

BVMedReport № 07-08/16

July/August 2016
Circulation: 2,200

Compromise on MDR Reached

Brussels. The European Parliament, Council, and Commission have agreed on a joint text for the new European Medical Device Regulation (MDR) in June 2016. The framework is presumed to come into force in early 2017 with a transition period of three years. Overall, the new regulatory framework is a good compromise and will further improve patient safety in Europe. The new regulations will raise the European safety level to the high standard of the German regulations.

G-BA Must Amend Medtech Benefit Assessment Rules

Berlin. The German Health Ministry has only partly approved the procedural rules of the Federal Joint Committee, G-BA, on the benefit assessment of new medical technology methods in hospitals. One of the points of criticism is that G-BA intends to exclude hospitals from using new methods unless they participate in randomized controlled trials, RCTs.

New Medical Device Research Program

Berlin. The German Research Ministry intends to counteract the challenges of an aging society by a new medical device program, which aims at meeting people's expectations to personalized medicine and at the same time providing relief for the healthcare system. The ministry will provide approximately 240 million euros over the next five years, of which 40 million euros are intended to be spent in 2017, and 50 million euros per year from 2018 onwards.

Amendment of Medical Devices Operator Ordinance

Berlin. The amendment of the German Medical Devices Operator Ordinance (Medizinprodukte-Betreiberverordnung, MPBetreibV) will oblige healthcare institutions with more than 20 regular employees to create the position of an authorized representative for the safety of medical devices.

Mainz. **Sabine Baetzing-Lichtenthaeler**, SPD, remains Minister of Health in the federal state of Rhineland-Palatinate.

Follow us on Twitter:
www.twitter.com/bvmed

“Joint Replacement Patients Well Taken Care of”

Berlin. “Key quality figures show that joint replacement patients in Germany are very well taken care of,” said IGES Institute director **Prof. Dr. Bertram Haeussler** on the presentation of the “Endoprosthetics White Book” in Berlin on June 7, 2016. The white book was prepared at the request of BVMed and, for the first time, combines all scientific data on hip and knee endoprostheses in Germany, together with associated expert assessments.

“The white book makes clear that we have reached a high level of patient satisfaction and treatment quality in Germany,” commented BVMed CEO **Joachim M. Schmitt**. He underlined

that a successful joint replacement requires the interaction of three elements: the surgical procedure, a high-quality implant, and supportive, responsible patient behavior. The president of the German Society for Orthopedics and Trauma, **Prof. Dr. Heiko Reichel**, described endoprosthetics as “THE surgical success story of the last decades.”

According to the information provided by IGES, approximately 370,000 patients received a new hip (219,000) or knee joint (149,000) in 2014. The number of interventions is largely in line with the increasingly aging population.

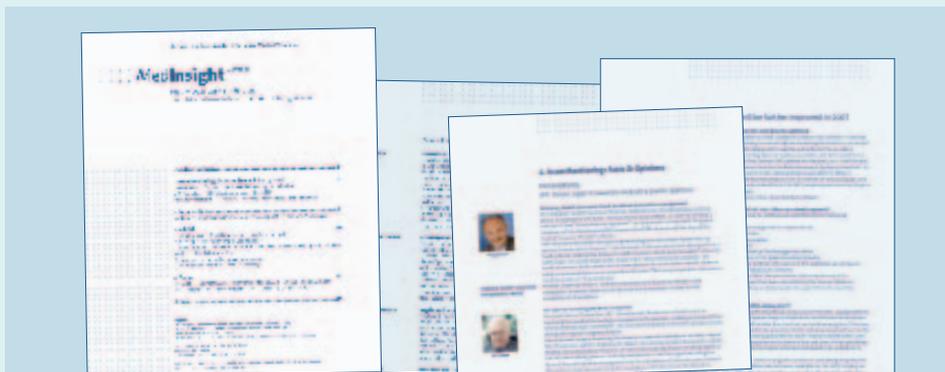
More at: medinsight.de

New “MedTech Radar” on Digital Health

Berlin. Digitalization has now become part of everyday life and the health sector is no exception. There are currently around 100,000 health apps on offer in the app stores and the billion dollar market is growing rapidly. Whether fitness, nutrition, disease diagnosis or doctor's appointments – there's a smartphone app for almost every aspect of health. The sixth issue of the joint media service “MedTech Radar,” published by BVMed, Earlybird Venture Capital, High-Tech Gründer-

fonds (HTGF) and Biocom, focuses on this growing market. It also introduces the Jena-based startup Preventicus. The company has developed an app which makes it easy for anyone with a smartphone to screen for serious diseases, such as heart attacks and strokes. BVMed also presents its own view of the digital health sector. The most recent issue of “MedTech Radar” is available for download as a PDF in German and English here: bvmed.de/medtech-radar.

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.: Compromise on MDR Reached; G-BA Must Amend Medtech Benefit Assessment Rules; “Joint Replacement Patients Well Taken Care of”; New Medical Device Research Program;

New “MedTech Radar” on Digital Health; Amendment of Medical Devices Operator Ordinance; Innovation Fund Resources for Healthcare Research Concepts; Continuous Glucose Monitoring Becomes SHI Service; Digitalization Overcomes Sectors.

Advamed, Eucomed and BVMed member companies receive “**MedInsight Germany**” at a discounted subscription price of 600 euros per year (10 issues). The normal subscription fee is 1,200 euros for one year. You can order a free trial copy of **MedInsight** at: medinsight.de