AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY

AESGP White Paper

Lessons learned with the MDR Implementation

Recommendations towards a Robust, Transparent, Predictable and Sustainable Regulatory Framework for Medical Devices Ensuring a High Level of Safety and Health Whilst Supporting Innovation

April 2024

Introduction

Recital (1) of the Medical Devices Regulation (MDR) **(1)** formulates the objective:

*"to establish a **robust, transparent, predictable and sustainable** regulatory framework for medical devices which ensures a **high level of safety and health whilst supporting innovation**".*

Recital (2) complements this objective by stating that the MDR:

*"aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a **high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises** that are active in the sector".*

The MDR entered into force in May 2017 and is applicable since May 2021. After almost seven years of implementing the requirements and rules provided for in the MDR, it has become manifest that the objectives laid down in the recitals of the MDR have not been attained.

In fact, **the regulatory framework as currently implemented under the MDR is marked by unpredictability, opacity, cumbersome and resource intensive processes as well as a high-cost environment affecting adversely business operators and, in particular, small-and medium sized enterprises.**

In other words, the current set-up of the regulatory framework undermines the innovative power and the competitiveness of the medical device industry and, notably, does not allow rapid and cost-efficient market access for medical devices, to the detriment of patients and healthcare professionals.

Objectives of the White Paper

To address these challenges and to meet the objectives of the MDR referred to above, AESGP proposes in the following paper certain measures to improve and optimize the existing regulatory system that involves non-legislative and legislative means without necessarily identifying them as such.

Importantly, the proposed reforms intend to maintain the base of a high level of health for patients and users as reflected in the MDR's current safety and quality requirements.

AESGP's approach in this white paper when it comes to suggestions entailing legislative action is to build upon and enhance existing provisions under the MDR, rather than proposing a complete overhaul of the legal framework applicable to medical devices.

In short, AESGP supports targeted and specific reforms to individual provisions of the MDR legal system complemented by non-legislative actions. This is to ensure that the investments and efforts that have been made so far and are ongoing in setting-up the regulatory infrastructure under the MDR by all stakeholders do not get completely lost and may be used as a foundation for improving the current conditions in a targeted approach.

Simultaneously, duplications in governance as well as administrative structures need to be disentangled and abolished where necessary to increase efficiency and flexibility, i.e. being able to address swiftly and decisively *ad-hoc* issues and challenges in the regulatory structure to meet the initial objectives (enshrined in the recitals of the MDR).

The proposed measures distinguish between elements designed to enhance transparency, predictability and as such legal certainty, efficiency as well as elements designed to optimize the governance structure under the MDR. The focus of the proposed measures will be on the former elements.

Based on this document, AESGP contributes to the public discussion in collaboration with other relevant stakeholders at EU level regarding the structural issues in the implementation of the MDR and how to address them.

(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, OJ L 117 5.5.2017, p. 1, as amended.

Elements to enhance Transparency, Predictability, Efficiency and Legal Certainty

Validity of certificates

- **The validity of certificates should be unlimited in time and therefore not be subject to re-certification every five years as currently applicable.**

- **The validity of the certificate should depend on compliance with the applicable post-market surveillance and vigilance requirements.**

These elements would contribute to generating efficiencies in relation to resources and capacities for notified bodies and manufacturers alike. Therefore, potential re-certification bottlenecks would be avoided. As a further beneficial consequence of this modification, certificates cannot expire as a result of the notified body not having scheduled audits timely or not completing conformity or QMS assessment before expiry date of the certificate.

Conformity assessment

- **Provide defined timelines in relation to conformity assessment procedures set out in Annex VII to the MDR.**

At the moment, significant differences exist when it comes to the completion of conformity assessment procedures. In addition, agreed deadlines upfront are not adhered to and are subject to delays.

Overall, these circumstances lead to unpredictability concerning review timelines of technical documentation and overall completion of conformity assessment procedures.

The provided timelines could **define maximum periods for the completion of conformity assessment procedures based on a staggered approach** depending on the risk classification of the device, i.e. distinguishing between low-risk, medium risk, or high risk.

Overall, the maximum periods for the conformity assessment of high-risk devices should be longer compared to the maximum periods for the conformity assessment of low-risk and medium-risk devices.

Cost predictability

- **Provide for predictability of costs associated with product or QMS certification and other procedures**.

At the moment, costs associated with conformity assessment procedures are not predictable at the beginning of the process.

Particular **funding schemes for SMEs to cover a certain part of the costs** associated with product or QMS certification and other procedures could be set up with the aim to reduce the financial burden for those businesses and, thereby, strengthening competition overall.

Pre-filing dialogue

- **A pre-filing dialogue between applicant and notified body before the conformity assessment should be established and allowed.**

This pre-filing dialogue between applicant and notified body before the conformity assessment procedure should aim at enhancing efficiency and predictability as well as clarification of notified body expectations on the technical documentation for a given product.

As a consequence, unnecessary rounds of questions later in the process could be avoided.

In short, it would accelerate the review circle and the conformity assessment procedure as a whole.

This also corresponds to action No.15 of MDCG 2022-14 (2) which, however, has not been consistently implemented so far.

Given that the MDCG position does not suffice to establish such dialogues and turn them into consistent prac-

(2) MDCG Position paper 2022-14. Transition to the MDR and IVDR. Notified body capacity and availability of medical devices and IVDs: https://health.ec.europa.eu/system/files/2022-08/mdcg_2022-14_en.pdf

tice, it is suggested to clarify in the legal text of the MDR that pre-filing dialogues before and during the conformity assessment may be held between applicant and notified body.

Medical Device Single Audit Program (MDSAP)

- **The MDSAP should be integrated in the EU regulatory framework so that audits on the manufacturer's quality management system conducted by other jurisdictions participating in the Program can be relied on.**

This element would promote more efficient and flexible use of regulatory resources on the sides of manufacturers and notified bodies while at the same time minimizing regulatory burden on industry.

Evidence from previous assessments

- **It should be made possible to make use of evidence from previous assessments under the Directives for the purpose of conformity assessment procedures under the MDR for all risk classes of devices.**

This element also corresponds to action No.3 of MDCG 2022-14 which, however, has not been implemented so far.

Helsinki procedure

- **In relation to the qualification and classification of products within the MDR context, the Helsinki procedure should be improved.**

In particular, it should be modified with the aim to increase transparency and legitimacy while ensuring scientific-based outcomes as well as competence and adequate expertise of the assessors involved.

Specific suggestions to achieve these objections on the Helsinki procedure:

◊ Manufacturers of a concerned product subjected to the procedure should be consulted, i.e via the National Competent Authorities, before any decision being taken.

◊ Notified Bodies of a concerned product subjected to the procedure should be consulted, i.e via the National Competent Authorities, before any decision being taken. The opinion of a Notified Body should be duly considered when dealing with borderline cases since the Notified Body for a concerned product made an assessment relying on the expertise of its own assessors (3).

◊ In general, all stakeholders should be consulted as early as possible in the process.

◊ If the initiating Competent Authority does not agree with the conclusion of the concerned manufacturer and NB, a scientific justification shall be drawn up and made available. In this situation, the possibility of an appeal-like process as part of the Helsinki procedure should be provided.

◊ Inclusion of a new case in the borderline manual only occurs if a simple majority among all 27 Member States is reached, i.e. 14 Member States must vote in favor.

◊ Any initiated procedures should be concluded swiftly by adhering to short defined timelines to avoid products getting caught in a regulatory "limbo" for years.

Classification disputes

- **The establishment of a publicly accessible registry as an exchange system for decisions reached by competent authorities on classification disputes would ensure more harmonization and transparency.**

(3) The expertise of the Notified Body personnel must meet specific requirements, see also Annex VII, part 3, to the MDR.

Agile processes

- **Reduce unnecessary bureaucracy in conformity assessment procedures to allow notified bodies to take a more efficient and "benefit-risk based" approach while maintaining a high standard concerning the assessment of safety and performance.**

In this regard, continuity in conformity assessment procedure should be ensured and, thereby, involvement of different assessors should be avoided.

Similarly, administrative inquiries on technical documentation that do not relate to the safety or performance of the device should not require formal follow-up questions and entail additional rounds of questions.

In addition, a uniform system among all designated notified bodies should be established for the submission of technical documentation.

Interpretation of MDCG Guidance

- **It is important that a pragmatic route of application and interpretation is followed in line with their status as guidance documents and not as legal instruments.**

The publication of MDCG Guidance documents and their implementation as well as interpretation, has shown that newly published documents are applied almost immediately (from one day to the next) and in a very legalistic manner.

So, some non-conformities are brought up against MDCG Guidance documents due to literal interpretation. However, this approach in practice does not correspond to their status as guidance documents which are not legally binding and are intended only as interpretation instruments for the respective legal requirements in the legislation.

Given the key role of MDCG Guidance documents in implementing MDR requirements and in light of their proliferation, it may be useful introducing a procedural step requiring a legal check by Commission services before the publication of the individual guidance to ensure legal coherence vis-à-vis the legal framework and to avoid the introduction of new "requirements".

Elements to optimise Governance under the MDR

The Medical Device Coordination Group (MDCG) has been established under the MDR as a central body and forum to achieve harmonized interpretation and practice through the provision of an extensive toolset **(4)**.

Arguably, the MDCG may have helped to contribute to an improved coordination and information exchange between competent authorities, but ultimately has not led to a harmonized interpretation and practice.

(4) Pursuant to Article 105 of the MDR, the MDCG has the following tasks: (a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV; (b) to advise the Commission, at its request, in matters concerning the coordination group of notified bodies as established pursuant to Article 49; (c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of clinical evaluations and investigations by manufacturers, assessment by notified bodies and vigilance activities; (d) to contribute to the continuous monitoring of technical progress and assessment of whether the general safety and performance requirements laid down in this Regulation and Regulation (EU) 2017/746 are adequate to ensure safety and performance of devices, and thereby contribute to identifying whether there is a need to amend Annex I to this Regulation; (e) to contribute to the development of device standards, of CS and of scientific guidelines, including product specific guidelines, on clinical investigation of certain devices in particular implantable devices and class III devices; (f) to assist the competent authorities of the Member States in their coordination activities in particular in the fields of classification and the determination of the regulatory status of devices, clinical investigations, vigilance and market surveillance including the development and maintenance of a framework for a European market surveillance programme with the objective of achieving efficiency and harmonisation of market surveillance in the Union, in accordance with Article 93; (g) to provide advice, either on its own initiative or at request of the Commission, in the assessment of any issue related to the implementation of this Regulation; (h) to contribute to harmonised administrative practice with regard to devices in the Member States.

MDCG consensus

- **The MDCG should endorse positions and in particular MDCG guidance documents only by consensus and without abstention (5).**

Endorsement of positions and in particular MDCG Guidance documents that lack consensus and for which diverging positions are recorded will not lead to effective and harmonized implementation of the MDR, but to the opposite.

A specific example in this regard is the MDCG 2022-5 on borderline between medical devices and medicinal products. (6)(7)

In addition, members of the MDCG should not be able to abstain when it comes to the endorsement of positions and guidance documents.

Consistent application of Guidance

- **The MDCG should put greater emphasis in ensuring the harmonized and consistent application of Guidance documents endorsed by the MDCG.**

MDCG and CAMD overlaps and duplication

- **The work of the MDCG and the forum of Competent Authorities for Medical Devices (CAMD) should be coordinated as closely as possible to avoid overlaps and duplication of work between the two bodies.**

CAMD is currently an umbrella group of national competent authorities that exists outside the legal framework of the MDR.

Drug-Device Combination Products working group

- **A new MDCG working group on drug-device combination products should be set-up to assist the MDCG on issues relating to the implementation of Article 117 MDR.**

This group should aim at a consistent, effective and harmonized application of that provision.

So far there is no specific forum or platform to discuss challenges in relation to drug-device combination products and implementation of Article 117 MDR.

(5) Pursuant to the current Rules of Procedure, the MDCG or its working groups shall act by consensus as far as possible. In the event of a vote, the outcome of the vote shall be decided by simple majority of all appointed members. See Point 8 (1) and 8 (2) of the MDCG Rules of Procedure: https://health.ec.europa.eu/system/files/2022-01/md_dialogue_mdcg_rules_procedure_en.pdf

(6) MDCG 2022-5. Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices: https://health.ec.europa.eu/system/files/2023-06/mdcg_2022-5_en.pdf

(7) The MDCG minutes of 24-25 October 2022 provide the diverging positions of Germany and Italy in relation to the endorsement of MDCG 2022-5: https://ec.europa.eu/transparency/expert-groups-register/core/api/front/document/95312/download

About

The **Association of the European Self-Care Industry (AESGP)** is a non-profit organisation which represents the manufacturers of non-prescription medicines, food supplements and self-care medical devices* in Europe, an area also referred to as consumer healthcare products.

**Self-care medical devices are generally available without medical prescription and are self-administered.*

Contact

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