

# BVMedReport № 03/13

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## Health Policy: The Opposition Can Block Legislation

Hannover. The CDU and FDP parties narrowly lost the state election in Lower Saxony at the end of January 2013, so that now yet another German state has switched over to being ruled by the SPD and Greens parties. This will also have an impact on the German Bundesrat (the Upper House of German Parliament, representing the German states) and hence on the health policy of the federal government. More at: [www.medinsight.de](http://www.medinsight.de).

## JFC Identifies Five Fields of Action

Berlin. In its latest meeting, the Joint Federal Committee identified five prioritized fields of action for dealing with quality assurance in the future. The selection criteria were incidence and prevalence, presumed improvement potential and the supply requirements for affected patients. More at: [www.medinsight.de](http://www.medinsight.de).

## Statutory Health Insurance as Motor of Innovation?

Düsseldorf. In the opinion of Professor Dietrich Grönemeyer of Witten University, the statutory health insurances should play a more active role in introducing innovations in the healthcare sector. The statutory health insurances should participate in the innovation process together with the developers in the industry and physicians, Grönemeyer said on the occasion of the Medica Econ Forum organized by the Techniker Krankenkasse (TK).

## Innovation Clause 2013

Cologne. The German DRG institute InEK has published its information about new examination and treatment methods for 2013 on its website. Hospitals have made 20,994 individual inquiries.

## People

Berlin. As of January 1st, 2013, Wolfgang Pfohler (59) was appointed the new President of the Board of Trustees of the German hospital institute (DKI).

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## MDR: Industry Asks for Immediate Action

Berlin. BVMed is asking the European Commission, the Council and the Parliament to take immediate action in bringing forward appropriate measures to improve the designation and surveillance of Notified Bodies and market surveillance of medical devices.

„Legal measures should be implemented early, preferably this year, to re-establish confidence in the system of market access and market surveillance“, stated BVMed Director General and Boardmember Joachim M. Schmitt in a letter to Health Commissioner Tonio Borg.

According to BVMed, the following proposals should be extracted from the Medical Devices Regulation (MDR) catalogue and be treated se-

parately: 1. Harmonization and improvement of the designation and surveillance of Notified Bodies; 2. harmonization and improvement of surveillance of manufacturers and market surveillance conducted by Notified Bodies and competent authorities; 3. centralization of the registration of manufacturers and of vigilance reporting via Eudamed.

BVMed agrees with the European Commission that the present EU legal framework all in all has proven to be effective. Nevertheless weak spots of the system have been identified in the designation and surveillance of Notified Bodies as well as surveillance of manufacturers and the market. More at [www.bvmed.de](http://www.bvmed.de) (Press Releases).

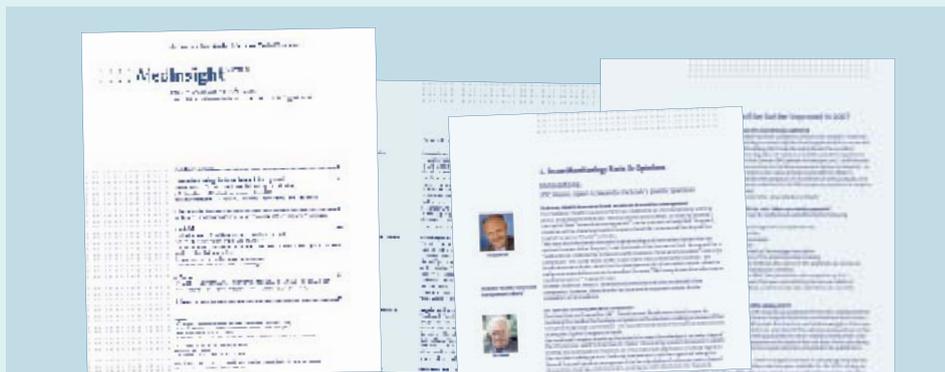
## Healthcare Compliance: Challenging Transparency

Berlin. A close cooperation between physicians, medical institutions and medtech companies is extremely important for medical progress and politically intended as well. The cooperation must be safe and transparent, and based on the compliance with a clear set of rules referred to as “healthcare compliance“. However, healthcare compliance may not result in preventing cooperation. This opinion was expressed in unison by

experts at the fourth Medtech Healthcare Compliance Conference in Berlin.

The medtech industry's compliance efforts are not only supported by the 1997 Medical Devices Code, but also by sample contract elements or the information and provision of practical examples by the “MedTech Compass“ campaign to promote transparent and good cooperation ([www.medtech-kompass.de](http://www.medtech-kompass.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 together with AdvaMed. MedInsight gives the latest news on Europe's biggest medtech market.

Topics from the new issue are e.g.: MDR: Industry Asks for Immediate Action; Health Policy: The Opposition Can Block Legislation; JFC Identifies Five Fields of Action; Statutory Health Insurance as

Motor of Innovation?; Healthcare Compliance: Challenging Transparency; Innovation Clause 2013; Hospitals Start Political Campaign; Motion for Boosting Innovations and Interest in Technology

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