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Medical Devices Regulation MDR: Negotiations Still Pending

Brussels. On 22 October, 2013, the European Parliament passed a resolution on the new Medical Device Regulation (MDR), rejecting the proposed establishment of a central approval system for medical devices. High-risk medical devices will require authorization by "specific" Notified Bodies appointed by the EU Commission. Once the governments of the member states in the European Council working group have formulated a common position on the MDR, the parliament can commence negotiations with the Council and the Commission (the other members of the so-called "trialogue") on the basis of the October vote. However, this is not expected to happen anytime soon. More information at: www.medinsight.de (order a free trial copy)

New Infograph and Article on Medtech Safety

Berlin. To illustrate the effectiveness of the existing procedures, BVMed published an infograph and a background article on "the long way of a medical device from the idea to the patient". It shows how medical devices are developed, technically and clinically tested, certified and, once approved, controlled. The infograph is available at www.bvmed.de/medizinprodukte.

DKG in Favor of Participating in Endoprostheses Register

Berlin. The German Hospital Federation recommends that all hospitals take part in the Endoprostheses Register Germany (EPRD). The database, which will be launched Germany-wide in January 2014, was important to assure the quality and the further development of endoprosthetic procedures, said **Georg Baum**.

Ulla Schmidt Elected as German Parliament VP

Berlin. Former Federal Minister of Health **Ulla Schmidt** (SPD) was elected as one of six new Vice Presidents of the German parliament in November 2013.

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New Government: Coalition Contract Published

Berlin. On 27 November, 2013, the CDU/CSU and SPD coalition published the new coalition contract. In a next step, the SPD members will vote on the coalition negotiations – a new element in the political decision finding process. After a positive vote of the SPD members, the contract will be signed and the ministers will be named. The chief negotiators for the healthcare sector were the present health policy spokesmen of the respective parliamentary groups, **Jens Spahn** (CDU) and **Prof. Dr. Karl Lauterbach** (SPD).

An "innovation fund" of 300 million euros is to be set up to finance new contract models and to support studies on treatment realities ("Versorgungsforschung") and post market clinical follow-up (PMCF studies). Hospitals using new medical devices with a high risk class shall be obliged to participate in post-marketing benefit and safety studies conducted by the JFC. The corresponding JFC method evaluation procedures shall regularly be completed within two years. More information at: www.medinsight.de.

Medtech Fall Survey: 2.6 Percent Growth

Berlin. In 2013, the expected sales trend in the medical technology industry has slowed down. The average growth rate is now just 2.6 percent as compared to around 5 percent in previous years. This is the result of the fall survey conducted by BVMed, in which 111 member companies participated. With an increase of around 4.4 percent, global sales show a brighter picture. BVMed Chairman of the Board **Dr. Meinrad Lugan** (B. Braun) spoke in favor of "coherent innovation-supporting measures" and binding deadlines for additional review processes. They were required to improve the use of the opportunities

offered by medtech innovations for patient care and for improving the efficiency of the healthcare system.

According to BVMed Director General and Member of the Board, **Joachim M. Schmitt**, the profits of medtech companies continue to decline. As stated by the BVMed fall survey, only one fourth of the companies is expecting higher profits in the German market for this year. More than one third expects profits to decline. The companies see the reimbursement sector as the main obstacle.

More at: www.bvmed.de (Press Releases).

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** together with AdvaMed. MedInsight gives the latest news on Europe's biggest medtech market.

Topics from the new issue are e.g.: New Government: Coalition Contract Published; Fall Survey: 2.6 Percent Growth; MDR: Negotiations Still Pending; Shall Reprocessors Be Treated as Manufacturers?; Artifi-

cial Joint Replacements Are a Success Story; New Infograph and Article on Medtech Safety; DKG in Favor of Participating in Endoprostheses Register; Clear Specifications for Medical Technical Aids and Homecare.

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