Electronic Submissions are the Future of Medical Device Regulation – Why the Wait?

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Introduction

According to the general policy objectives of the European Commission, their primary goal is to reduce reporting and bureaucracy while fostering greater trust, improving enforcement, and accelerating approval processes across Europe.

The ongoing transformation in the European regulatory environment, driven by the Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR), underscores the necessity for effective processes to maintain Europe's competitiveness in the global marketplace. The increase in regulatory requirements, costs, and timelines have led manufacturers to pull products from or delay entering the EU market, highlighting the inadequacy of the current system.

An essential part of this transformation involves optimizing the submission, review, and certification processes. For instance, standardization could encompass:

- Adopting common data dictionaries based on internationally recognized terminologies
- Implementing modular document structures aligned with the essential requirements of the MDR/IVDR (e.g. PDF documents stored in a directory structure, accessed through the XML backbone and with the files integrity guaranteed by a checksum)
- Allowing electronic data interchange formats for specific data elements (e.g. machine-to-machine communication)

This paper explores the significant benefits that such digitalized systems could bring, particularly in reducing the overall time and cost burdens on manufacturers as well as Notified Bodies and therefore ensuring that products get to patients in need faster.

Streamlining the Conformity Assessment Process

Current data from the recent MedTech Europe 2024 Regulatory Survey reveals that over 50% of the total time spent on conformity assessments for both in vitro diagnostics (IVDs) and medical devices (MDs) is consumed in the "pre-review" and "certificate issuance" phases, leaving less than 50% for actual documentation review. Optimizing the pre-submission phase—such as by implementing standardized and digitalized submission formats—could reduce the overall time for conformity assessments by over 30%. Assuming a modest 10% time saving in the certification process, manufacturers could launch products up to 3 months earlier. This timeline reduction would not only improve efficiency but would also allow products to be brought to market faster, reducing delays that can hinder innovation and growth within the European medical device sector, while accelerating revenue recognition.

Given the unique lifecycle characteristics and regulatory needs of Software as a Medical Device (SaMD), electronic submission systems should accommodate the specific requirements of these technologies. SaMD often requires more frequent updates, cybersecurity documentation, and algorithmic transparency. Integrating SaMD-specific modules—aligned with International Medical Device Regulators Forum (IMDRF) principles—into broader digital frameworks will ensure these submissions remain agile and globally interoperable, without fragmenting the regulatory landscape.

Reducing Manufacturer Costs

The financial burden on manufacturers is another critical concern. In the first year of obtaining and maintaining certification under IVDR or MDR, manufacturers spend a significant portion of their resources on personnel. Specifically, 90% of their total costs are allocated to personnel related to Quality Management Systems (QMS), technical documentation, and other certification-related processes, according to the 2024 MedTech Europe IVDR & MDR Survey. Notified Body fees account for 7% of the costs, while 3% is spent on yearly regulatory maintenance per device. Standardized electronic submissions could help streamline and automate processes, ultimately lowering personnel costs and reducing the overall burden on manufacturers. Again, efficiencies of just 10% in this cumbersome process could generate savings of around €245k (IVDs) or €446k (MDs) per product certification cycle, if we take the survey's average costs per certification as reference. This reduction of certification costs, which are inevitably passed on to patients and taxpayers, would fall in line with recent political emphasis to reduce governmental spending.

Reducing Costs and Improving Efficiency and Consistency for Notified Bodies

Beyond electronic submissions, standardizing formats can enable greater data interoperability. For example, manufacturers could reuse structured data fields for device characteristics, intended use, performance data, and risk assessments across different sections of the technical documentation and could potentially repurpose that data for post-market surveillance (PMS) activities. This would reduce redundant data entry, improve data consistency, and facilitate more efficient data analysis by both manufacturers and regulatory bodies.

Standardized electronic submissions meet the requirements of Annex II of the MDR and would significantly benefit Notified Bodies by providing a consistent and easily navigable format for technical documentation. This would streamline the initial completeness checks, reduce the time spent searching for specific information, and facilitate more focused and efficient reviews while increasing their consistency. The ability to electronically annotate and track review progress within a standardized system would further enhance efficiency and communication with manufacturers. Moreover, standardized data formats could enable Notified Bodies to leverage data analytics for trend analysis and risk-based auditing.

UK Regulatory Outlook

The UK is in the process of establishing a distinct regulatory regime under the UKCA framework, with reforms led by the UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA). These changes will be able to prioritize safety, innovation, and international alignment. Notable developments include the 2024 post-market surveillance regulations requiring structured digital data systems and planned interoperability with global standards, such as those from the IMDRF. These efforts echo the EU's electronic submission goals and offer future harmonization potential.

Harmonizing electronic submission systems between the UK and EU presents a valuable opportunity to reduce duplication, enhance data interoperability, and streamline regulatory processes. Initiatives such as mutual recognition of submission formats and joint participation in frameworks like the IMDRF could improve efficiency, reduce costs, and accelerate patient access to innovative medical technologies across both markets.

Impact on Market Choice and Competition

The financial and time-related challenges associated with obtaining certification in Europe are influencing manufacturers' decisions regarding market entry. Extreme regulatory bureaucracy and uncertainty are also proving to be detractors to innovation. As demonstrated in the MedTech Europe 2024 Regulatory Survey, choosing the EU as the first geography launch has decreased by 40% for large manufacturers and 12% for small and medium-sized enterprise IVD manufacturers. Similarly, 67% of responders of the ABHI Pulse of UK Healthtech survey have taken products off the UK market due to uncertainty caused by the withdrawal from the European Union, prioritising approvals in other markets.

This decline in interest undermines Europe's position as a leading market for innovation in medical devices. Member states have taken notice and a series of motions and initiatives are being put in front of the parliament to resolve this, leading to a Parliament resolution calling for the Commission to "address the most pressing challenges and bottlenecks in the implementation [of the MDR and IVDR]" and "streamline the regulatory process, improve transparency, and eliminate unnecessary administrative work for notified bodies and manufacturers".

While finding a Notified Body is no longer the primary concern for manufacturers, it is increasingly clear that issues such as cost, timelines, and predictability require urgent regulatory system improvements. Standardizing the submission process across Europe through electronic formats would create a more transparent, efficient, and predictable regulatory environment. Manufacturers would benefit from clearer guidelines, faster processing times, and reduced uncertainty, which would significantly enhance their ability to plan for and execute product launches in Europe. Electronic submissions would also enable easier portability of technical documentation between notified bodies.

Creating a Standardized Electronic Data Format

The development of European electronic data standards should actively consider and align with existing international efforts, such as the IMDRF's work on electronic submissions and exchange of regulatory information. Leveraging internationally recognized data standards and formats, where applicable, would not only promote global harmonization but also facilitate smoother market access for European manufacturers in other regions, and vice versa. On top of speeding up submissions, it could positively impact periodic reporting in PMS, which are currently manual tasks for manufacturers and Notified Bodies alike.

Defining the precise format for a European standardized electronic submission system for medical devices requires careful consideration of existing frameworks like eSTAR, IMDRF principles, and Team-NB checklists, with software providers standing ready to support any adopted format.

The Electronic Common Technical Document (eCTD) format utilized by pharma both in the US and EU offers a compelling example, where a 94% adoption rate by 2022 across all FDA submissions drastically reduced initial handling times from weeks to near-instantaneous routing, and significantly contributed to decreased median drug review times from 26.6 months to 9.9 months, leading to faster approvals and a 16% annual growth in submissions. In a recent Notified Body survey on certifications and applications, the vast majority of notified bodies (37 of 50) reports that over half of all submissions received are incomplete. The fact that this number still remains so high 8 years after the MDR introduction highlights a structural issue in the interface between manufacturers and notified bodies that electronic submissions could help with.

Moreover, the eCTD has enabled the broader use of electronic regulatory information management (RIM) systems in pharma, leading to substantial efficiency gains across the regulatory lifecycle for manufacturers, with unified data management enabling significant reductions in effort for key tasks and instances of documentation being submitted weeks ahead of schedule.

Thus, while the specific European standard for medical devices needs to be determined, we can learn from the success of eCTD and the benefits of integrated electronic management to drive significant improvements in efficiency, timelines, and predictability in conformity assessments, ultimately accelerating patient access to vital medical devices.

The establishment of a robust governance framework is crucial for the success of a pan-European electronic submission system. This could involve a dedicated task force comprising representatives from the European Commission, national competent authorities, Notified Bodies, and industry associations to define, maintain, and oversee the standards. A phased implementation approach, potentially starting with specific device categories or submission types, could facilitate a smoother transition. Consideration should be given to the establishment of interoperability standards that allow national systems to communicate seamlessly. Robust data security and access control mechanisms would be paramount to ensure the integrity and confidentiality of submitted information.

Unleashing Artificial Intelligence

Generative Artificial Intelligence (GenAI) holds significant promise for enhancing data analysis, streamlining reviews, and increasing consistency in medical device regulation. Numerous use cases demonstrate how this technology can improve and scale the delivery of safe and efficient devices. These range from trend identification and risk prediction to information retrieval and the automation of routine tasks, ultimately benefiting patients and fostering innovation.

The application of AI, facilitated by standardized data, will enable medtech and regulatory body professionals to focus on value-added activities required for increasingly complex evaluations. Because AI thrives on structured and consistent data, electronic submissions are crucial for manufacturers and regulatory bodies to develop and curate the necessary robust digital foundations. Without this robust digital foundation built upon standardized electronic submissions, the transformative power of AI in medical device regulation will likely remain largely unrealized. For example, the MDR and IVDR PMS regulatory processes were created with the intent for manufacturers to monitor the performance of their devices in the real world with fine-grained signal detection. AI as technology is perfect to support this and to help achieve regulatory objectives in efficient ways.

Conclusion and Calls to Action

Establishing electronic submission standards across both the EU and the UK is a critical step towards improving the regulatory process for IVDs and MDs and ensuring that medical devices reach those patients in need faster. We encourage both jurisdictions to pursue coordinated digital infrastructure and harmonized regulatory processes.

By addressing inefficiencies in the pre-submission phases, reducing the financial burdens on manufacturers, and improving the EU's attractiveness as a primary market for medical devices, Europe can reinforce its role as a global leader in medical innovation. The adoption of electronic submission standards would foster a more efficient, predictable, and competitive regulatory landscape, benefiting both manufacturers, reviewers, and patients alike.

To realize the significant benefits outlined in this paper, we recommend a call for evidence by the Commission on what electronic submissions for medical devices and IVDs would look like and how it could be implemented. This could then be followed by a call for evidence based on concrete proposals from stakeholders to define what a European electronic submission standard would look like.

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