

# BVMedReport № 02/17

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## MDR to Come Into Force in May or June 2017

Brussels. The European Commission expects the new EU Medical Device Regulation, MDR, to come into force in May or June 2017, EU Commission officials stated in December 2016. The new EU MDR and the In Vitro Diagnostic Medical Devices Regulation, IVDR, will apply directly in the member states without having to be transposed into national legislation. Thus, the German Federal Ministry of Health will set up a national working-group, which will structure and coordinate the resulting tasks. BVMed will be part of this group as well.

## G-BA Chairman Josef Hecken: The Workload Keeps Growing

Berlin. "In 2016, policy-makers continued to assign an enormous workload to the joint self-governing body. But, undeterred by confidence crises, the Federal Joint Committee succeeded in producing mostly timely results." This positive conclusion was drawn by G-BA chairman **Josef Hecken** in a commentary. In 2016, G-BA took a total of 374 decisions. This is a rise of almost 30 percent compared to 2015. Read more at [www.medinsight.de](http://www.medinsight.de).

## Surplus of Health Insurance Funds of Around € 1.55 Bn

Berlin. The financial situation of the German SHI funds has improved again. As of September 2016, the 117 funds had a surplus of € 1.55 bn. This means their financial reserves have risen to more than € 16 bn, according to the Health Ministry.

## Hospital Costs Rise by 3.8 Percent

Wiesbaden. Costs for inpatient hospital care in Germany rose by 3.8 percent to a total of € 84.2 bn in 2015, the Federal Statistical Office Destatis announced at the end of 2016. The results of the hospital statistics 2015 also pointed to increased total hospital costs of € 97.3 bn (as compared to € 93.7 bn in 2014). The costs are comprised mainly of staff costs of € 58.5 bn (up 4.1 percent), material costs of € 36.2 bn (up 3.4 percent), as well as contributions to the hospital training fund of € 1.3 bn (up 4.3 percent).

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## BVMed Is Calling for a "New Culture of Innovation"

Berlin. With a view to Germany's 2017 federal election, BVMed has called for a new "culture of innovation" and the further development and improvement of patient care in Germany through new technical solutions. State-of-the-art medical technologies or telemedicine applications oriented on patients' needs "should be promoted and implemented in a timely manner," says BVMed CEO **Joachim M. Schmitt**. The institutions of the self-governing bodies ought to establish a positive attitude towards medical-technological progress. According to BVMed, it was the best option to help patients and advance the level of healthcare in Germany.

The growing number of elderly people and of patients with chronic diseases or multi-morbidities – accompanied by a simultaneous decrease in the number of healthcare professionals – can only be mastered by further technical development and innovation. In the next legislative period, policy-makers should consequently introduce a "progress acceleration law" to pave the way for a new innovation culture. This would also include a better translation of research results, the more active involvement of interest groups and patient associations in the innovation process, and the inclusion of reasonable, available healthcare data. Read more at [www.medinsight.de](http://www.medinsight.de).

## G-BA Has Started Benefit Assessment Process

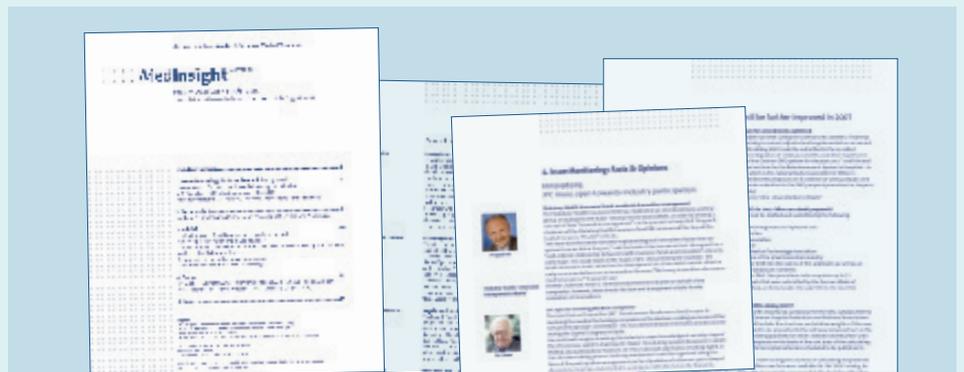
Berlin. After hospitals submitted their annual requests for "new diagnostic and treatment methods", NUB, to the InEK Institute for Hospital Reimbursement in fall 2016, the Federal Joint Committee, G-BA, has started to apply the new process for benefit assessment of NUB methods containing medical devices of high classes in hospitals (according to article 137 h, Social Security Code Book V).

The panel is preparing to issue their first deci-

sions, for instance on electro-stimulation of the peripheral nervous system by a partly implanted neuro-stimulation system for chronic pain, or a method for lung denervation in COPD patients. The process is initiated when a hospital transmits information on the status of scientific knowledge regarding the new method and the application of the medical device of a high-class to the G-BA committee.

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

## MedInsight Germany: Latest News on Europe's Biggest Market!



MedInform has published a new issue of **MedInsight** Germany, a background report authored by the German medtech experts **Joachim M. Schmitt** and **Manfred Beeres** in cooperation with Advamed. **MedInsight** gives the latest news on Europe's biggest medtech market.

Topics of the new issue are e.g.: MDR to Come Into Force in May or June 2017?; Federal Joint Committee Has Started MedTech Benefit Assessment Process; G-BA Chairman Hecken: The Workload Keeps Grow-

ing; BVMed Is Calling for a "New Culture of Innovation"; Surplus of Health Insurance Funds of Around € 1.55 Bn; Hospital Costs Rise by 3.8 Percent; G-BA Committee Passes Trial Regulation; Innovation Committee Funds Healthcare Research.

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