BUNDESVERBAND DEUTSCHER KRANKENHAUSAPOTHEKER E.V.

OPINION

of the

German Society of Hospital Pharmacists (ADKA) e.V.

of 03.08.2026

on

the **European Commission's proposal** for a targeted

Revision of the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR)

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I. EXECUTIVE SUMMARY

We welcome the targeted revision of the MDR and IVDR and expressly support the European Commission's response to market needs in order to establish the regulatory framework for a functional market in a timely manner and to ensure the availability of safe medical devices in patient care.

In this context, we propose that, as part of the already planned revision of Article 5(5) both of the MDR and IVDR, the routine preparation of substance-based medical devices and IVDs by pharmacies as health institutions be explicitly permitted – analogous to the preparation of medicinal products under the national provisions deriving from Article 3 of Directive 2001/83/EC. We fully support the remaining requirements of Article 5(5), in particular compliance with the essential safety and performance requirements set forth in Annex I; these are already in line with current standards manufacturing practices in pharmacies.

II. REASON AND BACKGROUND

In addition to the proposal`s numerous efforts for improvement, we would like to specifically highlight the preparation of substance-based medical devices by pharmacies pursuant to Article 5(5) of the MDR. In our view, the provision does not sufficiently take into account an existing, functioning supply structure.

Under the pharmaceutical regulatory framework, pharmacies are an integral part of daily patient care and have extensive experience in the preparation of health products under high quality and safety standards. Hospital pharmacies, in particular, adapt their routine care to meet high individual patient needs, complex procurement situations, and supply structure.

With this experience, we are observing a clear trend in the supply chain towards increasing shortages and product recalls in the area of substance-based medical devices. Allegedly due to the increased requirements of both MDR and IVDR, manufacturers are being forced to streamline their portfolios for economic reasons – in particular, basic products such as simple solutions and gels are being increasingly removed from the market.

The shortage of hand sanitizers during the COVID-19 pandemic is a concrete example that illustrates the importance of pharmacies also in the preparation of non-pharmaceutical products: Preparation on an "as-needed" basis ensured a wide supply coverage as a fall-back structure for challenging market situations. The proper handling of raw materials classified as hazardous chemicals, the evaluation of antimicrobial performance, and the formulation of a patient-tolerable preparation were comprehensively addressed through pharmaceutical expertise. Furthermore, as knowledgeable points of contact, pharmacies serve as a reliable element of vigilance. It is desirable to avoid having to regulate such acute supply shortages through general administrative orders involving cumbersome bureaucracy, but rather to directly embed the application of pharmaceutical expertise in the European device legislation.

III. THE MAGISTRAL AND OFFICIAL FORMULA AS EXAMPLE UNDER PHERMACEUTICAL REGULATION

Under Article 3 of Directive 2001/83/EC, member states are permitted to exempt the preparation of medicinal products in pharmacies from the requirements applicable to industrial manufacturing:

"This Directive shall not apply to:

1. Any medicinal product prepared in a pharmacy in accordance with a medical prescription for an individual patient (commonly known as the magistral formula).

2. Any medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question (commonly known as the official formula).

(...)" – Art. 3 of Directive 2001/83/EG

The preparation in accordance with relevant pharmaceutical standards is a prerequisite and is ensured in Germany as well as in other member states by the respective national pharmacy regulations. This structure represents a critical aspect of supply resilience: The current threat to clinical supply described at the outset due to supply bottlenecks is increasingly affecting not only the pharmaceutical sector but also the medical device sector. Where possible in individual cases, in-pharmacy preparation provides a reliable, expert infrastructure to maintain patient care when needed. This authorization is utilized daily in routine pharmaceutical practice.

IV. SPECIFIC PROPOSAL REGARDING ARTICLE 5(5) OF MDR AND IVDR

Since the MDR and IVDR are European regulations that are directly applicable, a required expansion as outlined in the summary is not subject to national, additional provisions. We therefore recommend revising Article 5(5) to include the possibility for pharmacies to prepare substance-based medical devices not only for specific, individual patients, but also to a certain, non-industrial extend for stock in advance.

To ensure smooth operation with daily obligations it is necessary to keep documentation obligations to a reasonable degree. While preparation documentation in terms of plausibility check, work instructions and protocols are commonly drawn up in pharmacies to ensure reproducibility and traceability upon request, the requirements currently set out in points (c), (d), (f) and (h) do not fit properly into the inner function of a pharmacy. It is therefore desirable to exempt in-pharmacy preparations from these obligations.

This would allow for the utilization of the existing, well-functioning resilience structure of pharmacies, which would benefit the medical device market as a whole. We expressly welcome the remaining provision of Article 5(5) and the revision proposal as they represent necessary requirements for product quality and ensure that an expansion of the scope of application does not come at the expense of patient safety.

V. CONTEXT OF PROFESSIONAL POLITICS

Beyond the specific regulatory adjustment, we also view this opinion as a reminder of the importance of pharmaceutical expertise for European healthcare. Pharmacists have specialized training and many years of experience in quality-assured manufacturing – including under aseptic conditions. This expertise is widely available, ready for immediate use, and already works closely with medical care today. Furthermore, pharmacies operate in accordance with the principles of quality and risk management, meaning that the requirements set forth in Annex I of MDR and IVDR reflect standard pharmaceutical manufacturing practices. Regulatory recognition of this expertise under MDR and IVDR would not only strengthen the safety of supply for substance-based medical devices but also send a clear signal regarding the importance of pharmacies as part of Europe's critical healthcare infrastructure.

VI. CONCLUSION

We ask that the revision of Article 5(5) of both MDR and IVDR is being used as an opportunity to strengthen the supply of substance-based medical devices by pharmacies, thereby utilizing an already existing and professionally recognized, European practice on a uniform and reliable base for the device sector.
We are available at any time to answer questions and engage in further discussion.

The German Society of Hospital Pharmacists (ADKA) *represents the interests of more than 90% of hospital pharmacists working in Germany. It serves both as a professional association and a scientific society and does not pursue any commercial interests.*
ADKA's stated objective is to ensure effective, safe and cost-effective medication therapy for all patients treated in German hospitals. ADKA is committed to continuously improving the quality of medication therapy both within hospitals and across transitions of care, with the aim of minimising risks and achieving the highest possible level of medication safety for patients.