Editorial

The greatest challenges in Germany are the evaluation and financing of innovations. The procedures of the Federal Joint Committee (G-BA) pose problems here. In the hospital sector, the G-BA wants to establish stricter regulations for the introduction of innovations, whereas BVMed advocates adherence to the innovation-friendly principle of “permission with the reservation of prohibition”. According to this, medical technological innovations in hospitals are subject to reimbursement by statutory health insurance, unless there has been a negative decision of the G-BA. Federal Health Minister Ulla Schmidt has now announced she would not accept the G-BA’s regulations as they are detrimental to innovations in the hospital sector. This is good news for innovative medical technologies in Germany. Best regards

Joachim M Schmitt, Director General

New Study on German MedTech industry

Berlin. The "Study on the Situation of Medical Technology in Germany in International Comparison" is now available on the internet. It was compiled by a consortium headed by the Aachen Competence Center of Medical Technology (AKM) and the German Society for Bio-medical Technology (DGBMT) on the order of the Federal Ministry for Research (BMBF). In the study, the situation of medical technology in Germany in comparison with significant co-competitive countries on the world market is analyzed comprehensively for the first time. Study at: www.gesundheitsforschung-bmbf.de/de/921.php

German Hospital Federation: Guarantee Access to Innovations

Berlin. In the view of the German Hospital Federation (Deutsche Krankenhaus-gesellschaft - DKG), innovations must continue to be provided within solidarity health insurance. This was declared by DKG president Wolfgang Pföhler at the 4th National DRG Forum in Berlin. However, this could only be achieved if adequate means of financing were given. Hospitals had made good progress in switching over to the DRG system. Nevertheless, they continued to require a high degree of planning security. More at: www.dkgev.de.

BVMed conference: Germany “good up to market access, but challenges in reimbursement”

Munich. In the promising field of medical technology, Germany has the best prospects to bring new products and procedures to the marketing stage due to its great number of educated doctors, researchers and engineers and due to the high standards in clinical research. There are, however, considerable challenges in introducing innovations into the reimbursement system so that they may then be speedily made available to patients. These were the conclusions drawn by experts at the BVMed special conference, entitled: “Medical technology innovation – From conception to realisation and on to reimbursement” in Munich.

“Through shorter approval times and extremely good and cost-effective clinical research in the medical technology sector, Germany has a considerable competitive advantage over the USA. In Germany, the cost of bringing a new idea to the marketing stage is at around 8 to 10 million Euros. At some 80 million Dollars, these costs are considerably higher in the US. However, due to reimbursement restrictions in Europe, companies are urged to turn to the US market,” said Thom Rasche, a finance expert from Earlybird’s office in Hamburg/Germany.

Similar views were expressed by Dr Martin Zauner, a scientific expert from Austria. “Through its university hospitals and numerous competence centres for medical technology, Germany has a great knowledge capacity, but this must be better exploited,” he said at the BVMed conference in front of 120 delegates from industry, hospitals and health insurance funds. More at www.bvmed.de (press).

“More cooperation in the healthcare economy”

Berlin. In Germany the healthcare economy would have a great potential for growth if the correct health policy conditions were introduced to set free the innovative capacity of the sector. This was the view put forward by experts at the MedIn conference entitled: “Healthcare economy: Innovative medical technologies as a motor for the growth market of healthcare” in Berlin. It is not necessary to regard innovations simply as cost generators, said Professor Marc O. Schurr from Steinbeis College in Berlin. “They could also create economic reserves, if they were employed in the correct healthcare political setting.”

State secretary for health Dr Klaus Theo Schröder envisages a good basis for innovation-friendly conditions in the health service. It will still be possible in the future to introduce innovations into hospitals without a general approval by the G-BA, he said. The new code of procedures from the G-BA would be critically assessed for this sector by the Ministry of Health. At the same time, a more representative presence of industry at the G-BA should be considered in order to allow for questions at its meetings, said Dr Schröder. More co-operation and more open dialogue: these were also the demands of medical technology companies at the conference.


DAMA: New agency will be established

Bonn. The change in the German competence authority body for devices from the BfArM institute to an agency, the DAMA (German Agency for Drugs and Medical Devices) in January 2006, will entail the establishment of a new medical technology regulatory department, called the “Bundesstelle für Medizinprodukte”. It is foreseen that BfArM’s current head of medical devices, Hans-Georg Will, will assume the devices head role in the agency, CLINICA reports. This unit will be based in Bonn, as will the rest of DAMA. The main tasks of DAMA in the devices field will be vigilance, risk assessment and evaluation, and rule making. Drugs will by 2010 be subject to cost recovery fees payable by the industry. This is not foreseen for devices, where approvals and CE marking are overseen by the notified bodies. BVMed is on the whole pleased that DAMA will not bring drastic change to the positive approach of European market access mechanisms for medical devices.