Joint Opinion of German industry associations: Urgent need for legal measures to facilitate MDR/IVDR implementation.

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The signing German industry associations greatly welcome the opportunity to propose several legal measures that would facilitate MDR/IVDR implementation and make the system more functional. Our proposals result from the experiences made since the MDR/IVDR entered into force in 2017. The solutions proposed aim to resolve some of the main issues for which there is common understanding and that have been identified in multiple surveys. The results of the data gathered from different sources repeatedly point out that the original objectives of MDR and IVDR are not met due to deficiencies in the system.

We observe the following:

> Devices and companies are disappearing from the market.

> Overall costs and time to market are unpredictable and have both increased considerably.

> Interpretations of the regulations and the application of guidance documents which vary greatly which contradicts the aim to harmonize.

> Products and especially innovations are being shifted to other markets.

> Small and medium sized enterprises (SMEs) are disproportionately affected.

All of this is leading to deterioration of patient care.

The proposal aims to provide solutions not only in relation to the targeted evaluation of the MDR/IVDR by the European Commission (COM) in accordance with Art.121 MDR and Art.111 IVDR, but also concerning the current MDD/MDR and IVDD/IVDR transfer activities of the manufacturers and Notified Bodies (NBs) and the “reduction of bureaucratic burden” package of the president of the European Commission.

Manufacturers and NBs require legal certainty for conformity assessment procedures (CAPs) and a common understanding and harmonized implementation of the legal requirements.

Whereas legally non-binding guidance documents are well meant to support implementation, experience shows, that where there is no common approach and understanding of its content as well as acceptance by all stakeholders, guidances fail to achieve their goal. A prominent example is MDCG 2022-14 which already recognized significant and urgent challenges and proposed a mix of solutions to improve the situation. However, more than two years later, there is little improvement as important actions have not been implemented.

Therefore, we propose legal measures that include amendments to the MDR/IVDR legal text, implementing acts (e.g., through Art. 36 (3) MDR and Art. 32 (3) IVDR, Art. 81 g) MDR and Art. 77 g) IVDR) and delegated acts as well as common specifications (CS).

While an ordinary legislative procedure to amendment the MDR/IVDR legal texts takes time, implementing and delegated acts as well as CS provide a suitable legal basis for short-term measures.

In summary, the following topics have the highest relevance to facilitate MDR/IVDR implementation. More detailed information is provided in the respective sections of Annex 1.

1.
Better planning of the certification processes to ensure predictability (see Annex 1, section 1)

MDCG-Guidance 2022-14 already includes several aspects, which could improve the predictability and planning of the certification processes (e.g., leveraging evidence, structured dialogue, streamline administrative procedures, etc.) They should be incorporated into implementing acts.

The harmonization of the application and the CAPs can be achieved by the following measures:

> Introduction and publication of fixed timelines for the CAP or parts of it (e.g. acknowledgement of receipt of application, completeness check, issuance of certificate after concluded review);

> Publication of notified bodies' average time needed for services provided in relation to their hourly fees, to allow economic operators to compare notified bodies fees and estimate the overall costs ;

> Template for the contract between the manufacturer and the NB to ensure contracts do not go beyond requirements in the MDR and to ensure level playing field for SMEs;

> Introduction of an accelerated pathway for innovations and orphan devices / IVDs

> Acceleration of the publication of harmonised standards used to demonstrate conformity of devices / IVDs with the GSPRs

> Implementation of a harmonised methodology for technical documentations including digitisation;

> Clarification in terms of the required activities for (substantial) changes and modifications;

> Clarification in terms of „structured dialogue";

> Clarification on leveraging evidence for legacy devices transitioning from MDD/IVDD to MDR/IVDR, as well as for successor devices.

> Implementation of a governance structure that ensure better harmonisation of notified body practices.

2
Proportionate assessment of the clinical evidence/performance (see Annex 1, section 2)

Legacy devices usually have a long-lasting history, and it is difficult and challenging to retrospectively establish all new requirements of the MDR/IVDR in regard to clinical evidence/performance. The strict application of the new clinical requirements, does not necessarily result in new information about the safety and efficacy of the affected legacy device under the MDR and IVDR.

In contrast, both the long-lasting surveillance by NBs and the post market surveillance (PMS) activities of the manufacturers usually provide a clear picture of the safety and efficacy profile of such medical devices/IVDs.

In order to avoid unnecessary time and cost intensive effort for the compilation of new data without an additional benefit the following short-term measures are proposed:

> Definition and extended use of the concept of „well established technologies“ (WET);
> Reassessment of the application of Art.61 (10) MDR and Art. 56 (4) IVDR;
> Revision of the principle of equivalence;
> Simplified requirements in regard to clinical evaluation for low-risk medical devices and IVDs without affecting patient safety.

3
Recertification / reassessment of certificate validity (see Annex 1, section 3)

The current re-certification procedures appear to be obsolete taking into account the life cycle approach with annual surveillance audits and activities by the NBs, as well as the post market surveillance (PMS) activities and the respective documentation (e.g. management review, trend report, summary of safety and clinical performance, clinical evaluation report, risk management, change management, reporting of severe incidents etc.). The quality management system as well as technical documentation of class III medical devices and class D IVDs are annually reviewed by the NBs.

Hence, instead of a formal and bureaucratic re-certification process the NBs may reassess the validity of the certificates and hereby reinforce the life cycle approach introduced by MDR/IVDR. Certificates should have unlimited validity provided that the surveillance activities of the NBs do not identify unsolved (major) non-conformities.

Furthermore, the sampling of class IIa and class IIb medical devices and class C IVDs should be streamlined; i.e. a complete review of the technical documentation every year, if a manufacturer just possesses one or less than 5 devices / IVDs is not appropriate as it does not result in an improved safety of efficacy profile of the affected product and is a competitive disadvantage for manufacturers with small product portfolios (typically SMEs) compared to those with a large variety of products. Products of class B IVDR should not undergo an

assessment of the technical documentation as described in Art. 49 (9) IVDR. The retention of this category should be reconsidered.

4
Adapt procedures for and content of some MDCG guidance documents (see Annex 1, section 4)

MDCG guidance documents are meant as interpretative aids that should facilitate a harmonized interpretation for the European Union, even though they are legally non-binding. However, MDCG guidance documents today, have a relevant impact on CAPs as they are usually considered not only by Competent Authorities and NB but also by civil and administrative courts (see 1)).

The release of new MDCG guidance documents during ongoing CAPs must not result in the rejection of an ongoing application solely due to non-compliance with any new MDCG guidance.

Furthermore, current MDCG guidances are limited by two factors:

1) Procedure: The endorsement of a MDCG guidance is problematic where a minority of votes in favour can lead to an adoption of the guidance[1]. It is highly questionable to regard such guidance documents as harmonised interpretation. There is also no harmonized and clear procedure for stakeholder consultation, and generally voting processes lack transparency.

2) Acceptance: Stakeholder participation varies greatly, and in some instances, affected stakeholders are not consulted at all. Stakeholders are also not entitled to vote.

In order to achieve a greater acceptance and a more harmonized implementation of MDCG guidance documents the following measures should be implemented for new and existing MDCG guidance documents, which should be revised according to the new principles:

> The objective and scope of a guidance document should be clearly communicated at the start of its compilation and all stakeholders should be able to provide input from the start;

> Clear procedures should be established and made transparent;

> The delegates of the Member States should be obliged to justify their voting (even in the case of abstention) in writing;

> Submitted comments of all stakeholders should be duly assessed and documented;

> A MDCG guidance document should only be endorsed in accordance with a revised voting procedure;

> The compliance with a newly endorsed MDCG guidance document must not be decisive for ongoing CAPs.

[1] MDCG 2022-5 has been endorsed based on 9 affirmative votes, whereas 2 MS voted against the endorsement and 16 MS abstained from voting, i.e. a majority of 18/27 MS did not support the proposed MDCG guidance text and MDCG 2022-5 is not a harmonized interpretation of the MDR

5
Further measures to facilitate the MDR/IVDR implementation (see Annex 1, section 5)

Apart from proposals (1) – (4) further measures would have a positive impact on the MDR/IVDR implementation. Without claim of completeness such measures include:

> Digitalisation of processes and documents / Broach application of electronic instruction for use (eIFU) (Art. 2 (14), Annex I, Impl. regulation 2021/2226);

> Reassessment of some classification rules (e.g. 6, 8, 11, 19) via implementing acts (Art. 51 (2) (3) (4) MDR, Annex VIII) / Publication of classification decisions;

> Others

The German industry associations highly welcome the European Parliament resolution of 23 October 2024 on the urgent need to revise the Medical Devices Regulation (2024/2849(RSP)) and support the proposed measures outlined therein.

We acknowledge the significant efforts already made to establish a reliable and suitable legal framework for medical devices and IVDs. We confirm our full commitment to provide further practical information and proposals to facilitate the MDR/IVDR implementation.

To ensure continuous and safe patient care, as well as innovations, it is important to act swiftly on the proposed actions. By doing so, the original objectives of the MDR /IVDR can be achieved for the benefit of patients, the national health economy, the industry and the EU as a key business location and innovation hub.

Please do not hesitate to contact us for any question.

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