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Medtech & Pharma Platform (MPP) Association
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To: European Commission,
Directorate-General for Health and Food Safety
Attn.: Mr. Rainer Becker, Ms. Flora Giorgio,
Ms. Caterina Gozzi
1049 Brussels
Belgium

21 October 2024

Dear Mr. Rainer Becker, dear Ms. Flora Giorgio, dear Ms. Caterina Gozzi,

We are writing to you about the planned targeted evaluation of the Medical Devices Regulation (MDR) and *In Vitro* Diagnostic Medical Device Regulation (IVDR) which is anticipated to start at the end of 2024. The implementation of the MDR and IVDR has made substantial progress in the last few years and important measures were put in place to address some of the most pressing issues. While the recent extension of the transition timelines, the gradual roll-out of EUDAMED and discussions on the context of the COMBINE project have had a positive impact, there remain significant challenges for medicinal products combined with medical devices or *in vitro* diagnostics (IVDs) (henceforth combined products) which are adversely impacting patients and innovation. In this letter, the MPP Association presents key aspects on which our members would welcome solutions as part of the expected targeted evaluation.

One of the most significant challenges affecting both industry and the EMA/Notified Bodies (NBs) concerns drug delivery devices that are used to deliver various medicinal products to patients. A survey report published in 2024 by the MPP Association highlighted that over 80% of its respondents saw non-compliance for combined products[1] - due to a lack of clarity in EU legislation for such products - as a risk to their business and thus to healthcare communities[2]. In addition, 45% of respondents have encountered repetitive reviews and delays in the approval of marketing authorization applications for combined products that incorporate previously used/existing delivery technology (i.e. platform technology). Many combined products, while featuring different medicinal products, rely on the same medical device technology platform, especially in cases such as syringes, injection pens, autoinjectors, and inhalers. These medical device technology platforms often rely on well-known legacy products. Although the same medical device technology platform is used in multiple combined products, this device part is nevertheless subject to repeated reviews under MDR Art. 117, leading to multiple applications. This leads to significant time being spent repeatedly reviewing the same content on the

[1] The MPP Association defines a combined product as any combined use of a medicinal product, including biologics and advanced therapy medicinal products (ATMPs), with a device or diagnostic for medical purposes, without forming necessarily an integrated unit, covering also e-/m-health products. Combination products are considered a sub-group of combined products.
[2] MPP Association. Survey Report "Navigating Regulatory Complexities for Integral and Non-Integral Drug-Device Combined Products". 2024. https://medtech-pharma.com/wp-content/uploads/2024/02/MPP-Survey-report-on-combined-products_February-2024.pdf

part of the reviewers, and to important time and resources (including financial) investment for MPP members. Potential solutions to address this issue include the following options:

- Apply a platform technology approach to the regulatory approval process of combined products. This could partially rely on utilizing existing data for the device part and would help streamline the submission process and avoid repetitive reviews.
- Allow NBs to provide an opinion on medical device technology platforms that are part of combined products.
- Lift obligations to provide a Notified Body opinion (NBOp) for medical device technology platforms that are well established while maintaining this obligation for new/non-established products.

The MPP Association would also like to draw your attention to the following challenges currently faced by our members in relation to the MDR compliance:

1. Scientific advice: The above-mentioned survey highlighted that 25% of respondents faced hurdles in obtaining advice for their integral and non-integral combined products due to the absence of appropriate stakeholders, including NBs, device manufacturers, or competent authorities, in the scientific advice discussions, adversely affecting registration timelines. One possible solution to address this aspect is to consider adopting a more flexible interpretation of the rule disallowing Notified Bodies to provide consultancy services to allow them to participate in scientific advice procedures.

2. Conflicting advice: Through our survey, it was also found that greater alignment between the EMA, National Competent Authorities (NCAs) and NBs is needed when assessing aspects like the summary of product characteristics (SmPC) and the package leaflet (PL) of co-packaged combined products. 55% of respondents reported having received conflicting requirements/advice from the EMA/NCA and NBs; of those 55%, 35% could find a compromise to address the conflicting feedback, while 20% reported that no compromise could be found and that they followed requirements formulated by the NB. The MPP would welcome common guidance and shared training between the EMA and the NBs to build staff expertise and expert knowledge on the specific aspects and implications of combined products. This would contribute to the high quality and reliability of the scientific evaluation and thus foster a mutual understanding and interpretation of applicable rules and standards.

3. Lifecycle management: There remains a lack of clarity around the lifecycle management of products under MDR Art. 117, especially around substantial changes. The MPP would like to highlight the need for further clarity on substantial changes and notes that it would be beneficial for all relevant stakeholders to discuss and agree on the specific definition and examples of what constitutes substantial changes with the potential to impact on safety and performance.

4. Repackaging/relabeling of medical devices: MDR Art. 16 proves challenging for companies that repackage and/or relabel medical devices when co-packing the medical device with a medicinal product. Neither EMA guidelines nor MDCG 2021-26 address the specific situation of highly regulated pharmaceutical companies co-packaging a device, typically obtaining the CE marked medical device as bulk ware from the legal manufacturer (without individual labeling). The MPP Association would welcome clarification of which obligations apply to such companies, including through the update of MDCG 2021-26.

5. Post market requirements for co-packaged medical devices: There remains uncertainty for pharmaceutical companies with regard to which post market obligations apply to pharmaceutical companies when putting a co-packaged medical device on the market. The MPP would welcome greater clarity and predictability on the responsibility and liability of the pharmaceutical company and the medical device legal manufacturer for a co-packaged product.

The MPP Association would be pleased to organize a meeting to provide more details and potential solutions proposed by our members for each of the challenges outlined above.

Finally, we would also like to refer to a separate position paper concerning the impact of the IVDR on the use of in-house devices by health institutions and central laboratories which will be published in due course. In this paper, we outline some perspectives from MPP Association members on how specific clarifications to the definition of health institution and applicability of the in-house device exemption can facilitate innovation and ultimately improve patient care outcomes. If this topic is of interest, the MPP would be glad to cover it in the meeting proposed in the previous paragraph.

MPP continuously seeks dialogue with relevant stakeholders to create an appropriate framework for combined products that enables compliance for involved players, fosters innovation, reduces time to market, and addresses patients' needs.

We thank you for considering our position and the proposals outlined above. The MPP Association is available for further dialogue and collaboration with the European Commission.

Yours sincerely,

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ABOUT THE MEDTECH & PHARMA PLATFORM ASSOCIATION

The Medtech & Pharma Platform Association (MPP) brings together companies from the pharmaceutical, medtech, diagnostic and tech sectors and provides opportunities to exchange knowledge and to collaborate in technology and regulatory areas related to combined products.

- To enhance synergies between the pharma, medtech, diagnostic and tech industries,
- To establish new collaboration models to ensure and accelerate market access for safe and innovative treatment options,
- To work toward the development of a balanced and proportionate regulatory and policy framework for combined products including connected combined products.