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Enhancing Health

Annual Report
2012/13

The Medical
Technology Companies :
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Eye surgery: Modern procedures for defective vision and cataract

Content

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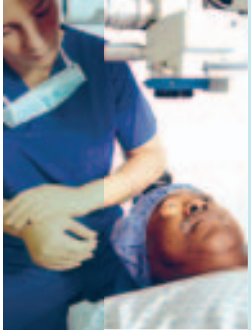
Intraocular lens for cataract



Cataract surgeries

Dr. Meinrad Lugan
Chairman of the Board of BVMed

Foreword

Working Together for Quality Improvements in 2013

Dear Members,

with regard to healthcare politics, 2012 was an ambivalent year for the manufacturers of medical devices. On the one hand, we received considerable support, e. g. through the medical technology strategy process. On the other hand, the Federal Association of the Statutory Health Insurance Funds and the Federal Association of the AOK initiated a political campaign to discredit especially innovative medical devices as dangerous and unsafe.

Medical technology innovations offer enormous opportunities for improving patient care in Germany. We must use these opportunities together instead of scaring patients through blanket statements. We need an alliance for medical technological progress, one that is safe, effective and tested.

Medical technology companies are campaigning for the following goals in 2013 in particular:

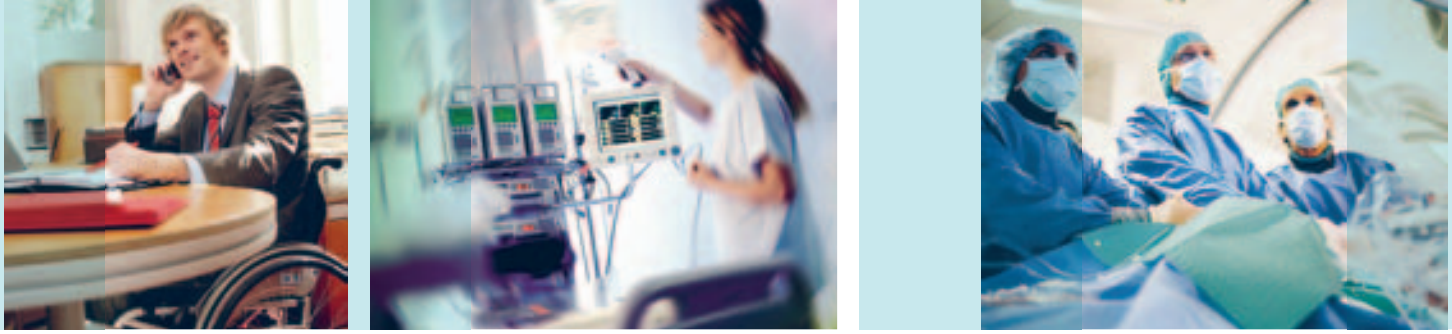
- The final report of the medical technology strategy process should be used as a starting point by the Ministries of Health, Economics and Research to intensify their joint implementations of projects.
- We need research funding programs which are better coordinated and based on actual requirements.
- We need to develop new ways of funding clinical studies.
- We need sensible levels of evidence and the relevant study designs for the benefit analyses of medical devices.
- We need adequate funding of the Joint Federal Committee so that all the trials can be carried out. One way of securing this could be an innovation fund.
- We also need more evaluations of routine data from health insurance funds and better quality assurance through registers.
- Regarding dressing materials and medical technical aids, we also need a stronger focus on quality through quality standards, with compliance monitored by the health insurance funds.
- We need more networking between the medtech and the IT industries.

All in all we need to boost Germany as a leading market and a center for healthcare competence. In order to do this we need an innovation-friendly environment as well as a strong German market, which will help us to use our strength, exporting medical technological products, in future as well.

We look forward to shaping healthcare with you!

Yours

Dr. Meinrad Lugan
Chairman of the Board of BVMed



From care with medical technical aids to the OR: Medical devices increase quality of life and save lives

Market and Member Developments

Member development

At this moment (March 2013) 234 industrial and trading companies are members of BVMed. In 2012, ten companies joined BVMed. In early 2013 another two joined as well. In 2012, eleven companies left the association, which was mainly due to takeovers and mergers. Despite consolidation processes, the number of BVMed-members continues to rise at a high level. A complete list of members can be found on pages 22 and 23.

Market development

The current BVMed survey conducted in fall 2012 shows that the medtech industry remains innovative, continues to grow and to create jobs. Economic growth on the other hand is slowing down and companies are increasingly dissatisfied with Germany as a location.

- Sales growth of medtech companies has slowed down compared to the previous year. According to the survey it was at an average of 4.4 percent in 2012. In the previous year it was at 5.3 percent. Development stagnated on the German market in particular. Export to foreign markets – especially to Asia – continued to grow strongly.
- Profits have been reduced due to the huge price pressure, especially from purchasing groups and tenders, the strong increase in commodity prices and higher levels of outstanding accounts. While Germany as a location is still viewed mostly positively, companies are increasingly criticizing the low level of remuneration and an innovation-hostile policy of the Statutory Health Insurance (SHI).
- Despite this difficult economic situation the medical technology industry continues to be a job engine in Germany. Almost 60 percent of companies have created jobs, only 13 percent had to cut jobs compared to the previous year. According to the survey, BVMed members alone created around 3,000 new jobs.

Results of the member survey

The fall 2012 survey conducted by BVMed, in which 101 member companies took part, produced the following further results:

- Only 37 percent of companies expect better business results in 2013. In the previous year this number was still at 46 percent. 20 percent of companies expect lower sales figures. This is a clear sign that the medtech industry, which is usually unaffected by the economic cycle, is slowing down.
- Less bureaucracy and accelerated decision-making processes are the top priorities (55 percent) when it comes to demands in connection with healthcare. This is directed especially at the Joint Federal Committee and the Federal Association of the Statutory Health Insurance Funds. Nearly 30 percent of companies are in favor of a reform of the self-governing bodies and a critical review of their responsibilities.
- All in all, medical technology companies still see Germany as a positive location for industry. 61 percent said the good infrastructure and 52 percent said the high level of care for patients were the strongest points of Germany as a location. Other strong points mentioned were: well-trained physicians (41 percent), fast admission to market (40 percent), well-trained scientists and engineers (35 percent) as well as a high standard of clinical research (34 percent). In general, the numbers have gone down significantly compared to the previous year. There is a trend to view Germany as a location in a more critical light than in previous years.
- The companies see some obstacles in the area of remuneration. 61 percent complain about increasing price pressure through purchasing groups, 48 percent about a level of remuneration in Germany that is generally too low. Almost 42 percent of companies criticize a health insurance fund policy that is hostile to innovations. The skills shortage is increasingly becoming an important issue. 32 percent are already calling this an obstacle to business.

The research, quality assurance, education and manufacturing in medtech companies have one goal: to help patients

Industry Report Medtech 2013

Growth market healthcare industry

The healthcare industry is one of the sectors with the highest potential for growth and large employment opportunities for qualified and skilled employees. With currently 5.4 million employees, the healthcare industry is the biggest employer in Germany. Almost one in seven jobs in Germany can be found in the healthcare industry. Since 2000 the number of employees in the healthcare system has risen by 500,000 (over 12 percent).

Expenditure on medical devices in Germany

Healthcare expenditure on medical devices (excluding investment goods and dental prostheses) in Germany was at around a total of 27 billion euros in 2010 (consumer prices; source: Healthcare Expenditure Report 2010 of the Federal Statistical Office, April 2012). Medical technical aids (all cost bearers) made up almost 14.2 billion euros (2009: 13.9 billion euros) and other medical requirements 12.1 billion euros (11.4 billion euros). In addition, around 1 billion euros are spent on dressings and bandages, which are grouped under pharmaceuticals. Of all the expenditure on medical devices, the Statutory Health Insurance (SHI) spends around 16.9 billion euros (about 64 percent). The SHI spent 6.3 billion euros on medical technical aids, and 10.6 billion euros on other medical needs.

Manufacturing of medical technology in Germany

The total revenue of the manufacturing medical technology companies in Germany increased by 4 percent to 22.2 billion euros in 2012, according to the official economic statistics (manufacturers prices). In the previous year revenue had increased by 6.9 percent. Foreign sales in 2012 rose by 6 percent to a total of 15 billion euros. Domestic revenue, however, stagnated another year with 7.2 billion euros.
Medical technology in Germany is a very export-intensive industry with export rates between 60 and 65 percent. In 2012 the export rate was as high as 66 percent. In the middle of the 1990s it was only at around 40 percent.

Worldwide growth market medical technologies

The medical technology industry is a worldwide growth market. Medical technological progress, the demographic developments with more and more older people and the extended definition of health all ensure that this will continue. The demand for healthcare services will rise further. Patients are increasingly willing to invest in their health.
The worldwide market for medical technologies amounts to 220 billion euros. The European market with 65 billion euros is the second largest market in the world after the US with 90 billion euros. Germany is the third largest market in the world after the US and Japan and by far the largest European market. It has about twice the size of the French market and is about three times as large as the Italian, British and Spanish ones.

Above-average innovative capacity

Medical technology is a dynamic and highly innovative industry. German medical technology manufacturers generate around one third of their sales from devices that are less than three years old. On average, medtech companies invest around 9 percent of their revenue in research and development. Germany as a location of innovation and research is therefore very important for medtech companies.

Medtech: A lucrative employer

The medical technology industry consists of almost 1,250 businesses (with more than 20 employees in each business) that employ over 100,000 people. In addition, almost 10,000 small businesses employ around 75,000 people. The core industry thus employs a total number of 175,000 people in over 11,000 companies in Germany. Further 29,000 employees work in the retail sector for medical and orthopedic goods. 15 percent of the employees work in research and development (R&D) – with an upward trend. Apart from a few large companies the sector mostly consists of medium-sized businesses. 95 percent of all businesses have fewer than 250 employees.

Healthcare political highlight of BVMed in 2012:
The “early-fall healthcare policy meeting” with Minister of Health Daniel Bahr and the health spokesmen of the other parties

Healthcare Policy

Because of the positive development of the job market the financial situation of the Statutory Health Insurance has turned around in 2012. What was feared to be a gap has turned into surpluses and reserves. Instead of passing a law on savings the government has decided to abolish the quarterly practice charge for medical appointments.

Strategy process medical technology

Last year medical devices were more in the focus of public and political perception than at any time before. The companies took a very positive view of the strategy process “Innovations in Medical Technology”, which was launched jointly by the Federal Ministries of Health, Economics and Research. The final report stresses the high capacity for innovation and the strong economic performance of the industry. The report, which was developed by more than 150 experts from science, business and the authorities, makes clear recommendations for action. Its goals are:

- to increase the competitiveness of the medical technology industry,
- to extend the capabilities of the healthcare system,
- to boost the innovative capacity of medical technological research.

It is important that politics and industry together implement the recommendations as soon as possible regardless of the elections to the German parliament in 2013.

Healthcare policy activities of BVMed

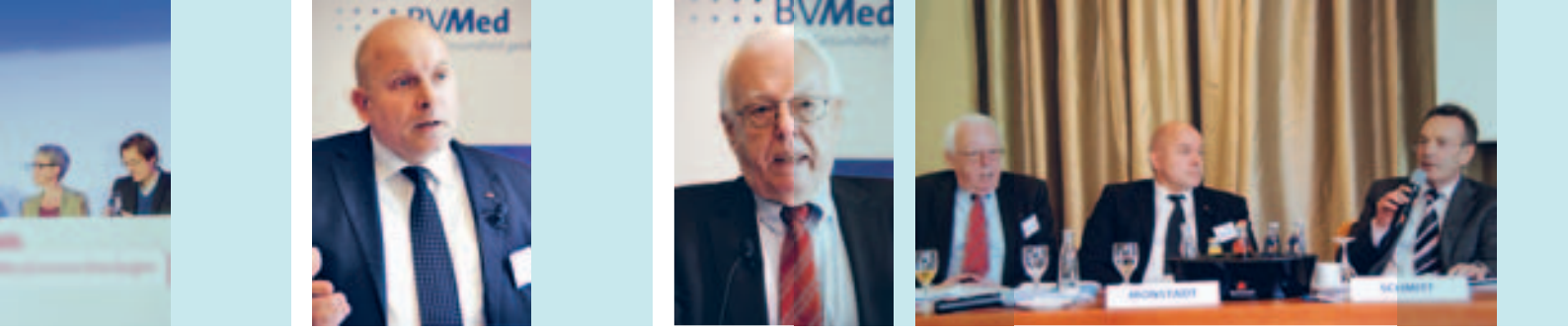
One year before the parliamentary elections BVMed is in the favorable position of being in regular contact with the German parliament, the office of the Chancellor as well as the Ministries of Health, Economics and Research. The association organized the round of health talks “Gesprächskreis Gesundheit”, breakfast meetings as well as several events at the German Parliamentary Society (Deutsche Parlamentarische Gesellschaft). Moreover, BVMed was actively involved in hearings and expert discussions in the parliamentary health committee. Another element of the association’s healthcare policy was the new early fall healthcare policy meeting, the BVMed-Früh-Herbst-Treff 2012. The German Federal Minister of Health Daniel Bahr, who was the keynote speaker, issued his clear support of the innovative power of the medtech sector. “We want to ensure continued free access to innovations in the healthcare system. We need advances in medical technology.”

Negative campaign of the federations of the Statutory Health Insurance funds

The medtech industry takes a very critical view of the campaign initiated mainly by the Federal Association of the Statutory Health Insurance Funds and the Federal Association of the AOK, which discredits all medical devices as dangerous and unsafe. These generalizations unsettle patients, when what is needed is analyzing and improving the quality of care together with physicians and companies.
The endoprosthesis register is a positive example of joint activities. It is supported not only by the professional organization of orthopedists and BVMed, but also by the Federal Association of the AOK and the Association of the Substitute Statutory Health Insurance Funds, Verband der Ersatzkassen (vdek), and funded by the Federal Ministry of Health. Representatives of BVMed companies are actively involved in its steering committees. Together with a IT service provider the endoprosthetics companies have developed the product database and entered the relevant product data. Hospitals can now access endoprosthetics data via a barcode scanner. The joint quality improvement project is on its way.

BVMed goes Brussels

A major focus of the association’s political activities is on the revision of the European regulatory framework for medical devices. As part of our European political program “BVMed goes Brussels” we organized several evening debates about the new EU Directive with the German community in Brussels working in the European parliament and administration. Also, several background meetings and talks with members of parliament took place. In close consultation with our European umbrella association Eucomed we will continue to closely accompany this process. Our guiding idea is: “Retaining proven practices – modernizing what needs to be changed.” Improvements can be achieved in appointing and monitoring the Notified Bodies in order to attain a uniformly high quality in Europe.



BVMed-Conference for trial regulation and benefit analysis with member of parliament Dietrich Monstadt and former JFC-chairman Dr. Rainer Hess

Health Services Research and Benefit Analysis

Trial regulation for new medtech methods

The German care structure law, Versorgungsstrukturgesetz, introduced a new instrument for testing examination and treatment methods with medical devices as of January 1st, 2012. These are conducted by the Joint Federal Committee (JFC). During the year the JFC code of procedure was adapted and details of the new regulation were decided.

The trial regulation is meant to make innovations available to patients more easily. It provides the JFC with the opportunity of testing promising innovative medical technologies for a limited period of time under structured conditions with scientific monitoring. It is hoped that this will accelerate the consultation process during the assessment of methods and facilitate the decision about the proof of benefit. Access to the trial regulation can be granted through the assessment of methods conducted by the JFC if the benefit of a method has not been sufficiently demonstrated. Alternatively, the manufacturer of a new medtech method can apply to the JFC to have the method tested. New rules were needed to give concrete form to the process.

Hearing on JFC code of procedure

BVMed was actively involved in both hearings taking place at the JFC in order to amend the code of procedure. By December 2012 the amendments of the code of procedure, the application procedure and the attending cost regulation were passed. After authorization by the Federal Ministry of Health the procedure can be used. From the point of view of BVMed, however, the existing decisions still need to be improved. There are considerable doubts as to the lawfulness of the code of procedure in its present form.

- The code of procedure contains too many vague legal terms making it impossible to judge its exact impact.
- The term “method” is not clearly distinguished from the medical device which is tested together with the method.
- The term “potential” has not been clearly defined and criteria for the evaluation of the potential are missing.
- There is no legal justification for the repayment obligation of the manufacturer after the procedure has been completed successfully.
- Competition problems arise from involving manufacturers, e. g. when other manufacturers enter the market with the method.
- There are uncertainties regarding the assignment of the evaluations to scientific institutions, e. g. the relevant manufacturers are not granted any rights of participation.

Moreover, the time line is entirely unclear, especially regarding the cost reimbursement in the outpatient sector after the successful trial. Legal clarifications are needed in order to ensure fast reimbursements for medical devices.

BVMed cooperation in the JFC consultation process

The SHI care structure law (GKV-Versorgungsstrukturgesetz) contains fundamental changes regarding the involvement of the medical devices industry and its associations in the JFC consultations. This applies in particular to the assessment of methods. The JFC has included BVMed as the leading association of medical device manufacturers, which was formed to represent their economic interests, into the group of organizations entitled to submit comments. BVMed will support its members during the guideline consultations if necessary.

HTA board of trustees of the DIMDI

BVMed has been appointed a permanent guest member of the HTA board of trustees of the German Institute of Medical Documentation and Information (Deutsches Institut für Medizinische Dokumentation und Information, DIMDI) and is actively involved in the consultations of the board. It assists with the consultation about the choice and evaluation of medical technological procedures and products for the qualification of an HTA procedure and the further development of the selection process.

Moreover, at the initiative of BVMed and other representatives of the healthcare industry, an industry advisory council within the network for health services research was formed. This is meant to ensure that the expertise of the medical devices industry will be considered in the debate about the further development of the health services research.


Endoprosthetics: Doctor-patient-talk about hip and knee replacements

Hospitals and the DRG System

Hospital financing and rising number of cases

In the tenth year after the introduction of the German DRG system the development of case numbers in German hospitals was at the forefront of debates about the system. Health insurance funds argued that a major part of rising numbers were due to wrong economic incentives, e. g. in implant treatments such as endoprosthetics, spine surgery and cardiology. Hospitals and physicians' professional organizations, however, justify the rising numbers with demographic developments and medical technological progress. In fact, regarding hip and knee joint replacements and some areas of cardiology, the development of services is stagnating or even decreasing. In addition, new and gentler procedures, such as the catheter-assisted aortic valve replacement, allow the treatment of patient groups who could not be operated on before.

Due to the rising number of cases, by law, remuneration for additional cases has been capped or cumulatively cut for two years while at the same time the remuneration system was introduced into psychiatric care. Moreover, the self-governing structure of the healthcare system has been asked to investigate the problem of additional numbers through commissioning scientific research, and to develop solutions. The results should be presented already in 2013.

Benchmark to supersede base salary development

From 2013 the benchmark, which was determined by the Federal Statistical Office in 2012, will be used for the price development of the basic case values for the first time. The benchmark is comprised of retrospective data of the developments of the labor costs and the costs of materials, including medical devices. The benchmark will replace the link to the base salary development, which has been in place so far. This will ensure that the cost structures and the developments of hospitals will be considered more properly. The value of 2.0 percent, which was determined for 2013, does not solve the problem of inappropriate reimbursement in the eyes of the hospitals. From the point of view of the hospitals the classification of data needs to be improved. Therefore, it can be expected that the price pressure on the manufacturers of medical devices by hospitals and their purchasing organizations will remain in place and affect medical care with high-quality medical devices.

Further development of the G-DRG system and the procedure for new examination and treatment methods

Contrary to the previous year, the parties to the self-governing structure of the healthcare system agreed on the DRG system 2013 consisting of the DRG catalog and the regulations for payment. In its tenth year of use the system is being further developed in a more nuanced way and reorganized. The numerous suggestions made for its further development, which were also submitted by BVMed, will form the basis for the adjustments. Hospital participation in the calculation is on the same level as in the previous year. The number of case groups is slightly lower while the number of additional remunerations, especially for medical technologies, will be increased.

The representation of new examination and treatment methods remains a problem. The integration of procedures with new examination and treatment methods using medical technologies into the case fee catalog or the additional remunerations is decreasing. The reason is that often there is no basis for their calculation because the new examination and treatment methods are not negotiated in a timely manner or not at all by the local cost-bearing institutions. Talks with the regional hospital associations in the federal states show that agreements on new examination and treatment methods are implemented in very different ways. The obstacles mentioned are legally different evaluations of the procedure concerning the new examination and treatment methods and the fact that the cost-bearing institutions link remuneration to irrelevant requirements for the evaluation of methods. The integration of new medical technologies into regular care also continues to be a problem.

Care with medical technical aids: Wound care, incontinence care, artificial nourishment and stoma care

Medical Technical Aids

Current developments in the area of medical technical aids

The current legal framework for medical technical aids has been in place for more than four years. Those involved have used this time to adapt their process and care structures appropriately and to adjust to the new market conditions such as contractual obligations and the prequalification.

SHI expenditure on medical technical aids has risen moderately over the first three quarters of 2012, compared to 2011, by 140 million euros to 4.74 billion euros. In view of these developments many health insurance funds are looking for ways of minimizing these high costs when they conclude contracts, e. g. by price cuts. Some cost-bearing institutions do not shy away from circumventing the existing requirements. Some care providers, however, were quick to notice violations of the law early so that these could be addressed.

Price pressure rising to dangerous levels

Regardless of the correct implementation of the framework for medical technical aids, the cost or price pressure in some product segments has by now reached dangerous levels. Especially tenders, which are solely focused on the lowest price as a criterion for a decision, threaten to undermine the principle of benefits in kind in the long run and pose a risk to the medically necessary quality of care. With the increase in flat-rate remunerations the economic risk will shift more and more to the care providers. They in turn are trying to compensate for lower prices partly through savings affecting the product or service quality or the required number of products as well as through additional payments by the insured. These developments are especially marked in the supply with absorbing incontinence products, where the surcharge for patients is often already higher than the reimbursement by the health insurance fund. In addition, some cost-bearing institutions are putting out to tender even individual parts of a comprehensive supply chain or medical technical aids that require a high level of service, e.g. in decubitus care, regardless of the specifications made in the recommendations on the effectiveness of tenders. BVMed advises against this development and calls on politics to prevent it.

Implementation of prequalification (PQ)

Since the prequalification recommendation came into force, the Federal Association of the Statutory Health Insurance Funds has registered 33 prequalification bodies. There are around 53,000 care providers and 24,500 of those have obtained a prequalification (data as of January 15th, 2013). As the grandfathering rule will end at the end of 2013, BVMed is working closely with other associations of service providers and the Federal Association of the Statutory Health Insurance Funds to develop a feasible and quality-assured concept for obtaining a comparable qualification as a technical director. In addition, BVMed is actively involved in the prequalification advisory council and among other things supports the Federal Association of the Statutory Health Insurance Funds in solving problems as well as the introduction of a monitoring concept for the PQ bodies.

New laws for medical technical aids

The long-term care restructuring law (Pflege-Neuausrichtungs-Gesetz), which came into force on January 1st, 2013, also contains an amendment of article 33 of the Social Security Code V. After article 33, section 5, of the Social Security Code V, a new section 5a is introduced. According to this sub-section, proof in the form of a prescription by a contractual physician is only required if an initial or renewed medical diagnosis or decision about the type of therapy is medically necessary. The amendment is made against the background of a legal decision by the Federal Social Court, which decided that patient care with the help of medical technical aids at the expense of the Statutory Health Insurance does not necessarily require a prescription by a contractual physician. The new section 5a is inserted to clarify and regulate this point. According to the justification for the law a prescription by a contractual physician is not always necessary for the use of disposable medical technical aids that patients require permanently. From BVMed's point of view, specific contractual provisions for proving the medical necessity existed even before the legislation initiative. Therefore, it is not clear at the moment whether this change in the law will actually improve the current contractual and care situation of the insured persons.



Homecare: Homecare companies care for patients with medical technical aids, enteral nutrition and surgical dressings – at home and in nursing homes

Homecare

Role of homecare in medical care

Around 6 million people rely on care being delivered by homecare providers. Extrapolations conducted by BVMed find that this number will double to 12 million patients by the year 2050. The growing demand will not only lead to an expanding market, but will also make it necessary to use existing resources more efficiently. From the point of view of the cost-bearing institutions this means reaching a quality of care that is as good as possible for their insured patients at increasingly lower costs.

Development of the quality of care

In 2012, a rise in the number of tenders could be observed. Although the health insurance funds are clearly trying to increase the quality definitions in their tender documents, a gradual loss of quality can be noted. Among other things, this is caused by the lack of regard for quality standards when awarding contracts. In addition, there is a lack of control of the agreed contents of contracts by the health insurance funds.

Some contracts based on article 127, section 2 of the Social Security Code V, also lead to distortions in care. Some Statutory Health Insurance funds use their market power and do not always negotiate with care providers on an equal footing. The contractual obligation to provide care to those insured with the Statutory Health Insurance funds furthers this development. Therefore, some care providers who fear that they would not be able to participate in the market anymore sign contracts containing clauses and price levels that they can hardly comply with or can only do so insufficiently. The resulting consequences must be born by the patients who receive either insufficient advice or care or sometimes have to pay for the care they desire themselves.

In some product areas the care providers can no longer bridge the gap between the increasingly lower contractual prices and the quality standards demanded by the health insurance funds.

BVMed works towards fairness between the contractual partners in order to enable genuine contract negotiations. To ensure the quality of care, BVMed considers it important that the Federal Association of the Statutory Health Insurance Funds implements the legal requirement for establishing the same standards of care all over the country in a timely manner. If necessary, a clear deadline should be set by law.

Strengthening homecare

The information campaign “Outpatient Perspectives” (Ambulante Perspektiven, *www.perspektive-homecare.de*), organized by the BVMed-homecare companies, aims at highlighting the image and the importance of homecare in the healthcare system. Started in 2011, the campaign addresses those in the healthcare system who decide about homecare services. The activities were continued successfully in 2012. The forum on medical technical aids at the exhibition for eldercare ALTEN-PFLEGE Messe in Hannover and that at the REHACARE fair in Düsseldorf also contribute to raising awareness for these issues. The expert lectures, panel discussions and the communication with all those concerned, such as the association of primary care physicians, which BVMed organized, were a great success.

German electronic health card

The electronic health card is being issued nationwide. After some initial troubles during the last years the project is progressing, despite continuing resistance from citizens, IT experts, data privacy advocates, pharmacists and physicians. Over 70 percent of those insured with the SHI have already been provided with an electronic health card. During trial phase I, which is planned for the second quarter of 2013, the update of the master data of the insured persons, a qualified electronic signature as well as the general suitability of the card for practical use will be tested. Only after this phase has been finished will it be possible to start the online rollout during which the physicians’ and dentists’ practices will be connected to the telematics infrastructure. Following this, trial phase II will be started, during which the potential applications of the electronic health card will be tested. These include emergency data management, secure communication between care providers or data migration from health data services to the telematics infrastructure, for which the example of the electronic case file will be used.

18th BVMed-Conference for the "Medical Devices Act":
Erik Hansson of the EU Commission, Dr. Matthias Neumann of the Ministry of Health, Dr. Wolfgang Lauer from the Federal Institute for Drugs and Medical Devices

Medical Devices Legislation

Proposal for an EU Medical Devices Regulation

In 2012, the further development of the European medical devices legislation was at the center of interest. The Directives 90/385/EEC (active implants) and 93/42/EEC (other medical devices) are to be integrated into one joint EU Medical Devices Regulation (MDR), which will directly come into force in the EU member states without being transposed into national law. Also the Directive 98/79/EC (in-vitro diagnostic medical devices) will be transferred into an EU regulation. Both proposals for new regulations were presented to the European Commission at the same time on September 26th, 2012. The new law will not come into force before 2017.

The political and media interest in the new regulatory framework for medical devices was boosted by the so-called PIP scandal, the debate about the abrasion of metal hip implants and reports by the British paper Daily Telegraph about the alleged corruption of Notified Bodies in Eastern Europe.

The proposal made by the EU Commission contains the introduction of new control procedures and mechanisms in order to improve the notification as well as the surveillance of Notified Bodies in the medical devices sector. An important suggestion is that notified bodies "should" (earlier "can") conduct unannounced audits of manufacturers.

Another focus is on the improvement and alignment of the market surveillance concerning medical devices by national authorities. The introduction of a Unique Device Identification (UDI) System is planned to facilitate market surveillance by improving the registration of products and the recording of further data via the European databank "Eudamed".

From a German perspective we welcome most of the planned measures, which reflect the standards already applied in Germany, e.g. the introduction of a "qualified person" (in Germany a security officer for medical devices), the appointment of Notified Bodies according to consistent rules and the surveillance of Notified Bodies by accompanying observed audits.

Immediate actions in 2013?

The proposed EU Regulation is accompanied by a comprehensive catalogue of immediate actions drawn up by the EU Commission. These should be implemented by 2014. In a letter to EU Health Commissioner Tonio Borg, BVMed called for restricting the immediate actions to the core issues: Notified Bodies and market surveillance, and implementing these in 2013 already in order to reduce the tension that has developed in the European market.

We regard the high number of 60 implementing acts contained in the proposal as a threat to the principle of subsidiarity, because these could lead to the erosion of the sovereignty of national lawmakers.

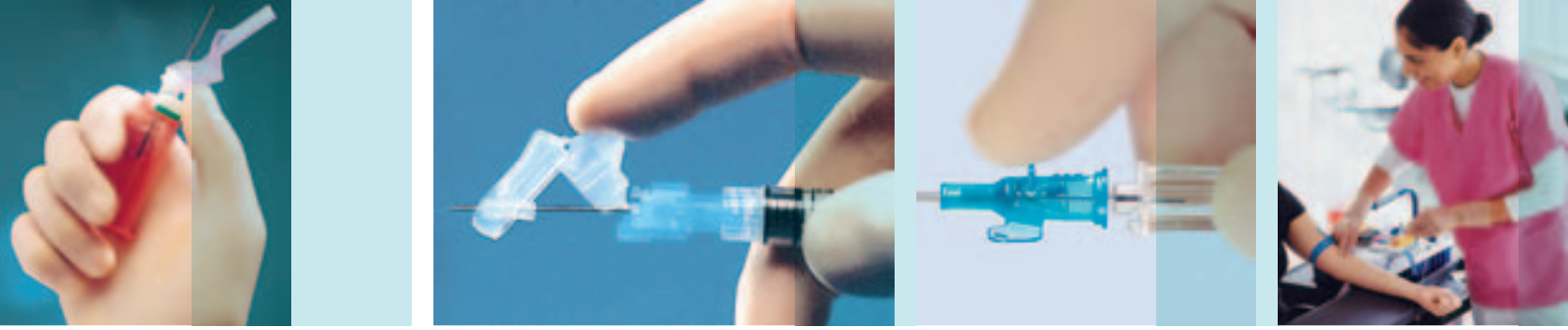
Retaining proven practices – modernizing what needs to be changed

From BVMed's point of view the legal regulations are absolutely sufficient in order to manufacture safe and effective medical devices and place them on the market. BVMed rejects mandatory official pre-market approval, since it would neither increase patient safety nor accelerate market access. Improvements can be achieved in notifying and monitoring the Notified Bodies so as to attain a uniformly high quality in Europe. Furthermore, all Notified Bodies should be re-notified by a new committee that consists of representatives of the Commission and the member states. From the perspective of BVMed there is no deficit of regulations regarding medical devices, but a deficit of implementation. Therefore, better controls of manufacturers and the market by Notified Bodies and competent authorities are necessary.

National law

The Second Law Amending Regulations on Medical Products and Other Regulations ("Zweites Gesetz zur Änderung arzneimittelrechtlicher und anderer Vorschriften") came into force on October 26th, 2012. The most important amendment of the Medical Devices Act (Medizinproduktegesetz, MPG) concerned the belated national implementation of the amending Directive 2007/47/EC insofar as it regulates the legal difference between medicinal products (pharmaceuticals) and medical devices.

The difference is drawn on the basis of their main mode of action (pharmacological versus physical/chemical) and not their outward appearance.



Safety devices to avoid needle stick injuries

Patient, Occupational and Environmental Safety

Protection of patients

Hospital infections: Around a third of the estimated 600,000 hospital infections and therefore several thousand deaths from nosocomial infections each year could be avoided, recent calculations show. In 2011, the amendment of the Infection Protection Law (Infektionsschutzgesetz) initiated a number of measures which are only slowly taking effect, e.g. improved diagnosis, the appropriate use of antibiotics and the consistent treatment of infected patients in the course of MRSA sanitation. MRSA can cause a number of typical hospital infections such as wound or urinary tract infections and pneumonia. Especially uncritical use of antibiotics has contributed to the strong increase in these bacteria in the 1990s. In certain cases MRSA sanitation is now reimbursed in practice-based care. The range of products used (drugs, medical devices, cosmetic products) that will be reimbursed may be known during the course of 2013.

Reprocessing of medical devices: Infections can also be caused by improperly reprocessed medical devices, i. e. reusable or single-use devices that are reused despite the manufacturer's specification as a single-use device. A European body that conducted a scientific assessment in 2010 found that there is a potential infection risk in medical devices which cannot be reprocessed and sterilized. The new European legislation on medical devices should lead to more patient safety in this matter. The draft of the "Medical Devices Regulation" (MDR) of September 2012, therefore, specifies the following measures: regulation of the reprocessors of single-use devices similarly to manufacturers and a ban of the reprocessing of surgically invasive devices while providing for exceptions for certain product groups if, based on scientific evidence, the commission has listed these products. In the interest of the protection of public health the member states will be able to ban reprocessing.

Occupational health

Needlestick injuries: By May 2013 the Directive 2010/32/EU on the prevention from sharps injuries in the hospital and healthcare sector must be implemented into national law. In Germany this will result in changes of the Biological Materials Act and, more specific, of the Technical Rule for Biological Materials in the healthcare sector, TRBA 250. So far, the conversion from conventional to safety devices is still unsatisfactory in some areas, e. g. in connection with injections in the hospital as well as especially the ambulatory sector.

Employee protection in medtech companies: Regularly, employees, e. g. field staff or those receiving goods, handle used medical devices of unknown contamination status during the maintenance of machines or when dealing with returned goods. How can the proper pretreatment of products be ensured? What does a risk assessment at the customer's premises consist of? Which measures must be taken to protect employees? The new working group "Occupational Safety and Health Protection for Employees of Medical Technology Companies" (Arbeits- und Gesundheitsschutz für die Mitarbeiter von Medizintechnik-Unternehmen), which was formed in 2012, will develop answers to these questions.

Environmental protection

The environmental challenges in 2012 concerned mostly the ban of certain substances as well as information and labeling obligations. With the amendment of the RoHS Directive on the avoidance of hazardous substances in electrical and electronic equipment, on July 22nd, 2014 the ban of lead, mercury and other substances will cover medical devices as well. Moreover, old devices that have already been on the market but do not conform to the Directive may not be distributed for further use from July 22nd, 2019. By 2012, 138 substances had been entered into the so-called "candidate list" (*http://echa.europa.eu/candidate-list-table*) of substances that the Chemicals Regulation REACH classifies as particularly alarming. Once a substance is listed, the supplier of a product that contains this substance in a concentration above a limit of 0.1 percent by mass must inform his commercial customers.

13th BVMed-Media Seminar in the House of the Federal Press Conference (Haus der Bundespressekonferenz)

Communication and Media Work

Measuring by the Human Standard. Medical Technology.

Providing information about the importance and value of medical technology remains an important task of BVMed: for the public, for healthcare, for the economy as a whole. This is necessary because knowledge about this highly heterogeneous industry and its characteristics is still too limited. An important element of the BVMed public relations work is the information campaign "Der Mensch als Massstab. Medizintechnologie" (Measuring by the Human Standard. Medical Technology.) (*www.massstab-mensch.de*), which was started in 2010. With its sophisticated esthetics, large posters and unusual magazines the campaign is breaking new ground in the medtech industry. On the website an "animated human" provides information about innovative medical technology and a map of Germany presents the research and manufacturing locations of the industry.

Film service and Aktion Meditech

Medical technological progress, an aging population, new information technology: comprehensible and up-to-date patient information is becoming more and more important against this background. BVMed has accepted this challenge for years with the medical technology film service "Filmservice Medizintechnologie" (*www.youtube.de/medizintechnologien*) and the network of physicians, patient groups, organizations and industry Aktion Meditech (*www.aktion-meditech.de*) – in both cases working closely together. The new film topics for instance deal with incontinence care or neurostimulation in epilepsy and severe migraine. With its own channels on youtube, sevenload and myvideo and a cooperation with doccheck, the film service reaches a wide audience. On the social media channels alone, the BVMed films were watched around 106,000 times in 2012. In addition, the film material is presented on a number of TV channels.

Social media and medical technology

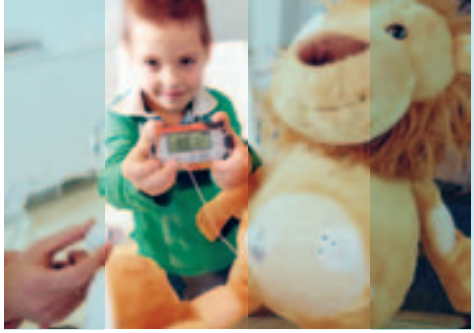
Social networks have become an important element for communication work of the medical technology industry. BVMed makes use of the opportunities that social networks offer, e. g. via its own twitter channel (*www.twitter.com/bvmed*) and a Facebook presence (*www.facebook.com/bvmed*). The BVMed website (*www.bvmed.de*) offers ten RSS feeds for different topics in order to provide more targeted information. The social media activity is closely linked to the website and the "classical" instruments of communication. How do increasing digitization and the mobile internet change corporate communication and marketing? This was the focus of the eighth BVMed communication congress for medical technology, which took place in Cologne in June 2012. In addition, the BVMed communications department organizes one-day seminars about online communication and social media strategies for companies.

Media work and the world of images

The "classic" media such as newspapers and magazines will remain important for communication work. Through continuous media work, BVMed was able to assure that around 1,200 articles mentioned BVMed in various print media and the accompanying portals in 2012. These reach over 110 million readers and have an advertising value equivalency of almost 2.6 million euros. The weekly BVMed newsletter with over 8,000 subscribers remains an important feature of the medtech industry. The other areas of media work are press conferences, the yearly media seminar as well as press releases, background services, guest articles and industry reports in German and English. Furthermore, the BVMed communications department organizes one-day seminars about media work, patient communication, crisis management as well as marketing strategies.

eHealth

Another important aspect is linking the healthcare industry electronically through eHealth. The eHealth conferences organized by the BVMed communications department have become yearly industry gatherings. Around 150 participants attended the fourteenth eHealth conference in February 2012. For the medical technology companies the focus is on electronic processes with the large medical devices customers: hospitals and medical institutions or retail. Using many examples from industry and hospital practice, the 15th eHealth conference in February 2013 presented the strengths and weaknesses, the opportunities and challenges of the "e" projects within the healthcare industry.

Diabetes: Insulin pumps and continuous glucose monitoring for children with diabetes

Reports from the BVMed Expert Committees

BVMed offers its members over 60 focus groups, sectoral interest groups and working groups, which function as a platform for constructive dialog and exchange, leading to the joint formation of opinions.

Focus groups deal on a continuous basis with issues of general concern to all members, irrespective of their particular products.

Sectoral interest groups consist of members working in a specific market or product area, who wish for additional representation of their particular specialist interests.

Working groups are committees set up on a temporary basis to deal with a specific subject and provide expert support to the Board of BVMed and the management team in this particular field.

A complete list of the groups of BVMed can be found at: *www.bvmed.de (About BVMed)*.

FOCUS GROUPS

Focus group "Hospital Market" (AK KHM)

The AK KHM provides a communication platform where joint projects and activities as well as legal matters concerning the buying process of medical technologies in the hospital market can be discussed. Moreover, the BVMed focus group functions as a contact point for hospitals on behalf of the medtech companies and brings together the industry-specific questions about the buying process. Together with the relevant purchasing organizations it discusses market requirements and process optimization during the buying process. The focus group is also in intensive dialog with the purchasing organizations about these issues.

Focus group "Legal Affairs" (AKR)

The AKR and the lawyers of the associated "Network Medical Devices Law" answer questions concerning legal matters from the BVMed working committees. To this end the AKR has formed twelve working and project groups.
The AKR is in charge of editing the BVMed loose-leaf commentary "WiKo – Medizinprodukterecht" interpreting the medical devices law, which was published in December 2012 in its eleventh edition. The commentary is accompanied by the blog *www.wiko-mpg.de*, which at the moment lists over 312 court decisions about medical devices linked to keywords. These court decisions are published immediately and independently of the printed commentaries and would otherwise not be published at all. A new focus of the AKR is on the data protection law as well as on drafting recommendations for manufacturers about how to react to improper uses of their products on the market.

Focus group "Regulatory and Public Affairs" (AKRP)

The AKRP answers questions concerning regulatory matters from the BVMed working committees. To this end the AKRP has formed nine working and project groups. The traditional focal topics are market surveillance and performing clinical investigations, to which has been added the assessment of the proposal for an EU Medical Devices Regulation. The focus group is in charge of the BVMed serial information "Medizinprodukterecht" (Medical Device Legislation), comprising ten guidelines on different regulatory matters. The AKRP will, like the AKR, organize two information events in 2013 (program at *www.bvmed.de/events*).

Focus group "Environment" (AKU)

From July 22nd, 2014, the ban of substances in electrical and electronic equipment will apply to medical devices as well. At the same time the "candidate list" of substances of very high concern of the REACH Regulation will be updated continuously. In view of the information deficit that has been found in the supply chain regarding the composition of pre-products and raw materials, the AKU functions as an early warning system which will make timely decisions easier for manufacturers in case of an impending ban or a restriction of substances. Other focal topics of the AKU were the European hearing in connection with the proposed "green buying" of medical devices, the amendment of the waste legislation and the implementation of environmental and social standards within the companies.

Cardiology: Cardiac pacemaker, implantable defibrillators and telecardiology monitoring of patients with pacemakers

SECTORAL INTEREST GROUPS

Sectoral interest group "Eye Surgery" (FBA)

Since January 1st, 2012, the so-called additional cost regulation for innovative intraocular lenses has been in force. This allows patients to have an innovative intraocular lens with additional functions implanted without having to bear the entire costs for the operation and the lens themselves. They only pay for the additional costs which exceed the health insurance fund benefit for a standard operation. The implementation of this regulation should have been specified in the Uniform Value Scale by the end of October 2012. Even in early 2013, however, there has been no result of the consultations. In the course of the "Cataract Initiative" (*www.initiative-grauer-star.de*), the manufacturers of intraocular lenses within the FBA intend to provide a comprehensive information package to eye specialists in order to allow them to broaden their knowledge about intraocular lenses with additional functions. As soon as clarity about the implementation of the additional cost regulation has been ensured the initiative will spread the relevant information through publications and trainings.

Sectoral interest group "Brachytherapy" (FBBT)

The working group Seeds / Prostate Cancer of the sectoral interest group FBBT supports the permanent inclusion of this technology into the SHI service catalogs. During the current JFC evaluation process the working group coordinates and guides the statements from the industry.

Sectoral interest group "Diabetes" (FBD)

During the Geriatric Care trade fair in Hannover in 2012, the FBD organized talks on – amongst other things – aspects of care in diabetes therapy and needlestick injuries. The FBD will continue this type of public relations work at the diabetes trade fair in Münster in spring 2013, where it will also present the issue of integrated diabetes management.

Sectoral interest group "Diagnosis Related Groups – Hospital Financing" (FB DRG)

The FB DRG actively accompanies the further development of the G-DRG system, focusing especially on the appropriate representation of medical technologies. It coordinates the BVMed suggestions for the further development of the DRG and the procedure classification OPS and communicates them to the relevant institutions (DIMDI, InEK). The FB DRG also draws up statements and position papers on legislative processes concerning medical technology.

Sectoral interest group "Endoprosthetics – Implants" (FBEI)

In order to improve the care and outcomes quality, the FBEI has created an entire product database, which is a significant part of the Endoprostheses Register Germany (EPRD). Together with the settlement data of the health insurance funds and the quality assurance data of the hospitals this database will make it possible to provide information about the quality of endoprosthetic care. If there are any irregularities, patients can be identified by decoding their pseudonymous data. Representatives of the sectoral interest group are working jointly with representatives of the professional organizations, the Federal Association of the AOK, the Association of the Substitute Statutory Health Insurance funds and the Federal Office for Quality Assurance BQS on the executive committee of the Endoprostheses Register Germany (EPRD), in order to establish mechanisms for the evaluation of the data collected. After the pilot phase has been finished successfully, the roll out of the register will start in 2013.

Another important issue for the sectoral interest group was the improvement of congresses with regard to content and expertise and their compliance with regulations. In this the group cooperated with the professional organizations. In addition, the FBEI carried out a great amount of public relations work such as interviews, press releases, films and discussion sessions with politicians, which happened against the background of negative press and television coverage of endoprosthetics. The FBEI always stresses that there are several factors that play an important role in successful operations, namely three important elements that must work together: a good device, an operation that is carried out professionally and last but not least the patient's behavior that is conducive to therapy success.

eHealth: Blood sugar measurement and doctor consultation with iPhone-app

Sectoral interest group “First-Aid Material” (FBEH)

The FBEH is the interest group of the manufacturers of first aid materials and kits, e.g. for cars and businesses. Its members campaign for the continuous adjustment of first aid materials according to the latest findings of modern emergency and disaster medicine. A core topic discussed will continue to be the question of how an increasing need for hygiene of the public can be answered more effectively. The working group “Communication” (AGK) of the manufacturers of first aid kits for cars will continue its press work regarding the manifold uses of the first aid kit in 2013.

Sectoral interest group “Health Technology Assessment” (FB HTA)

The FB HTA discusses and develops methods and suggestions for procedures regarding benefit analysis and health services research with medical technologies. It accompanies the development process of the new trial regulation in the JFC and develops suggestions on the code of procedure, also in cooperation with other associations. During the National Strategy Process for Innovations in Medical Technology the specific factors regarding the benefit analysis of medical devices are discussed with the companies involved from the interest group. The FB HTA works on the content of the statements for the HTA board of trustees of the German Institute of Medical Documentation and Information and develops concepts for seminars and conferences on the assessment of technology.

Sectoral interest group “Homecare” (FBHC)

The FBHC is concerned with stressing and strengthening the role and importance of homecare in outpatient care in Germany. The information campaign “Outpatient Perspectives” (Ambulante Perspektiven, *www.perspektive-homecare.de*), organized by the homecare companies in BVMed, uses interviews and initiatives to address decision makers in the healthcare system. This is intended to increase the awareness level and the recognition of the sector. In addition, the FBHC played an active part in the BVMed medical technical aid forum at the Geriatric Care trade fair in Hannover in 2012.

Sectoral interest group “Cardiac Medical Devices” (FBKMP)

The FBKMP focuses on medical technology which is used in cardiovascular treatments and examinations. Working groups and projects within the sectoral interest group focus on the areas of active implants (cardiac pacemakers, ICD-CRT systems, telecardiology), interventional technologies (stents) as well as interventions through heart surgery such as prosthetic heart valves, cardiopulmonary systems and artificial hearts. A product database for active stimulation technologies (*www.herzstimulation.info*) is offered to the users of these technologies. An exhibitor’s advisory council coordinates the cooperation with professional scientific bodies such as the medical and other professional organizations.

Sectoral interest group “Artificial Feeding” (FBKE)

The FBKE campaigns for the medically necessary and appropriate supply and reimbursement of medical enteral nutrition. In fall 2012 the FBKE together with the Diätverband, the Association of the Manufacturers of Foods for Special Dietary Use, organized a symposium of the Competence Network Enteral Nutrition, (Kompetenznetzwerk Enterale Ernährung), during which the categorization system developed by an interdisciplinary group of experts was presented to the public. During the Geriatric Care trade fair in Hannover in 2012 a forum on care competence in nutritional medicine was held. More aspects of enteral nutrition will be presented at the homecare fair in Leipzig in 2013.

Sectoral interest group “Benefits Law for Care Providers” (FBLL)

The FBLL actively deals with the current frameworks and new proposed legislation. It supports BVMed in drawing up law interpretations and statements. The main focus of the FBLL was on the analysis of the German Care Structure Law, Versorgungsstrukturgesetz (VStG), especially articles 127 and 128 of the Social Security Code V (SGB V), on the implementation of the prequalification, the necessity of presenting the issue of data protection as well as the impacts of the planned 8th amendment of the Law against Restraints of Competition (Gesetz gegen Wettbewerbsbeschränkungen, GWB).

Artificial heart: Life-saving cardiac support system for children with a heart condition

Sectoral interest group “Mechanical Thrombosis Prophylaxis” (FBMT)

Last year, the FBMT focused increasingly on public relations regarding the issue of the benefits and importance of using mechanical thrombosis prophylaxis alongside drug-based therapy. This included talks with various medical experts and, at the German Congress for Orthopedics and Trauma Surgery, a satellite symposium on the topic of “Thrombosis Prophylaxis Stockings – Protection or Risk?”. Several experts discussed the use of antithromboembolic stockings in hospitals. The group will continue its educational work.

Sectoral interest group “Modern Wound Care Products” (FBMW)

The FBMW is concerned with all topics associated with modern wound care. The sectoral interest group has developed a number of information publications and organizes events as well as training sessions. In addition, the FBMW, together with some representatives of health insurance funds, organized and held a workshop on the topic of improving access to care for chronic wounds in Germany.

Sectoral interest group “Needlestick Prevention” (FBNSP)

The manufacturers of safety devices in the FBNSP discussed how to raise awareness of the dangers posed by sharp medical devices in employers and employees of medical institutions. For this purpose, they addressed experts of occupational safety and industrial medicine. By May 11th, 2013 the European Directive on the avoidance of sharps injuries in the hospital and healthcare sector must be implemented. In Germany this will happen through the amendment of the Act on Biological Materials. The FBNSP wrote an extensive statement regarding the drafted amendment and took part in the hearing. The FBNSP also accompanies the adjustment of the Technical Rule for Biological Materials in the health care sector, TRBA 250, which is happening at the same time.

Sectoral interest group “Renal Replacement Therapy” (FBNE)

The members of the FBNE aim to inform the public about the importance of the life-saving dialysis technology and the conditions necessary to carry it out. This has resulted in the “Kidney Alliance” (Bündnis Niere, *www.buendnis-niere.de*). Its aim is to ensure, in cooperation with associations of patients, dialysis centers, physicians and nursing staff, that patients who rely on life-saving dialysis will continue to receive the best possible care.

Sectoral interest group “Nosocomial Infections” (FBNI)

The FBNI has set itself the goal of highlighting the contribution of medical technology towards the prevention of infections in medical institutions. The focus of the work of the FBNI during the reporting year was on intensifying its web presence on the spread and prevention of nosocomial and treatment-associated infections (*www.krankenhausinfektionen.info*), commenting on and evaluating the results of the working group “MRSA Sanitation Treatment” for the Joint Federal Committee (JFC) as well as organizing the “BVMed Hygiene Forum” for the employees of medical institutions and representatives of the self-governing bodies and politics.

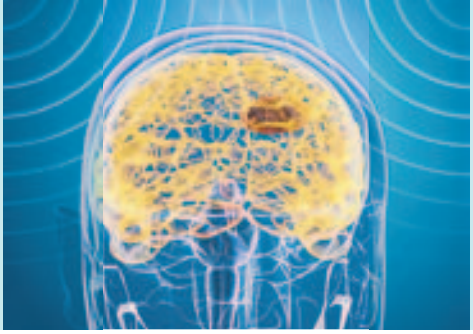
Sectoral interest group “Peripheral Vascular Medicine” (FBPG)

The FBPG is concerned with medical technologies in the peripheral circulatory system, e.g. PTA technologies and closure devices. Amongst other institutions it is in charge of a scientifically monitored register project on the treatment of PAOD with stent systems, called PTAREG, which BVMed coordinates. Together with the medical specialist bodies it discusses activities at specialist congresses, and with the help of exhibitor’s committees it coordinates congress activities.

Sectoral interest group “Absorbing Incontinence Care (Manufacturers)” (FBI-H)

The FBI-H focuses on the revision of the product group 15 for the area of absorbent incontinence helps in the register of medical technical aids. The sectoral interest group has made suggestions for a new testing method and developed the relevant adjustment of the classification of the product areas concerned. These have been submitted to the Federal Association of the Statutory Health Insurance Funds as a basis for discussion. Moreover, the

Neurostimulation for chronic migraines



Fighting cancer with nanomedical particles

Telemetric system for
intracranial pressure measurement (ICP)

FBI-H supports the Federal Association of the Statutory Health Insurance Funds in reviewing the fixed remuneration amounts by preparing the market analysis for absorbent incontinence products. In addition, it is strongly involved in looking at the care and contract situation for absorbing incontinence products. To this end it organized a round table talk with representatives of health insurance funds and old-age and residential nursing homes, which has resulted in a consensus paper on the use of absorbing incontinence products in nursing homes.

Sectoral interest group "Soft Tissue Repair Implants – Soft Tissue" (FB STRI)

The FB STRI represents the interests of the suppliers of implants for reinforcements of soft tissue. The group's aim is the discussion of the joint interests and needs for this type of product as well as the coordination of resulting activities, e.g. regarding reimbursement and aspects of quality. The group works especially on the therapy areas visceral surgery, gynecology and urology as well as plastic surgery. In the context of health services research the sectoral interest group accompanies the register project on hernias. The extension of health services research to new biological implants is in preparation.

Sectoral interest group "Spine Surgery" (FBSC)

The FBSC, which is concerned with medical technology for the spine, cooperates with the relevant medical specialist bodies in establishing and appropriately representing these technologies within the classification and remuneration catalogs. Also, it is concerned with developing instruments for health services research, e. g. register projects. Via BVMed the FBSC also functions as an advisory council of the German Spinal Column Society (Stiftung der Deutschen Wirbelsäulengesellschaft). In addition, an exhibitors advisory council as part of the professional societies is being established.

Sectoral interest group "Sterile Materials Care" (FBSV)

The FBSV is the main body for questions concerning the requirements of sterile products and their safe use. Specific topics are considered in the sectoral interest groups "Ethylene Oxide Sterilization" and "Radiosterilization" as well as in the working group for sterile packaging.

Sectoral interest group "Stoma / Incontinence Care" (FBSI)

The FBSI deals with the current situation concerning stoma and draining incontinence helps, patients' rights of choice as well as general conditions for the area of medical technical aids. At the end of 2011, the FBSI started a patient survey on the situation of care with draining incontinence products. Meanwhile the results have been evaluated and published. Moreover, the FBSI has developed and published contractual principles for draining incontinence care and dealt with the RKI guidelines "Recommendations for the Prevention and Control of Catheter-Related UrinaryTract Infections" (Empfehlungen zur Prävention und Kontrolle Katheter-assoziierter Harnwegsinfektionen), which it discusses with selected experts. It also supports the Federal Association of the Statutory Health Insurance Funds in reviewing the fixed remuneration amounts by presenting market relevant data records.

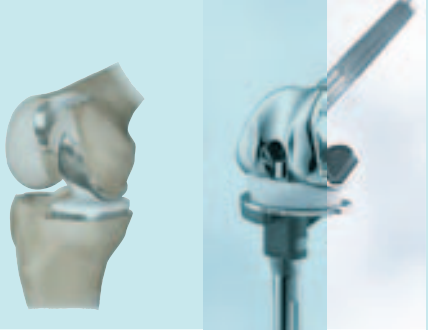
Sectoral interest group "Therapeutic Apheresis" (FBTA)

The members of the FBTA are companies that offer technologies for extracorporeal blood cleansing. One focus of the group's work is on the suggestion in the draft of the Medical Devices Regulation (data as of: September 2012) to move all devices used for apheresis to risk class III. The FBTA members are campaigning for an amendment, as they assume that the suggestion was made due to a lack of knowledge of medical technological procedures and the individual risk potential of the different devices.

Sectoral interest group "Tracheostomy / Laryngectomy" (FBTL)

The FBTL aims to communicate the importance and complexity of the different care needs of those patients who have undergone a tracheostomy and laryngectomy. The FBTL has prepared four specialist articles on this topic that have been published in various journals. All the articles that have been published so far can be accessed via the BVMed website (*www.bvmed.de/themen*). In addition, the FBTL is revising its brochures on the care for patients who have undergone a tracheostomy and laryngectomy. It is expected that the brochure "Recom-

Instruments for an exact positioning of a knee replacement



Knee replacement

Humerus-pin with screw-in-screw technology

mendations for the Care for Patients who Have Undergone a Tracheostomy" (Empfehlung für die Versorgung von tracheotomierten Patienten) will be published in October 2013. The brochure on the care for patients who have undergone a laryngectomy should be completed by the end of 2013. Another topic is the current development of medical technical aids and the relevant effects for patient care.

WORKING GROUPS

Decubitus Forum (DF)

The forum intends to make the public more aware of the issue of decubitus. The DF uses different instruments such as information material (brochures, information cards), press releases as well as the survey questionnaires for seating and rest aids. In addition, the forum has developed its own information platform, which was continually updated during 2012 with more reports and films (*www.dekubitus-forum.de*). The DF has also dealt extensively with the impact of tenders on the supply with medical technical aids for the prevention of decubitus. The DF is currently developing suggestions for the adjustment of product group 11 of the register of medical technical aids.

Project group "PVC" (PG PVC)

The PG PVC is concerned with the requirements for medical devices made of PVC, especially with the regulations and obligations for the use of PVC plasticizers such as DEHP, which result from the European chemicals and medical device legislation.

Project group "Reuse" (PG Re-Use)

The PG Re-Use deals with the reprocessing and reuse of medical devices, especially medical disposable devices. It welcomes the EU's intention to develop a uniform regulation for the reprocessing of single-use devices as part of the amendment of the European medical device legislation. The extensive statement of the PG Re-Use about the Joint Recommendation for Hygiene Requirements in Reprocessing Medical Devices (Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten), made by the Commission for Hospital Hygiene and Infection Prevention (KRINKO) of the Robert-Koch-Institut (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM), was hardly considered in the KRINKO / BfArM recommendation presented in 2012.

Project group "Tissues" (PGT)

The PGT is the body for the discussion of products that are manufactured using animal or human tissue, cells or blood. The main focus of its communication was on the revision of the TSE directive in the form of the Regulation no. 722/2012 of August 8th, 2012, dealing with special requirements for active implantable medical equipment and medical devices manufactured using animal tissue, as well as on providing information about advanced therapy medicinal products.

Working group "Occupational Safety and Health Protection for Employees of Medical Technology Companies"

The occupational safety working group was established twice in 2012. It consists of manufacturers from various product areas who are united by the aim of identifying the special characteristics of occupational safety and health protection for employees of medical technology companies. Ideally, they want to develop consistent recommendations for the implementation of safety measures.

Working group "eStandards" (AGE)

The AGE represents the BVMed members in the "Forum eStandards" made up of employees of hospital purchasing groups and companies. The forum aims to implement eCommerce on the basis of the standards for the classification of products and for the exchange of master and business data recommended in its "industry papers". Discussions with service providers and experts are meant to help especially small and medium-sized companies to use eBusiness in an effective way. To this end a training event for SME was organized in 2012 for the first time. BVMed is also a partner of the eCG project for standards supporting eCommerce in the healthcare system (Standards zur Unterstützung von eCommerce im Gesundheitswesen) funded by the Federal Ministry of Economics. Another focus of the AGE is on the concept of the UDI (Unique Device Identification), which should be introduced with the amendment of the European Medical Devices Law.

Spine implant

Fusion system for degenerative lumbar spine disorder

Treatment of vertebral body fractures with bone cement

Bone cement

BVMed: At Your Service!

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Prosthesis foot

Leg prosthesis

Patella orthesis

BVMed: Our Services for You!

BVMed represents more than 230 industry and trade companies. Among the members of the association are 20 of the largest medical device manufacturers worldwide in the consumer goods sector. Its scope comprises the entire sector of medical dressings, technical aids such as ostomy and incontinence products or bandages, plastic disposable items such as syringes, catheters and cannulae as well as the implants sector of intraocular lenses, hip, knee, shoulder and spinal implants, heart valves and defibrillators and even artificial hearts. Homecare services and biotechnology procedures, such as tissue engineering, are further fields of activity of its members.

As a trade association, BVMed promotes and represents the combined interests of the medical technology industry and trade companies. In various sectoral interest groups, focus groups, and working groups, the association offers its members a platform for a constructive dialog and exchange of views. BVMed represents the concerns of its member companies to policy makers and the public in general. This is achieved not only by information and public relations work, but also by participation in the development of laws, guidelines and standards. BVMed's services can be subdivided into four sectors:

1. Organization

BVMed carries out the joint formation of opinion in more than 50 committees covering specific subjects. You will find more information on the committees in this brochure starting on page 15. An up-to-date overview of BVMed's expert committees is available at *www.bvmed.de (About BVMed)*.

2. Consultancy

BVMed's experts are ready to offer accurate advice to members on such diverse topics as the Medical Devices Act, social legislation, the DRG law, the Act on Advertising in the Healthcare System, standardization projects, or ordinances.

3. Information

BVMed's multi-faceted information service is evident in both its internal and external communications. Examples of BVMed's communication efforts include:

INTERNAL COMMUNICATION

General circulars to all members, specific circulars for the individual Expert Committees, weekly newsletter, weekly chartpool, monthly report, Extranet for member companies.

EXTERNAL COMMUNICATION

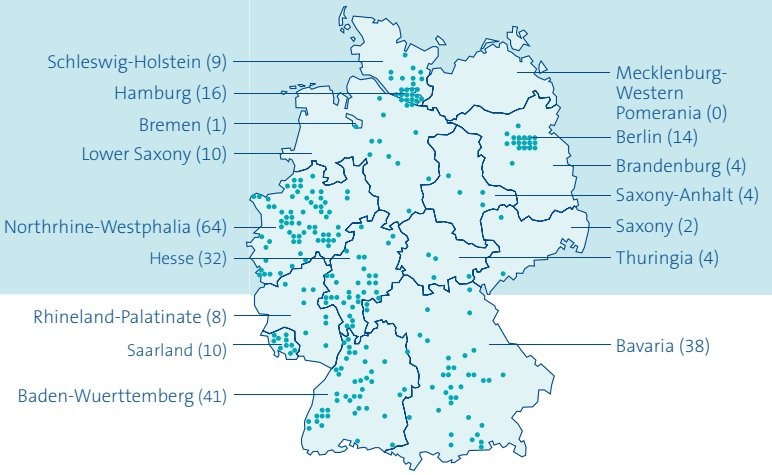
Website at *www.bvmed.de*, brochures, information cards, BVMed special events, Med**Inform** conferences, training seminars (medical device consultants, SHI training, workshops on bidding / tendering law and CRM topics), press releases and conferences, press seminars, TV service with film material, background discussions with the media and social media channels.

4. Representation

BVMed represents the interests of the medical technology sector. Important aspects of this work include political marketing and one-on-one interviews, the maintenance and support of networks, parliamentary discussion evenings, background discussions, participation in parliamentary hearings as well as representation in committees, advisory councils, commissions, etc.

How can your company become a member of BVMed?

The terms and conditions for membership of BVMed are stated in § 3 of the BVMed statutes, which you will find at *www.bvmed.de (About BVMed)* or receive from BVMed on request. Applications for membership must be submitted in a letter to the Director General of BVMed. Please contact us. We look forward to helping you!



Regional distribution of BVMed's member companies

As in March 2013: 234 members – current list available at *www.bvmed.de*

BVMed Member Companies

1stQ Deutschland GmbH & Co. KG
3M Deutschland GmbH – Health Care Business

aap Implantate AG
Abbott Vascular Deutschland GmbH
Abena GmbH
Abiomed Europe GmbH
Acandis GmbH & Co. KG
Actavis Deutschland GmbH & Co. KG
Advanced Medical Technologies AG
Aesculap AG
ALCON PHARMA GMBH
American Medical Systems Deutschland GmbH
AMO Abbott Medical Optics Germany GmbH
Andreas Fahl Medizintechnik-Vertrieb GmbH
ANM Adaptive Neuromodulation GmbH
Ansell GmbH
ArjoHuntleigh GmbH
ArthroCare (Deutschland) AG
ASSAmed GmbH
assist GmbH
ATMOS MedizinTechnik GmbH & Co. KG
Atos Medical GmbH
Attends GmbH
auric Hörsysteme GmbH & Co. KG

B. Braun Melsungen AG
Bausch & Lomb GmbH
Baxter Deutschland GmbH
Becton Dickinson GmbH
Berlin Heart GmbH
BGS Beta-Gamma-Service GmbH & Co. KG
biolitec biomedical technology GmbH
Biomet Deutschland GmbH
BIOTRONIK SE & Co. KG
BONESUPPORT GmbH
Boston Scientific Medizintechnik GmbH
BSN medical GmbH

C.R. Bard GmbH
Carl Zeiss Meditec Vertriebsgesellschaft mbH, Vertrieb Ophthalmo-Chirurgie
CeramTec GmbH
cerboMed GmbH
Chemische Fabrik Kreussler & Co. GmbH
CircuLite GmbH
Coloplast GmbH
Coltène / Whaledent GmbH + Co. KG
ConvaTec (Germany) GmbH
COOK Deutschland GmbH
Cordis Medizinische Apparate GmbH
Corin Germany GmbH
Corizon GmbH
Covidien Deutschland GmbH
curasan AG
curea medical GmbH
Cyberonics Europe BVBA

Dansac GmbH
DePuy Orthopädie GmbH
DEWE + Co. Verbandstoff-Fabrik Dr. Wüsthoff & Co.
DFine Europe GmbH
Diamed Medizintechnik GmbH
Domilens GmbH
Dr. Ausbüttel & Co. GmbH

Eckert & Ziegler BEBIG GmbH
Edwards Lifesciences Services GmbH
EMKA Verbandstoffe GmbH & Co. KG
Eurocor GmbH
ev3 GmbH

FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH
FOR LIFE GmbH
Franz Kalff GmbH
Fresenius SE & Co. KGaA
Fritz Osk. Michallik GmbH & Co. KG
Fuhrmann GmbH
Fumedica Medizintechnik GmbH

Gambro Dialysatoren GmbH
GerroMed Pflege- und Medizintechnik GmbH
Gesundheitsteam GmbH Bayern
GHD GesundHeits GmbH Deutschland
Given Imaging GmbH
Globus Medical Germany GmbH

HAEMONETICS GmbH
HANS HEPP GmbH & CO. KG
HEIMOMED Heinze GmbH & Co. KG
Helix Medical Europe KG
Helm Medical GmbH
Heraeus Medical GmbH
Hollister Incorporated Niederlassung Deutschland
Holthaus Medical GmbH & Co. KG
HOMANN - MEDICAL GmbH u. Co. KG
Hospira Deutschland GmbH
HOYA Surgical Optics GmbH

Illenseer Hospitalia GmbH
implantcast GmbH
Impulse Dynamics Germany GmbH
Integra GmbH
Intrinsic Therapeutics, Inc.

JenaValve Technology GmbH
Johnson & Johnson MEDICAL GmbH
Juka Pharma GmbH

Kaneka Pharma Europe N.V. German Branch
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KARL OTTO BRAUN GmbH & Co. KG
KCI Medizinprodukte GmbH
Kettenbach GmbH & Co. KG
Kramer MT GmbH & Co. KG
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KREWI Medical Produkte GmbH
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Mathys Orthopädie GmbH
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medi GmbH & Co. KG
Medi-Globe GmbH
medi1one medical gmbh
Medical Service GmbH
Mediq Direkt Diabetes GmbH

The two latest campaign-motifs from the “tattoo-series”

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Medizintechnik & Sanitätshaus Harald Kröger GmbH
Medline International Germany GmbH
Medtronic GmbH
megro GmbH & Co. KG Medizinischer Großhandel
Mentor Deutschland GmbH
Merete Medical GmbH
Meril GmbH
Miltenyi Biotec GmbH
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Mr. Clean – Gesund Schlafen GmbH
Mundipharma GmbH
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NAWA Heilmittel GmbH
Nestlé HealthCare Nutrition GmbH
neurotech Bio-Medical Research GmbH
NOBA Verbandmittel Danz GmbH u. Co. KG
noma med Schütze / Schuster GbR
Novalung GmbH
Novo Klinik-Service GmbH
NUTRICIA GmbH
Nycomed GmbH

Oculentis GmbH
Oncura GmbH
OptiMed Medizinische Instrumente GmbH
ORIPLAST Krayer GmbH
ORMED GmbH
Otsuka Pharma GmbH
Otto Bock HealthCare GmbH

P.J. Dahlhausen & Co. GmbH
Pajunk Medical Produkte GmbH
Pall GmbH Medical
Paradigm Spine GmbH
PARAM Großhandelsgesellschaft mbH
PAUL HARTMANN AG
Peter Brehm GmbH
pfm medical ag
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Pharm-Allergan GmbH
PMT Präzision-Medizin-Technik GmbH
POLYTECH Health & Aesthetics GmbH
POLYTECH Ophthalmologie GmbH
PubliCare GmbH
PULSION Medical Systems SE

Q-MED GmbH

R. Cegla GmbH & Co. KG
Raguse Gesellschaft für medizinische Produkte mbH
RAUMEDIC AG
Rayner Surgical GmbH
rehaVital Gesundheitsservice GmbH
RSR Reha-Service-Ring GmbH
Rölke Pharma GmbH

SANDER Chemisch-Pharmazeutische Fabrik GmbH
sangro medical service GmbH
SANIMED GmbH
Sanitop GmbH
Sanitätshaus Aktuell AG
Sanofi-Aventis Deutschland GmbH
SCA Hygiene Products Vertriebs GmbH
Schülke & Mayr GmbH
Sengewald Klinikprodukte GmbH
Servona GmbH
servoprax GmbH
sfm medical devices GmbH
SIGNUS Medizintechnik GmbH
SIGVARIS GmbH
Sirtex Medical Europe GmbH
SMB Sanitätshaus Müller Betten GmbH & Co. KG
Smith & Nephew GmbH
Smiths Medical Deutschland GmbH
sorbion GmbH & Co. KG
Sorin Group Deutschland GmbH
Spectranetics Deutschland GmbH
Spiegelberg GmbH & Co. KG
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St. Jude Medical GmbH
Stryker GmbH & Co. KG
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Synthes GmbH
Systagenix Wound Management (Germany) GmbH
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