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2022-10-09 Medidee's Tentative Translation of the Resolution of the German Bundesrat (chamber of the Länder), session 1025, Oct.07, 2022

Resolution of the Bundesrat - Urgent need for action in the implementation of the European Medical Devices Regulation (MDR)

1. The Bundesrat is committed to the fundamental objective of the European Medical Device Regulation (MDR) to strengthen patient protection. Medical device safety is an indispensable prerequisite for market access and use on patients.
2. At the same time, the Bundesrat notes that the implementation of the MDR is accompanied by major challenges and problems. On the one hand, there has been a significant increase in the effort required to certify medical devices, which has resulted in higher costs and the commitment of human resources on the part of manufacturers. On the other hand, there are increasingly clear supply problems for some products, as manufacturers are withdrawing safe and proven medical devices from the market as a consequence of increased costs and effort.
3. The Bundesrat points out that alarm signals from industry and supply chain are increasing and that there is an urgent need for action in order to continue to guarantee the supply of the necessary safe medical devices. The reports from the medical profession that interventions can no longer be performed in the usual quality or that liability risks exist because more and more off-label use is being practiced are unacceptable.
4. The Bundesrat is also concerned about the announcements by medical device manufacturers that they intend to relocate to non-European countries as a result of the MDR. There is a risk of know-how and jobs being lost in the EU. At the same time, manufacturers who remain in the EU have less time and capacity available for the development of innovative medical devices, as this is tied up by dealing with the requirements of the MDR. In the medium term, this will also be reflected in the supply of patients with innovative medical devices.
5. The Bundesrat has identified similar problems that are evident with the MDR for the implementation of the In Vitro Diagnostics Regulation (IVDR). The main problem here is the even smaller number of Notified Bodies, despite the fact that the number of IVDs to be certified is a multiple compared to the IVDD.
6. The Bundesrat welcomes the sub-legislative and thus non-binding position paper of the European Commission's Medical Device Coordination Group (MDCG), which was adopted at the end of August, (note Medidee: MDCG 2022-14) but considers the measures proposed therein to be insufficient and too vague and regrets the lack of deadlines for implementing the proposed measures.
7. The Bundesrat therefore calls on the German government to act at the European level, in cooperation with the other EU member states, and to campaign clearly and vehemently for significant improvements in the implementation of the European Medical Device Regulations. From the point of view of the Länder, timely solutions are needed. A further postponement of urgently needed decisions and measures to be taken by the EU Commission until December 2022 at the earliest, as proposed by the Commission itself, is viewed extremely critically by the Länder.

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8. The Bundesrat asks the German government to work at EU level towards facilitating the market access of niche and legacy products and thus to ensure the security of supply with safe medical devices. Measures to be taken should also consider a more efficient use of the scarce resources of the Notified Bodies already designated under MDR as well as the faster completion of the designation process of further Notified Bodies under MDR.
9. Considered measures must not be disproportionately burdensome to the Länder and their market surveillance authorities and lead to the creation of additional bureaucratic procedures.
10. To continue to ensure patient care, the Bundesrat advocates the following measures:
    a. Immediate solutions are needed for supply-relevant niche products (so-called "orphan devices") whose production has become uneconomical due to the low number of units and sales in view of the high certification costs under the MDR and which are therefore withdrawn from the market. This results in supply bottlenecks.
    b. Timely relief is needed for existing products (so-called "legacy devices") that have proven their value in the market over many years. Guidance should be provided on how clinical data, i.e. data on the safety or performance of medical devices obtained during use under the Medical Device Directives, can also be recognized as sufficient for MDR certification.
    c. It must be ensured that the certification of new, innovative medical devices in Europe, especially for SMEs, can be guaranteed quickly and with reasonable effort within the current legal framework.
    d. More capacity for MDR certifications is needed at the notified bodies: On the one hand, the scarce resources available at existing Notified Bodies must be better utilized for this purpose; on the other hand, the rapid completion of the ongoing designation procedures of additional, new Notified Bodies according to MDR is required to counteract the capacity bottleneck.
    e. As the certification bottleneck continues to tighten until May 2024, concrete legislative measures that give the entire system more time must also be quickly considered by the European Commission.

Substantiation:

The European Medical Device Regulation, which came into force in 2017, aims to improve patient protection. However, this can only be guaranteed if patient care is ensured in addition to medical device safety. Recent letters from medical societies and the German Hospital Association clearly indicate that the supply situation with safe medical devices is no longer fully guaranteed and could deteriorate further. A survey by the German Hospital Association revealed that several thousand medical devices are already unavailable now. The BMG's (Medidee : Bundesministerium für Gesundheit) report on the supply situation with safe medical products also speaks of around 6000 products that are not available. Physicians are highly concerned. Industry associations and notified bodies are alarming.

Apart from the supply situation, the Länder are concerned about the innovative strength of the medical device industry, because, according to manufacturers, the MDR has a negative impact on research and development activities and thus, in the medium term, on the availability of innovative medical devices in the EU.

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Some German Länder already addressed the looming supply problem to the European Commission and the German Federal Ministry of Health in 2019. Since then, there have been repeated discussions, letters, and events to raise awareness of the problem. Likewise, concrete proposals for solutions were already presented by the Länder in the fall of 2021.

The Conference of Economics Ministers and the Conference of Health Ministers (of the German Länder) then adopted unanimous resolutions on November 25, 2021, and December 22, 2021, respectively, calling on the German government to advocate for pragmatic solutions at the EU level, taking these recommendations for action into account.

As a result, a task force for niche products under German leadership (BMG) was established in December in the European Medical Device Coordination Group (MDCG) in accordance with Article 103 MDR. To date, however, this task force has not yet presented any results.

Now, time is pressing because manufacturers are withdrawing more and more products from the market because the certification requirements and the costs for certification have increased significantly with the transition from the Medical Device Directives to the Medical Devices Regulations, and cost-effectiveness is no longer a given.

Results from an association survey conducted in April 2022 show that, on average, less than 10% of existing products are certified according to MDR. In the highest risk class III, this value is less than 6%.

In this respect, the certification backlog that remains until the end of the transition period in May 2024 becomes obvious.

This is also illustrated by a TEAM NB statement published in April 2022, in which the European Association of Notified Bodies itself explicitly refers to capacity bottlenecks and the risk of supply shortages.

Currently, only 6,300 certificates could be issued per year. Although additional Notified Bodies are expected to be designated in the foreseeable future, there is still according to TEAM NB, a backlog of approximately 24,000 certificates.

The federal government and the Länder governments have therefore called on medical device manufacturers to step up efforts to submit certification applications in a timely manner, i.e., before the MDD certificates expire.

In the last EU Health Ministers Council on June 14, 2022, the implementation status of the MDR was also discussed. 18 member states expressed their concern. This shows that awareness of the problem for the current situation does not only exist in Germany, but that the urgent need for action for solutions at EU level is also seen in other member states.

The current hesitant approach in the MDCG and also the reluctant attitude of the German government so far worry the Länder.

Small steps, such as the draft 19-point position paper presented by the MDCG on July 8, 2022, to increase the effectiveness of the application of current regulatory requirements, are better than nothing from the Länder's perspective, but are far from sufficient as a signal to convince medical device manufacturers not to withdraw urgently needed products from the market.

The Länder take a skeptical view of a further postponement of urgently needed - including legislative - decisions and measures to be taken until December 2022, as proposed by the EU Commission.