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New Medtech HTA Schemes Ready to Start

Berlin. On August 23, 2016, the amended procedural rules of the Federal Joint Committee, G-BA, on the "scheme for benefit assessment of new methods involving medical devices of a high category" (§ 137 SGB V) became effective. This means the first health technology assessment procedures, HTA, can start in fall 2016. In this context, BVMed has repeatedly demanded separate methods for the benefit assessment of medical technologies. The industry is campaigning for a neutral institution to develop guidelines for the methodology of medtech benefit assessment.

2017 DRGs: Reduction of Material Costs Minimized

Berlin. Hospitals and health insurance funds have agreed on the first major issues regarding the implementation of the Hospital Structure Law, KHSG. The development of the catalog for the 2017 DRG system is therefore on schedule. What is particularly relevant for the medtech companies is the reduction of the remuneration for DRGs with high material costs, as this will affect especially the implants sector. The compromise reached stipulates a reduction by 5.75 percent. The initial concept of the DRG institute InEK, strongly criticized by BVMed, envisaged a general reduction of the material costs by up to 14 percent – a serious interference that could largely be averted.

MDR Now Available in German

Brussels. The European Parliament has published the German version of the Medical Device Regulation, MDR. It will now be examined with regard to language and in legal terms and is expected to be passed by the turn of the year.

Joachim Lang to Become New BDI Director General

Berlin. **Dr. Joachim Lang** will take over as director general of the Federation of German Industries, BDI, on April 1st, 2017. The vice presidents approved his nomination to the presidential board and the executive board.

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MDR: Bad Compromise on Reuse of SUDs

Berlin. "Even after the compromise on the new EU Medical Device Regulation, MDR, we still have a long way to go to reach our goal of having a uniform, Europe-wide regulation on the issue of reuse of medical devices." This was the conclusion drawn by BVMed's CEO **Joachim M. Schmitt** after an industry conference on the problematic nature of reusing single-use devices, SUDs. A number of hygiene incidents at German hospitals had shown how important the quality of medical device reprocessing was for patient safety, said the experts of the conference.
The MDR had missed an opportunity in this regard, said **Peter Schroeer** of the medical device manufacturer Johnson & Johnson and **Dr. Gerhard Sontheimer** of the reprocessing specialist Vanguard in unison. The original plan was that reprocessors would be treated as manufacturers. The text of the compromise now allows for national exceptions – for example for hospitals.
In contrast, the US authorities consider a reprocessor as a manufacturer. This was reasonable "because reprocessing today involves a highly complex process", said Schroeer. In Germany, the reprocessing of single-use devices is tolerated if the requirements of the KRINKO-BfArM hygiene recommendation are complied with.
Read more on this issue at **medinsight.de**.

Joint Replacements: Implant Problems Are Rare

Berlin. Joint replacement surgery has been one of the most successful surgical procedures of the last decades. It enables patients to regain mobility and be largely pain-free. The "White Paper on Artificial Joint Replacement" recently published by the IGES Institute confirms that joint replacement patients in Germany are very well taken care of. The development of the number of procedures and the indications also prove that the number of procedures performed in Germany is not excessive. It also does away with another myth: Material failure "very rarely" is the cause of exchange procedures (so-called "revisions") – "contrary to public opinion," the white paper says. "The white paper makes clear that we have reached a high level of patient satisfaction and treatment quality in Germany," commented BVMed's CEO **Joachim M. Schmitt**. Download: **www.bvmed.de/weissbuch-gelenkersatz**.
Read more on this issue at **medinsight.de**.

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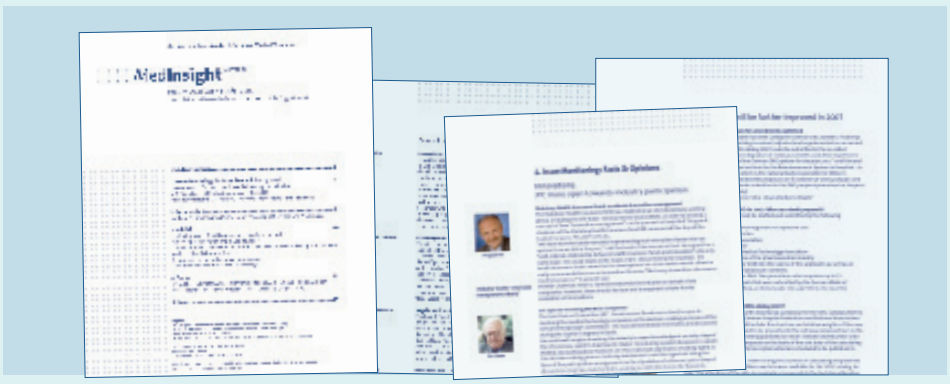

Med**Inform** has published a new issue of Med**Insight** Germany, a background report authored by the German medtech experts **Joachim M. Schmitt** and **Manfred Beeres** in cooperation with AdvaMed. Med**Insight** gives the latest news on Europe's biggest medtech market.

Topics of the new issue are e. g.: MDR: Bad Compromise on Reuse of SUDs; New Medtech HTA Schemes Ready to Start; 2017 DRGs: Reduction of Material Costs Minimized; White Paper on Joint Replacements: Implant Problems Are Rare; Bavarian Minister of Health Criticizes Association of SHI Funds; Health Insurance Funds Generate Surplus of Nearly 600 Million Euros; Government Approves Better Supply with Medical Technical Aids.

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