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Another Term for the Grand Coalition in Germany?

Berlin. On January 26, the parties CDU/CSU and SPD started their coalition negotiations for the formation of a new grand coalition led by Chancellor **Angela Merkel**. The results of the exploratory talks between the three parties will not mean any cuts or additional burdens for the medtech industry. The future coalition partners are planning an immediate-action program for more staff in elderly care and in hospitals. The uniform citizens' health insurance called for by the SPD is off the agenda. The question of who will become the next Health Minister remains open.

Josef Hecken, Chair of G-BA, Takes the Medtech Side

Berlin. The chairman of the Federal Joint Committee (G-BA), Josef Hecken, intends to further accelerate the committee's assessment procedures. Hecken clearly takes the side of the medtech industry when it comes to the benefit assessment of new methods involving medical devices, saying that the current regulations were not practicable. "I will try to persuade the legislator to always provide for testing in all cases where neither benefit nor harm can be confirmed," Hecken proposed. Furthermore, he urged to prefinance the trial costs for manufacturers.

MDR: Transitional Period for "Orphaned" Medtech Manufacturers

Brussels. The EU member states are establishing a procedure for "orphaned" manufacturers left without a Notified Body after the reduction of the scope of the latter or the withdrawal of notifications. Under certain circumstances, these manufacturers may continue to market their devices in the EU until their CE markings expire.

MedInsight Germany: February 2018 Issue Is Out

Get the latest news on Europe's biggest medtech market: MedInsight Germany is a background report authored by the German MedTech experts **Joachim M. Schmitt** and **Manfred Beeres** together with the US association **AdvaMed**. Order a free trial copy: insight@medinform.de.

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BVMed Calls For a "Better Culture of Progress"

Berlin. At the turn of 2017/18, BVMed called for a "better culture of progress," oriented more on patients' needs, and for faster assessment procedures for medical devices in Germany. "The benefit assessment of procedures involving medical devices needs to be accelerated in a way that patients will be able to benefit from advances in medical technology in a timely manner. We need faster procedures and an adequate methodology for medical devices," said BVMed's CEO **Joachim M. Schmitt** against the background of the talks to form a government.

Advances in medical technology are the result of a large number of continuous device and process improvements. Due to rapid innovation cycles, a

separate assessment methodology had to be developed for medical devices. The trial regulation (section 137e, SGB V) and the benefit assessment of new methods (section 137h SGB V) were "not suitable in practice."

A better culture of progress in the German patient care sector through new technical solutions, a positive environment for progress in medical technology, and faster transfer of research results all have the potential to improve healthcare. According to BVMed, "all stakeholders in the healthcare market should be committed to improving their cooperation in 2018 to jointly shape the future of healthcare."

Read more at www.medinsight.de.

Compliance: How to Avoid Suspicion of Corruption

Berlin. The new sections in the German Criminal Code on corruption in the healthcare market have not yet led to any larger investigation by public attorneys or any court decision. Uncertainty in the healthcare market therefore continues, as pointed out by the experts at a BVMed Compliance Conference. As even minor grounds could suffice to trigger an investigation, companies must do everything to avoid creating any initial suspicion. The four basic principles of separation,

transparency, documentation, and equivalence as described in detail in the Ethical Code for Medical Devices will help to achieve this.

In the course of the conference the compliance experts said that in order to entirely eliminate the risk associated with direct sponsoring of passive participation in conferences organized by third parties, companies might be required to cease any such support completely.

More at: www.medinsight.de.

German Med Tech industry at a glance

> High-growth industry – domestic growth rate of **3 to 4 %** and an export quota of **68 %**.



> Total production/turnover of all medical technology companies in Germany: **29 billion Euros**.

Expenditures on medical devices in Germany: **33 billion Euros**.



> Large job creator: more than **210.000 employees**
Every workplace in this industry secures 0,75 workplaces in other industries



> **9 % of turnover invested in R & D**

1/3 of turnover is achieved with products younger than three years.

Germany is the third biggest market for medical technologies in the world. The total revenue of the manufacturing medical technology companies (considered are those with more than 20 employees) in Germany is 28 billion euros, according to the official economic statistics. The ex-

port rate is at around 65 percent. The German MedTech market is about twice as large as the French and three times as large as the British or Italian market. The medical technology industry employs more than 210,000 people in Germany. More at: www.bvmed.de/branchenbericht