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German Society for Pediatric Cardiology and Congenital Heart Disease

DEUTSCHE KRANKENHAUS GESELLSCHAFT
Bundesverband der Krankenhausträger in der Bundesrepublik Deutschland

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EU Directive (EU) 2017/745 (Medical Device Regulation – MDR)
- Significant decline in the supply of medical devices

Dear Commissioner Kyriakides,

The renewed EU directive on medical device regulation was initiated with the aim of improving patient safety. During the protracted negotiations which took place throughout the entire process, many different protagonists drew attention, albeit unsuccessfully, to the possible negative consequences for the supply chain. The Medical Device Regulation (MDR) is now in force and has been subject to more intense criticism because it has not brought about an improvement in patient safety and has instead put some patients at risk. There is a lack of clarity as to how the complex requirements are to be implemented and there are increasing concerns that the negative developments for medical supply in Germany and Europe that exist at present will become more acute and will be even more clearly evident in 2023. We have reports from several physicians, hospitals, and scientific societies stating that patients can no longer receive adequate supplies and, in the most serious cases, are even at risk of dying. The following example may illustrate this: if complications occur during the dilatation of the atrial septum of a newborn with the heart defect referred to as D-Transposition of the Great Arteries because usable material is no longer available, the patient will die due to lack of oxygen.

Hospitals and physicians are starting to report delivery and supply bottlenecks. This can be traced back to the fundamental changes in market entry criteria that have occurred since the MDR came into force, such as the need to recertify all medical devices, the requirement also to perform clinical tests on existing products that already have a proven track record over many years and a fundamental lack of provision of the necessary

infrastructure in the form of a sufficient number of notified bodies and relevant implementing regulations. For the manufacturer, the redefined requirements mean greater administrative overheads and require significantly more human resources. As a consequence, they lead to high costs and ultimately greater market adjustments.

This topic is gaining in virulence in the area of ‘niche products’ which, although only required by relatively small groups of patients, are essential from a treatment standpoint. If these kinds of products are not available, are only available in certain sizes or in an inferior quality, some patients may only be treated following a conservative approach, without the option of surgical intervention. In medical terms, this represents a backward step of several decades. This is becoming acutely evident in the treatment of heart diseases in children (paediatric cardiology/paediatric heart surgery). Examples of important products, which are no longer on the market and which have not been replaced, are Cook PDA Coil Mreye, Medtronic Rashkind Balloon and the Mega LD and MaxLD stents by the company Medtronic. These retrogressive developments in the supply of medical devices are unacceptable. At present, there is only one product for performing a life-saving interventional catheter dilatation of the interatrial septum, and this product is less suitable for intervention than other products that have been available until recently. These deficiencies endanger the lives of new born infants!

A survey was carried out by the German Hospital Federation between 31.03.2022 and 29.04.2022. In this survey German hospitals should report which products have been or are due to be removed from the market due to the MDR. It revealed that several hundred products are no longer available today, and up to 60 manufacturers are affected. Excerpts of the corresponding overviews of the affected products are enclosed an ***Annex*** to this letter.

Right now, the majority of hospitals are confidentially describing delivery delays, current bottlenecks, streamlining of product ranges and/or discontinuation of products. Buyers are still attempting to counteract these developments by stockpiling. However, this attempt will only delay the point at which the problem will become clearly evident. Furthermore, there are reports that patient treatments have already been acutely in danger. The delivery of specific instruments has been discontinued at short notice for instance, which has endangered operating processes. In some areas there are adequate replacement products, and in other areas, only inferior quality substitutes are available, or there are no alternatives at all. Other products are only available in certain sizes, which means they are often unsuitable.

That some of the manufacturers have “not done their homework” and have not consulted the notified bodies in good time, or have made changes to products when outsourcing production, is an interpretation which has become well established in this context and may also be justified in certain cases. However, it would not seem appropriate, either objectively or in terms of content, to adopt this analysis accordingly and shift the responsibilities onto the shoulders of the industry as a whole, even in light of the above-mentioned numbers.

The current extent of the consequences still cannot be comprehensively evaluated today. However, the scope and severity of the cases that already have come to light illustrate the dramatic impact of the MDR. It becomes clearly evident that the difficulties presented by the MDR, its insufficient implementation, and a lack of efficient certification

infrastructure, must be taken into political consideration to ensure a reliable supply to patients and support the innovative power of the manufacturers to develop new safe medical devices. The consequences of the corona pandemic, Brexit and increasing costs of raw materials cannot be influenced. The consequences looming as a result of the MDR, especially at EU level, can at least be relativized by legislature.

Although solution mechanisms (Art. 59 – exceptions to conformity assessment procedures, special approval of niche products; implementing act in acc. with Art. 59 Para. 3; etc.) have indeed been created in the MDR and discussed many times over, they do not take this problem into account in any manner whatsoever. They are only feasible in individual exceptional cases, if at all. The physicians in our members' area have indicated unequivocally that special approvals by individual service physicians are not feasible from a professional, technical or financial standpoint.

Physicians and hospitals are responsible for looking after patients and not for approving the necessary medical devices. All the same, as professional associations and as the German Hospital Federation, we are acutely aware of our task to willingly participate in attempts to resolve the problem.

Alongside this, medical innovations in small and medium-sized German companies in particular have ground to a halt, as many human resources capacities are now tied up in the MDR, and also approvals of innovations have been relocated to other markets (USA, Asia, etc.), a development which was feared because none of the regulations in these countries are comparable with the MDR. This cuts deep into Germany, a location of high-tech medicine.

Even if this medical device-related legal theme has not just arisen purely as a result of the MDR, and could instead be much more down to a combination of various aspects (corona, Brexit, etc.) and in many cases is an outcome of decisions made by some companies based on economics, an aspect which is difficult to influence, it is causing significant problems. Therefore, we urge emphatically not to wait until the transitional periods have expired in May 2024 to discover that a supply emergency exists, and instead take the right steps right now to avoid endangering the supply of medical devices.

We are therefore asking you as a matter of urgency in the near future and as early as the approaching EU Council of Health Ministers on June 14th to advise on the topic and initiate the necessary steps.

Medical device manufacturers are currently preparing, or have already prepared, their economic plans for the coming year. If there is no prospect that the regulation will be eased, a large number of products will disappear from the German market, and therefore also the European market. Put plainly and simply, the requirements of the MDR are too stringent. This is why we appeal to you to extend the transitional periods, and alongside this create an exemption provision for existing products which have been used without problems for many years. A corresponding concept was worked out by the Association of Scientific Medical Societies in Germany (AWMF) 2019 and presented in the hearings for the law on adaptation of medical devices and at European level. In this regard, it is also important to redefine the requirements in relation to clinical data and establish an incentive system for niche products which is similar to the medical device system (see

Orphan drugs) in order to create opportunities across the whole of the EU. National short-term approvals are in any case not a viable solution.

Alongside this, it should also be noted that similar problems are on the horizon with the IVDR coming into force.

Yours sincerely

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Annex