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Implant registry:
Calling for swift implementation

Berlin. BVMed is committed to a swift implementation of the German Implant Registry. "The focus now introduced into the legislation, which is on the assurance of implant quality and the provision of implants at the responsible medical facilities, is the best way forward towards increasing the quality of patient care and patient safety," said BVMed CEO **Dr. Marc-Pierre Möll** at the German Bundestag's hearing of the respective law. The registry will be mandatory; meanwhile the law is to be passed by the Bundestag in October and will enter into force in January 2020.

Medtech Pricing Study:
Two-thirds engaged in price wars

Luxemburg. A recent study by Simon-Kucher shows: The pricing pressure in the medtech sector is high. Overall, 72 percent of all medtech companies currently feel involved in a price war. Thus, the percentage is significantly higher than in other industries.

Financial reserves of the health insurance funds remain stable

Berlin. The expenditure volume of the Statutory Health Insurance funds was at 62 billion euros in the first quarter of 2019 with a small deficit of around 102 million euros. The final annual results for 2018, which were presented at the same time, contained a surplus of 2.09 billion euros, about 100 million euros more than shown in the preliminary results.

Angela Merkel sings the praises of Jens Spahn

Berlin. During her traditional summer press conference, German Chancellor **Angela Merkel** called the cooperation with Health Minister **Jens Spahn** "very good." He got things done and also tackled "very hot potatoes."

German physician heads European Commission

Brussels. The election of the former German Federal Minister of Defense **Ursula von der Leyen** as President of the EU Commission means that this position is now held by a physician. She is a confidant of Chancellor **Angela Merkel**.

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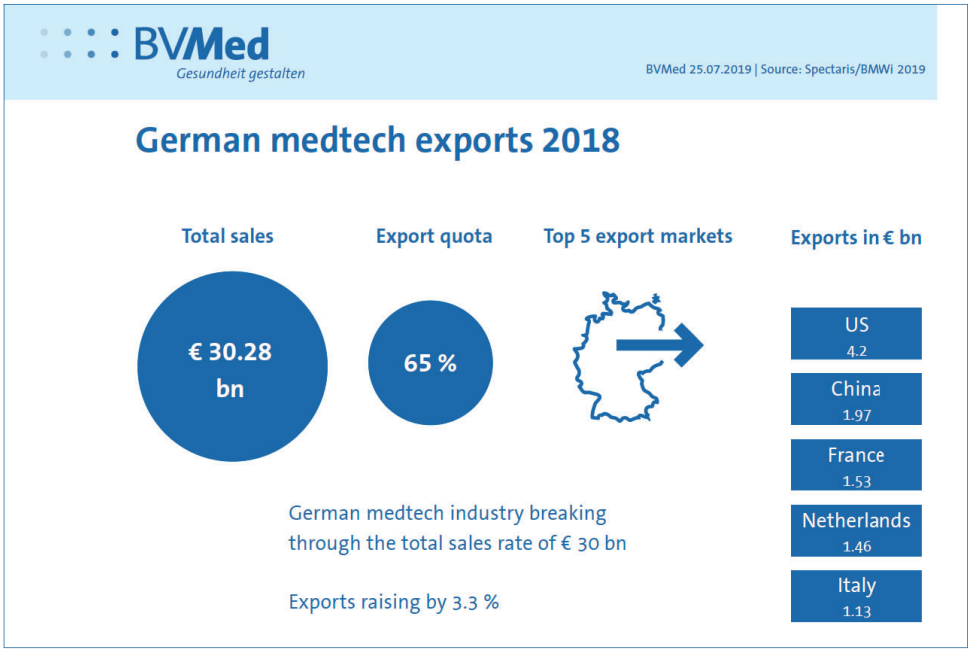
MDR: Spahn pushes for longer transition periods

Berlin. The German Health Minister **Jens Spahn** urges the European Commission to rapidly develop a "legally viable solution at European level" in order to solve the foreseeable implementation problems of the European Medical Device Regulation (MDR). The MDR will already come into force in May 2020. "With a view to our joint commitment to the success of this European project, I explicitly request that a realistic analysis of the existing difficulties in implementation is to be conducted and that legally viable and practically applicable solutions at European level are to be advanced forthwith," wrote Spahn in July 2019 to EU Industry Commissioner **Elzbieta Bienkowska** and EU Health Commissioner **Vytenis Andriukaitis**.
Spahn had already addressed the problem together with his Irish ministerial colleague at the EU meeting of health ministers in Luxemburg in June 2019. Further 18 EU countries joined the campaign. In view of possible supply bottlenecks for medical devices, the national governments want to ensure that stricter EU regulations only take effect later than planned. Spahn is calling for longer transition periods, for example for surgical instruments. The German federal government fears difficulties with the certification of medical devices, because the designation of the Notified Bodies for medical devices is dragging on. Only TÜV Süd, DEKRA, IMQ, and BSI in Great Britain have been approved as Notified Bodies so far. "Supply bottlenecks cannot – as things stand today – be ruled out," wrote the Federal Government in a response to a parliamentarian request by the FDP party. Read more at **www.medinsight.de**.

Medtech supply bottlenecks: Spahn meets BVMed

Berlin. The German Government no longer rules out bottlenecks in the supply of medical devices. Due to shortfalls in implementing the EU Medical Device Regulation, patient care might be at risk. German Minister of Health **Jens Spahn** said that the EU Regulation on stricter control of medical devices poses grave challenges on manufacturers. This was the background for a meeting in July 2019, when the minister welcomed experts from BVMed, headed by their CEO **Dr. Marc-Pierre Möll**.
"Spahn is fully aware of the implications of difficulties in implementing the MDR and its consequences for the reliability of patient care and for the medtech industry," Möll said after the meeting. A moratorium on the MDR requirements for class I medical devices was therefore suggested. "Unilateral national responses won't help much here. Spahn wants a European solution," said the BVMed CEO.
The German Hospital Federation (DKG) is also cautious: "There is a risk that starting in May hospitals will lack certain medical devices." Read more at **www.medinsight.de**.



The German medtech industry was breaking through the total sales rate of 30 billion euros in 2018. The export rate was at almost 65 per cent. The top 5 export markets are the US, China, France, the Netherlands, and Italy. More at **www.bvmed.de/branchenbericht**.