Mr Jyrki Katainen
Vice-President
Jobs, Growth, Investment, Competitiveness
European Commission
Rue de la Loi 200
B- 1049 Brussels

November 7, 2019

Via email

Re: Open letter on elevated labeling risk due to the Medical Device Regulation 745/2017 (MDR) effective date

Dear Vice-President Katainen:

As a 28-year supplier and Division President of the largest language services and content technology provider to the medical device industry, the first company registered to ISO 14971, and a co-author of the industry's only labeling translation risk management patent, I am writing to notify you of a growing MDR-related implementation risk that could negatively impact EU patient safety.

Although the MDR was designed to ensure patient safety, the regulation's effective date (May, 2020) versus manufacturers' ability to effectively comply is creating a hazard for EU patients. A recent open letter from MedTech Europe highlights a lack of functionality and critical resources (especially Notified Bodies) for effective implementation.

This lack of guidance and support for key areas such as labeling, in addition to the complexities of implementing known MDR requirements, will push the majority of manufacturers' labeling projects into 2020. In other words, due to deficiencies in the EC's roll-out of MDR, large portions of the device industry will be attempting the enormous task of compliance updates in English and translated labeling – which typically include reformatting and addition of new languages, all at the same time and within five (5) months or less (given end-of-year holidays). Although the issue is somewhat mitigated by the planned withdrawal of 20-30% of devices from the market and soft transition of others, it is expected that the industry-wide effort will encompass many hundreds of thousands, if not millions, of discreet documents.

There are technologies that can help industry and bring necessary automation to the labeling language process, including:

- XML content management systems (single-source, automated publishing)
- Translation management systems (shared linguistic assets, process automation)
- Specialized AI engines (computer-aided translation)

However, the translation activity itself still requires the direct involvement of qualified, skilled professional linguists – and the document-based applications predominately in-use across the industry (Word, FrameMaker, InDesign) still require manual updates and QC to millions of discreet labels, IFUs, PI's, user guides, etc . And, while the automation technologies mentioned above are powerful, they

require time and resources for implementation – time that's been hampered by regulatory uncertainty and resources that have been consumed addressing other urgent areas of MDR compliance.

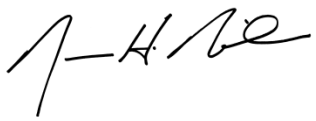
Together, the compressed implementation schedule, combined with manual processes and the volume of labeling that manufacturers need to address, will undoubtedly drive some to work with marginally (or completely) unqualified suppliers and opportunistic suppliers to enlist unqualified resources or insufficient processes (e.g. raw machine translation). The net effect will be an increase in patient safety risk due to labeling translation errors – quite contrary to the spirit and purpose of the MDR.

Labeling language and content management requirements are only one piece of the vast MDR puzzle. This regulation is also driving dramatic changes in key areas such as clinical data, post market surveillance, and supply chain management. I understand these functional areas are also facing similar challenges of time, resources, and regulatory clarity.

The EC recently announced that the Eudamed database would be delayed by two (2) years. This was a prudent decision in order to avoid industry disarray and protect patient safety. In order to avoid a similar circumstance in other areas of MDR implementation (such as labeling), we urge the Commission to consider a delay in the regulation's overall effective date. In the meantime, maintaining the MDR's requirements for post-market surveillance (as currently defined under soft transition) could provide enhanced risk management (versus the current state) while the remainder of the regulation is operationalized.

In short, now that the regulatory structure is (largely) in place and key resources (such as Notified Bodies) are beginning to become available, a deferment would provide the necessary time for a safe, orderly, and effective transition to MDR– to the benefit of both patients and healthcare systems across the EU.

Respectfully,



Marc H. Miller
Division President
TransPerfect Medical Device Solutions