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Initiative to reform German DRG system for hospital funding

Kiel. How shall hospitals be funded in the future? "Looking back, the DRG system is only a partial success," said **Heiner Garg** (FDP), Minister of Health of the federal state of Schleswig-Holstein. With the help of Germany's fifteen other federal states he intends to initiate a fundamental reform of the case-related group system (DRGs). The state politician has put a revenue-independent general funding scheme to complement the service-related DRG billing system at the top of his wish list.

DiGAV: Digital medicine will be reimbursed

Berlin. Healthcare professionals in Germany will in the future be able to prescribe digital healthcare applications that will be reimbursed by the Statutory Health Insurance. The Digital Healthcare Reimbursement Act that was passed in November 2019 provides for digital services to be introduced more quickly into standard healthcare in the future. The medtech industry is also calling for the inclusion of so-called "combined devices" that process data from another medical device such as a cardiac pacemaker for physician or patient information.

BfArM: Positive effects of apps plausibly presented

Bonn. The Federal Ministry of Health as well as the Federal Institute for Drugs and Medical Devices (BfArM) under its supervision are striving to make digital healthcare applications of lower risk categories available for standard patient care at high speed. In contrast to pharmaceuticals, the required proof of positive healthcare effects will not require randomized clinical trials (RCTs). "A plausible presentation of positive effects will initially suffice," stressed BfArM president **Professor Karl Broich**.

Safety devices to be remunerated

Berlin. Safety devices such as injection, port, or pen needles with safety mechanisms will in future be remunerated by the Statutory Health Insurance (SHI) when relatives or professional staff, e.g. in care homes, care for the patients. The G-BA committee amended the medical technical aids guideline accordingly.

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Medtech industry calling for MDR emergency plan

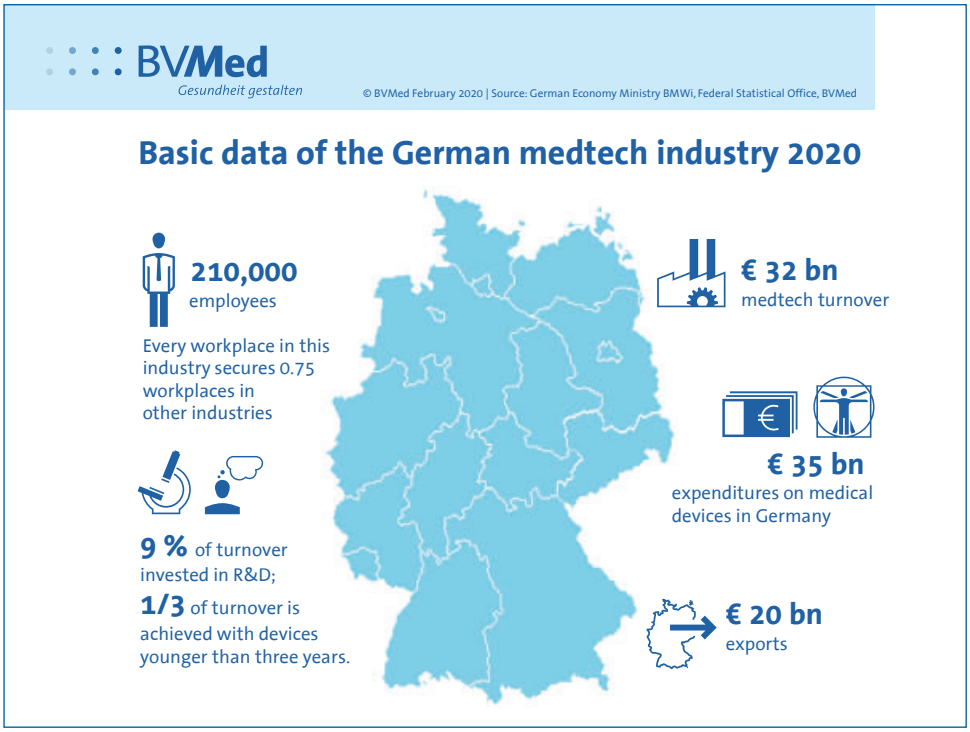
Berlin. The German medtech industry is calling for a harmonized EU-wide emergency plan. The plan must make provisions for, among other things, special approvals for manufacturers that can demonstrate their "orphaned" status – i.e. they currently have no contract with a Notified Body notified on the basis of the MDR – as well as for harmonized EU-wide permits for devices whose certification is currently on hold. BVMed is further calling for the publication of EU-wide guidelines as soon as possible in order to harmonize the activities of the Notified Bodies during the certification of manufacturers and medical devices. "Otherwise, we will see market distortions due to the present certification chaos," warns BVMed CEO **Dr. Marc-Pierre Möll**. The background to these worries and demands is the application date of the EU Medical Device Regulation (MDR) from May 26, 2020, while its implementation is still facing several major problems.
The second MDR corrigendum passed at the European level in mid-December 2019 was an important step in the right direction, but it concerned only a small number of around 450,000 affected medical devices, said Dr. Möll. "There are still many issues that need to be resolved, e.g. a shortage of Notified Bodies, capacity problems, the absence of implementing acts and guidelines."
Read more at **www.medinsight.de**.

MDR: Five demands by the medtech industry

Berlin. The medtech industry is prepared, but the certification system is not. Now it is up to all those involved – politics, the industry, health insurance funds, hospitals and physicians, the Notified Bodies – to combine all their efforts in order to avoid gaps in the provision of care. The five demands by BVMed:

1. Under the MDR the Notified Bodies must be appointed faster so that they can then certify the manufacturers' quality management systems as soon as possible.
2. The panels of experts must be appointed immediately in order to ensure the MDR certification of all the devices requiring certification.
3. The necessary implementing acts must be published as soon as possible, including the harmonized norms and common specifications.
4. We need high-quality guidelines to be published as soon as possible for the most urgent areas, e.g. the requirements for clinical evidence with regard to existing devices, or the definition of major changes as mentioned before, in order to ensure the swift and feasible MDR certification for as many devices as possible.
5. We need reliable time scales and deadlines for the processing of approval files by the Notified Bodies. Only these measures will allow the manufacturers to make binding plans.

Learn more at **www.bvmed.de/mdr**.



The German medtech industry has a total turnover of over 30 billion euros and provides 210,000 jobs.