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BVMed Board Elections: Meinrad Lugan Remains BVMed Chairman

Berlin. **Dr. Meinrad Lugan** of B. Braun was re-elected as BVMed board chairman for another two years. **Marc D. Michel** (Peter Brehm) and **Stefan Widensohler** (Krauth) were elected as vice-chairmen of the board of BVMed.

Jens Spahn Putting Pressure on Self-Governance Bodies

Berlin. The new Minister of Health has made clear demands on the members of the joint self-governing structure of the healthcare system. "I do expect you to implement the law," Mr. Spahn said at the spring reception by the German Hospital Federation with reference to the discussion about minimum staff requirements in hospital departments. Otherwise, he would be presenting legislative proposals for a reform. With regard to quality assurance and hospital planning, he said: "When you return to healthcare politics after a period of three years, you realize that you haven't missed much of the debate." The good thing was that there are many instruments to measure quality, "but we now need to see results."

Diabetes and Digital: "A New Medical Device Class"

Berlin. The German Diabetes Society has requested the implementation of a separate medical device class for "digital medical devices." Diabetes was a "model disease for digitization" because patients constantly had to measure and collect data. Therefore, separate criteria had to be applied to the approval and monitoring.

MP Dietrich Monstadt: Medtech Assessments Must Be Accelerated

A key point would be the acceleration of the assessment procedures of the G-BA committee, said the CDU party's delegate for medical devices, speaking at BVMed.

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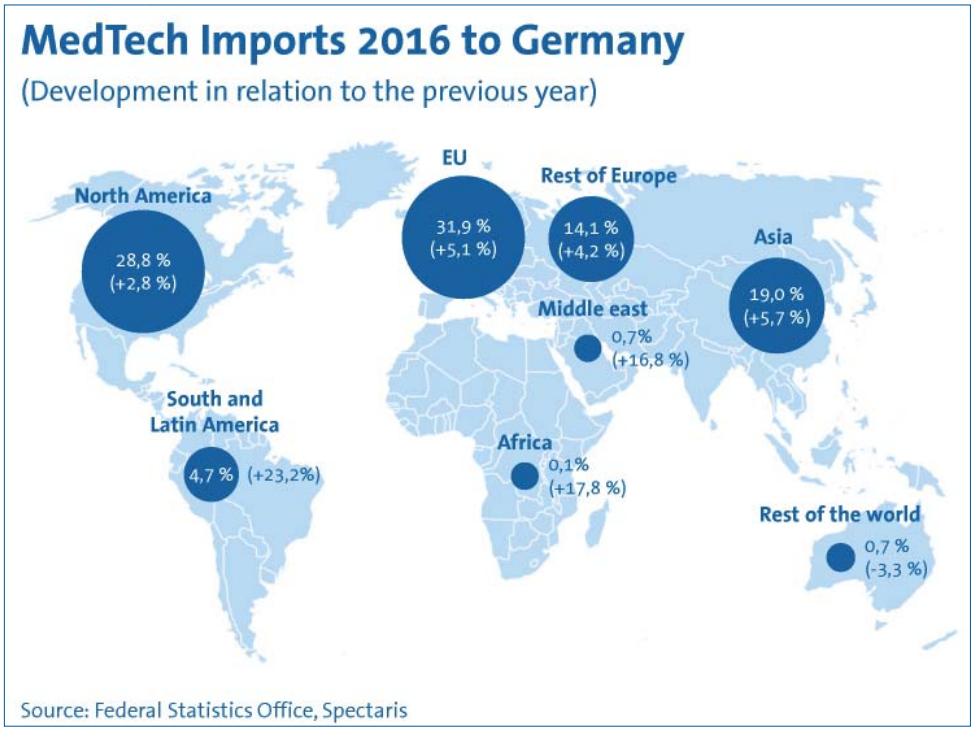
Medtech Ought to Be Removed from EU HTA

Berlin. BVMed advocates removing medical technologies from the planned EU legislation on benefit and risk assessment for health technology (European Health Technology Assessment, HTA). The European Commission proposal does not contribute to increasing patient safety, but rather leads to additional delays in providing patients with advanced medical technologies, according to BVMed CEO **Joachim M. Schmitt**. "This is unacceptable, as are the additional costs entailed for the companies."
The Commission's proposal on health technology assessment covers pharmaceuticals and in vitro diagnostic medical devices as well as implantable medical devices of class III and certain active medical devices of class IIb. Thus, a medical device, which has received a scientific report from the expert board within the scope of the scrutiny process under the Medical Device Regulation, can be subjected to an HTA after it has received the CE label.
BVMed experts criticize that the EU proposal is untimely. Authorities and companies are in the midst of implementing the new European Medical Device Directive MDR, which became effective in May 2017 and must be implemented by May 2020. "The MDR entails an enormous expenditure of time and resources for the companies," said Schmitt.
Read more at **www.medinsight.de**.

BVMed @ Spahn: Accelerate Benefit Assessment

Berlin. The medtech companies aim to accelerate the various benefit assessment procedures based on articles 135, 137e, and 137h of the Social Security Code V while making them more suitable for practical application. This was one of the key issues that BVMed CEO **Joachim M. Schmitt** voiced during his first meeting with the new Federal Minister of Health **Jens Spahn**. "The benefit assessment of methods employing medical devices is appropriate and important. The instruments for benefit assessment used so far as well as their application by the G-BA committee must, however, be critically evaluated and reformed."
The new government has recognized the deficits. The coalition agreement between CDU/CSU and SPD states that the G-BA processes are to be accelerated so that medical innovations can be integrated into regular care more quickly. Thus, the catalog of tasks and the operational structures will be streamlined. Decisions on new examination and treatment methods (NUB) are to be made faster.
More at **www.medinsight.de**.



Germany is the third biggest market for medical technologies in the world. Most of the medtech imports derive from the European Union and the US market.