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Spitzenverband

# High quality medical devices:
# Ensuring security of supply in Europe even during COVID-19 pandemic.

In recent weeks and months there have been many proposals to temporarily suspend the EU Medical Devices Regulation[1], to delay its entry into force by a moratorium[2], or to adopt a "national emergency plan"[3]. Behind many of these initiatives is the fear that due to real or perceived difficulties in the transition from old to new EU rules, a large number of medical devices could suddenly become unavailable because they lose their marketability. In view of the current COVID-19 pandemic, these fears, some of which are unfounded, are intensifying. The National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) comments as follows:

1. The current procurement and distribution problems encountered in the supply of medical equipment and products such as respiratory masks, protective clothing, disinfectants, or ventilators are due to sudden and exceptionally high demand. They are not related to the EU Medical Devices Regulation.
2. The new EU regulation includes a tightening of the medical device law. This is a Europe-wide political consensus and a necessary step. The EU regulation is intended to ensure that patients in Europe are provided with safe, effective and efficient medical devices and that major medical device scandals no longer occur. The new EU regulation sets new standards in patient safety.
3. It goes without saying that medical care of patients with high quality medical devices must be guaranteed at all times throughout Europe. Medical devices which have been reliably in service for years and which their manufacturers want to continue to make available on the market in the future should remain available for medical care. Possible conversion-related market access difficulties in the transition phase between the old and new law, which are not the manufacturer's responsibility, must be solved in a non-bureaucratic manner.
4. This of course applies to all medical technology and to all risk classes, both for the treatment of patients in connection with the COVID-19 pandemic and for all other medical devices to ensure medical care in Europe.

[1] https://www.evangelisch.de/inhalte/167357/18-03-2020/cdu-gesundheitspolitiker-liese-italien-corona-patienten-abnehmen
[2] https://www.bvmed.de/de/bvmed/presse/pressemeldungen/corona-und-mdr-bvmed-fordert-mdr-moratorium?pk_campaign=tsr_CHK&pk_kwd=startseite_tsr-aktuelles-gT_mi_corona-und-mdr-bvmed-fordert-mdr-moratorium
[3] https://www.bundestag.de/presse/hib/669232-669232

5. Many manufacturers have already taken precautions and have had their products re-certified in good time in accordance with the old EU directives. Due to the transitional provisions, these products may remain on the market for several years under the old rules.
6. Nevertheless, some cite the delayed designation of Notified Bodies under the new EU regulation and the resulting insufficient operating capacity as a possible reason for potential supply shortages. Furthermore, fears are being expressed that the COVID-19 pandemic will lead to a further shortage of capacity. However, there are currently no indications of concrete bottlenecks.
7. As soon as a tangible supply problem becomes apparent, it is important to solve it unbureaucratically and sustainably. At the same time, the protective effects of the new medical device law must not be impaired and the integrity of the European market must be maintained. National go-it-alones must remain the exception. They are not suitable for solving a potential supply problem in the European Single Market with free movement of goods.
8. A suspension of the new EU regulation would aggravate existing planning uncertainties for manufacturers, Notified Bodies and authorities, as the transformation process from the old to the new law is in full swing. Many manufacturers have adapted to the new requirements or have been preparing for this for years. The same applies to Notified Bodies. All relevant Notified Bodies have already been successfully designated or are in the process of being designated. In addition, national legislative processes are already at an advanced stage and would have to be withdrawn. The authorities are preparing for new tasks in terms of personnel and structure.

## Proposed solution

Medical device law is European law. And it must remain European law. The citizens of the Member States have a right to be supplied with high quality marketable medical devices. National solutions are just as unsuitable as a sudden suspension of the new EU regulation.
Based on Article 59 (3) sentence 2 of Regulation (EU) 2017/745 the EU Commission can adopt solutions applicable throughout Europe. It reads as follows:

*"On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 114(4)."*

On this basis, the GKV-Spitzenverband proposes a legal act with the following contents in the event of concrete supply bottlenecks:

Medical devices that were already placed on the market more than three years ago according to the rules of Directive 93/42/EEC or 90/385/EEC, whose CE certificates will expire within the next twelve months and for which their manufacturers have started a conformity assessment procedure according to the new EU regulation, may remain on the market by way of exception until 26 May 2022, provided the following conditions are met:

- The manufacturer has started a conformity assessment procedure in accordance with Regulation (EU) 2017/745 by 26 May 2020 and has commissioned a Notified Body with corresponding certification services.
- The Notified Body shall confirm in writing to the manufacturer that the commission has been received and that, for reasons of capacity, it is not in a position to carry out the necessary assessment steps to issue the certificates.
- The manufacturer shall apply to the national competent authority for continued marketability of the product or group of products concerned and shall forward the corresponding confirmation from the Notified Body.
- The competent national authority shall confirm the temporary marketability under this act in accordance with Article 59 (3) sentence 2 of Regulation (EU) 2017/745 and inform the European Commission of this decision. It may set a different period of validity, which however may not exceed 26 May 2022.
- The European Commission and the national authorities shall publish this information on their websites.
- The provisions of Regulation (EU) 2017/745 on market surveillance and vigilance shall apply to the medical devices concerned, with the exception of requirements involving activities of Notified Bodies.