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Regulatory Challenges of SAMD

Mr. Tejas. S. Aware*[1], Dr. Girish. B. Kashid[1], Mr. Sandeep S. Kulthe[1], Mrs. Rojana Patra[2], Ms. Pooja. B. Deore[3], Mr. Manish. B. Sahane[4]

1. Department of Drug Regulatory Affairs, Sanjivani College of Pharmaceutical Education and Research, Kopargoan, Maharashtra, India-423601.
2. Associate professor, Department -Quality assurance, Asian institute of pharmacy, Nashik.
3. Associate professor, Department-Quality assurance techniques. Asian Institute of pharmacy, Nashik.
4. Department of drug regulatory affairs, shriman Suresh dada Jain college of pharmacy and Research, chandwad, Maharashtra India – 423101

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ABSTRACT:
In the European Union, digital systems, particularly those utilized for health data surveillance, fall under complex regulatory frameworks, prominently the Medical Device Regulation (MDR). The MDR is pivotal, defining the scope of digital systems capable of modifying body functions autonomously, thus categorizing them under MDR's purview. Despite this, distinguishing which systems qualify remains challenging, especially when considering the preventive, diagnostic, and monitoring roles. As digital surveillance technologies advance, they encounter regulatory structures designed for traditional medical devices, creating hurdles for innovation and implementation. This paper examines the key regulatory challenges faced by Software as a Medical Device (SaMD), focusing on the need for clear definitions and the evolving regulatory landscape. The lack of consensus on SaMD definitions between the EU and other bodies, such as the IEC and WHO, complicates compliance and innovation. Moreover, the rapid evolution of digital health technologies demands adaptable regulatory frameworks to ensure safety and efficacy without stifling progress. Addressing these issues is crucial for fostering innovation while maintaining rigorous safety standards in the growing field of digital health surveillance.

1. Introduction

In the European Union, the plethora of legal implications attached to digital systems (software) make it difficult to draw a clear line between systems subject to the MDR and systems that are not 1. European Union legislators only aim to regulate considerably more complex systems that are distributed as commercially available medical technologies. Navigating these legal pathways is not straightforward. In particular, article 2(6)b of the MDR requires that a capacity of digital systems to modify body functions otherwise without the necessity of a healthcare practitioner—be taken into account. This defines the scope of 'physical' functions of the body and establishes the categories of digital systems (software) that fall within the scope of application of the MDR. Many surveillance systems of health data without owners' or users' consent could easily fall within the definitions of several categories found in the aforementioned article of the MDR if article 2(6)a and the related recitals have to be excluded from the analysis. Preventiveness of medical treatment or diagnosis and monitoring for health purposes ERREJÓN (with respect to mhealth) are key terms from article 2(6)a.

In recent years, it has been recognised that systems for digital surveillance of health data are subject to different laws than are other digital systems. Policy makers around the globe have sought to establish regulatory structures under which manufacturers may develop and commercialise systems for digital surveillance of health data 2. The European Union (EU), along with a few other

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jurisdictions, purposefully regulates for particular social, public interest objectives. Innovations that are digital systems intended to be used for surveillance of health data, without owners' or users' consent, are subject to a particular regulatory framework; the Medical Device Regulation (MDR) 3.

2. Key Regulatory Challenges

The aforementioned regulatory frameworks, that before new technological advancements were mainly focused on traditional medical devices, medications, and treatments, can be perceived as somewhat limiting the innovation and widespread use of Software as a Medical Device. Many stakeholders demand a faster approach to new SaMD regulation and incentives for virtual healthcare, seamless patient experiences, and advanced technologies such as artificial intelligence and machine learning. With the growing use of Software as a Medical Device, it is essential to focus on two central challenges: the increased risk associated with the use of these tools and the higher rate of regulatory vigilance required that has a potential impact on both development and investment in R&D. The broad diversity and complexity of Software as a Medical Device associated with potential functions pose regulatory dilemmas.

Digitalization is constantly evolving and has a significant impact on our daily lives. This transformation is no different in healthcare and creates potential benefits in terms of access to public health services, patient communication and education, engagement, and satisfaction. The increase in the use of Software as a Medical Device in clinical practice raises regulatory complexities. The demand for Software as a Medical Device grew so much that the U.S. Food and Drug Administration (FDA) had to commission the Digital Health Center of Excellence to regulate, modernize, and reform the medical software industry. A major advantage of Software as a Medical Device is the ability to adapt and evolve rapidly using innovative methodologies and advanced technology. However, this enabler exposes a key challenge of ensuring patient safety as key stakeholders in maintaining the appropriate effectiveness and safety of medical devices.

3. Evolving Regulatory Landscape

The dual problem exacerbates quickly, as whatever regulatory rubrics and processes that software as a medical device may find themselves in at the beginning of their development are only appropriate for that point in time and then swiftly become unsuitable with progress. The cycle of obsolescence is both a complaint from industry but also a significant challenge to regulators who are responsible for the safety and performance of software as a medical device. It is somewhat discourteous to dismiss these difficulties as mere growing pains, as some commentators are prone to do, as software as a medical device is slated to both grow as a function and swallow the low- to mid-risk market for traditional medical devices. Device developers move into this AI space eager to promote innate learning, machine learning, and deep learning functions, and it is essential to take the steps that underpin such quickly evolving and complex agile features safely and efficiently.

For instance, software programs that mirror handheld medical devices, which are clearly within the context of 'software as a medical device', are subject to the Food and Drug Administration (FDA) scrutiny, whilst consumer-grade apps that are frequently substituted for these essential functions, such as analyzing blood pressure or glucose levels, do not fall within the purview of the FDA and are subject instead to the regulations of the Federal Trade Commission, which supervises marketing practices. The United States is not alone in this dilemma, as the markets of other high-income countries also rack up similar complaints.

The swiftly changing diagnostic and therapeutic applications of current software as a medical device are far outpacing the established regulatory platforms for their evaluations. The breadth of these technologies is so vast, variable, and transient that regulatory pathways are often cumbersome and inflexible, even though the product of interest is a markedly intuitive and user-friendly tool that can very easily appropriate non-traditional regulatory pathways to be distributed.

4. Data Privacy and Security

Medical data also has an intrinsic value from an economically beneficial point of view. Unfortunately, humans are known to have an interest not only in legal ways of obtaining economic benefits but also in illegal schemes for making money. In 2020-2025, an increase in cyber-attacks is expected. The data protection officers (DPOs) from medical and healthcare organizations

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worldwide recommend, among other practices, moderating the exchange of data and investing in data protection. The DPOs stated that the interaction between data protection and innovations in data processing is highly beneficial. The European Commission is also investing in healthcare data protection by initiating innovative projects acting through the Horizon 2020 EU Research and Innovation Programmes. The Commission was providing funding for projects such as the Innovative Training Network on Privacy-as-you-go and two other projects on the architectural design and policy tools necessary for the implementation of Privacy-by-Design (PbD) in the IoT environment.

Health and healthcare data is valuable and sensitive data. Health data is sensitive by its nature as it can be used to identify a person (while in many other types of data removing any identifier can still lead to its re-identification). Thus, the data protection laws around the world specifically recognize and protect healthcare data, and in many countries, the legislation is much stricter in relation to healthcare data than other types of personal data. The definition of personal data in the GDPR by its nature is any information related to an individual. According to the UK Information Commissioner's Office, health data is one of the sensitive types of personal data as any information that can reveal an individual's state of health would likely be considered sensitive.

5. Impact on SaMD Development and Deployment

The second issue is dictated by the nature of the SaMD ecosystem. Unlike other industries which see the existence of a relatively few suppliers in tight collaboration with a multitude of downstream SME companies offering products of specific and limited uses, the SaMD ecosystem is following a and inspire paradigm, closely following internet trends. The ability to freely access software development tools and large datasets, reduced next to zero cost in starting a new venture, the seamless collaboration and availability of AI and ML as modular resources are perfect ingredients for a sunrising industry. Given that the tools, development environment, and methodologies have to rapidly change in execution with agile and other development practices, the imposition of regulatory measures based on the above-mentioned common set of principles would greatly hinder small companies in their potential growth. Adding standards that have additional layers on software-based products compared to classical devices only raise the entry cost even higher, which without any shadow of a doubt, would be unfair against big tech, who already dominate the area. Since almost by definition a new domain disrupter can capitalize on new unused resources by moving other older part of the industry out of it, the above proposal has the potential to severely offend SME innovation and drive the overall industry as an exclusive ecosystem reserved for Big Tech.

Given the broad complexity of software, AI, or ML mechanisms, and the current pace and nature of SaMD innovation and development coming from small and agile enterprises to big tech organizations and clinics, any significant change in the requirements of its regulation would potentially trigger three issues. First is the prescribed approach for creating a SaMD. In recent years, and despite the absence of specific regulation or international consensus, many institutions but also the public have come to regulate set criteria for transparency, interpretability, privacy, fairness, responsibility, and accountability that software, AI, and ML must respect. However, a specific regulatory framework targeting software in which all these core concepts are required for compliance does not exist. This implicit emergence of best practices is seen by many as a standard that is demanded of developers, potentially hindering innovation, adding significant non-productive workloads and cost on the development of SaMD.

We study the impact of strict regulatory requirements on the competitive performance of Software as a Medical Device (SaMD) vendors in the health-tech industry. Regulatory compliance costs of SaMD are substantial, which stalls providers from entering the market and competing with incumbent SaMD vendors. Existing regulation is shown to narrow the competitive landscape in the market for digital services. Tensions between established sector incumbents, new entrants, and regulators continue to result in broad social interest and legal battles regarding the regulatory future of SaMD. As governments attempt to strike the balance between protection, competition, and access – regulatory choices are often guided by intuition, lacking the necessary toolset.

The current market approach of fast progressing development and product life cycles still slows down the

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entry of SaMD software and digital health applications that can be classified as medical devices into the European market by licensure delay, and must fully comply with the MDR as of May 26th, 2021. The CE certification process and the inbuilt MDR requirements will not enable the quick release of SaMD by European developers, affecting clinicians' access to essential decision-making tools that may have a real impact on the healthcare of patients, all because of long delays in testing solid evidence and in licenses. In this event of regulatory uncertainty, the European Union can easily lose its competitiveness and leadership position in the market for SaMD and other innovative medical devices. QMS implementation and proof of efficiency certification as actual conformance evaluation bodies are themselves required for product release, without Nokia-style warnings. QTest and test evidence to be performed in healthcare-related interoperability with potential use of digital health data, AI, and other prototyping.

Software development and updating is still continuing after the marketing authorisation in rapid development environments to establish customer requirements, and applications requiring a license are required to be temporarily/permanently removed from the market or identified as an incident as a result of changes before the marketing authorization, which are important for customer safety and gain regulatory responsibility.

Recommendations for Addressing Regulatory Challenges

Improving essential quality and safety principles for medical software, including SaMD, especially those running algorithms, could guide us to improve the overall lifecycle of these devices by monitoring post-market data in attaining a quicker feedback loop for earlier reiterations. Extensive software verification and validation has to stress the explicitly customizable domains, the inclusion of the trailing, post-production phase performance data as a feedback source and the real-world evidence due mitigation possibilities of substantial risks related to the standalone nature of medical software devices.

During the evaluation of the existing, marketed devices or the introduction of new technology, health technology assessment (HTA) can analyse and evaluate the existing evidence around, for example, safety, performance, cost-effectiveness of such devices or the required unfamiliar regulatory evidence thereof. Decisions on the reimbursement and the subsequence funding requirements of technology can be discussed based on the findings of the HTA 4. Moreover, independently form the introduction of new technologies to the market, HTA could also think in the direction of implementing new, innovative digital evaluation methods, for example to support the existing regulatory requirements by drafting up new methods to take monitor the lifecycle of SaMD.

Regulation (EU) 2017/745 establishing specific requirements for the evaluation and the performance of standalone software medical devices mandates the compliance with the Medical Device Regulation. However, although harmonization on this matter seems beneficial in a unique European regulatory framework, the different translations of the regulation and its guidelines into the different countries' languages and regional interpretations of the legislations have represented lighthouse-decoration-like legislative unifications instead of the desired plug-and-play streamlining 5. In view of the different interpretations, understanding the need and possibility to build quality and safety into medical software, among which standalone software medical devices, must be the responsibility of all stakeholders.

Furthermore, ISO 14971 risk management standards and IEC 62366-1 usability engineering standards are taken into consideration in facilitating the regulatory compliance. For commercialization in the EU specifically, ISO 13485 standards need to be complied with, whereas to be successful in the US, digital pathology companies need to abide by the FDA's Quality System Regulation. In addition, the companies need to ensure that they satisfy the requirements of the EU's new Medical Device Regulation, the ISO/TR 20416 standards on post-market surveillance, and the EU's General Data Protection Regulation (GDPR), a European Union (EU) regulation related to data protection and privacy.

It is the necessity of time to build the policy at the harmonization level of the world for the safety, risk assessment, and benefits of health promotion. For this the world has adopted a harmonized model framework to improve management and safety. To promise worldwide accessibility of SaMD the harmonization efforts are conducted through many regulatory authorities like

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IMDRF and EU, and USFDA. The fully digital healthcare service is not supplied as now due to the unregulated and fragmented SaMD and an unstable triage test in different countries. When the products are certified as medical devices the security errors are detected and correct by the regulatory authorities. Therefore it is the time to build the fully harmonization for all nations to improve global access to health care.

6. Conclusion

The evolving landscape of digital health technologies, specifically Software as a Medical Device (SaMD), presents both significant opportunities and formidable regulatory challenges. In the European Union, the Medical Device Regulation (MDR) establishes a critical framework for categorizing and regulating these digital systems, yet the complexity and ambiguity in definitions create substantial hurdles for compliance and innovation. As SaMD becomes increasingly integral to healthcare, ensuring patient safety while fostering technological advancement requires adaptive and harmonized regulatory frameworks.

The rapid development of SaMD, driven by advancements in artificial intelligence and machine learning, underscores the need for clear, consistent definitions and regulatory pathways. The lack of consensus among international bodies, such as the EU, IEC, and WHO, complicates the regulatory landscape, potentially stifling innovation and hindering market entry for new players. Moreover, the dynamic nature of digital health technologies demands that regulatory frameworks evolve to remain relevant and effective.

Addressing these challenges necessitates a multifaceted approach. Improving the clarity and harmonization of regulatory definitions, enhancing post-market surveillance, and integrating health technology assessments are crucial steps. Additionally, fostering collaboration among global regulatory authorities can streamline processes and reduce barriers to market entry. By balancing rigorous safety standards with the need for innovation, regulators can support the development of SaMD, ensuring that these technologies contribute effectively to public health while protecting patient safety.

Ultimately, the goal is to create a regulatory environment that promotes the safe, effective, and rapid deployment of SaMD. This will require ongoing dialogue among stakeholders, continuous monitoring of technological advancements, and a commitment to flexible, forward-thinking regulatory practices. With these measures in place, the potential of SaMD to transform healthcare can be fully realized, benefiting patients and healthcare systems worldwide.

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