

# BVMedReport № 10/18

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## Agency for medtech breakthrough innovation

Berlin. At the end of August 2018, the German government decided to establish an agency to promote breakthrough innovations. The agency's aim is to provide financial resources and scope for innovation stakeholders in order to bring ground-breaking ideas into practice. When presenting the new agency, Federal Minister for Economic Affairs **Peter Altmaier** expressly mentioned medical technology. In the past years, a number of breakthrough innovations that were developed in Germany were brought to market maturity elsewhere. From the point of view of many experts, the potentials for breakthrough innovations are not sufficiently exploited.

## Trend reversed: Heart diseases on the rise

Munich. Cardiologists in Germany fear that the number of cardiovascular diseases may rise again. Cardiovascular mortality rates dropped by almost 50 percent since 1990. However, they have again been increasing steadily since 2015. This is provided by the head of the cardiology department of Munich-Bogenhausen Klinikum, **Professor Ellen Hoffmann**. Especially atrial fibrillation was about to become a widespread condition. By 2060, the number of patients affected is expected to double.

## New agreement on quality contracts in hospitals

Berlin. The SHI funds and the German Hospital Federation have agreed upon a framework, which allows for particular quality contracts between hospitals and insurances. The G-BA committee, the highest decision-making body of the joint self-government of the healthcare system, has chosen arthroplasty (joint replacement) and the prevention of postoperative delirium in the treatment of older patients for testing.

## Katrin Suder to chair Digital Council

Berlin. The former State Secretary in the Ministry of Defense and business consultant **Katrin Suder** chairs the new Digital Council that is to give practical advice and to spur the government into action in terms of digitization.

## MDR: Notified Bodies are the bottleneck

Berlin. At a joint information event, the German healthcare industry associations, including BVMed, Spectaris, VDGH, and ZVEI, pointed out that the remaining transition period for the new EU Medical Device Regulation, MDR, is only 20 months. Within this period of time, manufacturers must meet a number of modified as well as new requirements for the placing on the market of medical devices in the EU.

A particular problem is that, to this day, major prerequisites are lacking to prepare for the new *modus operandi*. These include, in particular the (re-)designation process for the Notified Bodies (NB), who will carry out the modified testing procedures accord-

ing to the MDR to be able to identify solutions for implementation problems. And already today, the limited capacity of NB constitutes a problem. With the MDR, the bodies are faced with additional hurdles regarding their re-designation. It is therefore highly unlikely that sufficient Notified Bodies will be available once the EU Medical Device Regulation will take effect.

The medical device manufacturers feel to be left alone with these problems. The German healthcare industry associations therefore advocate better support and more transparency regarding the implementation of the MDR by the EU legislator.

Read more at [www.medinsight.de](http://www.medinsight.de).

## New law by Minister Spahn contains medtech gaps

Berlin. In a statement made on the new Medical Appointment Service and Care Law "Terminservice- und Versorgungsgesetz (TSVG)" presented by Federal Minister of Health **Jens Spahn**, BVMed declared that medical progress should be given greater consideration in the further development of the remuneration system for ambulatory care through the Uniform Value Scale (Einheitlicher Bewertungsmaßstab, EBM). "This means taking into account the requirements of personal medicine as well as advanced examination and treatment methods in order to achieve the best possible care for patients," said BVMed CEO **Joachim M. Schmitt** in view of the hearing of the law.

Desired savings regarding certain types of diagnos-

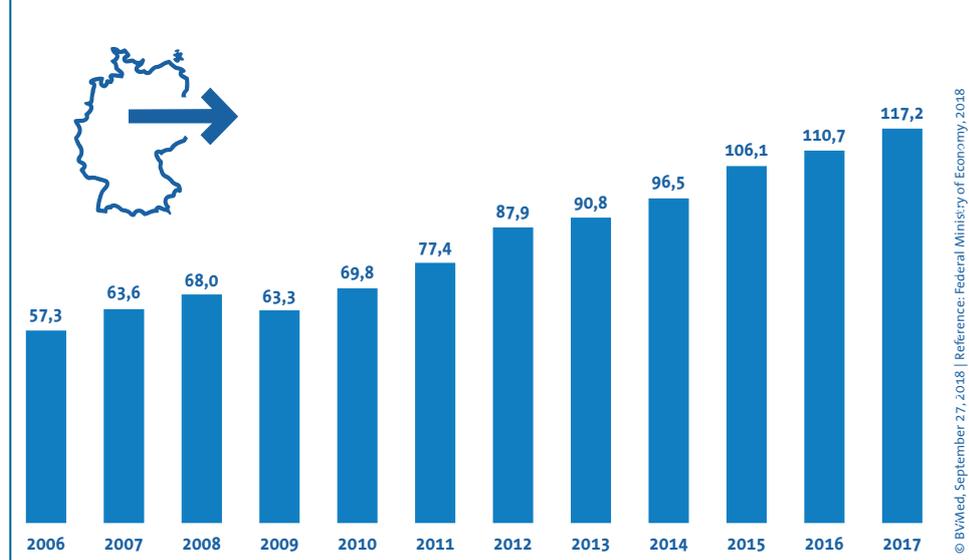
tics should not lead to deteriorating remuneration conditions for modern medical technologies as a whole. A general reduction of the remuneration of benefits that include a high proportion of technical services "could lead to a situation where the, politically desired, greater share of ambulatory care provision becomes less attractive so that the shift from surgeries performed during hospital stays to ambulatory procedures will fail," BVMed warns.

Regarding the strengthening of telemedicine as part of the Uniform Value Scale, as stipulated by law, BVMed calls for the inclusion of data-based treatment and telemonitoring procedures into ambulatory care.

More at [www.medinsight.de](http://www.medinsight.de).

## Exports of the German healthcare industry

in billion euros



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The German healthcare industry's exports amounted to 117.2 billion euros in 2017. Thus, export figures have doubled within the last 10 years. Exports referring to medtech amounted to 29.1 billion euros.