

Annual Report 2010/11

The Medical
Technology Companies
www.bvmed.de





Medical technologies are indispensable for people's health and quality of life:
They save life and promote healing – in every stage of life

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Dr. Meinrad Lugan
Chairman of the Board of BVMed

Editorial

Providing Perspectives for Medtech Innovations

In the past months, political decision-makers have increasingly come to realize and acknowledge the important contributions made by medtech companies to innovation and increased efficiency in the German health system. Numerous events concerning the health economy with Dr. Angela Merkel or Ministers Dr. Philipp Rösler and Rainer Brüderle bore witness to this positive development in 2010.

Medtech companies now expect clear perspectives for innovations in medical technology.

The general economic conditions in Germany for innovation and the development and introduction of modern medical technologies that help patients and make the health system more efficient must be continually analyzed and further adapted where necessary.

Desired improvements from the point of view of BVMed include clear stipulations on time periods as well as stronger participation rights in the Joint Federal Committee (JFC), the introduction of “innovation pools” in the Statutory Health Insurance (SHI), and the establishment of agreed processes for the assessment of benefits of medical technologies.

The issue “assessment of benefit” is currently high on the political agenda. The Institute for Quality and Efficiency in Healthcare (IQWiG), acting as service provider to the JFC, currently only evaluates benefits for patients. It remains to be resolved which institutions will be able to assess not only the benefits for patients, but also the benefits for the users and the benefits for the system. A correct decision as to which medtech innovations constitute medical and economic progress will only be possible after taking all these different kinds of benefits into account.

One important core demand of medtech companies remains retaining the principle of “permission with the reservation of prohibition” in the inpatient sector, and extending this innovation-friendly principle to the outpatient sector wherever structural preconditions are the same.

We offer clear perspectives with these positions: on ideas for innovations, on medical-technological and economic progress, and on the introduction of new products and methods.

There is a need for a common strategic positioning of industry, science, and politics on research, development, and innovation in medical technology in Germany. The “Medtech Strategy Process” jointly introduced by the Federal Ministries of Economics, Research and Health is an important step towards implementing concrete legislative action.

We are looking forward to shaping healthcare with you!

Yours sincerely,

Dr. Meinrad Lugan
Chairman of the Board of Directors of BVMed



The highest standards apply for the production and quality control of medical devices – whether hightech or textile processing

Market and Membership Development

Membership Development

BVMed presently (March 2011) represents some 234 industry and trade companies. This amounts to nine more companies than at the same time last year. Thus the number of BVMed members has continued to rise despite concentration processes in the industry. A total of 15 companies became BVMed members in 2010. This is countered by seven terminations of membership or companies going out of business. A complete list of members is provided on pages 22 and 23.

Market Development

The current BVMed survey carried out in fall 2010 proves that medtech companies remain strong on innovation and creating new jobs. The sales growth in 2010 was a stable 5.5 percent. The overall economic trend of the industry is good. Over 80 percent of the surveyed medtech companies expect higher sales results. The profit situation, however, is somewhat diminished by extreme price increases for raw materials and higher outstanding debts.

When looking at the labor market trend, the medtech industry remains a job motor. Half of the companies surveyed have created new jobs compared to last year. 96 percent of the companies have job vacancies. Career prospects in the medtech sector are thus excellent for engineers and medical technicians, but also for marketing specialists in general. Companies have difficulties in filling these positions with suitable candidates.

Results of the Membership Survey

The BVMed fall 2010 survey, in which 139 members participated, yielded the following additional results:

- > When asked about the specific effects of the economic and financial crisis, companies mainly cite the increased price pressure (70 percent), increased raw material prices (41 percent) and a tight financial situation in general (28 percent), as well as higher outstanding debts (27 percent).

- > The outlook of companies for 2011 is therefore only slightly more optimistic. 48 percent expect improved results compared to last year. Only 17 percent expect lower profits.
- > Prime issue among political demands is “less red tape and accelerated decision processes”. 60 percent of the companies cite this aspect as their most important demand. This is addressed mainly at the Joint Federal Committee. Consequently, a quarter of the companies advocate a reform of the self-governing bodies.
- > Further medtech company demands refer to the insured’s freedom of choice of suppliers of technical aids (37 percent), the introduction of fixed refund guarantees (36 percent), or the possibility of cost reimbursement in individual cases (33 percent).
- > On the whole, the medtech companies give good marks to Germany as a location for doing business. 60 percent appreciate the high level of care for patients. Other perceived strengths are highly qualified doctors (57 percent), a high standard of clinical research (48 percent), well-trained engineers (39 percent), and well-trained scientists (34 percent).
- > The companies perceive weak points in the reimbursement sector. Only a quarter of those surveyed consider the general conditions for the reimbursement of medical technology products as stable. And only 23 percent of the companies are satisfied with the level of reimbursement in Germany.



From left to right: Production of cardiopulmonary bypass machines; technical service for surgical instruments; production of ECG electrodes; clean room in the pacemaker-production; quality control of incontinence products; packaging solution in the clean room

Industry Report Medtech 2010 / 11

Growth Market Health Economy

The health economy is one of the industries with the greatest growth potential and the highest number of job opportunities for qualified skilled employees in Germany. A total of 5.4 million people are currently employed in healthcare, making the industry Germany's largest employer, meaning that about every seventh job is based in the health economy. Since 2000, employment in the health sector has risen by a total of 500,000 (more than 12 percent). According to the forecast of a 2010 study commissioned by the Federal Ministry of Economics, another two million employees will have joined the health economy by the year 2030.

Employment in the Medtech Industry

The medical technology industry employs 95,000 people in nearly 1,250 companies (with more than 20 employees per company). In addition there are roughly 10,000 small businesses working in the sector with about 75,000 employees. The core industry thus employs some 170,000 people in more than 11,000 companies. Another 29,000 people work in the retail trade for medical and orthopedic products. Approximately 15 percent are employed in research and development (R&D), with a trend toward continued increase. Apart from a few large companies, the industry is strongly dominated by medium-sized firms. 95 percent of the companies employ fewer than 250 people.

Expenditure for Medical Devices in Germany

Healthcare spending in the medical devices sector (without capital goods and prosthetic dentistry) amounted to about 25 billion euros. Of this amount, medical technical aids (all financing sources) account for about 12.8 billion euros, and other medical supplies for almost 11 billion euros. Medical dressings, which are listed in the "pharmaceuticals" category, account for another 1 billion euros. The amount of Statutory Health Insurance expenditure in the total expenditure amounted to some 16.5 billion euros.

Production and Export

The total business volume of manufacturing medical technology companies in Germany decreased by 4.3 percent to 18.3 billion euros in 2009, due to the economic

crisis. The loss resulted mainly from a downturn in export business of about nine percent to a value of 11.4 billion euros. Domestic sales were up 4.5 percent compared to the previous year, to nearly 6.9 billion euros. The most important target region of medtech exports in 2009 was the European Union, taking about 43 percent of the industry's exports. Together with exports to other European countries (11.3 percent), more than half of all exported medtech goods were headed for other European countries. The North American region took 20 percent of the exports, while the Asian share was 15.3 percent.

Worldwide Growth Market of Medical Technologies

The medical technology industry is a growth market worldwide. Advances in medical technology, demographic development with always more older people, and the expanded idea of health will ensure that this remains the case. The demand for healthcare services will continue to rise. Patients are increasingly prepared to invest in their health. The world market for medical technologies amounts to about 220 billion euros. After the USA at 90 billion euros, the European market at 65 billion euros is the second largest market in the world. Germany is the third largest market worldwide, and by far the largest market in Europe, after the USA and Japan. It is about twice as large as the French and three times as large as the Italian, British, or Spanish markets.

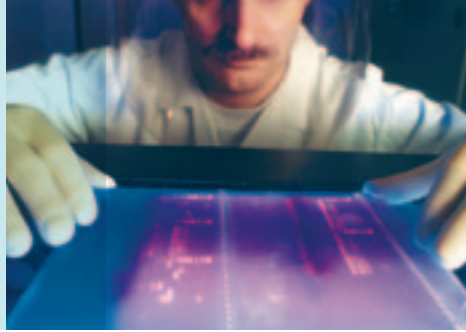
Outstanding Innovative Capability

The medical technology industry is dynamic and highly innovative. The German medical technology manufacturers achieve approximately a third of their business volume with products which are less than three years old. Medtech companies involved in research invest an average of about nine percent of their sales revenues in research and development. Germany as a venue for innovation and research thus plays a particularly important role for medtech companies.

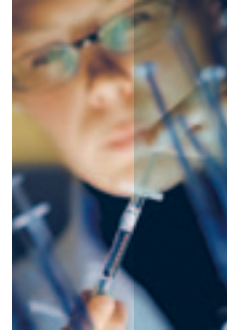
Further evidence of the industry's high innovation capability, according to the European Patent Office in Munich, is that medical technology heads the list of registered inventions with over 16,400 patents (as of 2009). This is 10.2 percent of all patent applications.



Production of pacemakers



The medtech companies invest an average of 9 percent of their sales volume in research and development



Expectations of the Decision-Makers

The health economy and especially the medtech industry have been the focus of keen political attention in the past twelve months. Politicians have come to recognize the important contribution made by companies in the medtech sector to increasing innovation and efficiency in the German healthcare system.

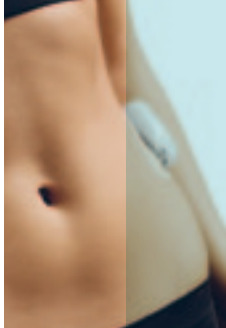
- > In April 2010, the Federal Ministry of Health held a large conference in Berlin on the future of the German health economy. Chancellor Dr. Angela Merkel and Health Minister Dr. Phillip Rösler emphasized the high value of Germany's innovative medtech industry, which is dominated by medium-sized businesses, for the future and for economic strength. The keyword was "hidden champions".
- > On October 4, 2010, another conference on the health economy took place at the Federal Ministry of Economics. Minister Rainer Brüderle emphasized the importance of medical technology for innovation and the job market.
- > On October 28, 2010, the Medtech Innovation Forum was held under the patronage of the Federal Ministry of Research and Technology, with the participation of BVMed.

The health economy has been called a "beacon of light" by Chancellor Merkel. The medtech companies expect these words by politicians to be followed by deeds. For 2011, we need clear perspectives for medtech innovations. In the light of increasingly rigorous competition in a globalized world, the domestic conditions for the innovation, development, and marketing of modern medical technologies must be continually monitored, analyzed, and further adapted as required.

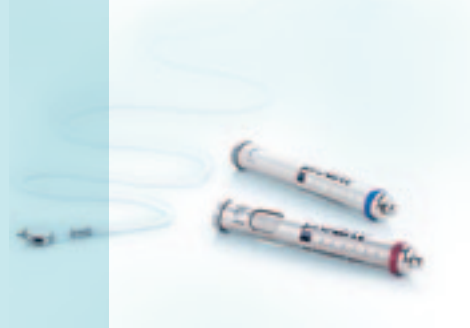
- > From the perspective of BVMed, one opportunity for improvement is the introduction of an **innovation pool** to enable the independent assessment of benefits. The health insurance companies also demand such a pool. It was suggested that three percent of the SHI expenses should be used for it. An argument for using this figure can be based on Germany's aim of reaching three percent expenditure for research. The inclusion of further funds, for example the research funding sector, should also be considered.

- > The **Joint Federal Committee** should be further developed in 2011 with the planned "Healthcare Provision Act" by making its organization more transparent and rendering more participation rights to all parties involved. As a major player in the healthcare system, the medtech industry must be enabled to participate actively in the process. A higher acceptance of the JFC's decisions could also be achieved by creating a clearer environment such as streamlined application procedures, deadlines, auditable decision processes, and legal processes and structures.
- > A few remarks on the discussion about the **assessment of benefit**: The IQWiG is currently only evaluating benefits for patients, as a service to the JFC. Beyond this scope it remains to be resolved which institutions will be able to assess not only the benefits for patients, but also the benefits for the user and benefits for the system. The JFC will only be able to decide correctly on which medtech innovations constitute medical and economic progress when it will be able to take all these different kinds of benefits into account. From the point of view of the medtech companies, it is important that the requirements for benefit assessment of medical technologies are developed and determined in a joint process. It is also necessary to address questions such as which data shall be collected, published, and taken into account, and when.
- > One central goal for medtech companies has been to secure the principle of "**reservation of prohibition**" in the inpatient sector, and to extend this innovation-friendly principle to the outpatient sector where structural preconditions are the same. There is also a need to cut red tape on the approval procedures for new examination and treatment methods (NUB) and to speed up processes. Remuneration agreements must be made binding.

We can provide a clear perspective by setting forth these points on ideas for innovations, progress in medical technology and the economy, and in introducing new products and methods.



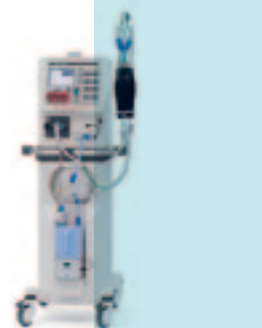
New medtech methods are the result of intensive research and development: Insulin patch pump for diabetics



adjustable shunt system for "hydrocephalus" patients



laryngoscope with video function



artificial lungs: high-frequency ventilation

Health Policy

Politicians have focused more of their attention on medical technology in the past year. One reason for this interest is the industry's resilience in economic crises, a consequence of being shaped by medium-sized businesses and its high innovation power in general. The special importance attached to the industry by politicians is reflected by the fact that several industry events were sponsored by various ministries, with the participation of Chancellor Dr. Angela Merkel and the Federal Ministers Dr. Philipp Rösler, Dr. Annette Schavan, and Rainer Brüderle. Chancellor Merkel also emphasized the great importance of the medtech industry at the opening of the world's largest medical trade fair, MEDICA.

Better Interaction between Ministries

Good news is the growing interaction and coordinated cooperation between ministries dealing with subjects related to medical technology. In fall 2010, the State Secretaries of the Federal Ministries of Health (BMG), Economy and Technology (BMWi), and Education and Research (BMBF) initiated a joint Medtech Strategy Process, which shall be further advanced in 2011. One important date is a big industry event in the summer of 2011 in Berlin. In numerous workshops, the situation of the industry, the opportunities and risks for the future, and the ensuing need for specific political actions will be discussed together with the decision-makers.

Health Policy

In terms of legislation, the year 2010 was characterized by the necessary financial consolidation of the Statutory Health Insurance. Diminished revenues during the financial and economic crisis had threatened the SHI with a deficit of 11 billion euros. Politicians have come to recognize that due to demographic changes and medical progress, the Statutory Health Insurance must expect annual expenditure increases of 3 to 5 percent. This altered mindset is also reflected by the fact that the Healthcare Reform in 2010 allocates more additional means to the SHI than are saved by the suppliers of services. Within the bigger framework of curbing expenditures in outpatient and inpatient sectors, the medtech industry contributes indirectly to expenditure savings. Also, there has been a functioning competition of services and prices between the medtech companies for years.

Health Research

Early in 2011, the Federal Ministries of Health and Education and Research decided upon a joint framework program on health research at a volume of 5.5 billion euros until 2014. The realignment of medical research funding is geared towards greater focus on researching widespread diseases and networking between research and practice. The guiding concept is to bring research results faster into standard medical care and thus to the patients who need them.

BVMed's Political Activities

In the year following parliamentary elections in Germany, BVMed further developed its existing contacts to Members of Parliament and the new Federal Government. Numerous discussions and meetings in Parliament, at the Chancellor's office and at the Ministries, as well as discussion groups on healthcare and economic issues with MPs or public debates, cover only some of the association's activities. One very positive result is the increased involvement of the association in working groups and committees, even at a ministerial level, such as the Health Research Council, medtech evaluation workshops, committees for the organization of industry conferences, and involvement in the Medtech Strategy Process.

At the European level, BVMed has strengthened its activities. Its format of parliamentary evening discussions and talks with relevant MPs and representatives of the European Commission, called "BVMed goes Brussels", has taken root. There is a strong resonance among parliamentarians and staff of the "German community" in Brussels on the subject of the German medtech industry and its requirements at European level.

Political Summary

For the companies in the health economy, a strong domestic market is key. It involves a Statutory Health Insurance with functioning competition and a rapid introduction of medical innovations. We need a common strategic positioning of industry, research, and politics towards innovation in medical technology. The Ministries of Economics, Research, and Health must coordinate their efforts better and open up opportunities for innovations.



Medical devices for high-quality care in the sensitive surgery sector: safe, reliable, sterile

Hospital Financing

Health Financing Act: Cost Containment also Affects Hospitals

The Health Financing Act is supposed to ensure a stable and sustainable financing of the German healthcare system and to reduce the deficit of the SHI expected for 2011. Hospitals are expected to make their contribution to achieving this. The increase in hospital expenses will be reduced for 2011 and 2012 by setting an upper limit for increases in the state-wide base values and fixing price reductions for extra services. Consequently, the implementation of the cost orientation value will be suspended and for the time being the basic wage rate will serve as the reference figure.

The fixed price reductions for additional services will be introduced for an unlimited period, beginning in 2011 at 30 percent. In 2012, their level will be subject to an agreement. The exceptions for these price reductions will be services where the share of material costs is more than two-thirds. In addition, most of the supplementary payments that also contain medical technologies are exempted from these fixed reductions. In total, the government expects to save around 500 million euros in the hospital sector through these measures in 2011. From the perspective of medtech companies, these intended cuts in the hospital sector are problematic. The reduction of the maximum budget increase and the cut in reimbursement for additional services may lead to increased price pressure on medical devices. Add to this are the higher raw material prices and the rising outstanding debts ("late payment"). This has a negative impact on an industry that is especially characterized by a high degree of innovation.

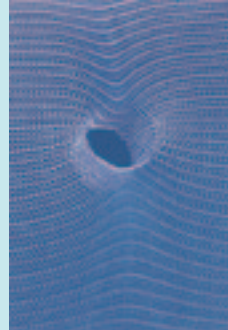
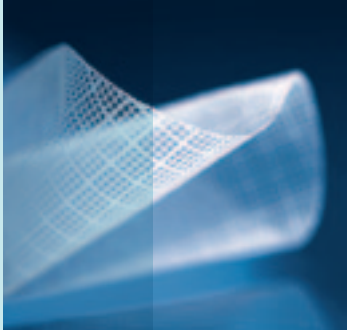
Development of the German DRG System

The German DRG system continues to evolve into a more and more homogenous case-related reimbursement system that strives for evermore exact representation and correct reimbursement of services rendered. The larger number of hospitals participating in the calculation process, the calculation routine, and the enhanced plausibility method enable a further optimization of the data quality – and thus more accurate calculation results. Countries like China and Switzerland have already modeled their systems according to the German DRG system.

The 2011 DRG catalog comprises a total of 1,194 DRGs, six less than in the previous year. The number of supplementary payments has risen to 146. Out of these, 31 are for medical technologies, 38 for therapies, 75 for drugs, and two for diagnostic methods. In the proposal process aimed at integrating medical, scientific, and other expertise in the further development of the G-DRG system, BVMed proposed numerous medical technologies for inclusion by the DRG Institute InEK. About 30 percent of the proposals were implemented. Thus a large proportion of the extensive modifications to the G-DRG system in 2011 were based on references taken from the proposal process.

New Examination and Treatment Methods: Innovation Clause (NUB)

The representation, integration, and adoption of new examination and treatment methods (NUBs) in the G-DRG system continue to be problematic. The DRG system cannot promptly represent innovative technologies due to a lack of information on cost. In order to close this innovation gap, the NUB process was created according to Article 6, Section 2 of the German Hospital Remuneration Act (KHEntgG). According to the Institute for Hospital Reimbursement InEK, out of 89 methods positively reviewed (status I), seven were integrated into the supplementary payment list for 2011, and two were integrated into DRGs. These also include medical technologies, for instance the drug-releasing balloon catheter. The remaining NUB methods require repeated individual reimbursement applications by the hospitals. For 2011, more than 15,000 single NUB applications were filed for 582 different services by 749 different hospitals. However, according to individual regional hospital associations, the revenue situation for the agreed innovations has not improved for the hospitals. This confirms the numbers published in the German Hospital Institute's (DKI) expert report: only 0.3 percent of the revenue of hospitals is refinanced by the health insurance funds for innovations. Another problem is the lack of a statutory regulation on the transfer of NUBs into the regular reimbursement scheme. BVMed demands the introduction of an innovation pool which objectively represents innovations outside the regular budget.



A new, dynamic product area: soft tissue implants. For example: mesh implants for hernia or chest surgery

Assessment of Benefit and Health Services Research

When the Drug Reimbursement Act in the Statutory Health Insurance (AMNOG) took effect at the beginning of 2011, a new chapter was opened in the evaluation of medical services. Pharmaceutical manufacturer must prove the additional benefit of new drugs. The goal is to achieve price negotiations between the manufacturer and the Federal Association of Health Insurance Funds. Consequently, the hitherto employed approach of a cost-benefit evaluation has been shifted to the background. The additional benefit shall be evaluated by the JFC with support from IQWiG within a short period of time. Medical technologies are not directly affected by this new law since medical devices are mostly integrated into the prices for medical services, as in the DRG case-related system. In addition, the criteria demanded for the proof of medical benefit cannot be automatically applied to medical devices.

Assessment of Benefit and Health Services Research for Medical Devices

Medical devices must be measured according to different standards than drugs. There are currently no clear specifications or criteria for the cost-benefit analysis of medical devices. From the point of view of BVMed, it is important that the requirements for assessing the benefits of medical technologies will be developed and determined with the participation of the medtech industry. In addition, better health service research data are necessary to ensure that all aspects of benefit can be examined more effectively. One good example for medical devices is the endoprosthesis register.

Fortschritt erLeben (Experience Improvement) – Beginning of a Dialog

From the point of view of the medtech industry, assessment of benefit doesn't only consist of benefits to the patient, as it is currently examined by IQWiG on behalf of the JFC, but also concerns aspects for the users and the benefit for the entire system. Only if these aspects are taken into account, a correct decision can be achieved concerning which medtech methods and innovations are to be considered medical and economic progress. It still must be clarified which institutions shall evaluate these other benefits and according to which methods. A dialog on this subject has been actively initi-

ated with the new director of the IQWiG, Professor Windeler, on the occasion of the BVMed conference "Fortschritt erLeben". He promised to discuss the conducting of workshops on guidelines for the benefit assessment of medical devices between the IQWiG and the industry.

Proposal to Integrate Industry into the JFC Evaluation Process

Medtech companies would like to see further development in the organization and operation of the JFC through the intended Healthcare Act. There should be more transparency and improved participation rights for the parties affected, and as a major party involved in the healthcare system, the medtech sector must be an active partner in the processes. A higher acceptance of the JFC's decisions could also be reached by creating a clearer environment such as streamlined application procedures, deadlines, auditable decision processes, and legal processes and structures.

One core demand of medtech companies is to keep the principle of "permission with the reservation of prohibition" in the inpatient sector, and to extend this innovation-friendly principle to the outpatient sector where structural preconditions are the same. Upon invitation of the JFC, BVMed actively participated in the expert conference on innovations.

HTA Advisory Council / Board

BVMed actively participates as a guest in the Health Technology Assessment (HTA) Advisory Council of DIMDI. There it supports the discussion on the selection and evaluation of medical-technological methods and products to be qualified for an HTA process and the further development of the selection process.



Examples of modern medical technical aids: draining incontinence catheter specifically designed for women

... and for the man

absorbing incontinence products with active skin protection

Technical Aids

Current Developments in the Technical Aids Sector

After a wave of new legislation (the SHI Competition Strengthening Act and the SHI Organization Development Act), the new regulations are now being implemented and the technical aids sector is expected to calm down. As of 2011, the marketing authorization for suppliers in the technical aids sector is a thing of the past. Instead, a contract between the insurer and the supplier in accordance with the new regulations is now the basis for authorized supply. Independently, the strong price competition continues apace. The increases in volume, a consequence of the demographic development with an ever older population, are leading to further moderate increases in expenditures for technical aids. The increase rates are below the average of SHI service expenditure increases. Nevertheless, there is a strong intention on the part of the health insurance funds to achieve further savings in the technical aids sector. The challenge will be to walk the fine line between the scarce resources and securing the medically necessary care.

Status of Implementation of the SHI Organization Development Act

Legislative amendments in the technical aids sector led to a decrease in the number of tenders. Many health insurance funds prefer using the instrument of advertised contracts. The right to accede to these contracts ensures that all qualified suppliers are able to take part in supplying healthcare to patients after the transition period ended in 2010. Under this system, no palpable bottlenecks in supply occurred for the insureds in general, nor were any suppliers excluded from participating in the market, as had originally been feared. This is also true for areas that are still without contract, where the individual case regulation applies. In addition, legislators received backing from the Higher Social Courts. The HSC in Essen ruled on April 14, 2010 that advertised contracts comply with European Law.

State of Prequalification

As the former licensing system is no longer in effect, suppliers are now obliged to prove their eligibility again to each Health Insurance Fund. By introducing a voluntary prequalification, the legislation intended to elimi-

nate this new bureaucratic obstacle. The SHI Organization Development Act commissions the Federal Association of the Health Insurance Funds and the relevant associations of suppliers to agree on a nationwide pre-qualification process. By doing so, the legislator has for the first time declared both sides to be partners with equal rights. A body of 16 relevant supplier organizations was formed, among them BVMed and the Federal Association of the Health Insurance Funds, which in turn has involved all kinds of health insurance funds in the negotiations.

After some initial difficulties, this heterogeneous circle successfully passed an agreement for the prequalification process on March 29, 2010. Thanks to the active participation of BVMed and its members it was possible to establish a non-bureaucratic, practical, and rapid process. The costs shall be determined by competition.

Contents and Prequalification Bodies

Following the agreement, the contents of prequalification were negotiated. This resulted in the recommendations of the Federal Association of the Health Insurance Funds according to Article 126, Section 1, Clause 3 SGB V (Social Security Code V). The supplier associations were successful in negotiating a stipulation on the preservation of the status quo for a period of three years with regard to the requirements for the expert executive. The recommendation came into effect on January 1, 2011. However, it is not complete yet. As a next step, training and qualification for suppliers and qualification of caregiving staff must be defined. BVMed has submitted initial discussion papers on these issues. The Federal Association of the Health Insurance Funds is responsible for naming and monitoring the prequalifying bodies, with the support of the advisory board. BVMed is one of 14 members in this advisory body.

Effects of the Changed Course of Law for Award Procedures

With the new Drug Reimbursement Act (AMNOG), the legal process of the second instance has been altered for award procedures. As of January 1, 2011, appeals are referred to the Higher Regional Courts instead of the Higher Social Courts.



very quiet tracheal suction device for children



Homecare services: modern medical devices improve the quality of life and allow nursing care at home



Patient consultation in a medical store

Homecare

The population is growing older. Thus the demand for homecare services is steadily on the rise. This is basically the best prerequisite for sustaining an interesting growth market. The products and services required for homecare are predominately financed by the Statutory Health Insurance. However, the SHI is suffering serious cost pressures due to rising expenses and sinking revenues.

What Kind of Quality Will Prevail?

This leads to two questions: To what extent are patients prepared to make supplementary payments out of their own pockets for superior-grade services? Which quality level will prevail in the SHI market? The first question can be quite easily answered for the typical homecare patient. Such patients are often chronically ill, and cannot usually be expected to shoulder any larger financial burden. The second question can be divided into structural, process, and result quality.

Regarding structural quality, there is now a unified situation since the criteria for prequalification of suppliers were established at the end of 2010. Regarding the quality of processes and results, contractual agreements between the parties remain to be made. It appears that accession contracts according to Article 127, Section 2, 2a SGB V have become the means of choice in the homecare sector. In 2010, the Higher Social Court in Essen ruled in the so-called Mako Case that accession contracts conform to European legal requirements. This initially provided legal certainty and some planning certainty for all parties involved.

Strengthening of Homecare through Public Relations

BVMed's homecare companies are planning a number of activities in 2011 to highlight the image and importance of homecare within the healthcare system. While the term "homecare" has taken root in the healthcare sector, the services of the homecare companies organized in BVMed still aren't visible enough to the stakeholders within the healthcare system. This is to change in 2011. First steps were already taken in 2010 by the "Homecare"

forum at the Geriatric Care trade fair in Hannover, the Technical Aids forum at the REHACARE in Düsseldorf, and a series of lectures at the Homecare trade fair in Leipzig. The talks given by experts, lively podium discussions, and exchange of information among all participants were successful and well-received, and will be continued in 2011.

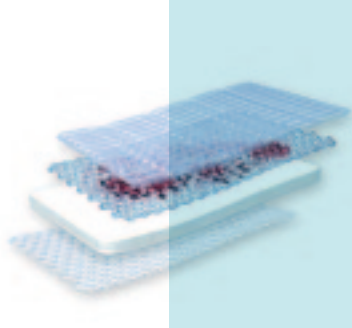
Electronic Health Card

The change of government at the end of 2009 led to a moratorium on the introduction of electronic prescriptions within the scope of the telematics infrastructure. The "old" concept of the Electronic Health Card is now under scrutiny.

The Federal Ministry of Health was commissioned to revise the structures of Gematik (the company originally charged with introducing the Electronic Health Card). After a period of restructuring, work on the project has recommenced. The insured will receive new cards that feature some new functions, for example emergency patient data. The other service providers are monitoring the current status and are using the time to work on practicable concepts for their sectors.

New Models of Care

Integrated care models are still a rarity in the homecare sector. There are regional approaches especially in the wound care sector. As of January 1, 2011, it is now possible that manufacturers of medical devices can become direct contract partners in integrated care. This has extended the participation opportunities in the homecare industry. It remains to be seen whether new networks to optimize existing care structures will be established. The medtech companies can make a valuable contribution to achieving this.



Products for modern wound care:
modern wound dressing with four layers



drug-free dressing
for the reduction of germs



innovative drainage supply



vacuum therapy for
problem wounds

Medical Device Legislation

Fourth Amendment to the Medical Devices Act (MPG)

The year 2010 brought a number of new national regulations for the industry. The “Fourth Amendment to the Medical Devices Act” of July 29, 2009 became effective on March 21, 2010. The amendment changes the Medical Devices Act (MPG) and numerous ordinances.

One goal of the amendment was to ensure the national implementation of the 2007/47/EC Directive. It also contains a number of new national specifics, especially an increased scope of tasks for the Federal Institute for Drugs and Medical Devices (BfArM). As of March 21, 2010, the institute is the designated authority to be notified and to approve clinical trials with medical devices. It must also be notified in the case of severe adverse events with medical devices during clinical trials, and will evaluate such cases. Also, the BfArM now decides – instead of the federal Länder – about the legal allocation and classification of medical devices. All services of the BfArM that are not considered “administrative assistance” are subject to charges.

BVMed Positions

BVMed criticizes that the need to report incidents and severe adverse events during clinical trials for medical devices bearing the CE marking constitutes a national exception which leads to redundant reports. In addition, BVMed favors the establishment of liaison officers for recalls (“vigilance officers”) in hospitals. This is a function that could be combined with the “medical devices officer” in the hospital (Article 5 of the Medical Devices Operator Ordinance).

Ordinances

The “Ordinance on Clinical Trials with Medical Devices” (MPKPV) dated May 10, 2010, governs the new evaluation procedure by ethics committees that have to be constituted under public laws and the new approval procedure by BfArM required for all clinical trials with medical devices, as far as such trials are conducted for the purpose of conformity assessment procedures.

The “First Amendment on the Ordinance” on the German Institute of Medical Documentation and Information (DIMDI), of May 10, 2010, governs the new registration

and reporting obligations in connection with the amended Medical Devices Act (MPG), the new Medical Devices Safety Plan Ordinance (MPSV), and the introduction of the Ordinance on Clinical Trials with Medical Devices (MPKPV).

European Law/MDD Recast

The first draft of “MDD Recast”, another amendment of the Directives 90/385/EEC and 93/42/EEC, will not be published before 2012. Under consideration is a merger of the Directives 90/385/EEC and 93/42/EEC into a single EU Directive or a single EU Regulation which would justify the term “Recast”, as it would form a new legal basis. Furthermore, there is no agreement on the future legislation on “high risk devices” (classes IIb and III) and on “new technologies”, e.g. the coating of joint implants with denatured tissue of human origin, or nanotechnology.

The EU Commission fears that the competent national authorities could be unable to keep pace with the technological progress and therefore considers creating the legal basis to shift competences for “high risk medical devices” and “new technologies” to the European Medicines Agency (EMA). BVMed opposes a general responsibility of EMA for medical devices in principle, since they fear this would trigger a process in which medical devices are increasingly governed by laws similar to those governing drugs. Medtech companies advocate keeping the “New Approach”, that is sticking to self-governance of manufacturers, surveilled by notified bodies and by national competent authorities.

If reports about certain inefficient notified bodies within the EU turn out to be true, BVMed would prefer to have these notified bodies subordinated to a surveilling EU agency. It makes no sense to challenge the “New Approach” and discuss possible administrative approval scenarios.



Prevention of sharps injuries: safety needle and safety pin



Modern needles and tubes:
modifiable endotracheal tube



tracheostomy tube
with suction device

Patient and User Safety / Environmental Issues

Hospital Infections

The issue of hospital hygiene has gained importance in public. Various events triggered the need to investigate the quality of hospital hygiene in Germany and pushed the topic up on the political agenda. The Federal Government announced that it intends to improve the state of hygiene in German hospitals in 2011 by harmonizing the federal regulations. The perceived weak points are mainly the deficiencies in hospital staffing and the insufficient implementation of existing standards and guidelines.

In light of this, the initiative of the BVMed subgroup “Nosocomial Infections” gains special significance. Its dedicated website (www.krankenhausinfektionen.info) wants to make a contribution to avoiding hospital infections. The main aim is to deepen the awareness about major routes of infection and their prevention. The contents are being developed in cooperation with hygiene experts at the Charité hospital in Berlin. The website features illustrations which can be downloaded for private training or educational purposes for free.

Protection from Sharps Injuries

The risk of infection for medical staff through injuries caused by sharp instruments should not be underestimated. Thanks to numerous publications, in particular by the German Social Accident Insurance for the Healthcare Sector, the free BVMed educational CD on sharps injuries has been in high demand, especially in the past few months.

Reprocessing Medical Devices

Medical procedures are only one significant source of hospital infections. We must also focus on the reprocessing of medical devices. The reprocessing departments of several hospitals were recently shut down due to non-sterile or polluted products, which shows that the theoretical foundations of infection prevention still need to be better implemented in medical practice.

At the end of August 2010, the EU presented its report on the reprocessing of medical devices. BVMed and individual member companies had collected data and facts for this report that prove the risk of reprocessing in cer-

tain cases. The EU report is critical of the current reprocessing practice, and it emphasizes the risks of contamination and chemical residues, and the risk of changes in functionality of reprocessed single-use products. The report suggests to introduce the obligatory informing of patients and users, and to make the use of reprocessed single-use products contingent on the patient's consent.

Environmental Issues

At the beginning of 2011, the “candidate list” of substances of very high concern according to the European Community Regulation on Chemicals (REACH) already included 46 substances. Suppliers of products containing more than 0.1 mass percent of any listed substance must inform their customers immediately upon publication of the list. This may be done by including a note on the invoice or on the dispatch note or by referring to relevant information on the company's website.

BVMed regularly informs its members about potential and definite candidates and if known about their possible relevance for medtech companies. The amended RoHS Directive on the “Restriction of Hazardous Substances in electrical and electronic equipment”, which will probably be published in spring 2011, will squash the exceptions for medical devices made up to now as of March / April 2014. The WEEE Directive on Waste Electrical and Electronic Equipment up for revision currently makes an exception for infectious medical devices, absolving them from the necessity of being recycled. BVMed advocates retaining this exception in the new version of the directive.

In another statement referring to the intended amendment of the German Waste Management Act, BVMed emphasized that the planned changes must not aggravate the conditions for medical institutions.



BVMed's Media Seminar in 2010 with the focus on diabetes included Prof. Dr. Thomas Danne

Shooting of the BVMed Film Service on telecardiology with Dr. Volker Leonhardt

Communication / Media Relations

Communicating the Value of Medical Technologies

The most important task of BVMed communication activities is to communicate the value of medical technologies – for people, for healthcare, for the national economy. One important aspect of public relations is the BVMed information campaign “Der Mensch als Massstab. Medizintechnologie” – which can be translated into: “Measuring by the human standard. Medical Technology” (www.masstab-mensch.de). The campaign was launched in April 2010. It pursues new paths in the medtech industry by employing a sophisticated aesthetic approach, including large posters and unconventional magazines. On its website, an “animated man” informs about innovative medical technologies and a map of Germany provides an overview of locations for manufacturing and R&D.

BVMed Film Service and Campaign Aktion Meditech

Medical technological progress, an aging population, new information technologies: All these factors make clear and updated patient information more important than ever. BVMed has met this challenge for years with its “Film Service Medical Technology” (www.youtube.de/medizintechnologien) and its patient information campaign “Aktion Meditech” (www.aktion-meditech.de), which were both developed in close cooperation with physicians and patient groups. More recent subjects in the series were telecardiology, low-impact implant of heart valves via catheter, and home dialysis in the event of kidney failure. Thanks to its own portals on YouTube, sevenload, and myVideo, and a cooperation with Doc-Check, this film service reaches a broad audience. On the social media channels alone, BVMed films were requested more than 50,000 times in 2010. Many films of the series were also broadcasted by various TV stations. New paths of patient communication were also the focal topic of the 6th annual communication conference on medical technology held in Frankfurt in June 2010.

Social Media and Medical Technology

Regarding social media: Online communication is an important building block in the professionalization of communication in the medtech industry. Twitter, blogs, and social networks have become a dominant feature in

online communication. BVMed is tapping these new channels and has established its own Twitter channel (www.twitter.com/bvmed) and a Facebook profile (www.facebook.com/bvmed). The improved BVMed website (www.bvmed.de) offers ten RSS feeds on specific subjects, in order to better focus its information offer. The social media activities are closely linked to the website and “classic” means of communication. Questions of how social media and the demographic changes are affecting corporate communication will be the key issue of the seventh annual BVMed communication conference on June 6 and 7 in Leipzig. Furthermore, the BVMed communication department organizes day seminars on online communication and social media strategies for companies.

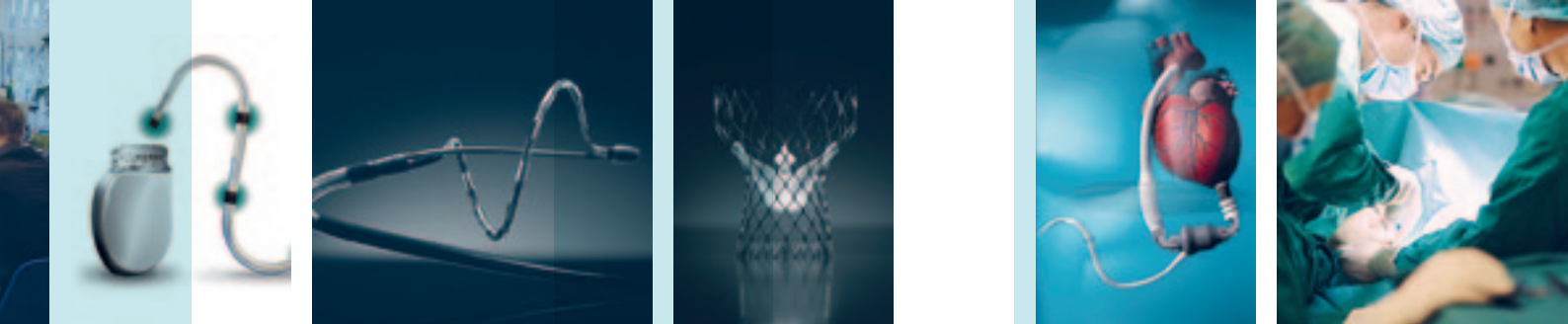
Media Relations

The “classic” media like newspapers and magazines will continue to retain their importance in communication. BVMed has therefore further intensified its relations with these media. For the first time in 2010, more than 1,000 articles citing BVMed appeared in different print media and their associated online portals, reaching an estimated readership of 60 million. One important figurehead of the industry remains the weekly BVMed newsletter, with more than 8,000 subscribers. The layouted PDF version containing the “graphic of the week” has been complemented by an online edition in 2011. This means that these newsletters are included in the full text search feature on the BVMed website now.

Other aspects of media relation activities are press conferences and the annual media seminar, as well as press releases, background services, guest contributions, and industry reports in German and English. The BVMed communication department also offers day seminars on media relations, communication concepts, and crisis communication and crisis management.

eHealth

Another important issue is the electronic networking of the health economy by eHealth. The eHealth conferences organized by the BVMed communication department have become a popular annual get-together of the medtech industry.



Medical technologies in cardiology: pacemaker for cardiac resynchronization therapy (CRT)

High-frequency catheter ablation

Transcatheter heart valve

Implantable cardiac support system

Use of a cardiac pacemaker system in surgery

Reports from BVMed's Expert Committees

In more than 50 focus groups, sectoral interest groups, and working groups, BVMed offers its members a platform for constructive dialog and exchange of views, thus leading to a unified position on matters of common interest.

Focus groups address topics of general concern to all members, irrespective of their particular products, on a continual basis.

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

Working groups and sub-groups are committees set up on a temporary or restricted basis which provide the board and management with expert support in a specific field.

A complete list of BVMed Expert Committees is provided on the internet at: www.bvmed.de (About BVMed).

FOCUS GROUPS

Focus Group "Hospital Market" (AKKHM)

The procurement processes in German hospitals have changed fundamentally due to the creation of purchasing pools and tendering. The AKKHM offers a communication platform to discuss common projects and activities as well as legal questions with regard to procurement processes. The focus group consolidates industry-specific questions and is thus a knowledgeable cross-company medtech contact partner for hospitals.

Focus Group "Legal Issues" (AKR)

The AKR cooperates with 19 members of the "Medical Device Legislation Network", a group of specialized lawyers. The focus group has eleven sub-groups dealing with specific legal issues and is responsible for publishing and continually updating the legal commentary "WiKo – Medizinprodukterecht" on medical device law. The focus group will conduct the sixth annual BVMed Symposium "Current Legal Questions on Medical Devices" in April 2011, and cooperates with the "Legal Affairs Focus Group" of the European manufacturing association Eucomed.

Focus Group "Regulatory and Public Affairs" (AKRP)

The key topics of this focus group include dealing with new requirements of amended medical device law, especially the Ordinance on Clinical Trials with Medical Devices (MPKPV). The AKRP is responsible for the BVMed information series on "Medizinprodukterecht" ("Medical Device Legislation"), which comprises ten guidelines on various regulatory topics. The AKRP will conduct two information events in 2011: "Clinical trials of medical devices and the safety officer for medical devices" (March 2011) and "The Medical Devices Act in practical use" (November 2011).

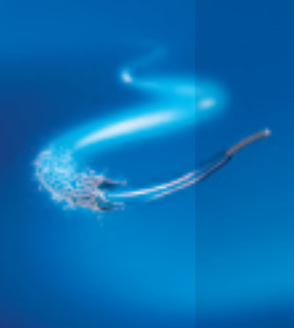
Focus Group "Environment" (AKU)

Medical devices are not excluded from the EU environmental protection regulations. The key issue for the AKU was the European Regulation on the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH). The primary concern was the reporting requirements on substances in articles and the obligation to register high-volume substances. The "REACH" sub-group of the AKU harmonized a position statement on overlaps between REACH and other codes and regulations, especially existing medical device legislation. Another position statement was developed by the sub-group "Packaging Ordinance" on the planned amendment of the German Waste Management Act. Other key topics included the pending amendments of two EU directives, the Directive on the "Restriction of Hazardous Substances in electrical and electronic equipment" (RoHS) and the Directive on Waste Electricals and Electronic Equipment (WEEE), as well as the planned Biocide Regulation Ordinance.

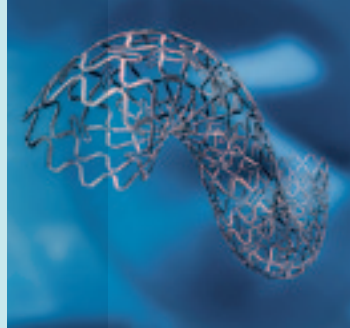
SECTORAL INTEREST GROUPS

Sectoral Interest Group "Eye Surgery" (FBA)

The sectoral interest group of manufacturers of intraocular lenses decided on a complete relaunch of the "Initiative Grauer Star" (cataracts initiative). The PR sub-group in the FBA has developed a concept to actively integrate ophthalmologists in information about the performance spectrum of premium intraocular lenses in 2011. The "Public Affairs" sub-group (AG PA) deals with innovative reimbursement concepts to help patients get their cata-



Medical technologies for the vessels:
different coronary stent systems for vascular blockage



Clip for the interventional treatment
of mitral regurgitation



Drug-eluting balloon

ract surgery covered by their Statutory Health Insurance even when they decide for the implantation of a premium lens.

Sectoral Interest Group “Blood” (FB Blood)

This sectoral interest group unites the manufacturers of blood bags and devices for plasmapheresis and is concerned with the regulatory requirements on these particular products. It is also the respective contact partner for the authorities.

Sectoral Interest Group “Brachytherapy” (FB BT)

The working group “Seeds for prostate Cancer” (AGSP) of the sectoral interest group “Brachytherapy” promotes the admission of this treatment method into the reimbursement catalog. The BVMed experts coordinate the positions in the assessment process and initiate scientific symposia and discussion events.

Sectoral Interest Group “Diabetes” (FBD)

This sectoral interest group was newly formed in 2010. It wants to contribute to developing a vision for the care of patients with diabetes mellitus in Germany. The group aims to illustrate a holistic therapeutic approach for reducing the long-term consequences of diabetes mellitus with appropriate measures. Physicians and company representatives presented the latest technologies to the German capital’s major media during the BVMed Media Seminar 2010.

Sectoral Interest Group “Diagnosis Related Groups – Hospital Financing” (FB DRG)

The FB DRG accompanies the discussion on the reimbursement of medical devices in hospitals and develops positions in the legislation process. It coordinates the proposals for further developing the Diagnosis Related Groups (DRG) and Operations and Procedures Code (OPS) classifications. It also develops specialist brochures and events.

Sectoral Interest Group “First-Aid Materials” (FBEH)

The manufacturers of first-aid kits for cars and working areas advocate that their product always meets the needs of lay-helpers as well as the demands of modern

emergency and emergency medicine. For the work of standardization, this primarily means taking into account latest developments in hygiene and ergonomics. The sub-group “Communication” (AGK) will continue its press relations efforts to inform the public of the diverse potential uses of first-aid kits.

Sectoral Interest Group “Endoprosthesis Implants” (FBEI)

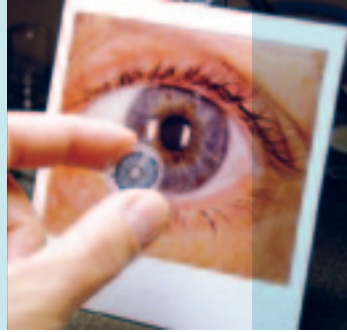
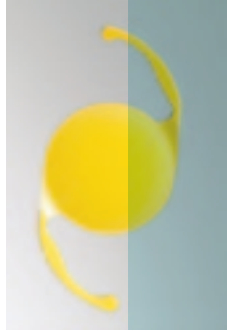
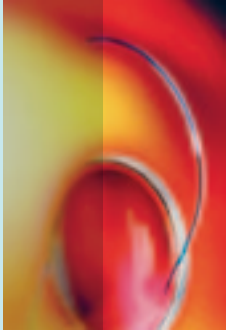
The FBEI is primarily occupied with establishing a German endoprosthesis register. Implant manufacturers have been actively promoting the project and been involved in its realization for many years. Representatives of this group work together with the professional associations, the German Hospital Federation (DKG), the National Association of the AOK, and the Association of Substitute Statutory Health Insurance Funds (vdek) to develop such a register. The implant manufacturers represented in the FBEI are prepared to support the conception and creation of a German endoprosthesis register through active participation in the relevant working and decision-making committees, and especially by setting-up and operating an independent implant reference database.

Sectoral Interest Group “Ethylene Oxide Sterilization” (FBE0)

FBE0 topics included the discussion about Workplace Exposure Standards as well as the plan to develop the current European Biocide Directive into a Biocide Regulation.

Sectoral Interest Group “Health Technology Assessment” (FBHTA)

The FBHTA develops positions on proposals for methods and procedures to assess technology and healthcare research with medical technologies. The group also creates proposals for elaborating and further developing quality requirements for medical technical services within the scope of cross-sector quality assurance. Furthermore, it coordinates BVMed participation and positions on the HTA Board of Trustees at the DIMDI and develops concepts for seminars and conferences on technology assessment.



To see again – medical devices in eye surgery: modern intraocular lenses (IOL), artificial iris, production of artificial lenses

Sectoral Interest Group “Homecare” (FBHC)

The FBHC wishes to boost awareness among policy-makers in the healthcare system of homecare services, its therapies, and quality aspects. The political activities concentrate on the discussion about fixed allowances in the technical aids sector. The group drafted a discussion paper on the subject, explaining the advantages of the current reimbursement scheme for the chronically ill. In addition, the FBHC is working on a concept which will do justice to demographic challenges and simultaneously scarce resources.

Sectoral Interest Group “Absorbing Incontinence Care (Manufacturers)” (FBI-H)

The FBI-H supported the National Associations of SHI in the review of reference prices. Furthermore, it critically examined the care and contractual situation regarding absorbing incontinence products. The experts are looking for solutions of how patient-oriented and medically necessary care can be ensured in the long term.

Sectoral Interest Group “Infusion Therapy” (FBIV)

FBIV is developing care standards in the infusion therapy sector. The members are concentrating on the use of infusion therapies in specialized palliative care.

Sectoral Interest Group “Cardiac Medical Devices” (FBKMP)

FBKMP operates a database for active implants at www.herzstimulation.de. An exhibitor committee coordinates the cooperation with scientific organizations as well as professional organizations and associations.

Sectoral Interest Group “Artificial Feeding” (FBKE)

The FBKE advocates the reimbursement of enteral feeding. After an initial exploratory discussion with the JFC, a category system was developed together with the Association of Special Dietary Food Producers. This system is to be the basis for alterations and modifications of the pharmaceutical guidelines (AMR). At the same time, an initial exchange of information has taken place with the members of the Federal Association of Self-Help

Organizations on issues of reimbursement for enteral feeding.

Sectoral Interest Group “Health Insurance Law for Suppliers of Technical Aids” (FBLL)

The key issues concerning the FBLL were the analysis of the new Drug Reimbursement Act (AMNOG), the legal foundation of case management, as well as right of information and accession to contracts pursuant to Article 127, SGB V. The group also analyzed established judicial precedents concerning practice supplies. Possible alternative models for the supply of technical aids and its legal foundations and potential snares were discussed.

Sectoral Interest Group “Mechanical Thrombosis Prophylaxis” (FBMT)

The FBMT advocates equal treatment of the outpatient and inpatient sectors in medical thrombosis prophylaxis, and created an information brochure on the subject. The FBMT also made use of targeted professional discussions and publications to promote public relations work for mechanical thrombosis prophylaxis.

Sectoral Interest Group “Modern Wound Care Products” (FBMW)

The FBMW continued to expand its educational modules on the prescribability, reimbursability, and economic efficiency of hydroactive wound care products in 2010. These include the updated information card “Prescribability and Reimbursability of Wound Care Products”, the information sheet “Classification and Related Purpose of Dressing Materials”, the brochure “Use of Hydroactive Wound Dressings”, the dressing materials chapter “Wound Care in the Physician’s Practice” of the so-called “Yellow List” pharmaceutical index (Gelbe Liste Pharmaindex), the annual information event on “Modern Wound Care”, and training sessions conducted with the Association of Medical Professions.

Sectoral Interest Group “Renal Replacement Therapy” (FBNE)

The “Kidney Alliance” initiative sponsored by suppliers of products for dialysis technology reached a climax in 2010 with a political panel discussion including representatives from patients, politics, the medical profession,



Medical technology brings back mobility – implants for bones and joints: hip implant, knee implant, shoulder prosthesis, base system for femoral fractures for amputees

and self-governing bodies. Participants discussed the question of whether it will be possible to finance patient-oriented treatment in the future.

Sectoral Interest Group “Nosocomial Infections” (FBNI)

The “Nosocomial Infections” sub-group was given the status of sectoral interest group in order to better pursue the comprehensive, long-term objectives of its active members. In 2010 the FBNI set up its website on nosocomial infections (www.krankenhausinfektionen.info) and prepared high-quality illustrations for any interested party free of charge. The website presents the most important routes of infections and informs on how to avoid hospital infections.

Sectoral Interest Group “Sharps Injuries Prevention” (FBNSP)

The FBNSP is the special committee for suppliers of safety devices to protect from injuries caused by cutting, pricking, and scratching during daily medical practice. In 2010 the FBNSP intensified its cooperation with the accident insurance companies. Great demand generated the need to reprint its training CD with comprehensive teaching materials on sharps injuries, their causes, and how to avoid them.

Sectoral Interest Group “Peripheral Vascular Medicine” (FBPG)

The FBPG supports the promotion of medical technologies in the peripheral vascular system, such as PTA technologies and occlusion systems. Under the coordination of BVMed, the group also participates in the maintenance and evaluation of the scientific register “PTAREG”, which records the treatment of patients suffering from peripheral occlusive arterial disease before or after undergoing PTA. Another topic comprises education and training events at professional congresses.

Sectoral Interest Group “Radiation Sterilization” (FBS)

The FBS is the forum of operators of radiation facilities for sterilizing medical devices. The group concentrates mainly on the implementation of regulatory requirements and educational work to explain what radiation sterilization can do.

Sectoral Interest Group “Spine Surgery” (FBSC)

The FBSC is concerned with medical technologies for the spine, and in cooperation with the medical expert groups supports the establishment and proper representation of these technologies in the fees catalogs. Another key topic is quality assurance.

Sectoral Interest Group “Ostomy / Incontinence Care” (FBSI)

The main topics handled by the FBSI were the supply situation for ostomy care and draining incontinence aids, the voting rights of insurants, and the changed general conditions in the medical technical aids sector. The FBSI supported the National Associations of SHI in checking the reference pricing with relevant market datasets and key points for developing a quality-controlled system for technical aids. The sectoral interest group also updated and published the information card “Reimbursement of Ostomy Products”.

Sectoral Interest Group “Practice Supplies, Pharmacy Supplies, Medical Dressings” (FBSRV)

The FBSRV is critically examining the changed market conditions for practice supplies. One key topic is the fusion of the General Local Insurance Funds AOK Berlin with AOK Brandenburg. The group has prepared an information sheet for physicians and other care providers on the new situation regarding practice supplies in Brandenburg. Furthermore, the group continued its discussions with the regional associations of pharmacists on developments in the market for dressing materials and practice supplies.

Sectoral Interest Group “Soft Tissue Repair Implants” (FBSTRI)

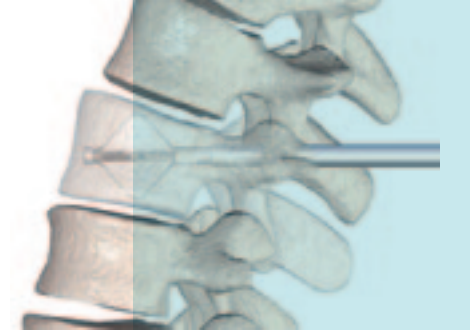
This group represents the interests of suppliers of implants to reinforce soft tissue such as hernias or ligaments. It concentrates on reimbursement questions and quality aspects. There is need for action in the inpatient as well as the outpatient sector. The group focuses on treatments of visceral surgery, gynecology, urology, and plastic surgery. It is currently working with the expert societies to develop a classification system for the sector.



Artificial intervertebral disk replacement



Gentle treatment of vertebral fractures



Cement application into the vertebral body by pressing a button outside the X-ray range

Sectoral Interest Group “Supply of Sterile Goods” (FBSV)

The FBSV is the first point of contact for all questions pertaining to the requirements on sterile goods and their safe use. The main topic was the planned ISO guideline on standards for sterile goods packages.

Sectoral Interest Group “Therapeutic Apheresis” (FBTA)

The sub-group “Lp(a)-Apheresis” within FBTA accompanied and supported the work of the medical planning group for a prospective controlled study to evaluate the effect of apheresis in patients with elevated lipoprotein (a) – a study that has long been called for by the Joint Federal Committee.

Sectoral Interest Group “Tracheostomy / Laryngectomy” (FBTL)

The FBTL communicates the significance and complexity of the various necessary kinds of care for tracheotomized and laryngectomized patients. For instance, it works on producing corresponding professional articles on the subject.

WORKING GROUPS AND SUB-GROUPS

Working Group “Decubitus Forum” (DF)

The main focus of the DF is to raise public awareness on the topic of decubitus. To this end, the DF makes use of various modules such as information material (brochures, info cards), press releases, and the data entry forms for sitting and reclining aids. The DF conducted an online survey of nursing staff as well as a survey of patients to obtain valid information about the current situation. More at: www.dekubitus-forum.de.

Working Group “Electronic Health Card” (PG eGeK)

The group prepared a proposal for the assignment of health professional cards to other types of care providers and specialist dealers of medical supplies. In a joint workshop with a trust center (dgn-service), an actually technically feasible concept was developed for this application process.

Working Group “PVC” (PG PVC)

The working group PG PVC is concerned with the regulations on phthalate DEHP, a PVC softening agent used in many medical devices. As of March 2010, manufacturers are not only obliged to supply information according to the REACH Regulation, but they must also comply with the labeling requirement according to medical device legislation. The harmonized standard on labeling has not yet been passed. Since DEHP is also one of the first six substances included in Annex XIV of the REACH Regulation, listing substances that require authorization, the search for possible substitutes is likely to grow.

Working Group “Reuse” (PG Reuse)

The Reuse working group is concerned with patient safety in the reprocessing and reuse of medical devices, especial medical single-use devices. Data material on the reprocessing risks was compiled for the European Commission report on the reprocessing of medical devices. The EU report describes several critical aspects of reprocessing. Now the task will be to implement the results.

Working Group “Material Costs and Outpatient Surgery” (PG SAO)

The working group coordinates proposals for the inclusion and financing of medical technologies in the service catalog for outpatient surgery in hospitals. The group engages in dialog with the contract partners on the proper representation of applied medical technologies in various outpatient scenarios.

Working Group “Tissues” (PGT)

This group is concerned with products made of animal or human tissue, cells, or blood. The issues often deal with delineations to pharmaceutical law.

Sub-group “eStandards” (AGE)

The sub-group “E-Standards” represents companies in the “Forum eStandards”. The forum of representatives from hospital organizations and medtech companies adopted recommendations on “Classification” and “Product Master Data” as well as an industry focus “EDI, Provider, and Standards”.



BVMed's Head Office in Berlin



Speakers at conferences held by BVMed and MedInform:
JFC Chairman Dr. Rainer Hess and IQWiG Institute's
Director Prof. Dr. Jürgen Windeler



BVMed's Chairman of the Board Dr. Meinrad Lugan with
the Department of Health: Minister Dr. Rösler and
the State Secretaries Dr. Widmann-Mauz and Kapferer

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“Human as the standard. Medical Technology.” State Secretary Daniel Bahr, delivery of the first campaign magazine to the health minister of Schleswig-Holstein Dr. Heiner Garg

BVMed – Our Services for You

BVMed represents more than 200 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 on the internet 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, MedInform 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.

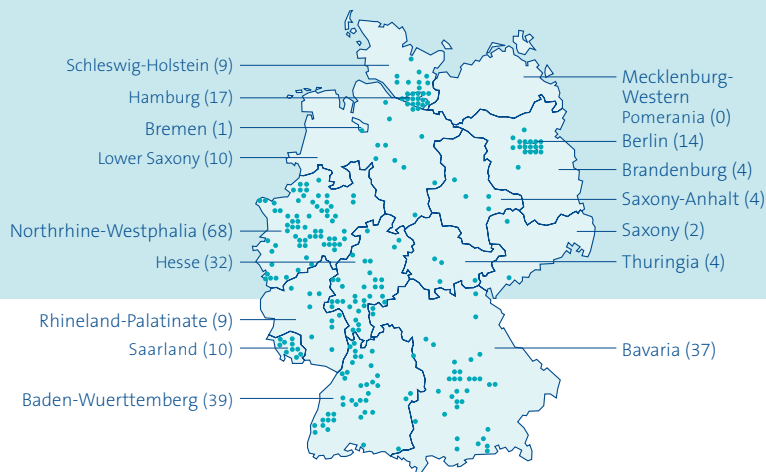
4. Representation

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 on the internet 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 2011: 234 members – current list available at www.bvmed.de

BVMed Membership List

1

1stQ Deutschland GmbH & Co. KG

3

3M Medica Zweigniederlassung der 3M Deutschland GmbH

A

aap Implantate AG
 Abbott GmbH & Co. KG
 Abbott Medical Optics
 *Abbott Vascular Deutschland GmbH
 Abena GmbH
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 Actavis Deutschland GmbH & Co. KG
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 AGA Medical Deutschland GmbH
 ALCON PHARMA GMBH
 American Medical Systems Deutschland GmbH
 Andreas Fahl Medizintechnik-Vertrieb GmbH
 Ansell GmbH
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 Biomet Deutschland GmbH
 BIOTRONIK SE & Co. KG.
 BONESUPPORT GmbH
 Boston Scientific Medizintechnik GmbH
 *BSN medical GmbH

C

C. R. Bard GmbH
 Care Fusion Germany 206 GmbH
 CeramOptec GmbH

CeramTec GmbH
 cerboMed GmbH
 Chemische Fabrik Kreussler + Co. GmbH
 *Coloplast GmbH
 Coltène /Whaledent GmbH + Co. KG
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 COOK Deutschland GmbH
 Cordis Medizinische Apparate GmbH
 *Corin Germany GmbH
 Corizon GmbH
 *Covidien Deutschland GmbH
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 curea medical GmbH
 Cyberonics Europe S. A.

D

Dansac GmbH
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 Devicor Medical Germany GmbH
 DEWE & Co. Verbandstoff-Fabrik Dr. Wüsthoff & Co.
 *DFine Europe GmbH
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 Dr. Ausbüttel & Co. GmbH
 Dr. Schmidt Intraocularlinsen GmbH

E

Edwards Lifesciences Germany GmbH
 EMKA Verbandstoffe GmbH & Co. KG
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 Eurocor GmbH
 ev3 GmbH

F

*FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH
 FOR LIFE Produktions- und Vertriebsgesellschaft für Heil- und Hilfsmittel mbH
 Franz Kalff GmbH
 *FRESENIUS SE
 Fritz Osk. Michallik GmbH & Co. KG
 Fuhrmann GmbH
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G

Gambro Dialysatoren GmbH
 Ganymed GmbH
 Genzyme GmbH
 GerroMed Pflege- und Medizintechnik GmbH
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GHD Gesundheits GmbH Deutschland
 Given Imaging GmbH
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H

HAEMONETICS GmbH
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K

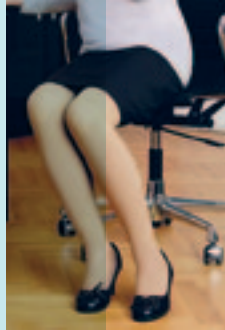
Kaneka Pharma Europe N.V. German Branch
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Technical aids and medical dressings for prevention and healing: wrist brace



medical compression stocking for the function zone knee



compression socking made by designer Wolfgang Joop



elastic support bandages

M

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 *MAQUET Cardiopulmonary AG
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 POLYTECH Ophthalmologie GmbH
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 Rayner Surgical GmbH
 rehaVital Gesundheitsservice GmbH
 RSR Reha-Service-Ring GmbH
 Röлке Pharma GmbH

S

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T

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 We would like to thank the companies marked with an asterisk* for the pictures they provided. More pictures of products and applications are located on the internet at www.bvmed.de (Pictures).

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