Monthly news from the German Medical Technology Association: BVMed, Reinhardtstraße 29b, D-10117 Berlin
Editor: Manfred Beeres, Phone: +49 (0) 30 - 24 62 55 - 20, E-Mail: beeres@bvmed.de, www.bvmed.de

BVMed Report № 05/15

May 2015
Circulation: 2,200

MDR Discussion: Unannounced Audits Are Working

Bonn. The unannounced audits (UA) of medical device manufacturers carried out more frequently since fall 2013 are effective and an important step to further increase patient safety. This was the experts' upshot at the conference "Current Developments in Medical Devices Legislation" held in Bonn.
Industry representatives demanded that the unannounced audits should be recognized as part of the regular audit cycle in medtech companies in order to cut red tape and financial burdens. More bureaucracy in the approval process for medical devices would only be justified if this would verifiably increase patient safety. This goal could be achieved better by improving the existing system than by establishing a centralized approval system, said **Susanne Conze** from the Federal Ministry of Health. The EU implementing regulation enacted already in 2013 showed first success, as the number of Notified Bodies for medical devices was decreasing all over Europe. Now, however, the discussion is moving towards higher standards required by clinical trials. More at: **www.medinsight.de**

Costs of Medical-Technical Progress Overestimated

Berlin. The importance of medical-technical progress concerning the development of costs in the healthcare system is overestimated. At the same time there are "many indications that point to the positive effects of medtech progess on public health as well as the economic development of a country," the Office of Technology Assessment at the German Parliament, TAB, finds.
On behalf of the research committee, the scientific consulting body has presented its expert opinion on the issue of technical progress in the healthcare system as a source of rising costs or an opportunity for lowering costs, "Technischer Fortschritt im Gesundheitswesen: Quelle für Kostensteigerungen oder Chance für Kostensenkungen?".
So far, studies have attributed between 40 and 60 percent of all cost increases in the healthcare system to medtech progess. This means that the role of medical-technical development has been "systematically overestimated", the TAB office finds. Read more on the study and its goals at the TAB website: **www.tab-beim-bundestag.de/en/research/ul0024.html**

Parliamentary Hearing on Benefit Assessment

Berlin. In its statement on the parliamentary hearing on the draft legislation of the German Healthcare Service Strengthening Act for the Statutory Health Insurance, BVMed has suggested improvements to the scheduled provisions regarding the benefit assessment of medical technologies. They include a proposal for a stepped process, better participation of the involved medical device manufacturers, and the option to suspend an assessment procedure if studies are about to be completed.

Medtech Expenditure in 2013: 31 Billion Euros

Wiesbaden. According to the Federal Statistical Office the total health expenses attributable to the medical devices sector in Germany in 2013 were approximately 31 billion euros, of which 17.1 billion euros were attributable to aids and 13.3 billion euros to other medical devices. In addition, there is an amount of almost 1 billion euros spent for medical dressings, which are included in the "medicinal products" category. The total sales of the medical device manufacturers in Germany increased by 2.3 percent to 25.19 billion euros in 2014.

Hospital Infections: 10-Point Action Plan

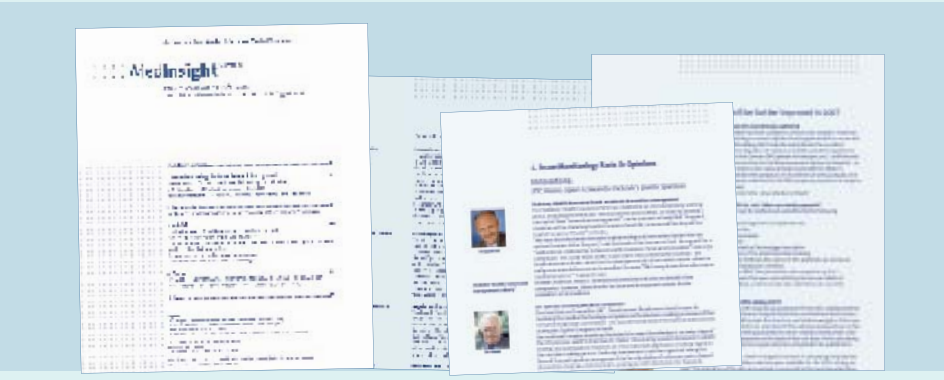
Berlin. Federal Minister of Health **Hermann Groehe** intends to combat the development of multi-resistant pathogens in hospitals. A 10-point action plan was developed by his ministry. According to the paper, the measures taken so far are not sufficient and hygiene, quality assurance and transparency would not always obtain the "necessary priority" when it comes to infections caused by treatments in hospitals.

Prof. Montgomery Vice President of World Medical Association

Oslo. In mid-April 2015, the president of the German Medical Association, **Prof. Dr. Frank Ulrich Montgomery**, was elected vice-president of the board of the World Medical Association.

Follow us on Twitter:
www.twitter.com/bvmed

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

Topics of the new issue are e. g.: MDR Discussion: Unannounced Audits Are Working; Parliamentary Hearing on Benefit Assessment; German Medtech Expenditure in 2013: 31 Billion Euros; Hospital Infections: 10-Point Action Plan; Costs of Medical-Technical Progress Overestimated; Need for Improvement of Anti-Corruption Law; Number of Physicians in Hospitals Increasing; Quality Standards for Anti-Decubitus Care; Patient Survey on ISC Care.

AdvaMed, Eucomed and BVMed member companies receive "MedInsight Germany" at a discounted subscription price of 600 euros per year (10 issues). The normal subscription fee is 1,200 euros for one year. You can order a free trial copy of MedInsight at: **www.medinsight.de**