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Strengthening Alliances for Medical Progress and Quality

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In Germany healthcare spending in the medical technology sector amounts to more than 23 billion euros. The medical technology industry employs 170,000 people in more than 11,000 companies in the country.

Outstanding Innovative Capability

The medical technology industry is dynamic and highly innovative. German medical technology manufacturers achieve approximately a third of their business volume with products that are less than three years old. The researching companies in the medtech sector invest an average of about nine percent of their sales revenues in research and development.

Another proof of the industry‘s high innovation capability: according to the European Patent Office in Munich, medical technology heads the list of registered inventions with 11.4 percent of patent applicationsover 15,700 patents. Tthus originate from the medtech field, which is followed by telecommunications (10 percent) and IT (6.7 percent).

10 Points for Providing Patients with Advanced Medical Technology

How will the medtech sector further develop in Germany? The days of the grand coalition (CDU/CSU and SPD) and of healthcare minister Ulla Schmidt (SPD) are numbered. The Christian Union of CDU/CSU under the leadership of Chancellor Angela Merkel and the pro-business Free Democrat Party (Liberals) have won the German general election on 27 September 2009. Consequently, Angela Merkel won a second term and ditched the centre-left Social Democrats with whom she has shared power in an uneasy coalition since 2005. The Liberals have been the preferred partner of the Christian Union.

BVMed has published a "10 point plan" for the care of patients with advanced medical technology" as discussion points for the health policy negotiations of the new government. The plan was send to the plan to the decision makers of CDU, Liberals and CSU to give impetus for the elaboration of the new government programme.

Information Campaign on Healthcare Compliance

Another important issue for hospitals and the medtech industry is healthcare compliance. The medical technology companies and their trade association BVMed seek to provide orientation with a new information campaign called "MedTech Compass" to promote transparent and good cooperation between industry, medical facilities and physicians. The "Compass" uses its own website (www.medtech-kompass.de), an informative flyer, regular newsletters, e-learning tools and films to advocate the existing recommendations for cooperation in the healthcare market, with the help of clear principles and reallife examples.

Cooperation Between Industry and Hospitals as Innovation Motor

This topic is particularly important for Medtech companies and hospitals, since the cooperation between medical facilities, physicians and industry is a prerequisite for medical advances. Politically, such cooperation is also desired. Together with partners in the hospitals and the medical profession, the Medtech companies in Germany have endeavored for many years to provide a secure and transparent basis for cooperation in the healthcare market.

In order to offer clear recommendations for an effective and transparent cooperation, industry, health insurance funds, physicians and hospital associations in Germany have developed the "Medical Device Code of Ethics", the "Common Viewpoint" and numerous model contracts. The contents of these recommendations are lived day in and day out in many places. Nevertheless, questions and uncertainties often arise in practice. The Medtech Compass is to provide answers to these questions and thus offer more security in daily routine.

Four Principles as "Pillars" of Healthcare Compliance

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The basis of an effective and transparent cooperation between industry, medical facilities and physicians are the following four principles:

Separation Principle: We advocate the strict separation of donations, benefits and sales. Specifically, this means, for instance: It is wrongful to sponsor a medical event after being assured that medical technology products will be purchased.

Transparency Principle: Every donation and reimbursement received must be disclosed. The consequence being: All services for a medical facility or a physician must be communicated to the employer and specified in writing.

Equivalence Principle: Performance and recompense must have a reasonable relationship to each other. If, for instance, a physician produces a study relevant to medical technology, his fee must be appropriate to his effort and expense.

Documentation Principle: All services must be documented in writing. The written agreements will stipulate in detail what kind of funding it is, which purpose it has and which services have actually been performed.

10 Points for Providing Patients with Advanced Medical Technology

1. The Quality Rating of Medical Devices Must be Demonstrated by Means of a CE-Med Quality Mark,

The CE quality mark for medical devices differs from that for other products in that it does not only guarantee the safety of the product, but in addition stands for a proven performance capability. A distinctive CEMed quality mark should therefore be introduced for all medical devices.

2. Access to Medical-Technical Innovations Should be Designed to be Unbureaucratic and Flexible

In order to enable patients to gain more flexible and faster access to medical-technical progress, BVMed suggests simplifying and deregulating the remuneration of new examination and treatment methods (Neue Untersuchungs- und Behandlungsmethoden, NUB) within the Statutory Health Insurance (SHI).

3. It Must be Possible to Introduce Medical-Technical Innovations into Hospitals Without Restrictions

When launched onto the market, many medical-technical innovations are first used in hospitals because these have suitable staff and adequate technical infrastructure. This process must be continued in order to make innovative medical technologies available to all patients in Germany who need them, without delay. If similar structures exist in the outpatient sector, the same procedure should be possible for this sector as well.

4. We Advocate an Innovation Pool to Accelerate the Introduction of Medical-Technological Innovations into the SHI

Medical-technical progress should be made available to patients as soon as possible. At present, it takes up to four years to assure adequate remuneration. In order to accelerate the introduction into the SHI service catalogue, funds should be paid by the SHI into a so-called "innovation pool" to be used for the purpose of medical-technical innovations. The inclusion of additional funds, e.g. from research funding, should be considered as well.

5. We Campaign for a Tax-Advantaged Innovation Savings Scheme (Steuerbegünstigtes Innovations Sparen, SIS)

There is great demand for additional services outside the range of the SHI service catalog. In this context, we suggest granting tax privileges for savings schemes in the healthcare sector, similar to those for the pension savings scheme “Riester-Rente”. This would create an important incentive to make provisions in time, especially for younger people. Certain innovative and desirable services that exceed the care provided by the SHI benefits would be supported. Such optional schemes increase the freedom of choice for patients.

6. We Consider Health Services Research a Useful and Necessary Joint Task for all Players in the Healthcare System

Health services research is the basis for decisions that are relevant to health and can increase the planning assurance for all those involved in the healthcare system. Actively involving all players in the healthcare system in the process is important if health service research is to be generally accepted.

7. Cooperation Between Medical Institutions and Industry is Desired and Essential for the Improvement of Patient Care

An idea for a device or procedure is often jointly realised by physicians and the engineers in the companies. This cooperation leads to excellent products. Together with its partners in the hospitals and among physicians, BVMed has been working for many years on providing a secure and transparent basis for the necessary cooperation in the healthcare market. This includes extensive information and advisory services. In the area of medical care, profitable cooperation takes place between companies, service providers, SHI-physicians and hospital physicians, hospital

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operators. This is now being restricted unnecessarily by the amendment of section 128 Social Security Code V (SGB V). Regarding this situation, there is urgent need for action.

8. Emphasis Must Again be on the Quality of Medical Devices (e.g. Regarding Aids and Appliances). Patients Must be Able to Freely Choose Their Service Provider and their Products

The MedTech companies recommend a competition for the best quality in medical care, not for the lowest price without consideration of quality and qualification. Therefore, we advocate developing and establishing criteria for proper quality competition in cooperation with the health insurance funds in order to counter the trend towards cheap medical care.

9. Homecare Should Become Regular Part of SHI

Six million people in Germany use aids and appliances supplied by homecare companies, zand the number is rising daily. We live in a society where people are getting older and older, not least thanks to medical- technical advances. Older patients mostly have several chronic diseases. Changes in hospitals mean that they are transferred to ambulatory care as soon as possible. Homecare companies have been successfully meeting the challenges this poses for years. Trust and professional counselling require that services are provided close to home. Therefore, the patient should be entitled not only to the product (medical device) but also to comprehensive homecare treatment.

10. Telemedicine Should Become Part of Regular Care

E-Health, telemedicine and telemonitoring by means of medical technologies and the required networking lead to better, safer, optimised, and more cost-effective care and must therefore become part of standard care.

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