July 2021

MDR implementation: Recommendations for action to tackle the supply crisis for niche and existing products (addressee: European Union institutions)

A. Catastrophic supply situation

A steadily growing number of developers and manufacturers of so-called niche and existing products are no longer able to supply doctors and their patients with vital medical devices. Children in particular belong to the group of patients particularly affected by this.
This catastrophic supply situation is attributable to the in part excessive requirements of Regulation (EU) 2017/745 on medical devices (Medical Device Regulation - "**MDR"**), which has been in force since 26 May 2021, together with its deficient implementation. Although there is still a transitional arrangement for existing products certified according to the previous Directive 93/42/EEC (Medical Device Directive - "**MDD"**), this will expire on 26 May 2024 at the latest; the new approach is based on the validity of certificates issued by a Notified Body. The stricter requirements for clinical evaluation, including evidence of clinical data, require a considerable amount of additional work, which small and medium-sized enterprises (SMEs) often cannot afford due in part to a lack of sufficient manpower. Furthermore, the significantly increased costs mean that manufacturers can no longer achieve the necessary return on investment in the market.
In addition to the halting of innovative activities by companies, this fragile cost situation also leads to product portfolio adjustments, i.e., tried and tested medical products that are urgently needed for medical reasons are withdrawn from the market and are then no longer available for use in medical treatment (cf. Annex 1 and Annex 5). In addition, in Germany, but also in other EU member states, SMEs are unable to properly engage with the private Notified Bodies, which are mandated to certify products in accordance with the MDR depending on the product class, due to a bottleneck situation that still exists. Not least due to various external conditions (Brexit, negotiations with the USA, agreements with Switzerland and Turkey, and the Corona pandemic as well, according to Commission expert Erik Hansson), far too few Notified Bodies have been newly designated.
Companies with certain product classes are nevertheless obliged to engage with a Notified Body in the certification procedure. Because of the excess demand and the resulting questions of market clout, SMEs experience that preference in the conformity assessment procedure is first given to large regular customers. In contrast, the Notified Bodies are sometimes not available to SMEs, or at least not within an appropriate timeframe (cf. Annex 2 and 3). A legally imposed obligation to accept a certification application submitted by a manufacturer - i.e., an obligation to contract for Notified Bodies - does not exist. With so-called niche products, small product ranges and small patient groups (e.g. for rare diseases), these SMEs, which are strongly represented especially in Baden-Württemberg, but also in other regions of Germany and the EU, are in fact prevented from placing their products on the market. Even if the manufacturers are able to find a Notified Body to work with, conformity assessment procedures for existing products can often fail because clinical trials for products that have been tried and tested over many years are required as part of the clinical evaluation, and it

is not ethically justifiable to carry them out. This is because clinical trials whose results have already been obtained from earlier studies with the very same product usually fail in their review with their competent ethics committee (cf. Annex 2 and 4).

In summary, it can be said that an untenable health policy scenario is threatening to become reality, specifically the **lack of availability of vital medical products.** Already now, gaps in supply have arisen that result in the death of patients. Even if individual medical devices can continue to be used by treating physicians without the required CE marking, this pushes them into a hopeless conflict of duties. If they use non-certified medical devices (off-label use), they fulfil their contractual and professional obligations, but expose themselves to additional liability risks.
Another consequence of the outlined development is that the innovative strength of SMEs is severely weakened.

> Practical example:
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> A company can no longer produce baby stents because this would almost certainly result in insolvency and dissolution of the company. Further, attempts have been made to attract other companies to manufacture the products and sell specialist knowledge, but this has failed because the patient groups and the associated number of units to be sold are too low to be profitable (cf. Annexes 5). Paediatricians are absolutely dependent on these products (cf. Annex 6, there under no. 4). The same applies to other products, such as implantable HSM adapters (cf. Annex 5a). Underage patients in particular, but also adult patients, are going to die from lack of treatment alternatives if companies no longer manufacture these products (cf. Annex 6, no. 4).

B. Legal assessment

The MDR aims to create a regulatory framework that ensures a high level of safety and health protection while ensuring innovation and a properly functioning internal market for medical devices. SMEs' concerns must also be taken into account. Moreover, recital 2 clearly states:

> *"The two objectives are to be pursued in parallel; they are inextricably linked and of absolutely equal importance."*

However, if the requirements of the MDR have the effect that medical devices disappear from the market only due to increased costs without additional safety gains, resulting in supply shortages that are dangerous to life and health, innovative medical devices will no longer be developed and companies will be driven into insolvency, these outcomes will run diametrically counter to their own objectives.

I. Primary transposition requirements

All activities of the institutions, bodies, offices and agencies of the European Union (EU) that violate fundamental and human rights are unlawful. “Respect for human rights” is classified as one of the fundamental values of the EU in Article 2 of the Treaty on European Union (TEU). Therefore, no measures that are incompatible with human rights can be recognised as lawful in the Union. In fleshing out Art. 2 TEU, Art. 6 TEU constitutes the central basic provision of Union law on the fundamental rights of the Union. It emphasises the weight of fundamental rights from a prominent point in the EU Treaty. According to Art. 6 (1) TEU, the Charter of Fundamental Rights of the EU (CFR) has the same weight as the Treaties. The CFR constitutes therefore an integral part of EU primary law. A provision of Union law that infringes a fundamental right is in principle invalid, i.e., null and void, as can also be seen from Article 277 of the Treaty on the Functioning of the European Union (TFEU). In order to avoid the invalidity of secondary law due to a violation of fundamental rights, it is generally considered that it must be interpreted as far as possible in the light of fundamental rights, i.e., in conformity with fundamental rights. This also applies to the Member States and their bodies when applying EU law. They may not rely on an interpretation of Union law that conflicts with the fundamental rights protected by the Union's legal order.
The primacy of these primary law requirements for the application and interpretation of the MDR is expressed declaratively in its recital 89 as follows:

> *"This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter, notably the respect for human dignity and the right to the integrity of the person, the protection of personal data, the freedom of art and science, the freedom to conduct a business and the right to property. This Regulation should be applied by Member States in accordance with those rights and principles."*

In the case of imminent and existing gaps in the supply of medical devices due to regulatory requirements of the MDR, there is an indirect interference with the fundamental rights to life and physical integrity of the patients affected thereby in Art. 2(1) and Art. 3(1) CFR. At least together with these fundamental rights, Art. 35 p. 1 CFR also guarantees the actual provision of medical care. In the case of gaps in care where no alternative treatment is available, the minimum level of medical care that is thus required is no longer guaranteed. Finally, the fundamental rights of physicians to freely exercise their profession in the form of freedom of therapy (Art. 15 para. 1 CFR) and the entrepreneurial freedom (Art. 16 CFR) of manufacturers are encroached upon. The legitimisation of these encroachments on fundamental rights by the objective pursued by the MDR, namely to ensure a high level of safety and health protection (cf. inter alia recitals 1 and 2), is evidently no longer valid if the application and interpretation of its provisions have harmful effects on patients thereby turning the original regulatory intention of the Union legislature on its head.

All in all, it remains to be seen that it is necessary under primary law to interpret the provisions of the MDR in such a way that gaps in the supply of vital medical devices are avoided as far as possible.

II. Impacted medical devices and their special features

Two areas are particularly affected by the developments described above:

1. Niche products

There is low demand for these medical products, for example due to the rarity of the disease or the low number of patients. New development and maintenance of already existing niche products is economically undesirable due to the special market situation (see A.). This disproportionately affects SMEs in particular. These specialise much more frequently in niche products than larger companies, which have a much broader and diversified product portfolio. Unlike companies with a broad product range, SMEs specialising in niche products have no possibility of cross-subsidising these products. If there is a lack of profitability, the companies concerned will find their existence threatened.

In addition, the very high regulatory requirements generally applicable to medical devices, e.g. for clinical evaluation, can in part simply not be met because clinical data are not available to the required extent due to the very specialised or small patient groups involved.

The existing regulations in the MDR do not take into account the particularities of this special product category of niche products. A “one-size-fits-all" approach cannot apply due to the special nature of the products. This evaluation was made within the framework of the MDR for so-called custom-made products, among others, for which deviating regulations therefore apply to a certain extent. A corresponding evaluation can also be applied to niche products.

The following examples show that such a classification is necessary and has already been implemented in other regulations.

a) “Humanitarian Use Device” (HUD)

The US Food and Drug Administration (FDA), which is also responsible for medical devices, sets an approval procedure that allows the sale of medical devices intended to help people with rare diseases or symptoms without proof of efficacy. In order to obtain such approval, no more than 8,000 people per year in the USA may be affected. It must also be proven that no other access to the market is possible and that no comparable product is available. A product approved in this way is called a “Humanitarian Use Device” (HUD).

b) “Orphan drug” - medicinal product for the treatment of rare diseases

Medicinal products for the treatment of rare diseases are called “orphan drugs” in the English-speaking world. They are given that name because the pharmaceutical industry has little financial interest in developing and marketing drugs that are intended for only a small number of patients with very rare conditions. Pharmaceutical companies are not willing to invest in their research under normal market conditions. Regulation

(EC) No 141/2000 on orphan medicinal products accordingly established a specific legal framework for these products with incentives for their research, development and marketing.

For a medicinal product to be granted orphan drug status, manufacturers must demonstrate, among other things, that without incentives the release of the medicinal product on the EU market would not generate sufficient profit to justify the required investment and that no satisfactory alternative exists or, where treatments already exist, that the proposed treatment should be of significant benefit. It is also possible to show that the medicinal product is intended for the diagnosis, prevention or treatment of a condition that is life-threatening or chronically debilitating and affects only a very small number of people in the EU.

2. Existing products

These medical devices are products that have already been certified for many years under the requirements of the MDD and have been placed on the market by their manufacturers. They fall into the category of tried and tested technologies. Existing products have a known safety profile and do not have any safety problems. They have known clinical performance characteristics and are considered an established standard in practice. Their applications and the state of the art they use have evolved only slightly over time.

Nevertheless, for many existing products, manufacturers cannot successfully carry out a conformity assessment procedure according to the requirements of the MDR. The implementation of the requirements becomes critical above all when no sufficient clinical data are available for the existing products on the market because, for example, the requirements for equivalency comparisons have changed significantly and have also become much more stringent. A product is only deemed equivalent if it has the same technical, biological and clinical characteristics. Only if this equivalence is demonstrated may the clinical data be used to prove the safety, performance and clinical benefit of a company's own product. If one wants to use the clinical data of another manufacturer's product, it is necessary to conclude a contract with the competitor that allows unrestricted access to its technical documentation at all times. In practice, it is completely unrealistic for competitors to come together contractually in this way in order to pursue the path of equivalence.

If equivalence comparison is not possible, clinical trials become necessary. The following problems can then arise with existing products: Applications for clinical trials with existing products are usually rejected by the ethics committee because they are not ethically justifiable. The fundamental attitude being expressed here is that no human test subjects should be used for the testing of existing products. In addition, there are no clinical investigators who are willing to make capacities available for studies on long-established products, partly because the resulting publications are not considered enticing.

III. Regulatory approaches within the MDR framework

Existing MDR regulations do not take into account the specifics of the problems just outlined under II. The MDR does not contain any definition or regulation with regard to niche products. Nor does it contain provisions for the case of a "stalemate", i.e. when

the respective requirements are mutually exclusive to such an extent that a manufacturer cannot therefore place the product on the market. Against the backdrop of the primary law implementation requirements (see I.), possible regulatory solutions are accordingly presented here. Specifically, we will discuss whether and to what extent they are suitable for defusing the looming catastrophic supply situation (see A.) under the MDR.

1. Special authorisation of niche products

Sometimes reference is made to the possibility of using a special authorisation according to Art. 59 MDR in order to place niche products on the market.

In practice, Art. 59 MDR proves to be an unsustainable solution for sustainable market placement or for the development and long-term marketing of niche products.

Art. 59 MDR basically provides for a staged procedure for a product's market access, which as a first step requires its special authorisation in just one single EU member state. A manufacturer must submit an application in accordance with the applicable regulations of the Member State in which the special authorisation is applied for in order to obtain such authorisation. In Germany, the Federal Institute for Drugs and Medical Devices is responsible for special marketing authorisations and grants them on the basis of the German Medical Devices Act. Each Member State can - as it has to rely on national legal provisions - only approve a special authorisation for its respective country - not for the whole of Europe. Consequently, a manufacturer needs 27 individual special approvals to be able to sell its product throughout Europe. This is not feasible. After all, national regulations differ and each procedure requires a lot of time and money. In addition, in Germany special approvals can only be granted under certain conditions, for a limited period of time, and only in exceptional cases, not as a general rule. Furthermore, the product does not receive a regular CE marking, which is extremely disadvantageous in terms of its marketing. In the case of a special approval in Germany, the product is accompanied by a cover letter (usually in German), which considerably reduces the acceptance of the product for approval procedures abroad (e.g. USA) and thus further limits its marketability.

Consequently, a special authorisation for a niche product, which is limited to one member state and often also subject to conditions, is a costly loss-making venture. This applies to SMEs, but also to larger companies if they are not willing or able to cross-subsidise the niche product. This is often the case, because large (US) companies regularly buy niche products from German SMEs that specialise in them.

The Commission can only decide on a possible Europe-wide special authorisation in a second step - but again only in exceptional cases. It should be noted that this is a "may" provision and the decision can only be adopted as an implementing act within the framework of a prescribed procedure.

It is true that the EU Commission can also adopt immediately applicable implementing acts “in duly justified cases of extreme urgency relating to human health and safety”. However, such an act would only be valid for a maximum of six months (cf. Art. 114 (4) MDR in conjunction with Art. 8 of EU Regulation 182/2011).

The manufacturer cannot apply for an EU-wide authorisation. In order to obtain such authorisation, the manufacturer would need to submit 27 different applications for authorisation in the respective Member States.

For these reasons, the procedure provided for in Art. 59 MDR is not suitable for ensuring the availability of niche products in the EU in the long term.

2. Clinical evaluation

a) Proven technologies

The Medical Device Coordination Group ("**MDCG**") regularly publishes documents compiled by various subgroups to assist stakeholders in interpreting the provisions of the MDR. Members of the subgroups are appointed by Member States for a limited period of time. In addition, selected stakeholders participate as observers. However, these observers do not have voting rights. The members of the MDCG meet regularly under the chairmanship of a representative of the European Commission.

The MDCG has already addressed the issue of sufficient clinical evidence for existing devices in the context of guideline development. According to the MDCG Guideline 2020-06 of April 2020 "Guidance on sufficient clinical evidence for legacy devices" defines the term "well-established technology" for the first time. Although this term, which is very important for existing products, is used in the context of conformity assessment (Art. 52(5) MDR) and clinical evaluation (Art. 61(8) MDR), this term is not legally defined in the Medical Devices Regulation (MDR). The MDR has added little clarity with this lack of definition.

MDCG Guideline 2020-06 defines the term “well-established technology” as follows:

> *'"well-established technology': this terminology is used in Article 52(5) and Article 61(8) of the MDR, but is not defined in these articles. The term is not restricted to the devices listed in Article 61(6b); Article 61(8) explicitly states that this includes devices similar to the exempted devices listed in Article 61(6b), which might be added to that list in future. The common features of the devices which are well-established technologies are that they all have:*
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> - *relatively simple, common and stable designs with little evolution;*
> - *their generic device group has well-known safety and has not been associated with safety issues in the past;*
> - *well-known clinical performance characteristics and their generic device group are standard of care devices where there is little evolution in indications and the state of the art;*
> - *a long history on the market.*
>
> *Therefore, any devices that meet all these criteria may be considered “well-established technologies”.*

However, the provisions of the MDR that refer to well-established technologies only deal with class III devices and implantable devices. Only for certain devices listed in the MDR is a clinical investigation exceptionally not required. In addition, privileged treatment in the area of the conformity assessment procedure is even provided for these products. This list can be extended by the EU Commission within the framework of a delegated act.

The clinical evaluation of existing products currently presents a similar problem when the performance of clinical trials as part of clinical data is demanded by Notified Bodies and competent authorities without regard to the fact that these are already proven technologies. Ethics committees, rather, quite rightly, reject an application to conduct a clinical trial of existing products on ethical grounds if they already qualify as proven technologies. It is contrary to all ethical standards to subject patients, including children, to strenuous clinical trials when sufficient information on the risks and benefits of proven technologies is available (see b). For the manufacturers of these existing products, it is impossible to reconcile the conflict between a clinical trial to be carried out on a regular basis on the one hand and the prohibition on carrying out a clinical trial for ethical reasons on the other.

It is therefore to be requested that the idea behind proven technologies also be applied to such existing products that are not similar to the products specified by the MDCG Guideline 2020-06 and are also not to be assessed as straightforward in design, but which fulfil the further criteria of a proven technology. The manufacturers of existing products must first submit equivalence data as clinical data. However, if sufficient equivalence data are not available, the outcome for existing products from the field of proven technologies cannot necessarily be the conduct of a clinical trial. Proactive PMS data, registry studies or other forms of trials must be sufficient in these cases to ensure seamless care for the patients concerned. The framework and limits for this are to be defined accordingly in an MDCG guideline (see C.III.).

b) Additional aspects

The requirements of the MDR on clinical evaluation are to be interpreted broadly in accordance with fundamental rights if there is a risk of a gap in supply (see B.I.). This applies not only to the criterion of proven technologies within the meaning of Art. 61 (8) MDR, but also to all provisions concerning the scope and necessity of clinical evidence. In essence, a distinction can be made between two constellations that constitute exceptions to the rule of Art. 61 (1) MDR.
Firstly, Art. 61 (4), (5), (6) and (8) MDR allow clinical trials to be dispensed with under certain conditions (see aa). Secondly, Art. 61 (10) MDR provides for an exemption from the requirement to demonstrate the compliance of the medical device with essential safety and performance requirements on the basis of clinical data (see bb). Both exemption constellations are of utmost importance, especially in the case of niche products that have already proven themselves in clinical practice over a longer period of time, as the extent of the effort required on the part of the manufacturer determines whether the product can be further marketed. Relevant determinants of interpretation in this context are not only the fundamental rights violated in each case, but also other normative aspects that are relevant by virtue of the express provision of the MDR.

aa) Waiving clinical trials

- In deciding whether a clinical trial of the product can be waived within the framework of Article 61 (4), (5), (6) and (8) MDR, at least in the case of a looming gap in supply for which there is no alternative, ethical considerations are of the utmost importance in addition to the determinants of interpretation in conformity with fundamental rights. This is precisely why they are mentioned at several points in the MDR. For example, according to Annex XV, Chapter 1, Section 1 of the MDR, ethical principles are to be taken into account from the very first considerations about the necessity and justification of the study. In addition, according to recital 64 p. 2 MDR, the provisions on clinical trials are to be in line with the latest version of the World Medical Association's Helsinki Declaration on Ethical Principles for Medical Research Involving Human Subjects. The basic ethical principle of *primum nihil nocere* (principle of no harm) is to be expressed in the balancing of foreseeable risks and disadvantages against the benefits for the persons concerned and the probable therapeutic significance of the research project (cf. in particular paragraph 16 ff. of the Helsinki Declaration).
  This weighing of benefits would be meaningless if it did not also take into account a possible prevention of market access in the result of the decision on the requirement of the clinical trial. In other words, it must always be taken into account - especially in the case of proven existing and niche products - that the obligation to conduct a clinical trial can also mean the end of their (further) sale. The "expected benefit for the trial subjects", which is relevant for the admissibility of a clinical trial according to Art. 61(4)(e) MDR, would also be called into question in the event of a withdrawal of the medical device from the market following the conduct of the trial. In any case, it would hardly be convincing, even in the light of the alternative factual criterion of public health - and thus implicitly also of general security of supply - expressly addressed in Art. 61(4)(e) MDR, not to take into account the risk to public health posed by an expected gap in supply in the context of the required risk-benefit assessment.

- The guideline of the International Medical Device Regulators Forum (IMDRF) “IMDRF MDCE WG/N57FINAL:2019 Clinical Investigation” (p. 7), which according to recital 5 is to be taken into account as far as possible in the interpretation and application of the MDR, also emphasises the ethical importance of public health:

  “The desire to protect human subjects from unnecessary or inappropriate experimentation must be balanced with the need to protect public health through the use of clinical investigations where they are indicated.”

  Furthermore, it is emphasised in this context that clinical studies should be dispensed with if there is sufficient evidence, which can be assumed, especially for niche products that have been tried and tested on the market for years:

  “It is ethically important in deciding to conduct a clinical investigation that it should generate new data and answer specific safety, clinical performance, and/or effectiveness questions that remain unanswered by the current body of knowledge.”

- It also appears necessary, from the point of view of fundamental rights, but also according to teleological interpretation, to interpret the contract requirement in Art. 61 (5) MDR (cf. also II.1. above), which makes practical implementation

more difficult, in such a way that it permits a trustee model. Unrestricted access of a second manufacturer to the technical documentation can be guaranteed via a trustee appointed by both contracting parties as an intermediary, without the first manufacturer disclosing its trade secrets.

- It also appears necessary, from the point of view of fundamental rights, but also according to teleological interpretation, to interpret the contract requirement in Art. 61 (5) MDR (cf. also II.1. above), which makes practical implementation more difficult, in such a way that it permits a trustee model.

  "13. What procedure applies for clinical investigations of custom-made devices or in-house manufactured devices?
  Custom-made devices are defined in Article 2(3) of the MDR.
  In-house manufacturing, modifying and use of devices within health institutions is provided for in Article 5(5) of the MDR.
  The relevant general safety and performance requirements set out in Annex I of the MDR apply to both of these device types. As such, clinical investigations may be undertaken with respect to these device types, and they may fall under Article 62 or 82."

  Although this is worded relatively openly in linguistic terms, it could lead to the assumption that, contrary to the express stipulation in Art. 62 MDR ("for conformity assessment purposes"), a clinical trial must also be carried out in individual cases under certain conditions for custom-made products and medical devices manufactured in-house. In contrast, a waiver of clinical trials is required in this context because we are not dealing here with industrially manufactured medical devices for small patient groups.

bb) Clinical evidence waiver

The waiving of clinical data for the proof of compliance with essential safety and performance requirements, which is expressly permitted by the legislator in Art. 68 (10) MDR, is also to be interpreted in conformity with fundamental rights and in accordance with the ethical requirements outlined in more detail under aa) above in such a way that gaps in supply are avoided in the specific case.

C. Necessary steps and recommendations for action

I. Primary legal obligations to act

If there is a threat of gaps in the supply of vital medical products, the Union institutions have a duty underpinned by fundamental rights to take action. The fundamental rights to life and physical integrity enshrined in Article 2(1) and Article 3(1) of the Charter of Fundamental Rights, as well as the fundamental right to a minimum level of medical care enshrined in the first sentence of Article 35 of the Charter of Fundamental Rights, are not only to be understood as defensive rights, but also as having a protective dimension. The duty of the Union institutions to protect is exercised if a danger exists, but also, too, if risks exist for the possibility of imminent serious or irreparable damage.

A sufficiently tangible risk situation alone may qualify as an encroachment on fundamental rights. In this case, the Union institutions are obliged to protect and safeguard the legal interests of physical and mental integrity and life.
In order to fulfil this duty to act under primary law, the EU Commission can make use of relevant authorisations for implementing acts in the MDR and/or implement amendments and additions to existing guidelines in the relevant MDCG subgroup, which it chairs.

II. Implementing acts

There are various possibilities for the EU Commission to take immediate action to substantiate the duty to protect on the basis of the enabling provisions already anchored in the regulation's text, without the need to amend the MDR itself.

1. Art. 59 para. 3 MDR

Art. 59 MDR expresses a general assessment of the legislator: for reasons of public health or patient safety, authorities may deviate from the standard requirements for carrying out a conformity assessment procedure. Recital 93 also makes it clear that not only the Member State authorities but also the Commission should act if this is imperative for reasons of extreme urgency. Here, the MDR places the immediate availability of products in the interest of best patient care higher than the completeness and completion of the conformity assessment procedure.

In order to prevent the already announced and threatened discontinuation of further niche products with the consequence of an acute endangerment of certain patient groups, an immediately applicable implementing act according to Article 59 (3) MDR would have to be considered. However, it must be taken into account that this can only be a temporary option for action, initially limited to six months. Art. 59 MDR is not suitable as a permanent solution for the preservation and innovation of new niche products (see B.III.1.).

2. Definition and regulation of a new product category “niche products” - Art. 51 para. 4 in conjunction with para. 3 b MDR. Para. 3 b MDR

If a product is to be qualified as a medical device (e.g. as opposed to a medicinal product), it generally falls within the scope of the MDR. As a consequence, it must be classified. The basis for this is Art. 51 MDR in conjunction with Annex VIII. Products are generally classified in risk classes I, IIa, IIb and III, depending on their intended purpose.

As already explained (see B.II.1.), niche products are characterised by the fact that they are intended for a special patient group and only a very small number of patients. New development and maintenance of already existing niche products is economically unattractive due to the special market situation. Should these niche products no longer be available to patients who depend on them, this can have life-threatening consequences for such patients (see A). The existing regulations in the MDR do not take into account the special features of this special category of products.

Art. 51 para. 4 in conjunction with. Para. 3 b MDR should therefore be used as a legal basis to create a new product category for niche products to be classified by means of an implementing act by the Commission.

Paragraph 4 states:

> *"The Commission may also, on its own initiative and after consulting the MDCG, decide by means of implementing acts on the issues referred to in points (a) and (b) of paragraph 3.*

Paragraph 3 states:

> *“The Commission shall, at the request of a Member State and after consulting the MDCG, decide, by means of implementing acts, on:*
> *a) ...*
> *(b) the classification, by way of derogation from Annex VIII, of a device, category of devices or group of devices in another class for reasons of public health in accordance with the most recent scientific evidence or on the basis of information becoming available through vigilance and market surveillance activities.”*

Since, as explained (see B.II.1.), there is neither a definition nor specific special rules for niche products in the MDR, the creation of a new product classification category for niche products, which is required by fundamental law, takes place in derogation of the previous classification rules. In view of the discontinuations of products that have already taken place, this is imperative to ensure the care of the patients concerned and, consequently, for public health reasons. It is not only a matter of announced or foreseeable product discontinuations, which in themselves would be sufficient to justify an obligation to act due to the duty to protect required by fundamental rights. The authorities in Germany even have concrete and verified information of examples of products which are no longer available. Sufficient information is thus available to justify action under Article 51(3) and (4) MDR.

Since the implementing acts under these paragraphs 3 and 4 are adopted in accordance with the review procedure referred to in Art. 114(3) MDR, they - unlike immediately applicable implementing acts (see B.II.1.) - do not need to be limited in time. The implementing act could thus also ensure a permanent, legally secure possibility to regulate niche products under the MDR.

III. MDCG Guidelines

The MDCG guidance documents “MDCG 2021-6 Regulation (EU) 2017/745 - Questions & Answers regarding clinical investigation April 2021” and “MDCG 2020-6 Regulation (EU) 2017/745” recommend that: “Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC A guide for manufacturers and notified bodies April 2020” for the reasons explained in detail under B.II.2. above, clarifications are to be made to the effect that the exemption provisions of Art. 61 (4), (5), (6), (8), (10) MDR are to be interpreted broadly in the case of threatened or already existing gaps in the supply of patients using vital medical devices. This also applies, for example, to the constituent elements "contract" in Art. 61 (5) MDR, "proven technologies" in Art. 61 (8) MDR or "taking into account the specific characteristics of the interaction between a device and the human body" in Art. 61 (10) MDR. In addition,

it should be clarified that clinical investigations are not required for custom-made devices and in-house manufacture of medical devices.

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