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Bahr and Rösler Leaving Parliament
Berlin. Federal Minister of Economics **Dr. Philipp Rösler** and Federal Minister of Health **Daniel Bahr** (both FDP) are no longer members of the newly elected German Federal Parliament as their party FDP failed to reach at least 5 percent of the votes in the general elections.

Forming of the New German Government Still Pending
Berlin. Weeks after the federal elections of 22 September 2013, the forming of the new government in Germany and, hence, the succession of Health Minister **Daniel Bahr** is still pending. The first official coalition negotiations between CDU/CSU and SPD were launched at the end of October. The forming of a government and a new federal cabinet is not expected before the end of November 2013.

2014 DRG Catalog Available Now
Berlin. Sickness Funds and the Hospital Association have agreed on the 2014 DRG Catalog for hospitals. The 2014 DRG Catalog contains a total of 1,196 DRGs, nine more than this year, calculated on the basis of data provided by 247 hospitals, including 12 university hospitals. More at: **www.medinsight.de**.

BVMed Supports the New Measures Adopted by the Commission
Brussels/Berlin. BVMed supports the measures to improve the safety of medical devices adopted by the European Commission at the end of September 2013. A new implementation regulation provides stricter criteria for the Notified Bodies. The Commission recommendation also clarifies the tasks these bodies have to undertake when performing audits and assessments in the medical devices sector. Thus, EU Commissioner **Neven Mimica** swiftly puts requests for an action plan into practice. "The new set of rules could prove within a short period of time how the major weakness of lacking or Europe-wide differing controls of companies and market surveillance can be eliminated," says BVMed.

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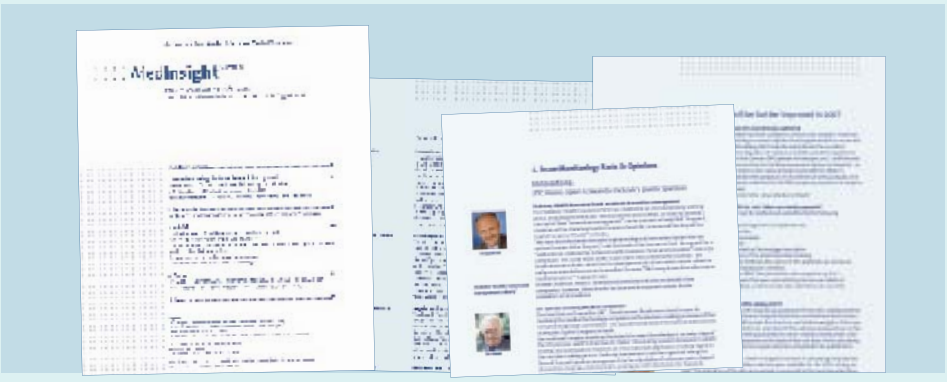
JFC Trial Regulation: Opportunities and Challenges

Berlin. The trial regulation for new examination and treatment methods of medical technologies can help accelerating the pace at which medtech innovations are accepted into comprehensive coverage. The trial regulation, a new instrument for the Joint Federal Committee (JFC) offers a simplified and quicker access to the outpatient sector, claimed **Olaf Winkler** of BVMed on the intention of German legislation at the conference "The Trial Regulation for Medical Devices in Practice". **Dr. Fülöp Scheibler** from the Institute for Quality and Economic Efficiency in Healthcare (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG) is optimistic about the trial regulation: "It is an additional option. It does not eliminate any of the other procedures. It provides a path to get innovations on the market more rapidly." Consultant **Dr. Hubertus Rosery** considers it positive that manufacturers have a right to apply themselves, thereby shortening the usual benefit analysis of the JFC for the outpatient sector. Rosery recommends medtech companies to take advantage of a consultation with the JFC on this issue.
Read more on the trial regulation at: **www.bvmed.de (Press Releases)**.

MDR: EU Parliament Opposes Centralized Approval

Brussels. In a plenary vote on the new Medical Device Regulation (MDR) at the end of October 2013, the European Parliament spoke against a general centralized state market approval for medical devices in analogy to the decision on pharmaceutical products. However, so-called "Special Notified Bodies" are set up for certain high-risk devices such as implants. Furthermore, a new scrutiny process shall be introduced for specific high-risk products, which may be applied on a case-by-case basis. The Medical Devices Coordination Group (MDCG) and an "Assessment Committee for Medical Devices (ACMD)" within the EU Commission composed of medical experts shall then decide whether an additional scrutiny process will be required. The decision by the European Parliament together with the Commission proposal will be negotiated with the European Council of Ministers. A final decision can be expected no earlier than in the next year.
More information in the new MedInsight issue at: **www.medinsight.de** (order a free trial copy).

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



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

Topics from the new issue are e. g.: Forming of the Government Still Pending; MDR: Parliament Opposes State Market Approval; Medtech Trial Regulation Also Has Advantages; 2014 DRG Catalog Available Now; Barmer GEK Calls for Return to Individual Contribution Rates; Hospitals: JFC Quality Report Proves High Level of Care; Basic Remuneration Rate Rises to 2.81 Percent; DIMDI Publishes Definite ICD Catalog 2014.

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