6 January 2025

LEGAL OPINION

For

BUNDESVERBAND MEDIZINTECHNOLOGIE E.V. (BVMED)

on

Art. 10a MDR

Legal assessment and practical interpretation of the newly introduced information obligation

CMS law·tax·future

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A. Background

On 13 June 2024, the European Parliament and the Council of the European Union adopted Regulation (EU) 2024/1860 (hereinafter "**Amending Regulation**")[1] amending Regulation (EU) 2017/745 (hereinafter "**MDR**")[2] and Regulation (EU) 2017/746 (hereinafter "**IVDR**")[3]. The Amending Regulation, among other things, provides for the insertion of an Art. 10a MDR and an Art. 10a IVDR[4]. These articles stipulate an information obligation for manufacturers of medical devices and in vitro diagnostics in the event of an interruption or discontinuation of supply with effect as of 10 January 2025.

On 30 October 2024, the European Commission published a Q&A document on the practical aspects of the new information obligation[5], followed by the publication of a "Manufacturer Information Form" for the practical implementation by the Medical Device Coordination Group (hereinafter "**MDCG**") on 6 December 2024[6] together with a corresponding "Device Identification Table".[7] Further, the publication of a decision tree diagram on the manufacturer's risk assessment was announced[8], but is still pending on the date of completion of this legal opinion.

CMS has been asked to assess the scope and the interpretation of the new information obligation under Art. 10a MDR from a legal perspective and to provide practical guidance on its implementation in practice.

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[1] Regulation (EU) 2024/1860, available at: https://eur-lex.europa.eu/eli/reg/2024/1860/oj (last access: 06 January 2025).
[2] Regulation (EU) 2017/745, available at: https://eur-lex.europa.eu/eli/reg/2017/745/oj (last access: 06 January 2025).
[3] Regulation (EU) 2017/756, available at: https://eur-lex.europa.eu/eli/reg/2017/746/oj (last access: 06 January 2025).
[4] For reasons of clarity, the legal opinion focusses on Art. 10a MDR. The following considerations are nonetheless applicable to Art. 10a IVDR.
[5] European Commission, Q&A The information obligation in case of interruption or discontinuation of supply of certain medical devices and in vitro diagnostic medical devices, 30 October 2024 (hereinafter: "Q&A"), available at: https://health.ec.europa.eu/latest-updates/qa-obligation-inform-case-interruption-or-discontinuation-supply-2024-10-30_en (last access: 06 January 2025).
[6] MDCG 2024 – 16, Manufacturer Information Form on Interruption or Discontinuation of Supply of certain medical devices and certain in vitro diagnostic medical devices (as per Article 10a of Regulation (EU) 2024/1860 amending Regulation (EU) 2017/745 and Regulation (EU) 2017/746), available at: https://health.ec.europa.eu/document/download/919061d9-5dfa-4d0b-ab9b-3543eed98f76_en?filename=md_mdc-2024-16_en.pdf (last access: 06 January 2025).
[7] MDCG 2024-16 – Annex, available at: https://health.ec.europa.eu/document/download/b4a7dea7-ae73-4e13-a8a8-11dcd2678d38_en?filename=md_mdc-2024-16_annex_en.pdf (last access: 06 January 2025).
[8] Q&A, B.11., page 9.

B. Executive Summary

- With effect from 10 January 2025, Art. 10a MDR stipulates a duty of information for manufacturers of medical devices in the event of an interruption or discontinuation of supply with a far-reaching personal and material scope of application.

- The wording of Art. 10a MDR contains a number of undefined legal terms that need to be interpreted. This interpretation needs to take into account, amongst others, the principle of proportionality as well as fundamental rights and other opposing legal obligations on manufacturers, such as competition law requirements.

- Taking into account these principles and limitations, Art. 10a MDR needs to be interpreted in a narrow way.

- While the Q&A document published by the EU Commission provides valuable guidance in some respects, it does not fully reflect and cover the legal aspects that need to be considered. As it is non-binding, it is not the only source of interpretation and can thus be supplemented by additional sources of interpretation.

- More concretely, Art. 10a MDR requires manufacturers to implement a procedure in their Quality Management System to comply with the new information obligation.

  When determining whether an information obligation exists, manufacturers can use the following steps as a guideline:

  1. Manufacturers have to determine interruptions or discontinuations of supply within their own (subjective) sphere. More specifically, the manufacturer must consider whether the placing on the market of a particular product group will be interrupted or discontinued without the manufacturer being able to provide a replacement product or draw on sufficient stocks to bridge a supply interruption.

     Only those interruptions or discontinuations that are anticipated from 10 January 2025 onwards are to be taken into account.

     A relevant interruption is excluded if the manufacturer anticipates an interruption of less than 60 days.

  2. As soon as an interruption or discontinuation of supply is determined, manufacturers must assess whether alternatives in supply exist.

Alternatives in supply exist, if an alternative device may be offered by other manufacturers or an alternative form of therapy or diagnosis method is available on the market.

3. In the absence of alternatives in supply, diagnosis or treatment, manufacturers must assess whether the interruption or discontinuation causes serious harm or the risk of serious harm to patients or public health. To assess the possible risks to patients or public health, the manufacturer is required to make a prognosis based on his knowledge, but is not obliged to carry out a comprehensive research.

   As a general rule, relevant harm due to the unavailability of a device can only be assumed for certain critical devices of particular importance, such as life-saving or life-sustaining devices, which are able to prevent serious harm to patients or public health caused by (the progression of) the patients' disease, injury or disability. The majority of devices will not fall into this category and their unavailability will therefore not trigger a notification obligation in accordance with Art. 10a MDR by their manufacturers. For further guidance, manufacturers may as well refer to the Critical Medical Device List (hereinafter "**CMDL**")[9] as a further guideline in their risk assessment, at least until there is a comparable list in the EU.

4. In case serious harm or the risk of serious harm to patients or public health is reasonably foreseeable as a result of the unavailability of a device to the manufacturer, the manufacturer has to inform the national competent authority in the respective(s) Member State(s) as well as the economic operators, health institutions and healthcare professionals to which the concerned device is directly supplied.

   Only those economic operators, health institutions and healthcare professionals who are impacted by the supply interruptions or discontinuation must be informed. An impact is only to be assumed if there is an ongoing direct supply relationship.

   The information must be provided at least six months before the anticipated interruption or discontinuation. In the event of exceptional

[9] See for further information: https://files.asprtracie.hhs.gov/documents/critical-medical-device-list-recommendations-report.pdf (last access: 06 January 2025).

circumstances, particularly sudden and unexpected external or internal **circumstances**, it is permissible to fall short of the six-month deadline.

It is recommended that manufacturers maintain a continuously updated list of the economic operators, health institutions and healthcare professionals who may need to be informed for the device in question.

C. Legal assessment

I. Art. 10a MDR in a nutshell

1. Wording of Art. 10a MDR

Art. 10a MDR is entitled "Obligations in case of interruption or discontinuation of supply of certain devices" and has the following wording:

> "*1. Where a manufacturer anticipates an interruption or a discontinuation of the supply of a device, other than a custom-made device, and where it is reasonably foreseeable that such interruption or discontinuation could result in serious harm or a risk of serious harm to patients or public health in one or more Member States, the manufacturer shall inform the competent authority of the Member State where it or its authorised representative is established, as well as the economic operators, health institutions and healthcare professionals to whom it directly supplies the device, of the anticipated interruption or discontinuation.*
>
> *The information referred to in the first subparagraph shall, other than in exceptional circumstances, be provided at least 6 months before the anticipated interruption or discontinuation. The manufacturer shall specify the reasons for the interruption or discontinuation in the information provided to the competent authority.*
>
> *2. The competent authority that has received the information referred to in paragraph 1 shall, without undue delay, inform the competent authorities of the other Member States and the Commission of the anticipated interruption or discontinuation.*
>
> *3. The economic operators who have received the information from the manufacturer in accordance with paragraph 1 or from another economic operator in the supply chain shall, without undue delay, inform any other economic operators, health institutions and healthcare professionals to whom they directly supply the device, of the anticipated interruption or discontinuation.*"

The wording of Art. 10a MDR is very broad. Taken literally, it would introduce a massive administrative burden on all manufacturers of medical devices on the EU market, disproportionate to the effect the article seeks to achieve. This calls for an interpretation taking into account the purpose on the one hand and the rights and interests of the manufacturers on the other.

2. Legislative procedure

In view of the far-reaching scope of application and the massive consequences feared for manufacturers, the speed of adoption of the Amending Regulation is astonishing. The Amending Regulation was adopted in the ordinary legislative procedure. Yet, the Commission considered it appropriate to invoke the exception to the eight-week period provided for in Art. 4 of Protocol No. 1 on the role of national Parliaments in the European Union, annexed to the Treaty on European Union (hereinafter "**TEU**").[10] Further, the Commission's proposal was not accompanied by a dedicated impact assessment as it "*does not alter the MDR or IVDR in substance and does not impose new obligations on the concerned parties*."[11] With regard to the insertion of Art. 10a MDR, this reasoning is simply not true. Nevertheless, based on this reasoning, the Commission only carried out targeted exchanges with Member States and stakeholders instead of a broad public consultation.[12] After all, the Commission's proposal was adopted by the European Parliament at first reading.[13] A comprehensive debate on the scope of Art. 10a MDR did not take place. Neither the European Parliament nor the Council of the European Union put forward considerations on the consequences of Art. 10a MDR or proposed amendments for public debate.

3. Systematic categorisation

Art. 10a MDR deviates significantly from the regulatory context of the MDR to date. While a comparable notification obligation already exists in France,[14] the obligations of manufacturers under the MDR have so far focused strongly on ensuring a high standard

[10] European Commission, Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746, COM(2024) 43 final, recital 17, page 16.
[11] European Commission, Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746, COM(2024) 43 final, page 9.
[12] European Commission, Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746, COM(2024) 43 final, page 9.
[13] More information on procedure available at: https://eur-lex.europa.eu/legal-content/EN/HIS/?uri=CELEX:32024R1860 (last access: 06 January 2025).
[14] See information from the *Agence nationale de sécurité du médicament et des produits de santé*, available at: https://ansm.sante.fr/disponibilites-des-produits-de-sante/dispositifs-medicaux (last access: 06 January 2025).

of product quality and product safety.[15] The information obligation in the event of discontinuation or interruption of supply is therefore an alien element in the MDR, as it does not address the risk posed by a product, but the risk posed by the unavailability of the product.

In the wider context of EU regulations, Art. 10a MDR can be regarded as part of a series of measures to deal with threats on public and patients health. One of these measures was the establishment of the Health Emergency Preparedness and Response Authority (hereinafter "**HERA**") at the European Commission.[16] HERA is intended to ensure the safety of public health in the European Union (hereinafter "**EU**") in the event of pandemics or other threats to public health.[17] Furthermore, the European Medicines Agency (hereinafter "**EMA**") received an enhanced role in crisis preparedness and management in relation to medicinal products and medical devices with the implementation of Regulation (EU) 2022/123. Art. 21 et seq. Regulation (EU) 2022/123 provides for the establishment of the Medical Device Shortages Steering Group (hereinafter "**MDSSG**") to ensure a rapid response to public health emergencies and to assess the need for urgent, coordinated action across the EU to address issues related to the availability of medical devices that are considered critical during a public health emergency.[18] Following the recognition of a public health emergency, the MDSSG shall adopt a list of categories of critical medical devices which it considers to be critical during the public health emergency ("public health emergency critical devices list").[19] Manufacturers are obliged to provide information in accordance with Art. 26 Regulation (EU) 2022/123.

Despite these existing measures, the legislative bodies have opted for an additional information obligation under the MDR. However, since this obligation is systematically not fitting, the interpretation of the new provision should take into account the exceptional nature and the narrow interpretation that is also applied in the context of the HERA provisions.

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[15] See Art. 10 MDR; Regulation (EU) 745/17, recital 2.
[16] See HERA website, available at: https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera_en (last access: 06 January 2025).
[17] See areas of responsibility: HERA factsheet, available at: https://health.ec.europa.eu/document/download/b5a6ba4e-ccc3-4a70-8a94-97f6332fa9df_en?filename=hera_general_factsheet_en.pdf (last access: 06 January 2025).
[18] See overview, available at: https://eur-lex.europa.eu/EN/legal-content/summary/european-medicines-agency-reinforced-role-in-crisis-preparedness-and-management-for-medicinal-products-and-medical-devices.html (last access: 06 January 2025).
[19] Art. 22 para. 1 subpara. 1 sentence 2 Regulation (EU) 2022/123.

4. Meaning and purpose of Art. 10a MDR

According to the recitals of the Amending Regulation, the insertion of Art. 10a MDR is intended to address the potential impact of shortages of certain medical devices on patient safety and public health.[20] A prior notice mechanism should be introduced to enable competent authorities and health institutions, in particular, to take mitigating measures where necessary to ensure patient health and safety.[21]

II. Scope of application of Art. 10a MDR

1. Temporal scope of application

According to Art. 3 of the Amending Regulation, Art. 10a MDR takes effect from 10 January 2025. All interruptions and discontinuations of supply that have occurred before 10 January 2025 are not subject to the information obligation. As Art. 10a para. 1 MDR does not link the obligation to provide information to the occurrence of the interruption or discontinuation, but rather to the manufacturer's anticipation of such, interruptions and discontinuations of supply that occur after 10 January 2025 but were already anticipated before are not covered.[22]

2. Personal scope of application

In personal terms, all manufacturers within the meaning of Art. 2 No. 30 MDR are covered by the information obligation. There is no restriction to manufacturers based in a Member State. Manufacturers from non-EU countries shall inform the competent authority of the Member State where its authorised representative is established.

In the case of imported products from non-EU manufacturers, the obligation to provide information only applies to the manufacturers, not to the Authorized Representatives ("**EC Reps**"). This extends the catalogue of obligations for manufacturers under Art. 10 MDR.[23] However, the obligations of the EC Rep under Art. 11 MDR have not been adapted accordingly.[24] Therefore, it remains questionable how compliance with the information obligations of non-EU manufacturers can be monitored, as there is practically speaking no real possibility of such monitoring.[25]

[20] Regulation (EU) 2024/1860, recital 15.
[21] Regulation (EU) 2024/1860, recital 15.
[22] See also Q&A, A.1., page 4.
[23] Handorn, MPR 2024, 225 (227).
[24] Handorn, MPR 2024, 225 (227).
[25] Handorn, MPR 2024, 225 (227).

The economic operators who have been informed by the manufacturer in accordance with Art. 10a para. 1 subpara. 1 MDR are obliged to pass on the information to all other economic operators, healthcare institutions and healthcare professionals to whom they supply the device directly. Art. 10a MDR does neither provide further requirements for the obligation to pass on the information, nor does it allow for exceptions. Thus, economic operators such as distributors are obliged to pass on the information even if they are capable of ensuring uninterrupted supply due to existing stocks. Economic operators, health institutions and healthcare professionals who have not been informed by the manufacturer are not subject to any obligations.

3. Material scope of application

In material terms, the information obligation extends to all "devices" within the meaning of Art. 1 para. 4 MDR, i.e. medical devices, accessories for medical devices, and products listed in Annex XVI to the MDR.[26] Only custom-made devices are excluded. According to the Q&A, Art. 10a MDR applies to all models or types of devices, including legacy devices, placed on the EU market.[27]

III. Extent of the information obligation under Art. 10a MDR

1. Necessity of interpretation

The requirements for the information obligation under Art. 10a MDR are linked to a number of undefined legal terms, the scope of which is unclear.

From a plain reading, it remains unclear, for example, which standard a manufacturer should apply to its anticipation of an interruption or discontinuation of supply, in which cases serious harm or the risk of serious harm to patients or public health is foreseeable and what kind of conditions are set for the existence of exceptional circumstances that justify providing information later than six months before the anticipated interruption. Further, neither Art. 10a MDR itself, nor the Q&A specify when a device is "directly supplied" to the economic operator, health institution or healthcare professional. This creates uncertainty, especially in case a longer period has passed since the last delivery of a product or in case no further orders are pending.

[26] The information obligation also applies to legacy devices, see Q&A, A.3, page 4, footnote 3.
[27] See also Q&A, A.3., page 4.

For the practical handling of Art. 10a MDR, these undefined legal terms require interpretation. To date, there are no corresponding guidelines from the MDCG.[28] The Manufacturer Information Form by the MDCG and the Q&A by the Commission provide initial guidance on the application of Art. 10a MDR. However, the Q&A does not address all relevant questions. Also, both the Q&A and the Manufacturer Information Form are not legally binding but set out a possible way of interpreting the law.[29] Other ways of interpretation remain possible and can, with good reason, be applied in practice where this is considered appropriate.

2. Criteria for interpretation

a) Principle of proportionality

aa) Objectives of Art. 10a MDR

Legislative measures such as the introduction of Art. 10a MDR must comply with the principle of proportionality set out in Art. 5 para. 1 sentence 2, para. 4 of the TEU. According to this principle, the content and form of EU action shall not exceed what is necessary to achieve the objectives of the Treaties. 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. At the same time, the MDR ensures high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products.[30] The newly inserted Art. 10a MDR must also be interpreted in the light of these objectives.

First of all, it should be noted that the internal market or health protection is not affected in all cases of interruption or discontinuation of the supply of a device. The interruption or discontinuation of supply does not in itself say anything about, for example, available stocks of the device on the market with various economic operators in the supply chain. According to the Q&A, manufacturers are required to consider the quantity of the device concerned that

[28] The Commission expressly referred to the possibility of adopting such guidelines in accordance with Art. 105 MDR in its draft regulation, see COM(2024) 43 final, page 7 f., available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2024%3A43%3AFIN (last access: 06 January 2025).
[29] See Q&A, page 1; see MDCG 2024 – 16, Manufacturer Information Form, page 1; In this regard, it is imprecise to speak of clarifications by the Q&A document, see Maxwell, EC Releases Document on Device Shortage, Reporting Obligations, available at: https://insights.citeline.com/medtech-insight/ec-plans-document-on-device-shortage-reporting-obligations-TIXTISI4LJG65AC4J5HF2W2ZVY/ (last access: 06 January 2025).
[30] Regulation (EU) 2017/745, Recital 2; cf. Art. 9, 168 TFEU and Art. 35 CFR Charter; Art. 3 para. 3 subpara. 1 sentence 1 TEU, Art. 26, 114 para. 1, para. 3 TFEU.

has already been made available on the market in one or more Member States.[31] However, manufacturers will often not know whether the devices they supply are still available to economic operators or have already been supplied to healthcare institutions, healthcare professionals or patients. In this respect, the obligation on manufacturers to provide information appears unsuitable for achieving the objectives.

Furthermore, it must be borne in mind that manufacturer information in itself will neither lead to the achievement of a high level of health protection nor to the safeguarding of the internal market. Appropriate measures are required in response to the respective information. Yet, countermeasures by the competent authorities were not standardised in the course of the introduction of Art. 10a MDR. The competent authorities to which the information is reported lack powers to ensure supply, for example in the form of replacement purchases by the Member States. The Commission's Q&A does also not address any countermeasures.

Countermeasures at national level could at most be derogations from Art. 52 MDR granted by the competent authority in accordance with Art. 59 para. 1 MDR, primarily for a single member state. Such derogation would authorise manufacturers and/or importers to place a specific device on the market and to put it into service in a single Member State without carrying out a conformity procedure if the derogation is in the interest of public health or patient safety. However, the derogation from the conformity assessment requires a duly justified request, filed by a third person. There is no provision for the authority to act *ex officio*. Nor is there any provision for the competent authorities to review or carry out their own risk assessment. The competent authority's ability to review is also limited by the large number of undefined legal terms.

Conceivable follow-up measures are limited to possible reactions by other players in the healthcare sector, for example, the expansion of production by other manufacturers or the application by a healthcare facility or doctor for a derogation in accordance with Art. 59 MDR. It is not clear what the scope of such a derogation would be in practice. Since an obligation to provide information would only arise in the absence of any alternative therapy and diagnostic methods, the scope of application would probably be limited to the

[31] Q&A, B.9.2., page 9.

authorisation of devices for which a conformity assessment procedure has not been carried out. It is unclear whether and how this would happen in practice.

In sum, any reactions to the information under Art. 10a MDR remain unclear and have not been predetermined by the legislative bodies of the EU.

bb) Consequences for manufacturers

The questionable suitability for achieving the regulatory objective must be set against the consequences for manufacturers of providing such information. The consequences include a massive administrative burden due to the lack of restriction to certain types or groups of devices (a positive list of addressed devices is not available from the commission or MDCG) and the large number of addressees who must be informed. The addressees of the information are not limited to the respective competent authority but extend to all economic operators, health institutions and healthcare professionals to whom the manufacturer directly supplies the device.

As a result, the information obligation has an impact on manufacturers' supply relationships. This constitutes a restriction of the manufacturers' freedom to conduct business guaranteed by Art. 16 of the Charter of Fundamental Rights of the European Union (hereinafter "**CFR Charter**"), which includes the freedom to conduct business and the freedom of contract of companies as well as the protection of business and trade secrets.[32]

Restrictions on the freedom to conduct business - in particular to guarantee the overarching objective of a high level of health protection - are permissible. Yet, any restrictions must be suitable and necessary to achieve the objective in accordance with the principle of proportionality enshrined in Art. 52 para. 1 sentence 2 CFR Charter. In this respect, the fact that the obligation to provide information may also include information which can have a significant impact on the manufacturer's competitiveness and reputation may have a sensitive effect on manufacturers' interests. According to Art. 10a para. 1 subpara. 2 sentence 2 MDR, manufacturers shall also specify the reasons for the interruption or discontinuation. Such information may be sensitive. However, it is not clear whether such information would remain confidential. Likely it will not. A confidential treatment of the shared information by the

[32] Jarass GRCh, 4th ed. 2021, EU Charter of Fundamental Rights Art. 16 para. 10 with further references.

competent authorities is not guaranteed, at least following the Q&A. The Q&A states that competent authorities will have to share the information not only with competent authorities of other Member States and the Commission but also with health institutions, healthcare professionals, importers. Considerations of the competent authorities to ensure confidentiality have not been disclosed yet.

As possible countermeasures remain unclear, the suitability and necessity of the information obligation appears questionable and due to the drastic consequences for manufacturers, a restrictive interpretation of Art. 10a MDR is required. Otherwise, a far-reaching application of the information obligation could reverse the objective of Art. 10a MDR, i.e. ensuring the security of supply, due to the possible resulting economic weakening of manufacturers.[33]

b) Limits under competition law

When interpreting Art. 10a MDR, limits set out by competition law must be observed. An interpretation of the information obligation must not lead to manufacturers violating legal prohibitions under competition law, in particular antitrust law, by implementing Art. 10a MDR.

If, for example, the assessment of whether serious harm or the risk of serious harm to patients or public health is only possible by considering information from competitors, national and European antitrust law is likely to prevent the procurement of this information in many cases.

§ 1 German Competition Act (ger.: "**GWB**") and Art. 101 TFEU standardise a ban on cartels that prohibits any unilateral or bilateral exchange of information between companies with a subsequent, causal market behavior.[34] As a result, manufacturers will often be prevented from obtaining information from competitors for legal reasons, for example, on product alternatives and their availability.[35] In any case, a legal case-by-case examination will be necessary before any exchange of information. After all, alternatives in therapy, including pharmaceutical treatments, can only be assessed by the attending physicians in individual cases. As a consequence,

[33] Regulation (EU) 2024/1860, recital 15.
[34] See BeckOK KartellR/Füller, 13th ed. 1.7.2024, GWB § 1 para. 19-21; Streinz/Eilmansberger/Kruis, 3rd ed. 2018, TFEU Art. 101 para. 12-17.
[35] See on the classification under European law (in German): Brunnschweiler/Sommer/Raemy, "Informationsaustausch zwischen Wettbewerbern", available at: https://cms.law/de/che/publication/informationsaustausch-zwischen-wettbewerbern (last access: 06 January 2025).

manufacturers will often not be able to obtain the information necessary to fully assess the criteria of Art. 10a MDR for legal reasons.

3. Narrow interpretation of Art. 10a MDR

Based on the criteria of interpretation and the considerable legal limits outlined above, the following considerations can be provided for practical implementation of the information obligation:

a) Manufacturer's anticipation

The prerequisite for the information obligation to arise is the anticipation of an interruption or discontinuation of the supply of a medical device by the manufacturer. Such interruption or discontinuation of the supply must be systematically distinguished from the term "*shortage*" within the meaning of Art. 21 et seq. of Regulation (EU) 2022/123.

Art. 2 lit. h Regulation (EU) 2022/123 defines a shortage as a situation in which the supply of a CE-marked medical device does not meet the demand for that medical device at a national level, regardless of the cause. In contrast, Art. 10a para. 1 MDR requires the interruption of supply, which goes beyond a mere shortage. In this respect, equating the interruption of supply with a shortage is misleading.[36] Accordingly, Art. 10a MDR does not apply in case the manufacturer has a stock of the device that can bridge an anticipated interruption in production.[37]

When determining an anticipated interruption or discontinuation of supply and in light of the health protection objective pursued by the information obligation, it must be taken into account that not every delay in supply is associated with negative effects on health protection. Rather, this should only be considered in case of significant interruptions or the definitive discontinuation of supply.

Correctly, only a complete interruption or discontinuation of the placing on the market of a specific device triggers the information obligation under Art. 10a MDR. A mere reduction in the range of products offered within certain product groups or potential supply bottlenecks do not suffice.[38]

[36] See, for example, Maxwell, loc. cit.
[37] See also Q&A, B.7., page 7.
[38] See also Handorn, MPR 2024, 225 (228).

According to the Commission's Q&A, a duration of more than 60 days may indicate a reportable interruption. The Q&A calls industry not use the full period especially in case serious harm or the risk of serious harm is imminent.[39] It can be assumed that the Q&A is referring to calendar days, not business days, in this context.

The wording of Art. 10a MDR is linked to the manufacturer's anticipation of an interruption or discontinuation of the supply. The manufacturer's anticipation is based on its own positive knowledge, for example its knowledge of operating procedures, production and delivery capacities and its own (economic) decisions as well as recalls and expirations of approvals or discontinuation of a supplier or unavailability of a necessary component.[40] With regard to the threshold of an anticipation by the manufacturer, a mere possibility of an interruption or discontinuation will not suffice. Rather, the wording suggests that the manufacturer must consider the interruption or discontinuation to be certain ("anticipates"). Accordingly, the Commission's Q&A also assumes that the necessary "anticipation" only arises when the manufacturer can confirm that the interruption or discontinuation will occur.[41] The view that the obligation to provide information arises from the mere probability of an interruption or discontinuation[42] is therefore too extensive.

According to the meaning and purpose of Art. 10a MDR, the obligation to provide information is not to be applied in cases where the manufacturer replaces the device with a successor product that serves a similar purpose and is to be used as an alternative or where the manufacturer has a stockpile to bridge the time until the availability of the successor device.[43] In such cases, the supply is ensured despite the discontinuation of the supply of the specific device.

b) Reasonable foreseeability

The manufacturer's anticipation of an interruption or discontinuation of supply does not always trigger a duty to inform. Rather, it must be reasonably foreseeable for the manufacturer that serious harm or the risk of serious harm to patients or public health will occur.

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[39] Q&A, B.7., page 6.
[40] As applicable Q&A, B.7., page 6.
[41] Q&A, B.7., page 6: *"This 'confirmation' includes the analysis of the problem or business decision at hand, the evaluation of mitigation measures in operations and in the supply chain as well as the development of appropriate communication strategies for stakeholders to be addressed."*
[42] See Maxwell, loc. cit., who speaks of the "likelihood of device interruption or discontinuation".
[43] The Q&A assumes an (unwritten) exception to the obligation to provide information, see Q&A, B.7., page 7.

Serious risk to public health is defined in Art. 2 para. 66 MDR as an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time.

It should be noted that the definition of serious risk to public health normally describes a risk emanating from the device itself, i.e. the potential harm that a device can cause. Contrary to this understanding, a serious risk to public health in the context of Art. 10a MDR is described as a risk arising from the unavailability of the device. Yet, a device that is not available cannot in itself pose a risk to patients. Risk assessment therefore require manufacturers to take into account factors beyond their responsibility and, in some cases, their knowledge[44], such as the general availability of alternative products on the market as well as their suitability to replace the concerned device.

The legal definition makes it clear that only foreseeable effects of significant weight are covered. If the effects of the interruption or discontinuation are limited to individual cases, there is no obligation to provide information under Art. 10a MDR.[45] Accordingly, the recitals of the Amending Regulation provide that the risk of serious harm to patients or public health can, for example, be due to the relevance of such devices for ensuring essential healthcare services in one or more Member States, the dependency of patient health and safety on the continuous availability of such devices in one or more Member States, or the absence of suitable alternatives, also in light of the expected length of the interruption, the quantities of devices already made available on the market and available stocks or timelines for procuring alternatives for such devices.[46]

The serious harm or risk of serious harm must be reasonably foreseeable to the manufacturer according to Art. 10a MDR. The term "reasonably" shows that manufacturers are granted a margin of discretion in their assessment, while the manufacturer's decision must remain within the limits of reasonable judgement. In doing so, the manufacturer must take into account the information available.[47] At the same

[44] See also Handorn, MPR 2024, 225 (229).
[45] As applicable Q&A, B.9.1.1, page 8.
[46] Regulation (EU) 2024/1860, recital 15; see also European Commission, Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746, COM(2024) 43 final, page 7 et seq.
[47] A comprehensive market analysis is not required, see Q&A, B.9.1, page 8.

time, the manufacturer cannot be required to consider information that the manufacturer is unable to access. The Q&A, in this regard, refers to various aspects that the manufacturer is regularly unable to assess – for example, the restriction of access to certain medical treatments due to an interruption or discontinuation of supply, the dependence of patient health and safety on the uninterrupted availability of the medical device or suitable product alternatives from other manufacturers that meet the expected demand.[48] The manufacturer can only be expected to take such information into account if the information has already been made available. According to the Q&A, Art. 10a MDR does not contain an obligation to obtain information from healthcare institutions and healthcare professionals.[49] Obtaining information from other manufacturers is even likely to be restricted by competition law in the vast majority of cases.

Moreover, the manufacturer is encouraged to consult a physician or other medical institution for the assessment of possible consequences on patients or public health. It should be noted, however, that Art. 10a MDR does not allow the manufacturer to delegate its information obligations. The manufacturer remains legally responsible irrespective of any consultations. Nevertheless, consultation of physicians and/or other medical institutions can provide assurance in the form of a well-founded medical opinion.

Manufacturers may as well refer to the CMDL established in the US for further guidance. A comparable list does not exist in the EU but is publically discussed in the context of the Regulation (EU) 2022/123, HERA under the acronym of MD MCM (Medical Device – Medical Countermeasurers). A classification of products for which an interruption in supply would cause a serious risk to public health and patients' safety would be beneficial in the EU as well, given the legal uncertainty arising from the large number of undefined legal terms in the wording of Art. 10a MDR. As long as a corresponding list does not exist in the EU, the CMDL can at least serve as an indication for serious harm/the risk of serious harm to patients or public health resulting from an anticipated interruption/discontinuation of supply.

c) Specification of reasons

According to Art. 10a para. 1 subpara. 2 MDR, the manufacturer must state the reasons for the interruption or discontinuation in the information provided to the

[48] Q&A, B.9.2, page 9.
[49] Q&A, B.9.1, page 8 "*[...] the manufacturer may consult with physicians, medical societies, or health care facilities [...]*" (emphasis added).

(home) competent authority. The Q&A assumes that the indication of all information required by the Manufacturer Information Form and not expressly labelled "voluntary" will be mandatory.[50] This understanding by the Q&A would require manufacturers to provide information on all aspects subject to section 7 of the Manufacturer Information Form, including information on the assessment of the situation. However, as long as the Manufacturer Information Form is not legally binding, the wording of Art. 10a MDR remains decisive for the scope of the information obligation. Art. 10a para. 1 subpara. 2 MDR, in this regard, only stipulates that the reasons must be stated, meaning that it is up to the manufacturer to formulate the reasons and decide whether to provide further details. This specifically applies in case a interruption or discontinuation in supply is due to an economic decision of the manufacturer. Art. 10a MDR does not stipulate a legal obligation on manufacturers to their economic decision making.

With regard to the assessment of the situation, the manufacturer is implicitly disclosing the result of the assessment by submitting the Manufacturer Information Form. Beyond that, Art. 10a MDR does not require manufacturers to provide information on the assessment of the situation. The fourth and fifth field of section 7 of the Manufacturer Information Form should therefore not be labelled as "if available" but "voluntary". This narrow interpretation is also reflected by the Manufacturers Information Form when marking many sections as "voluntary" and allowing for an individual specification of reasons.[51] The view that the relevant form will specify the information to be provided,[52] does not recognise that the scope of the information obligation is defined in Art. 10a MDR and not by the Manufacturer Information Form.

d) Time of information; exceptional circumstances

According to Art. 10a para. 1 subpara. 2 MDR, the information must be provided no later than six months before the anticipated interruption or discontinuation of supply. If the manufacturer's anticipation occurs at an earlier point in time, the manufacturer is free to decide whether to submit the information immediately or only six months before it occurs. Art. 10a para. 3 MDR stipulates an obligation on immediate notification only for economic operators in the supply chain who have been informed by the manufacturer.

[50] Q&A, B.12., page 10.
[51] See Manufacturer Information Form, section 7, page 4.
[52] See Maxwell, loc. cit.

In the event of exceptional circumstances, it is also permissible to fall short of the six-month deadline. Exceptional circumstances are likely to exist in cases where the manufacturer only learns about the circumstances requiring information later than six months before the anticipated interruption or discontinuation of supply. In other cases, special justification is required on a case-by-case basis. The manufacturer must be able to explain circumstances that are recognisably different from normal operating procedures or lie outside the manufacturer's sphere of influence. The Q&A points out that exceptional circumstances can be sudden and unexpected external or internal circumstances - such as a natural disaster, an interruption due to a sudden inability to obtain raw materials or components, or a discontinuation due to unexpected circumstances including of an economic or financial nature. [53] Similar reasons may be economic inefficiency due to significantly increased cost or decreased production volumes, price reductions, loss or reduction of reimbursement or loss of tender contract.

e) Addressees of the information

If the conditions for an information obligation are met, the manufacturer must address the information to the competent authority and all economic operators[54], healthcare institutions[55] and healthcare professionals to whom the manufacturer supplies the device directly. In this context, it remains unclear to which economic operators, health institutions and healthcare professionals the device is directly supplied. Would the requirement of direct supply be fulfilled if a distributor was supplied years ago or only received few individual devices? Does the obligation to provide information also apply to economic operators for whom a consignment warehouse has been set up but which has never been used?

According to the Q&A, only those economic operators, health institutions and healthcare professionals who are impacted by the interruption or discontinuation of supply need to be informed.[56] It can be assumed that those will only be impacted by the interruption or discontinuation of supply if there is an ongoing supply relationship (and who reasonably expect future supply due to a valid offer, order or contract). Manufacturers are therefore not obliged to inform other economic operators, health institutions and healthcare professionals to whom they do not, no

[53] Q&A, B.6., page 6.
[54] See Art. 2 para. 35 MDR.
[55] See Art. 2 para. 36 MDR.
[56] See also, Q&A, B.4., page 5.

longer or not directly supply the device.[57] As a consequence, manufacturers are not obliged to inform those actors who had been supplied in the past but do not hold any outstanding orders or continuing supply agreements. This understanding of the Q&A complies with the narrow interpretation of Art. 10a MDR lined out above.

Also, Art. 10a MDR only covers, due to its geographical reach in this respect, those economic operators, health institutions and healthcare professional who are established in the EU.

The (home) competent authority forwards the information to the competent authorities in the other Member States and the Commission in accordance with Art. 10a para. 2 MDR. This significantly restricts confidentiality in the sense of Art. 109 MDR. According to the Q&A, the competent authorities are also required to share the information with healthcare institutions, healthcare professionals, importers and distributors in their jurisdiction in order to respond to the information.[58] This interpretation, however, is not reflected in the wording of Art. 10a para. 2 MDR.

At national level, the Member States need to determine the competent authority under Art. 10a MDR. In Germany, the Federal Institute for Drugs and Medical Devices (hereinafter "**BfArM**") is declared responsible.[59]

4. Consequences

Given the far-reaching scope of application of Art. 10a MDR, the possible consequences of the new information obligation are rather limited. National competent authorities were not equipped with specific rights of intervention based on the obtained information. Whereas the prior notification mechanism aims to enable countermeasures taken by the competent authorities, such countermeasures have neither been formally regulated within the Amending Regulation, nor do countermeasures appear practically possible in case of a lack of alternatives in products and/or therapy.[60] Especially, there is no legal base to oblige the manufacturer to maintain the supply despite the anticipated interruption or discontinuation.

[57].See also, Q&A, B.4., page 5.
[58] Q&A, page 9; see also Maxwell, loc. cit.
[59] See § 85 para 2 Sentence 1 no. 4a MPDG; see also the reporting channels already set up in accordance with MDR, IVDR and MPDG, available at: https://www.bfarm.de/EN/Medical-devices/Applications-and-reports/Overview-reporting-channels/_node.html (last access: 06 January 2025).
[60] See also Handorn, MPR 2024, 225 (231).

Art. 10a MDR itself does not regulate the consequences of non-compliance with the information obligation. Sanctions are subject to the legislative competence of the Member States according to Art. 113 MDR. Member States have so far made use of their competence only in few cases.[61] This reluctance is appropriate in the light of the principle of proportionality.

Art. 10a MDR in any event leaves the contractual relationships between manufacturers and their business partners, especially distributors and customers, unaffected. These civil law relationships are subject to the respective contracts in place. Art. 10a MDR may not be interpreted as imposing any obligations going beyond the – narrowly interpreted – information obligation, for instance delivery obligations or stock piling obligations. Thinking in this direction would over-interpret and extend the stipulation by far, and there is no legal basis in the norm for this. The same applies to potential claims for damages by third parties, Art. 10a MDR is no suitable basis for that.

IV. Practical implementation: Step-wise approach

The introduction of Art. 10a MDR requires manufacturers to adapt their quality management systems and provide processes for how the information requirements will be handled.

Having in mind the need for a narrow interpretation of the requirements of Art. 10a MDR and adding to – in some respects deviating from – the Q&A, the following step-wise decision-making aid can be used to assess whether there is an information obligation:

1. Step one: Timely determination of interruptions or discontinuations of supply

First, the manufacturer has to determine interruptions or discontinuations of supply within its own (subjective) sphere. More specifically, the manufacturer must consider whether the placing on the market of a particular product group will be interrupted or discontinued without the manufacturer being able to provide a replacement product or draw on sufficient stocks to bridge a supply interruption.[62]

Only those interruptions/discontinuations that are anticipated from 10 January 2025 onwards are to be taken into account.

[61] See, for example: Art. 88 para. 6 Belgian Medical Devices Act (be.: Loi relative aux dispositifs médicaux).
[62] See also Handorn, MPR 2024, 225 (230).

The timely determination of interruptions/discontinuations requires a tight monitoring of triggers that may result in an inability of supply. Such triggers may be but are not limited to:

- missing components or materials,
- machine breakdowns, lack of suitable production space or qualified personnel,
- non-compliance with the conditions for placing legacy devices on the market,
- expiry of a certification without timely re-certification or transfer to the MDR/IVDR,
- other (natural) disasters affecting the manufacturing facilities,
- the inefficiency of manufacturing a product,
- changeover to a successor product, or
- strategic business decision.

A relevant interruption or discontinuance can be excluded if, for example, one of the following conditions is met:

- The relevant device is a custom-made device as defined in Art. 2 no. 3 MDR.
- The manufacturer has sufficient quantities of the device in stock, is able to provide an alternative device or a suitable successor that can be used for the relevant therapy or diagnostic method.
- The manufacturer anticipates an interruption or discontinuation of less than 60 days.

2. Step two: Alternatives in supply

Secondly, manufacturers need to consider whether there are sufficient alternative products or alternative forms of therapy on the market, without being obliged to carry out a market survey. The following questions may, among others, provide for guidance in the assessment:

- Is it possible to provide an alternative product within the relevant time (i.e. typically 60 days) or do necessary infrastructure changes or training sessions, for example, prevent the timely provision of an alternative product?
- Is an identical or alternative product also offered by other manufacturers?
- Is an alternative form of therapy or diagnosis available on the market?

3. Step three: Serious harm or the risk of serious harm to patients or public health

Thirdly, the manufacturer must provide a prognosis – based on the manufacturer's awareness of its own device supply, not necessarily based on market analysis[63] – as to whether the unavailability of the device and the lack of an alternative product or alternative therapeutic or diagnostic method, is likely to result in serious harm or the risk of serious harm to patients or public health in one or more EU Member States.[64]

As a general rule, relevant harm due to the unavailability of a device can only be assumed for certain critical devices of particular importance, which are able to prevent serious harm to patients or public health, such as life-saving or life-sustaining devices.[65] The unavailability of less critical devices cannot cause serious harm in the first place.

Taking into account the case groups mentioned in the Q&A[66], serious harm or risk of serious harm to patients or public health is only to be assumed if patients face to following conditions:

- an imminent risk of death,
- a serious deterioration of patient health, such as a life-threatening illness or injury, temporary or permanent impairment of a body structure or a body function, a condition necessitating hospitalisation or prolongation of existing hospitalisation or a chronic disease.
- a life-threatening condition,
- events that are of significant and unexpected nature, such that they become alarming as a potential public health hazard[67] or
- an equally significant risk of serious harm to patients of public health.

Consultations of physicians and/or other medical institutions for risk assessment is not mandatory. Nevertheless, medical advice can provide assurance in the form of a well-founded medical opinion on possible consequences on patients or public health.

Manufacturers may as well refer to the CMDL as a further source of guidance in their risk assessment, at least until there is a comparable list in the EU. The appearance of a

[63] Q&A, B. 9.1, page 8.
[64] See also Handorn, MPR 2024, 225 (230).
[65] Q&A, B.9.2, page 8.
[66] Q&A, B.9., page 8.
[67] MDCG 2023-3 Rev. 1, page 10, available at: https://health.ec.europa.eu/document/download/af1433fd-ed64-4c53-abc7-612a7f16f976_en?filename=mdcg_2023-3_en.pdf (last access: 06 January 2025).

device in the CMDL may indicate a potential risk of the interruption or discontinuation of supply to patients or public health.

4. Step four: Ways of communication

If an obligation to provide information is affirmed, manufacturers must determine and define which economic operators, health institutions and healthcare professionals need to be informed by them. It is recommended that manufacturers maintain a continuously updated list of the economic operators, health institutions and healthcare professionals who may need to be informed for the device in question.

According to the Q&A, only those economic operators, health institutions and healthcare professionals are to be informed by the manufacturer "who are impacted by the supply interruptions or discontinuation."[68] An impact is only to be assumed if there is an ongoing direct supply relationship.

In the examples below, economic operators, health institutions and healthcare professionals are not impacted by the interruption or discontinuation, e.g.:

- The supply has already been stopped before the inability to supply occurs (this includes economic operators who had been supplied in the past but do not hold any outstanding orders or continuing supply agreements),
- A consignment warehouse has been set up but has never been used.

The manufacturer information form can be used to provide the information. However, there is no legal obligation to use the form.

The information must be provided at least six months before the anticipated interruption or discontinuation. In the event of exceptional circumstances, particularly sudden and unexpected external or internal circumstances, it is permissible to fall short of the six-month deadline.

Hamburg, 6 January 2025

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[68] Q&A, B.4., page 5.