) came to force in the European Union (EU) on May 25, 2017, however, its implementation was later delayed until May 2021 [4, 10]. As a high-level objective, MDR seeks to ensure that medical devices available in the EU market are safe to use and perform efficiently. Notably, health information systems and software may be considered as medical devices under the new regulation. MDR compliance defines requirements that manufacturers, authorized representatives, importers, and distributors need to comply with. These requirements may have both positive and negative impacts on software product development. When much innovation happens in small companies, the heavy load imposed by the regulation may relatively speaking, impact them more than large companies [11, 12].

Behaviour change support systems (BCSS) are technologies that are designed to influence the habits, behaviours, and attitudes of users without deception or coercion; designing such technology requires a deep understanding of the interplay between people, technology, and behaviour change [13]. The Persuasive Systems Design model (PSD) is a comprehensive framework for designing, developing, and evaluating persuasive technologies [13]. The model describes the fundamental issues behind persuasive systems and the context in which a system will be used and specifies design principles for supporting (1) a user to perform the primary behaviour change activities or tasks (i.e. Primary task support), (2) ongoing interaction between the computer and the user (i.e. Dialogue support), (3) the credibility of the persuasive system (i.e. System credibility support), and (4) users via social influence (i.e. Social support) [13]. Such systems designed for the medical domain provide benefits that help monitor and manage health conditions and improve the quality of life.

In this paper, we consider MDR and its impact on the development of hBCSS. Key aspects of the regulation and its requirements as well as notable changes from the previous directive, MDD, are highlighted. We outline what it takes to qualify an hBCSS as a medical device, what determines its risk class, and how it impacts the design and development process. Finally, we discuss cost-related implications.

2 Medical Device Regulation (MDR)

MDR aims to ensure high standards of safety and performance for medical devices across the EU [10]. The new regulation replaces MDD [5]. Other regions of the world and many national markets outside the EU have regulations that share similarities. However, MDR is stricter than for example a similar regulation in the United States by the Food and Drugs Administration (FDA) and brings more scrutiny and oversight for medical devices. It also makes the regulation more uniform across the EU leaving less room for national legislation. Moreover, MDR defines harmonized standards (cf Article 8 [10]), introduces common specifications (cf Article 9 [10]), and refines the roles and actions of Notified Bodies [14].

All medical devices must possess a Unique Device Identifier (UDI) to enable traceability [15]. Competent authorities use UDI and the European database on medical devices (EUDAMED) to monitor devices on the market, thus improving safety and performance [15]. Manufacturers must carry out post-market surveillance activities and record them in the EUDAMED system. The scope of post-market activities depends on the risk class of the device. Manufacturers who identify safety or performance issues or incidents with their devices must report them and take corrective actions promptly [10]. To implement this and to improve transparency and coordination, the EUDAMED database is available publicly. In the database, devices and certifications will be registered alongside economic operators (i.e., manufacturers, authorized representatives, importers, and distributors) in the supply chain. The system includes reports from performance studies and clinical investigations while containing vigilance and post-market surveillance activities of manufacturers [16].

2.1 Transition Timeline

Developers of hBCSS should be aware of transition timelines for MDR [17]. The transition from MDD to MDR will take place in several steps. MDR entered into force and has been partially applicable since 26th May 2017. The key date was 26th May 2021 when MDR became fully applicable [10] after which all new medical devices must conform with the regulation. Manufacturers can use the transition period to acquire MDR certification. On May 26th, 2024, all medical devices on the market that fall under MDR must be certified. Notably, there is a grace period until 27th May 2025 for devices with a valid MDD certification.

Medical devices and software under MDR are assigned classes (i.e. Class I, IIa, IIb, and III) [10] based on the risks they pose to users with Class I posing the lowest risk and Class III, the highest risk. There are two exceptions for Class I devices when it comes to the transition timeline. Firstly, export declarations for Class I devices that fall under a higher risk class in the new regulation expire on 26th May 2024. Secondly, export declarations issued for Class I devices that did not require a conformité européenne (CE) certificate under MDD expired on 26th May 2021. For other risk classes, previous MDD certifications are valid until they expire, but will require registration in the EUDAMED system [17].

2.2 Notable Changes from MDD to MDR

MDR has more requirements than MDD but has retained aspects of MDD. These aspects are risk classes of devices, classification rules, general safety and performance requirements (formerly essential requirements under MDD), technical documentation, conformity assessment, registration of actors, notified bodies, and the EUDAMED system formerly known as Eudamed2 (European Databank on Medical Devices) [18]. In essence, MDR extends MDD requirements to cover some new areas that were not previously covered in the directive [19]. Table 1 provides details on notable changes when moving from MDD to MDR.

Table 1. Notable changes when moving from MDD to MDR

Change	Nature of change	Implication
Definition for qualifying medical device	Broader definitions to certain types of devices	New manufacturers will have to qualify their software based on the medical device definition. Manufacturers will have to re-qualify their devices as a medical device or not
Classifying software based on the risk class	New classification rules for medical device software	Manufacturers need to determine the risk class for their medical device software or reclassify devices. While most software was Class 1 in MDD, most will be at least Class IIa in MDR
General safety and performance requirements	The essential requirements have been extended	Manufacturers will have to comply with the additional requirements
Technical documentation	Detailed and additional requirements	Manufacturers must include new requirements in the technical documentation
Registration of economic operators	Manufacturers, distributors, authorized representatives, system/procedure pack producers, and importers	Obligations for importers and distributors have been clearly defined in MDR. Different operators have more responsibilities
Notified Bodies	More requirements, supervision, and oversight	Since almost all software is Class IIa or higher in MDR, Notified Body involvement is needed
EUDAMED database	EU-wide and expands Eudamed2 (used between national Competent Authorities and the European Commission)	Information was largely kept in national repositories, EUDAMED centralizes these databases and increases access to information on medical devices and economic operators; adds requirements that did not exist before, available publicly to increase transparency
Post-market Surveillance	New requirements	Manufacturers need to produce a post-market surveillance report and a periodic safety update report (depending on the risk class)
Unique Device Identification (UDI)	A new requirement	Manufacturers will need to acquire a UDI for their software and update the UDI when there are software updates

The requirements of MDR include post-market surveillance report and periodic safety update report, UDI for tracking medical devices, requirements for economic operators (i.e., importers and distributors) of medical devices operating from outside the EU, a quality/regulatory compliance/safety manager, and extension of the medical device regulation definition to cover products without an intended medical purpose but analogous to devices with a medical purpose [18].

It is possible and even likely that many hBCSS will require a higher risk classification. A major change to MDR is the definitions used to qualify and classify software as a medical device. For example, an app that aids the selection and dose calculation of cytostatic drugs was previously a Class I device under MDD but is now a Class III device under MDR [20]. Also, an app for diagnosing sleep apnea that used to be a Class I device will now be at least a Class IIa device [20]. Moreover, it may be unclear when software is a medical device or not. Many such devices fall into the borderline category and are defined based on the medical purpose of the device according to the MDR's definition of medical devices [21].

2.3 Compliance process

hBCSS developers are required to determine if their product is a medical device or not. After that, developers must use a conformity assessment to demonstrate compliance. A CE mark is awarded to indicate to users that the product has gone through the process and is certified. Developers of Class I devices can typically complete the certification process without involving a Notified Body. During the compliance process, developers must produce documentation and evidence that demonstrates MDR compliance. Developers need to have several processes and systems in place as outlined in the regulation. These include establishing a quality management system, conducting clinical evaluations, instituting post-market surveillance, and handling liability for defective products. Depending on the risk classification and outcomes of the clinical evaluation, developers may be required to conduct a clinical investigation. This is to ensure that the product is safe to use and effective such that the potential risks to end-users have been sufficiently mitigated. Class III devices have a mandatory requirement to conduct a clinical investigation. In addition, products will need to be registered to the EUDAMED system before they can be released onto the market. Figure 1 is a simplified overview of the MDR process for developers of hBCSS. Keutzer and Simonsson describe a simplified process, but they do not cover the whole lifecycle [3]. The factsheet and step-by-step guide for manufacturers from the European Commission contain further information worth taking into account when planning activities regarding MDR [22, 23].

The first three steps of Figure 1 are discussed later in Section 3. The risk classification of a medical device is a complex process and can be even more challenging for manufacturers of so-called borderline devices that may be very close to a higher risk class [21]. If a developer is applying the MDR process for the first time and lacks in-house expertise, we recommend seeking expert help to manage the process. Notified Body, if needed, should be contacted early in the process to ensure that assessment can be completed in accordance with the development and go-to-market schedule.

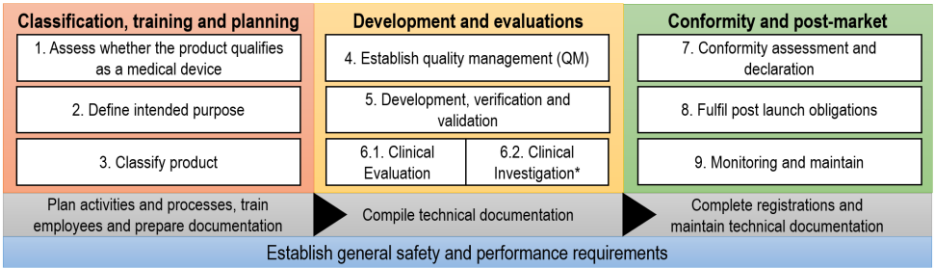

Figure 1 Main steps to complete MDR compliance process for developers of hBCSS

Through the hBCSS development process, it is important to consider general safety and performance requirements. These technical documents together with other documentation demonstrate conformity with the requirements [24] in Annex I of the MDR documentation [10]. Also, Figure 2 shows quality assurance-related harmonized standards that can be used to gain appropriate certifications to ensure compliance. The quality management system is subject to auditing by a Notified Body. While Class I devices do not require full certification of ISO 13485, evidence must be provided for quality management and software lifecycle management, risk management, and usability engineering. Conformity and post-market requirements are expanded in the new regulation. It is important to maintain technical documentation throughout the life cycle of the product. In addition, the product and related actors involved (manufacturers, authorized representatives, distributors, subcontractors, etc.) need to be registered in the EUDAMED system, which contains evaluation reports and other specified materials produced throughout the life cycle of the product.

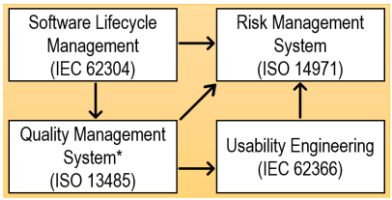

Figure 2 Quality assurance certifications and related harmonized standards

3 Qualification and Classifications

Medical device software is software (including accessories) intended by the manufacturer to be used by human beings for a specific medical purpose [10, 25] such as (1) *diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease, (2) diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, (3) investigation, replacement, or modification of the anatomy or of a physiological or pathological process or state, (4) providing information using in vitro examination of specimens derived from the human body, including organ, blood,*

and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its function by such means, and (5) devices for the control or support of conception.

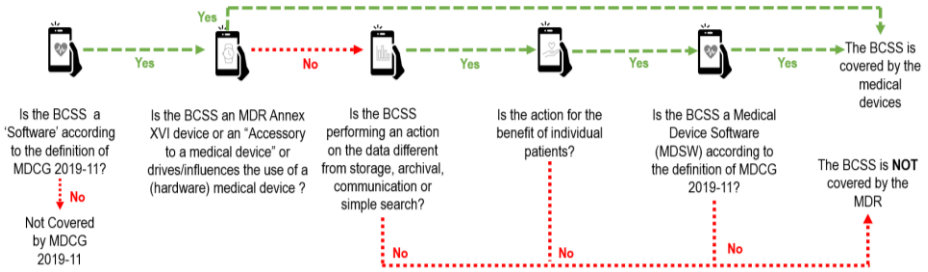

Figure 3 Qualification process diagram for hBCSS software according to [25]

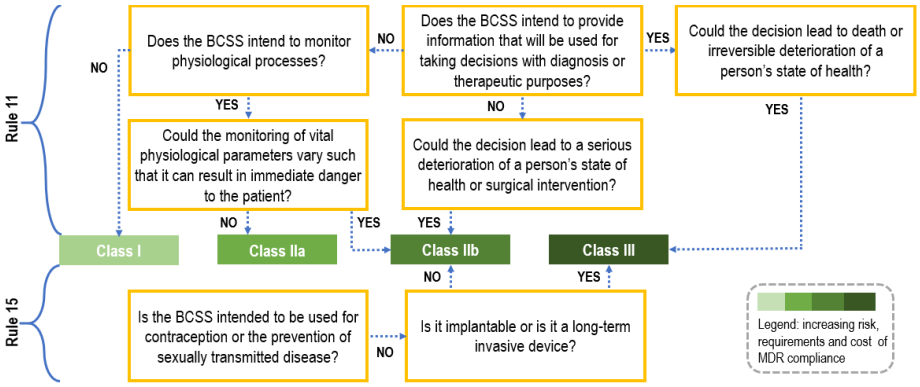

Figure 4 Risk classification process of hBCSS according to Annex VIII adapted from [10]

Figure 3 shows the process of qualifying software as a medical device. A software with any of the above medical device modules, accessory, or a device with medical device modules qualifies as a medical device [3]. This decision of whether a software product is a medical device is made by the manufacturer or developer. However, wrongly qualifying a medical device and/or misclassifying its risk class can have serious repercussions. According to Article 51, medical device software can be assigned to different classes (i.e. Class I, IIa, IIb, and III) [10] based on the risks and intended purpose. Factors that influence the classification include the duration of use, the nature of the type of interaction (i.e., active, invasive), and the kind of harm it may cause. There are 22 Rules for dividing medical devices into various classes (cf. Annex VIII Chapter III). Rule 11 is specifically for medical device software. Figure 4 describes software features, inherent risk, and the resulting risk classification based on Rule 11 and 15 of MDR. Rule 15 makes software like Nature cycles a Class IIb device [26, 27]. This risk classification determines the steps to obtain compliance certification in the form of a CE marking and post-production surveillance activities.

4 Design and Cost implications

4.1 Design Implications

The enforcement of MDR brings new requirements that must be fulfilled by manufacturers, sub-contractors, distributors, suppliers, and authorized representatives to ensure the safety and performance of medical devices and software. hBCSS vary in terms of their use and may pose certain risks to users.

Table 2. Examples of medical and non-medical hBCSS

Device/App name	Persuasive features	Invasive	Class
The Corona App	Disease monitoring	No	Class I [28]
Proteus IEM	Diagnosing app	Yes	Class IIa [29]
DIABETESMART	Diabetes management	No	Class IIa [30]
Nature cycles	Period tracking & conception	No	Class IIb [26, 27]
Omron HeartAdvisor	Blood pressure, sleep, and weight monitoring	No	Not medical
Nerva	Symptom monitoring and hypnotherapy	No	Not medical
MyTherapy Pill Reminder	Medication monitoring	No	Not medical
Bearable	Mood and symptom tracking	No	Not medical

The qualification process determines if for instance an app is a medical device or not; this depends on whether its intended purpose fits with the MDR definition of a medical device (cf. Article 2(1) [10]). The risk Class (I, II, or III) of a device or software is determined by (1) the intended purpose, (2) duration of use, the nature (thus if it is an active device or an invasive device), and (3) the inherent risks (including correct use, unexpected use, and errors). A medical device software may be embedded software in a device (i.e., part of hardware), a mobile or web app (standalone or module), or an expert or decision support system (standalone or module) [10]. In Table 2, we show examples of hBCSS and their risk level classification. These systems may be used by users for a short period (i.e., less than 30 days) or longer. According to the classification rules in Annex VIII of MDR, a software can be classified as an active medical device when they rely on electrical energy to function [25].

Also, there are persuasive systems designed to be used for health and wellbeing purposes that are not medical. Such systems can easily become medical devices with e.g., the introduction of medical functionalities related to monitoring and diagnosing. For example, *My dose coach*, an app for determining the dosage of insulin is a Class IIa medical device software (according to the less strict regulation of FDA in the US) because of the dosage calculation functionality in the app. *My dose coach* is likely to have a higher risk classification under the MDR (Class IIa or higher) because an improper dosage calculation can harm the user and even lead to death. On the other hand, *MyTherapy Pill Reminder* simply helps the user to monitor the intake of medi-

cation and thus is not a medical device. A major difference between these apps is the function that calculates the dosage. *FreeStyle Libre Pro Flash Glucose Monitoring* system, a Class III medical device under the FDA's medical regulation may be a good example of an MDR Class III medical device software [31].

4.2 Cost Implications

Compliance with MDR requires time and resources. If a company is managing the process for the first time without in-house expertise [11, 12], it is likely to face many challenges during the certification process. Table 3 describes in-house and expert-related cost components. Experts and consultants can help to prepare documentation, adjust development processes, and define the classification, among other things. The cost of devices with a higher risk class will increase because Notified Bodies are needed to check requirements for conformity. For example, Class III devices will often need to go through expensive clinical investigations. Developers need to conduct post-market clinical follow-ups as part of their post-market surveillance activities after the release of the medical device [10]. These activities can be more demanding for higher-risk classes.

Developing hBCSS that seek to prevent or solve health problems are currently popular both within the industry and academia. A lot of innovation and development activity is ongoing in this area with over 2000 published studies since 2007 and around 1500 in the last five years according to an industry report [2]. It is reported that 81% of manufacturers find MDR challenging, and for over 70%, the main concern is related to increased resources and costs, while over 50% are worried about a lack of clarity on requirements [32]. Developers of hBCSS are likely to have similar concerns and may not necessarily be prepared to handle all facets of the MDR implementation. A high number of medical device innovators and manufacturers are small and medium enterprises (SME) [2, 33, 34]. The cost of MDR compliance when moving from MDD to MDR can be high and proportionally, it affects the revenues of smaller manufacturers more than medium and large manufacturers [11, 32]. Furthermore, developers operating from outside the EU need to hire an authorized representative, who will act on behalf of the developer in specified tasks.

New qualification and classification requirements mean that devices, including software, that were not considered medical devices previously may now meet the threshold and must conform to the regulation [11]. Many hBCSS which were not medical devices under MDD may now fall under the Class I or Class IIa devices under MDR. While the cost associated with conformity assessment is not going to increase significantly for Class I devices, the cost can be much higher for other classes [12, 28]. Moreover, some fitness and wellbeing apps and devices may turn out to be medical devices under MDR and will have to go through the compliance process resulting in additional costs. Alternatively, developers may choose to remove software features that increase the risk class. Medical hBCSS that are already on the market will have to recertify once the current certificate expires or be prepared to remove the product from the EU market. Removal of these hBCSS is likely to result in decreased availability of innovative apps for users.

Table 3. Expertise-related cost components [11, 12]

Activity	Develop internal expertise	Potential external resources	Risk class-specific
Recruitment and training of personnel to handle the compliance process	Organization level MDR expertise, person responsible for regulatory compliance	MDR experts and trainers	
Establish general safety and performance requirements, risk management, and technical documentation	Quality management and assurance, person responsible for regulatory compliance	MDR product experts	
Quality management system and its certification	Quality management and its processes, person responsible for regulatory compliance	Consultants to help with standards (e.g., see Figure 2), Notified Body	Class I devices have lower requirements
Verification, validation, usability engineering	Quality management, software development process, usability engineering specialist	MDR experts / consultants, physicians, and test participants	
Product manual, labels, and translation work	Technical writing and label designing	Translators, and reviewers with clinical expertise	
Clinical evaluations, and clinical investigations	Clinical evaluator, physician reviewers, person responsible for regulatory compliance	MDR experts / consultants, physicians, Contract Research Organization / investigators	Clinical investigations mandatory for Class III
Product notification and certification, CE conformity declaration	Quality assurance, person responsible for regulatory compliance	Notified body for Class IIa – III devices	Notification for Class I devices
EUDAMED database	Person responsible for regulatory compliance		
Vigilance reports	Quality assurance, person responsible for regulatory compliance		
Post-market surveillance (PMS) and post-market clinical follow up (PMCF)	Quality assurance, person responsible for regulatory compliance	PMCF: Notified Body, other parties for clinical investigations	Higher risk classes can require more activities

Developers of medical apps may be forced to withdraw their products from the EU market if they are ill-prepared to comply with MDR. There are concerns on how this will impact innovation, as it will drive smaller manufacturers to rethink their approach or at the very least to lower the risk class of their products [11, 12, 35]. The regulation

may ensure that products are safer and perform efficiently while increasing transparency to users but it may result in higher costs and delays in product development [34].

5 Discussion

Implications for design and development of persuasive technology. The MDR regulation influences the design and development processes of medical devices. It outlines requirements for clinical evaluations, premarket approval, registration, manufacturing, storage, advertising and promotions, selling, distributing, exporting, importing, and monitoring the device after it has been placed on the market [10, 36]. Developers of hBCSS need to be aware of MDR and other regulations in the healthcare domain. They need to determine if the technology they are designing or developing is classified as a medical device or not as it influences the selection of software features.

Developers may have to contend with classification issues related to borderline devices. Classifying such devices can be challenging and the risk of misclassification should not be taken lightly. If the risk class is increased later, stricter regulatory requirements are likely to apply and lead to much higher costs and significant delays. Designating a lower risk class may lead to non-compliance issues and may require pulling the device from the EU market. Also, existing hBCSS on the market must be checked for compliance before the transition period ends or risk penalties (Article 113 [10]) and even face the removal of the device from the EU market. In addition, CE marking must be obtained for medical devices. CE marking should be clearly visible on a product. Users should have access to easy-to-understand documentation including user manuals, terms of use, and privacy policies. The terms of use must spell out what makes the product a medical device and highlight its risks.

MDR is designed with general safety and performance in mind [10, 36]. The use of strict quality management standards leads to the availability of products with better quality to users. Although this is a step in the positive direction, making a medical software device comes with increased costs to the manufacturer [36] which we believe will be passed down to the user. In the future, digital platforms (e.g., Google Play Store and Apple Store) may require a CE marking for medical devices to be distributed through their platforms. As it stands, the criteria being used by digital platforms to verify medical devices is unclear. If a digital platform acts as a distributor in the EU, they will be required to comply with the regulation. Digital platforms may need to reconsider their product categories to make it easier to identify certified medical devices.

Exemptions to MDR. Academic researchers who want to commercialize their products will need to comply with MDR. Although in theory, academic researchers can be manufacturers, in-house devices or devices produced in health institutions within the EU are exempt from the MDR regulation. This exemption applies if the rights are not transferred to another legal entity and other conditions set in Article 5 are met [10]. If a health institution qualifies for the exemption, it must comply with the applicable general safety and performance requirements set out in Annex I [10].

Additionally, there are exemptions for custom-made devices intended for the sole use by a particular patient (MDR Article 2(2) [10] in MDR Article 52(8) and Annex XIII [10]). We believe that custom-made hBCSS may be very rare or non-existent but if such a medical device is developed, then MDR exemptions may apply. Medical devices developed in-house or for investigational purposes for a group of patients with similar health conditions may fall under the health institution exemption in Article 5 of MDR [10].

Future innovation. According to Porter, strict regulations such as MDR can induce efficiency, promote innovation, and improve the competitiveness of companies [37], even if there are also contradictory perspectives [36]. Cost savings made from using more efficient processes can compensate for the cost directly attributed to the regulation [36, 37]. This means that manufacturers operating in the EU may benefit from the stricter regulation and possibly gain a competitive advantage with safer and more efficient products in less regulated markets [36]. We believe that the extra cost from MDR can offset the costs that would otherwise come from product recalls and compensations to users harmed by defective devices [38].

The MDR regulation is cost-intensive and innovation in the medical industry is driven by SMEs. There is speculation that a regulation like this will have a strong negative impact on innovation is somewhat overemphasized. New regulations do not necessarily result in decreased innovation activity but commercialization of innovative medical devices does require increased collaboration among stakeholders to ensure a smooth transition [39]. We believe that the negative effects are more profound for micro and small enterprises. Presently, the challenges faced by the industry as a whole are being countered to an extent by increased investments in digital health [2, 34]. It seems that the main risk is not to innovation but to the survival of small innovative companies who may be forced to leave the market if unable to cope with the cost of the regulation. To survive, these companies will have to seek synergies. We agree with [11] that innovation activity over the next few years amongst SMEs is worth monitoring [34]. Indeed, there may be some decline in the innovation of hBCSS over the next few years in comparison to other types of BCSS which have more relaxed development requirements and less regulation to contend with.

6 Conclusions

To conclude, we recommend designers, developers, and researchers of hBCSS to get well-familiarized with MDR. The regulation impacts the whole medical device lifecycle and measures should be put in place to ensure compliance. Developers should decide early on whether to develop a medical device or not. It is important to determine which risk class the device will be and has bearings with the process and costs. Failure to comply with MDR (e.g., misclassification) comes with fines and penalties and possible withdrawal of medical devices from the EU market.

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