Navigating challenges: the use of advanced materials in medical devices

Susanne Resch[1], Julia Voglhuber-Höller[1], Andreas Falk[1]

1. Introduction

Advanced materials and its subgroup of nanomaterials enable the improvement and optimization of medical devices through targeted use. The special effects that these materials produce on the surface of certain products open up new possibilities for better treatment of patients. Still, the associated potential risks by using new, advanced materials should be controlled appropriately.

While medical devices are generally highly regulated (e.g., through the Medical Device Regulation (MDR) [1] in the European Union), the incorporation of advanced materials can generate risks and safety concerns (both for humans and the environment) that need to be addressed in order to achieve a predominantly beneficial use of advanced materials in medical devices and fully exploit their innovative potential.

2. Methods

Based on desk research, experts' interviews and workshops, the relevance of the MDR for advanced materials and nanomaterials was determined and gaps were identified. In addition, the relationship and links to other relevant guidance documents (e.g. ISO/TR 10993-22) were elaborated.

Next, safety concerns of selected advanced materials in medical devices were investigated along the value chain and the real-life applicability of the MDR was evaluated. The specific use cases were based on medical devices with antimicrobial and/or filtering effect, namely: (i) face masks made from antimicrobial textiles with silver nanoparticles, (ii) personal protective equipment based on textiles with an antiviral effect using zinc-oxide nanoparticles, and (iii) wound dressings with improved wound healing through advanced materials.

In addition, the potential added value of the Safe-and-Sustainable-by-Design (SSbD) concept to these use cases was investigated.

[1] BioNanoNet Forschungsgesellschaft mbH (BNN); susanne.resch@bnn.at

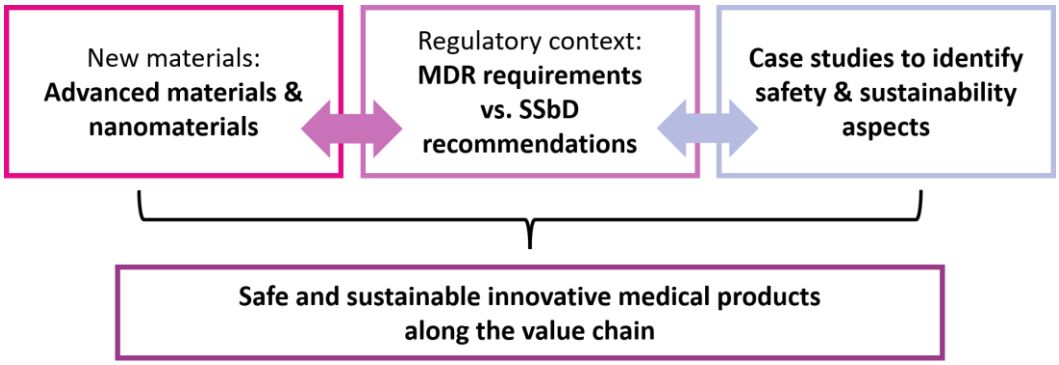

Figure 1: Methodological approach to evaluate the potential role of advanced materials in medical devices, their regulatory requirements as well as pre-market SSbD considerations to ultimately achieve safe and sustainable medical products along their value chain.

SSbD is aimed at developing safer and more sustainable substances via an iterative approach initiated in the early phases of innovation. The concept focuses on chemical substances and materials and covers their entire life cycle. It also incorporates safety and sustainability aspects into processes and related end products to ensure the protection of human health and the environment in all life cycle phases while balancing socio-economic aspects. The designated task for SSbD is to support achieving the objectives set in the European Green Deal. The SSbD framework [2] published by the European Commission's Joint Research Centre in 2022 describes the holistic approach in five steps, focusing on chemicals and materials; ultimately, the concept can be applied to R&D&I in all sectors, including the medical sector and medical devices.

Putting SSbD into practice by designing advanced materials as safe and sustainable as possible requires tools and models that enable the assessment of material properties such as reactivity, inflammatory and cytotoxicity potential. The HARMLESS SSbD framework builds on three pillars: (i) safer materials and products, (ii) safer production processes and safer use, and (iii) end-of-life. It is a stage-gate model with an implemented life cycle thinking approach that takes into account safety and sustainability, including design principles and different tools. It evaluates the safety, sustainability and functionality of the advanced material in the ideation and business phase, the lab phase as well as the pilot phase. As pre-market approach, it supports implementing SSbD in early innovation phases. The potential impact of the HARMLESS SSbD framework was assessed with a medical device use case and lessons learned for its applicability in this sector could be derived.

3. Conclusions

There is a need to investigate both benefits and risks associated with advanced materials in medical device development, not only to protect patients but also in a wider context to ensure the safe and sustainable use of new, advanced materials with (at least partly) unknown properties. The challenge lies in appropriate regulation that protects human health and the environment while not hindering innovation and market access, especially in Europe. The SSbD framework as a pre-regulatory approach supports a holistic design approach that emphasizes not only functionality but also safety and sustainability in the early innovation phase. However, it remains to be determined how the medical device market can benefit from this innovative approach and to what extent

it can complement regulatory requirements without placing additional burdens on the medical device development process.

4. References

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

[2] Caldeira, C., Farcal, R., Garmendia Aguirre, I., Mancini, L., Tosches, D., Amelio, A., Rasmussen, K., Rauscher, H., Riego Sintes, J. and Sala, S., Safe and sustainable by design chemicals and materials - Framework for the definition of criteria and evaluation procedure for chemicals and materials, EUR 31100 EN, Publications Office of the European Union, Luxembourg, 2022, ISBN 978-92-76-53264-4, doi:10.2760/487955, JRC128591.

5. Acknowledgements

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