Contents

FOREWORD
3 Strengthening the German Medtech Market, Supporting SMEs
4 Market and Member Development

INDIVIDUAL TOPICS
5 Healthcare Politics
6 Medtech Benefit Assessment
7 Hospitals
8 Medical Technical Aids
9 Homecare
10 Medical Devices Law
11 Patients, Occupational and Environmental Safety
12 Communications and Media Projects

13–19 REPORTS FROM THE BVMED EXPERT COMMITTEES

SERVICE
20 BVMed: At Your Service
  Board and Office
21 BVMed: Our Services for You
22–23 BVMed Member Companies

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Foreword

Strengthening the German Medtech Market, Supporting SMEs

Dear Members,

The medtech industry is overwhelmingly characterized by small and medium-sized enterprises (SMEs). 95 percent of all medtech businesses have fewer than 250 employees.

The general conditions under which our industry operates are changing dramatically. The new European Medical Device Regulation, MDR, will lead to higher costs and longer approval processes. The unannounced controls by the Notified Bodies have already brought with them rising costs and extensive administrative burdens for the medtech companies. Additional legal requirements, such as benefit assessment procedures, will continue to put pressure especially on SMEs.

For 2016, this highly innovative industry, which mostly consists of medium-sized businesses, needs an appropriate legal framework that will facilitate market access and strengthen the domestic market in Germany.

It is not only multinational companies that drive progress in medical technology, but also small and medium-sized businesses.

Economic, research, and healthcare policymakers will therefore have to answer the following questions: How are they going to give more political support to medium-sized medical device companies? Which state-run programs can grant funding for research to small and medium-sized businesses and help to speed up decision-making processes while removing bureaucratic impediments? How can the domestic market be strengthened, especially given the fact that a prospering and growing domestic development is the precondition for any successful export business?

BVMed desires the introduction of a law that will accelerate access to innovations, as well as the better involvement of the medtech industry in decision-making processes of the Federal Joint Committee, G-BA, and the Institute for Quality Assurance and Transparency in the Healthcare System, IQTIG. All our companies need uniform European benefit assessment procedures and the mutual recognition of studies. In addition, health services’ research data should become more transparent and be used more profoundly than before.

Together we will continue to shape health and extend high-quality care with modern medical devices, save lives, restore mobility, and help to improve people’s quality of life.

Yours

Dr. Meinrad Lugan
Chairman of the Board of BVMed
Market and Member Development

Member development
For the time being (April 2016), 230 industrial and trading companies are members of BVMed. In 2015, 13 companies joined BVMed. In early 2016, another six joined as well, while 11 companies left BVMed. There were also 9 instances of mergers or acquisitions in 2015. Despite noticeable consolidation processes and increasing pressure on margins, BVMed’s number of members is still remaining stable. A complete list of members can be found on the last two pages of this Annual Report.

Industry data 2014 / 15
Manufacturing of Medical Devices in Germany
The total revenue of the manufacturing medical technology companies (considered are those with more than 20 employees) in Germany increased by 3.3 percent to 25.4 billion euros in 2014, according to the official economic statistics. Domestic sales rose by 4.1 percent to a total of 8.2 billion euros. Foreign sales rose by 3 percent to a total of 17.2 billion euros in 2014. Thus, the export rate was at 68 percent, the highest figure ever accounted. In the middle of the 1990s it was only at around 40 percent.

SHI Expenditure on Medical Devices
Of all the expenditure on medical devices, the Statutory Health Insurance, SHI, spends around 18.8 billion euros per year. The SHI spent 7.2 billion euros on medical technical aids, and 11.6 billion euros on other medical needs.

Above-average Innovative Capacity
Medical technology is a dynamic and highly innovative industry. German medical technology manufacturers make around one third of their sales from devices that are less than three years old. On average, medtech companies invest around nine percent of their revenue in research and development.

Jobs and Medium-sized Companies
The medical technology industry consists of 1,200 businesses (considered are those with more than 20 employees in each business) that employ around 125,000 people.

In addition, another 11,300 small businesses and trading companies employ around 67,000 people. The core industry thus employs a total number of around 195,000 people in over 12,000 companies in Germany (source: Economic Statistics, 2014). Apart from a few large companies, the sector mostly consists of medium-sized businesses. Around 95 percent of all businesses have fewer than 250 employees.

Market development 2015 / 16
The manufacturers of medical devices that are members of BVMed are still growing much faster abroad than on the domestic market. According to the fall survey 2015 conducted by BVMed, in which 90 companies took part, the expected worldwide sales growth in 2015 was at approximately 7 percent. The most important results are:

> The German market for medical devices is still facing significant pressure. On the hand, the expected average sales growth is at nearly 4 percent due to rising sales numbers and new treatment methods; on the other hand, the companies’ profits are still declining and the margins are decreasing. The increasing price pressure through bundling purchasing activities in the hospital sector and tendering for medical technical aids might be responsible for these facts.

> BVMed’s innovation climate index is still at 4.9 on a scale of 10, i.e. at the same level as last year, after it had fallen sharply the year before. The companies predominantly criticize health insurance funds that are hostile to innovations, bureaucratic procedures, the low level of remuneration in Germany, and the uncertainties surrounding the future benefit assessment of medical devices.

> Despite the difficult domestic situation, the medical technology industry in Germany continues to create jobs. 51 percent of BVMed’s companies created more jobs, only 11 percent cut jobs. The job prospects for junior staff are rated “very good” or “good” by 97 percent of the companies. Especially engineers and medical technicians are in demand. Vacancies can be found particularly in sales and marketing.
Healthcare Politics

Healthcare politics in 2015 was characterized by a large number of legislative proposals, which affect medical devices companies directly or indirectly. These laws include the Care Provision Strengthening Act (GKV-Versorgungsstärkungsgesetz), the Hospital Structure Act (Krankenhausstrukturgesetz), the E-Health Act (E-Health-Gesetz), or the Anti-bribery Act in Healthcare (Gesetz zur Bekämpfung von Korruption im Gesundheitswesen). Several other important legislative proposals were discussed, such as the Pflegestärkungsgesetz II for the reinforcement of long-term care, the Prevention Law, and the improvement of hospice and palliative care. The coalition government thus processed the majority of the projects planned in the coalition agreement.

Healthcare political activities

A particular challenge for BVMed’s political activities was posed by the need to raise awareness of the necessities of the medical technology industry among political decision-makers, as consultations for many proposals were taking place simultaneously. With regard to its healthcare political activities, BVMed trusts its proven mix of parliamentary events, receptions, specialist events, rounds of talk, as well as background and one-on-one talks with Members of Parliament, parliamentary and ministerial staff, and representatives of the self-governing structure.

The companies especially consider the hospital reform in a positive light. In the hospital sector there is generally more funding available for better patient care. Another positive factor is the extension of the program for the improvement of hygiene. Regarding hospital remuneration, where costs of materials account for more than two thirds of the overall amount, there were no reductions imposed for additional quantities, which can be considered a success. New examination and treatment methods are not affected by economization.

Precise definition of benefit assessment procedures

Another thematic focus of the healthcare political work of BVMed was on benefit assessment procedures of medical technologies. Concerning the healthcare political activities, the matter discussed was the precise scheme of the regulations for the assessment of new examination and treatment methods in hospitals with medical devices of higher risk classes whose application requires a new theoretical-scientific concept and which are especially invasive. To this end, BVMed presented suggestions, took part in hearings and held talks about the potential implementations with all those concerned. The so-called Regulation on the Assessment of Methods for Medical Devices (Medizinproduktemethodenbewertungsverordnung, MeMBV) came into force at the beginning of 2016. Now, the second step is required. Thereby, the Federal Joint Committee, G-BA, will develop a code of procedure. The initiation of the first definite procedure can be expected for the end of 2016. BVMed wants to ensure that the procedure will not lead to a delay in the introduction of innovations.

Need for improvement regarding e-health and medical technical aids

The E-Health Act was an important topic of conversation last year. BVMed has advocated the inclusion of tele-monitoring procedures and extended access rights to data for other care providers according to article 291 a of the Social Security Code V, SGB V. Other care providers should be included in the telematics infrastructure earlier. As far as BVMed is concerned, many more discussions and improvements are needed. There were also many discussions and events regarding medical technical aids. These raised awareness among politicians that changes are needed with regard to the applicable law, as well as the actual implementation, such as the revision of the register of medical technical aids. The reason for this are extremely low fixed monthly rates for incontinence care, which have led to complaints and petitions by patients. An expert discussion on this matter was held in the parliamentary health committee in the summer of 2015, where BVMed also made a statement. In order to improve the supply of medical technical aids, relevant legal regulations have been announced for 2016.

“BVMed goes Brussels”

At the European level, BVMed has continued its round of talks with German policy decision-makers in Brussels about the European Medical Device Regulation, MDR.
Medtech Benefit Assessment

**Benefit assessment of NUB procedures using medical devices**

The Care Provision Strengthening Act, GKV-Versorgungstärkungsgesetz, has developed benefit assessment procedures of hospital services with new medical devices of higher classes in more detail. The intention of such evaluation schemes was fixed in the coalition agreement of the current German government. Accordingly, hospitals are required to provide information on the latest scientific findings regarding the application of the medical device as well as the individual method to the G-BA committee. These steps are compulsory when demanding remuneration for new examination and treatment methods involving a high-class medical device, NUB, for the first time. This procedure must take place in consultation with the manufacturer of the medical device. However, the manufacturers are not entitled to make applications. In addition, G-BA has to assess to what extent the device has a particularly invasive character and whether the method is based on a new theoretical-scientific concept. This stage of the procedure is defined in more detail by a regulation of the Federal Ministry of Health, which will come into force in early 2016.

**G-BA committee must adapt code of procedure**

The G-BA committee will review the information submitted and decide whether the benefit of the method has been proved sufficiently or, if not, if the method offers the potential for a successful treatment alternative and thus will be tested further. Harmful or ineffective methods will be excluded through a procedure defined in article 137 c of Social Security Code V. The assessment procedure for the classification of the NUB application is set to take four and a half months at the most. If a trial regulation is necessary, G-BA has to decide within six months. As a general rule, the trial must be finished within two years; the period can be extended, however. The costs of the trial are to be borne by the manufacturer alone. The manufacturers and the hospitals may receive cost-free advice from the G-BA committee in advance. This opportunity will establish a legally binding form that explains to what extent the technology fulfills the conditions for an assessment procedure.

**Consequences of the new regulation**

The new regulation shifts the former NUB procedure, which was negotiated at a decentralized level with the local health insurance funds, to G-BA as the central institution. In addition, the former innovation-friendly principle of “permission subject to prohibition” in hospitals will de facto be abolished for these procedures, although similar assessment schemes already exist according to article 137 c of Social Security Code V. The clarification of the new terms, e.g. the new theoretical-scientific concept, leaves much room for interpretation and therefore leads to a lack of legal certainty. The fact that manufacturers are not actively involved in the process will not contribute to increasing their trust in this procedure. Another problem remains unsolved, i.e. protecting innovations from imitator technologies. Benefit assessment must not become another obstacle to the introduction of medical-technological innovations into everyday care.

**Expectations of medtech benefit assessment**

It is not possible to transfer the assessment methods that have been established for pharmaceuticals to medical devices. Due to the wide variety of medical technologies, there can be no single rule that regulates which study design is required for the relevant proof of benefit. BVMed is still advocating a neutral development of scientific guidelines for the benefit assessment of medical technologies. It ought to better take into account the specific characteristics of the respective medical devices. In order to achieve appropriate, transparent and feasible benefit assessment procedures, all those examinations that ensure a high rate of transferability of the results to the reality of healthcare should be considered. Randomized controlled trials, RCT, are neither necessary nor possible in any case, nor are they ethically acceptable. The use and efficiency of a new method may also be proved through case and observational studies, insights from routine and accounting data, registers, as well as other procedures.
What is positive is the fact that exceptions for case fees with very high costs of materials will be retained. The integration of NUB services into the hospital budget will also no longer be a burden to the basic case value in each federal state.

Quality management
Future quality in hospital care is to be improved through various measures. Quality should lead to consequences in hospital planning. The quality guidelines of the G-BA committee will be made mandatory and the regulation for minimum quantities will be arranged in such a way that it leads to legal certainty. Finally, differences in quality for certain services that have to be defined by G-BA will be tariffed with surcharges or discounts in terms of remuneration.

BVMed supports the intention behind the legislation, i.e. improving the quality of hospital care. Therefore, the association basically endorses remuneration based on different quality levels. In this respect, the outcome quality from the patients’ point of view will be of central importance. Especially innovative medical devices can significantly contribute in this regard. The criteria for remuneration based on differences of quality must explicitly consider the relevant methods using high-grade medical devices. Medical devices of special quality must be assessed based on different criteria. In future, quality indicators should take into account the contribution that medical devices make to the provision of high-quality care, e.g. lower numbers of revision or follow-up surgery, higher precision and less invasive procedures, longer service lives and run times of active implants (battery run times), or the prevention of infections through implants with bioactive coatings.

Modern medical technologies can reduce the rates of complications and the hospital treatment times for patients and assure a timely return to work. Quality should primarily be assessed based on medical criteria and not only with economic factors in mind. The outcome quality is of particular importance. To this end, BVMed suggests entering into a structured dialog during a yearly process with all those involved, similar to the long-established process of the further development of the G-DRG system.
Medical Technical Aids

In 2015, there were once again many tenders for medical technical aids, also in areas where tenders are inappropriate. Many health insurance funds, however, use the more reasonable instrument of framework agreements which service providers may join in. In total, there were 20 tenders for medical technical aids in 2015 compared to 81 framework agreements. Quality in the supply of medical technical aids is remaining a key topic.

Quality in supply of medical technical aids: need for reform
Seven years after the introduction of tenders for medical technical aids, the price competition escalated in 2015. It has now become apparent that medically necessary services cannot be provided or implemented at those rates offered by the tenders. This fact has been dealt with in several media reports and is high on the healthcare policy agenda.

In order to guarantee the quality-assured provision of medical technical aids over the medium and long term, the major associations of service providers have developed common position papers with suggestions for solutions and made these available for discussion. BVMed played a substantial role in this process and coordinated these political activities. These measures have, among other things, resulted in the parliamentary health committee organizing e.g. an expert hearing to review in detail the current situation of the provision of medical technical aids to patients. The patient commissioner of the federal government, Karl-Josef Laumann, has addressed this issue as well and commissioned a study on the product quality of absorbent incontinence helps. The Federal Ministry of Health has also recognized the need for action and announced a reform regarding medical technical aids in 2016.

Key points of the medical technical aids reform
The key points presented for the legislative initiative announced take up the major industry demands for the abolishment of the deficits that have been recognized. Accordingly, the Federal Ministry of Health sees the need for reform in the following areas: prequalification procedures, modification of tenders, monitoring of contract implementation, as well as an update of the register of medical technical aids. BVMed will get involved in the legislative process with specific suggestions for solutions.

The fact that also health insurance funds have recognized the unbearable consequences of the price competition caused by tenders is considered positive, too. One large health insurance fund e.g. has withdrawn a tender for absorbent incontinence helps because the tenders submitted by service providers did not cover the costs.

Register of medical technical aids: update announced
The political discussion has made clear that the quality of the provision of medical technical aids can only be improved through a register that reflects current medical-technological progress. Due to public pressure, the Federal Association of the Statutory Health Insurance Funds, GKV-Spitzenverband, has announced an update of the register of medical technical aids and the extension of the standards of care. This is to be achieved for 80 percent of all areas of care over the coming two years. With this measure the association fulfills a long-standing demand of BVMed. BVMed has offered its active support for the update of the register of medical technical aids and the development of device and service standards. In 2015, it suggested specific service criteria in product groups 11, 15, and 29 to the association. Currently, the sectoral interest groups of BVMed that are concerned with medical technical aids are developing service criteria for other areas of care as well.

In addition, BVMed considers it necessary to define the requirements for care staff in the prequalification recommendation (structural quality) in a timely manner.

Prequalification (PQ) implemented and developed further
The protection rule for other care providers ended in 2015. Until then institutions were able to gain a qualification for their professional directors based on the relevant suitability criteria for the area of care. In its sixth update the Federal Association of the Statutory Health Insurance Funds has updated the prequalification recommendation. BVMed is still being actively involved with various current issues concerning prequalification in the PQ advisory council.
Homecare

Due to the growing number of aging and chronically ill as well as multimorbid patients the healthcare system is facing enormous challenges. Only a comprehensive treatment and therapy approach, including all those who are involved in providing healthcare, can assure the desired success of the provision of care. The desire to live a self-determined life in one’s own home is of predominant importance. Homecare companies, with their long-established structures and qualified medical staff, importantly contribute to meet these demands. Homecare ensures that patients receive medical technical aids, surgical dressings, and special medical nutrition together with any relevant product- and patient-specific services at home and in nursing and retirement homes.

Challenge for homecare services
Homecare companies are confronted with the challenge that their services are not included in the Social Security Law. In addition, increasing price competition makes the funding of the services that must be provided difficult. In the course of its political activities, BVMed is therefore advocating that the cost-bearing as well as political institutions specify the benefit entitlement of the insured persons especially with regard to services, and fund these benefits adequately.

BVMed’s homecare companies are demanding the following points: The health insurance funds must be obliged to monitor the fulfillment of the contracts. A statutory deadline must be set for the Federal Association of the Statutory Health Insurance Funds in order to develop consistent standards of care all over Germany. On the positive side, the Federal Ministry of Health has already announced that the issues of monitoring of contracts and standards of care will become part of the planned reform with regard to medical technical aids.

Awareness for homecare
In November 2015, the second Homecare Management Congress took place in Berlin. Politicians, hospital and care representatives, physicians, health insurance funds and businesses discussed interconnected solutions for meeting the challenges of demographic change. The focus areas of the congress were discharge management and the complexity of ambulatory care. The dialog is to be continued at the third Homecare Management Congress on December 1st, 2016. It is accompanied by communication through the homecare newsletter, which has been published regularly since 2014 (www.bvmed.de/homecare-news).

Discharge management
The Care Reinforcement Law (Versorgungsstärkungsgesetz, GKV-VSG) intends to clarify the patients’ entitlement to discharge management by implementing the latter for bridging gaps in the provision of care. In addition, the law also regulates the circumstances under which hospitals may prescribe medical technical aids and pharmaceutical drugs. The G-BA committee has regulated the relevant legal framework in the prescription and medical technical aids guidelines. BVMed was involved in the commenting procedure through written statements as well as taking part in face-to-face discussions. Doing this, BVMed has been able to ensure that G-BA will consider the special characteristics of the prescription of medical technical aids in the respective guidelines.

Electronic health insurance card
The electronic health insurance card has been obligatory since January 1st, 2015. BVMed is working towards the digitalization of the healthcare system, e.g. through political rounds of talk and statements. One of its aims is the timely and non-discriminatory integration of all care providers into the digital processes. Networks of all care providers for patients and the transmission of all relevant data are the prerequisite for an efficiently interconnected future healthcare system. BVMed is also involved in the advisory council of the Electronic Register of Healthcare Professions (elektronisches Gesundheitsberuferegister, eGBR), which campaigns for the needs of care providers that are not academically qualified.
EU Medical Device Regulation

Three years after the announcement of the two Commission proposals for the European Medical Device Regulation, MDR, and the European In Vitro Diagnostic Device Regulation, IVDR, on September 26th, 2012, the Council passed a general approach and presented the consolidated amendments of the drafts in all official EU languages on October 5th, 2015. Thus, the currently ongoing informal “trilogue” between the Commission, Parliament, and Council has started.

If the regulations came into force in 2016, their application would become mandatory three years later. At that point in time (at the end of 2019), old certificates that have already been issued will remain valid for at most another five years (MDR) or two years (IVDR). The new EU regulatory framework will not lead to easier market launches of medical devices in the internal EU market, as initially envisaged by the Commission, but will in fact complicate this process further: Instead of 12 annexes, as before, the MDR will contain 15 annexes and is to be extended by 39 new implementing and delegating acts that will yet have to be developed. The requirements for the performance of clinical trials will be tightened; literature reviews for high-risk devices will become an exception. Moreover, certain medical devices will be classified higher, e.g., surgical instruments for reuse and medical devices that are applied orally or used invasively. Due to the change of the legal framework, all Notified Bodies in Europe will lose their notification after the MDR and IVDR will have come into force; they will have to be notified anew within six months.

BVMed rejects scrutiny procedure

After a decision passed by the European Parliament, class III implants and class IIb devices for the application or removal of medical drugs will have to undergo a scrutiny procedure before they are brought onto the market. This procedure will be a repetition of the audits that have already been carried out by the Notified Bodies, in particular the correct preparation of the documentation including the clinical data. BVMed rejects the scrutiny procedure because it would lead to unnecessary bureaucracy and duplicate testing without offering greater patient safety.

National law

Since October 1st, 2015, German hospitals have been obliged to provide patients who receive devices according to annex 3 of the Medical Devices Operator Ordinance (Medizinprodukte-Betreiberverordnung), e.g., cardiac pacemakers or artificial heart valves, with information on aftercare, as well as implant passes for better traceability of patients. Hospitals are obliged to store this documentation so that the respective patients can be identified within three working days if corrective measures become necessary. In addition, since October 2015, reprocessors of critical medical devices, which also include “single-use devices,” have been obliged to implement a quality management system certified by a Notified Body. Violations of the law are punishable with a fine, obligations, or the closure of the company.

The Federal Ministry of Health is planning amendments of the MDR, the Medical Devices Operator Ordinance, and the Medical Devices Security Plan Regulation, and has published a draft regulation to this end on December 7th, 2015. Among other things, the term “operator” of medical devices is to be provided with a legal definition and the function of an “authorized representative for the safety of medical devices” is to be introduced in healthcare institutions with more than 20 employees.
Patients, Occupational and Environmental Safety

Hygiene and medical devices
Hospital hygiene has become an ever more important issue. The German government made the fight against infections a topic on the agenda of the G7 Summit in Elmau, Bavaria, in June 2015. The Federal Ministry of Health prepared a 10-point plan that, among other things, calls for an improvement of hygiene standards and more information on the hygiene quality in hospitals. Experts estimate that there are up to 600,000 cases of nosocomial infections in medical institutions every year – and up to 15,000 deaths resulting from these. According to estimates, up to 30 percent of these infections could be prevented. Hospital infections can also occur in connection with the application of medical devices. Therefore, BVMed aims to contribute to prevent this type of infection. The initiative’s website (www.krankenhausinfektionen.info) provides information about the most important kinds of hospital infections and their prevention with clear graphic presentations, most recently also about the norovirus infection, which occurs every year. The “Hygiene Forum” of BVMed, which takes place once a year, presents current developments in the field of hospital hygiene to hospitals themselves, representatives of the self-governing structure of the health insurance funds, as well as to politicians. It also illustrates how medical technology can contribute to prevent nosocomial infections.

Reprocessing of medical devices
The proper handling of medical devices contributes to the protection of patients, and this effect begins even before the patient is treated, e.g. when devices are previously being reprocessed. Reprocessing also happens in cases where the manufacturer has not developed the device for reprocessing and reuse. In order to prevent patients from being infected or injured, the EU Commission has proposed a regulation for single-use devices and their reprocessing as part of the proposed amendment of the European law on medical devices, the Medical Device Regulation, MDR. By now, the proposals made by the EU Parliament and the EU Council have been presented, too. BVMed demands that only those medical devices are reused whose potential reprocessing has been proven and validated with regard to safe reuse.

Furthermore, BVMed supports the Commission’s proposal for a regulation that will treat reprocessors of single-use devices in the same way as manufacturers.

Employee protection: sharp injuries and contaminated returns
Risks of injury and infection from the handling of medical devices also exist for employees in medical institutions as well as in the supplier companies. These include in particular injuries from sharp medical instruments (needlestick injuries), as well as contamination during the maintenance or return of used medical devices. The Technical Rule for Biological Agents TRBA 250 “Biological Agents in Healthcare and Welfare Facilities” implements the requirements of the EU directive on the avoidance of injuries from sharp instruments and makes the use of safety devices mandatory. However, there is still considerable uncertainty with regard to the question of who will bear the costs in the ambulatory sector. In 2015, BVMed presented a completely revised version of its “return papers” for the protection of employees who handle returns of potentially contaminated medical devices. The return papers contain recommendations for medical institutions, as well as sample procedural instructions for companies.

Environmental protection in the medtech industry
The European Union Chemicals Regulation REACH with its information and registration requirements and restrictions of the use of substances and mixtures pursues an EU-wide improvement of occupational safety, health and environmental protection. In addition, the RoHS Directive contains bans of toxic substances in electronic devices. Both regulations are continuously updated due to new rules for substances, and therefore the discussion about materials is dominating the issue of environmental topics at BVMed. The focus is on CMR substances, which are classified as carcinogenic, mutagenic, or toxic to reproduction, as well as on endocrine-active substances that interfere with the hormone system. Especially with regard to the application of medical devices, these substances will be regulated in the future European Medical Device Regulation.
Communications and Media Projects

Information campaign “Der Mensch als Maßstab”
Providing information about the importance and value of medical technologies is an important task of BVMed: for the public, for healthcare, for the economy in general. A core element of BVMed’s public relations activities is the information campaign “Der Mensch als Maßstab. Medizintechnologie” – Measuring by the Human Standard. Medical Technologies – (www.massstab-mensch.de), which was started in 2010. With its sophisticated aesthetics, large posters, and unusual magazines the campaign is breaking new ground in the medtech industry.

Patients showing “Body Pride”
The campaign continued in 2015 with a new series of themes called “Körperstolz” (“Body Pride”, www.bvmed.de/koerperstolz). They portray patients with chronic diseases who live their lives to the fullest. The campaign focuses on four motifs – ostomy, incontinence, artificial nourishment, and diabetes –, as well as in-depth interviews with patients. In 2016, the topics tracheotomy, laryngectomy, and home dialysis will be added. The campaign aims to improve the public’s understanding of the situations the patients face in their lives, and to show the importance of medical devices for a self-determined life. The motto is: “Every human being is unique. We help some of them to live like everybody else.”

Video channel “I am MedTech”
The new video channel “I am MedTech” on Facebook (www.facebook.com/iammedtech) and Youtube is also focusing on patients. Videos are posted on a weekly basis and show the benefit of medical technologies from the patients’ perspective.

Reports “From the Idea to the Patient”
While the “Body Pride” and “I am MedTech” campaigns place the focus on patients, in the series of reports titled “From the Idea to the Patient” (www.bvmed.de/reportagen) it is the researchers and developers of the BVMed’s companies that are at the center. The reports portray the employees responsible for the areas of research and development, clinical studies, approval, quality assurance and market observation. By looking behind the scenes of the development of medtech devices we want to show the motivation of the people in the industry and the diverse efforts the companies make to assure high-quality and safe care for patients.

Patient information
Medical-technological progress, an aging population, new information technologies: comprehensible and up-to-date patient information is becoming more and more important against this background. BVMed has accepted this challenge with “Aktion Meditech” (www.aktion-meditech.de) – always working closely together with physicians and patient groups. BVMed’s website (www.bvmed.de) also offers clearly structured information about medical-technological solutions for various diseases, as well as patient information films.

Social media and medical technology
Social networks have become an important element of the communication activities 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) with more than 1,500 followers as well as several Facebook pages displaying technological and career topics.

Media activities and photo gallery
BVMed is continuously addressing and working with the media. Thus, BVMed was able to assure that over 3,600 articles mentioned the association in various print and online publications in 2015, reaching over 110 million readers. The weekly BVMed newsletter with more than 8,000 subscribers remains an important feature of the medtech industry. The other areas of media work are our own photo galleries, “BVMed Bilderwelten”, press conferences, the annual Media Seminar, as well as press releases, background services, guest articles, and industry reports in German and English. The eleventh BVMed Communication Congress for Medical Technologies, which took place in Cologne in June 2015, presented ways to make the communication activities of medtech companies more professional. Furthermore, the BVMed press department organizes one-day seminars dealing with media work, patient communications, crisis management, online communications, as well as social media and marketing strategies.
Reports from the BVMed Expert Committees

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

Working groups deal with issues of general concern to all members on a continuous basis, 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.

Project groups are committees set up on a temporary basis. They 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 BVMed’s groups can be found at: www.bvmed.de/arbeitsgremien.

WORKING GROUPS

Working group “eStandards” (AKE)
AKE is the representation of the BVMed members in the “Forum eStandards”. The forum consists of representatives of hospital purchasing groups and BVMed member companies, and has established itself as a platform for the joint development and dissemination of recommendations for electronic communications in the exchange of business data. The basis are the papers published by the forum, which recommend a standardized approach to implementing product classification, master data exchange, electronic data interchange, and electronic invoicing. BVMed is a partner of the “eCG” project “Standards Supporting E-Commerce in the Healthcare System” (Standards zur Unterstützung von E-Commerce im Gesundheitswesen) funded by the Federal Ministry of Economics. As such, it works towards the adherence to the recommended standards. Another focus of AKE is on the concept of the UDI (Unique Device Identification), which is meant to be introduced with the amendment of the European Medical Devices Law. With regard to different e-commerce standards, AKE will in future increasingly focus on EU-wide and global developments, too.

Working group “Hospital Market” (AK HM)
AK H M deals with projects and activities regarding the hospital buying process as well as the rules for submitting tenders. The BVMed working group functions as a contact point for hospitals on behalf of the German 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. Its range of tasks also includes logistic processes between the companies, service providers, and hospitals. In addition, AK KH M cooperates with AKE on the further development of data exchange standards in business dealings between purchasing organizations and manufacturers.

Working group “Legal Affairs” (AKR)
The members of AKR (in-house legal advisers) and the external lawyers of the associated “Network Medical Devices Law” answer questions concerning legal matters from the BVMed working committees. To this end, AKR has formed 16 sub-working and project groups. AKR mostly deals with the legal issues “compliance” and “data protection in the healthcare system” on a national and European level. AKR provides member companies with legal assistance via the compilation, publication, and update of legal guidelines, journal articles and comments, as well as through legal symposia and seminars. The members of AKR also update the BVMed loose-leaf commentary on the Medical Devices Law “WiKo – Medizinproduktrecht”, which was published in April 2015 in its 15th edition. The commentary is accompanied by a blog (www.wiko-mpg.de), which is updated daily. The blog is an online law database, which is currently listing over 400 court decisions about medical devices.

Working group “Regulatory and Public Affairs” (AK RP)
AKRP observes the regulatory industry environment and participates in shaping it. The priority issue in 2015 was the legislative process for the introduction of an EU Medical Device Regulation. AKRP rejects the introduction...
of a scrutiny procedure (EU double check) for high-risk devices. It supports the uniform application and monitoring of the existing legal framework across the European Union by qualified Notified Bodies and authorities. AKRP cooperates closely with national and European expert groups: DIN German Institute for Standardization, Germany’s national accreditation body DAkkS, the Federal Ministry of Health, the authorities of the federal states, ZLG (central authority of the federal states for health protection with regard to pharmaceutical products and medical devices), the Notified Bodies, the Federal Institute for Drugs and Medical Devices, the German Institute of Medical Documentation and Information, the European Commission, MedTech Europe, the European Committee for Standardization (CEN), and ISO. Within the national Medical Devices Law working-group of the associations of the medtech industry (Arbeitsgruppe MPG der Industriefachverbände, AG MPG), AKRP develops regulatory statements and flyers. AKRP also answers questions concerning regulatory matters from the BVMed working committees. To this end, AKRP has formed eleven sub-working and project groups. In addition, AKRP is in charge of editing the BVMed information sequence “Medizinproduktrecht” (Medical Devices Law), which is currently consisting of eleven guidelines on different legal and regulatory matters.

**Working group “Environment” (AKU)**
The members of AKU exchange information on the relevant requirements posed by environmental law. In the reporting year, AKU formed sub-working groups for several key issues in order to be able to operate more quickly and efficiently. The members of the sub-working group on circular economy developed arguments for the appropriate implementation of the 7th amendment of the Packaging Ordinance through the public authority document “LAGA M 37”. The information and registration requirements, restrictions and bans contained in the European Union Chemicals Regulation REACH and the RoHS Directive on the avoidance of hazardous substances in electric devices are updated on a continuous basis. Therefore, the evaluation of substances in medical devices and possible alternatives will remain a permanent topic for AKU. Another key issue for the future will be the law on recyclable materials.

**Healthcare Compliance Committee (HCCC)**
The key issue in 2015 was the draft Anti-bribery Act in Healthcare. The background to this is a decision by the Federal Court of Justice from 2012 according to which the criminal offense of bribery does not apply to practice-based statutory health insurance physicians. Despite improvements to the advisor’s draft law, the legal committee and other experts are highly critical of the so-called “second alternative of the elements of the case.” The provision was too vague and could create unnecessary suspicion of corruption with regard to cooperation models desired by social law. BVMed has called for the deletion of this alternative of the elements of the case. Only in this way is it possible to guarantee that useful cooperation without corruption can take place between physicians and the industry in the interest of appropriate and high-quality patient care.

**SECTORAL INTEREST GROUPS**

**Sectoral interest group “Eye Surgery” (FBA)**
FBA represents the manufacturers and distributors of medical devices used in surgery on or in the eye, especially intraocular lenses (IOL). FBA calls for appropriate and uniform quality requirements for IOL on the basis of international standards. FBA bases its information campaign “Cataract Initiative” (www.initiativegrauerstar.de) about the additional benefits of innovative intraocular lenses on the further development and patient-friendly design of its web presence.

**Sectoral interest group “Brachytherapy” (FBBT)**
The working group Seeds / Prostate Cancer of FBBT supports the inclusion of this technology into the SHI service catalog. On behalf of the companies involved, BVMed accompanies the method evaluation (benefit assessment) and quality assurance process of the G-BA committee.
Sectoral interest group “Diabetes” (FBD)
FBD aims to ensure that innovative diabetes technologies and therapies are available to all those who need them on a timely basis. Through its active public relations work and in cooperation with other relevant organizations, FBD is establishing itself as a competent point of contact with regard to diabetes technologies.

Sectoral interest group “Diagnosis Related Groups – Hospital Financing” (FB DRG)
FB DRG aims to ensure the appropriate representation of medical technologies during the further development of the G-DRG system. The sectoral interest group coordinates the various suggestions made for the further development of the DRG and OPS classifications. FB DRG analyzes the current legislative activities, e.g., the hospital reform, and draws up relevant statements. Besides, it develops events as well as informational material on this matter. It is in dialog with partners in the healthcare system, such as the hospital federations, the health insurance funds and the hospital market associations.

Sectoral interest group “Endoprosthetics – Implants” (FBEI)
Artificial joint replacements have been among the most successful surgical interventions over the last few decades. They enable patients to enjoy new mobility and live a largely pain-free life. Increasingly, however, the media are using tragic isolated cases as an occasion for discrediting endoprosthetics as a whole. This causes uncertainty in the patients concerned, who will delay necessary operations. The member companies of FBEI supply information about all aspects of endoprosthetic care in coordination with the professional medical associations. In 2016, the White Paper on Joint Replacements ("Weißbuch Gelenkersatz") will be published. It will provide a compendium with the most important facts and figures to support arguments in favor of endoprosthetics. Together with the health insurance funds, the hospitals and the Federal Ministry of Health, the FBEI companies support the Endoprosthesen Register Germany (Endoprothesenregister Deutschland, EPRD). As of the beginning of 2016, almost 500 hospitals had recorded over 200,000 cases in the register. Currently, a concept for the evaluation of the submitted data is being developed. During the reporting year, the work of the EPRD database has become more professional. It was able to acquire skilled professionals so that the register’s office can now be operated by the EPRD association itself.

Sectoral interest group “First-Aid Material” (FBEH)
FBEH is the interest group of the manufacturers of first aid materials and kits, which are used for cars, motorcycles, and businesses. Its members campaign for the continuous adjustment of first aid materials according to the latest findings of modern emergency and disaster medicine. The working group “Communications” (AGK) of the manufacturers of first aid kits for motor vehicles provides information about the importance and benefits of first aid kits and about the duties of the users through its continuous press work.

Sectoral interest group “Homecare” (FBHC)
FBHC was predominantly concerned with the topics of quality of care, tenders, and discharge management in relation to medical technical aids. FBHC aims to raise awareness for homecare and to stress the importance and role of homecare in ambulatory care. It was involved in the organization of the second Homecare Management Congress. A regular homecare newsletter accompanies its activities and provides decision-makers in the healthcare system with targeted information about homecare topics and issues.

Sectoral interest group “Cardiac Medical Devices” (FBKMP)
FBKMP is concerned with medical technologies that are used in cardiovascular examinations and treatments. Working groups and projects within the sectoral interest group exist for active implants (cardiac pacemakers, ICD-CRT systems, telecardiology), interventional technologies (stents), as well as interventions through heart surgery, such as prosthetic heart valve technologies, cardiopulmonary systems, or artificial heart technologies. An exhibitors’ advisory council is in dialog with the medical societies and professional associations in terms of congress and further training activities.
Sectoral interest group “Artificial Nourishment” (FBKE)
FBKE campaigns for the medically necessary, sufficient, and appropriate supply and reimbursement of medical enteral nutrition. It was closely involved with the upcoming amendment of the prescription guideline Arzneimittelrichtlinie and the respective commenting procedure at the G-BA committee. FBKE is in close contact with the “Diätverband”, the association of the manufacturers of food for special dietary use. In order to classify enteral nutrition therapy in a way that is sensible and clear for physicians prescribing it as well as for payers, FBKE and Diätverband have published a joint category system depicting enteral nourishment in English. Thereby, both associations are contributing to security. In addition, the sectoral interest group is currently developing a suggestion for the definition of Germany-wide standards for providing care with medical technical aids used in the application of enteral nutrition and tube feeding.

Sectoral interest group “Health Insurance Law for Service Providers” (FBLL)
FBLL is concerned with the current framework created by social security and procurement law as well as with new legislative proposals. Thus, it supports BVMed in drawing up statements. In 2015, the focus of its activities was, among other things, on the Statutory Health Insurance Care Reinforcement Law (GKV-Versorgungstärkungsgesetz), especially with regard to discharge management. Furthermore, the sectoral interest group was preoccupied with the anti-corruption law and the law on modernizing procurement. FBLL is closely concerned with the issue of tenders and discussed social law approaches in order to ensure high quality in the supply of medical technical aids. In this context, FBLL was involved in the activities of the Medical Technical Aids Interest Group, Interessengemeinschaft Hilfsmittelversorgung (IGHV), in which several associations cooperate.

Sectoral interest group “Market Access” (FBMA)
FBMA combines the activities for the timely market launch of innovative medical devices and their representation in the service catalogs. This involves adequate reimbursement levels and overcoming access barriers to remuneration and refunding. Other focal topics of FBMA are benefit assessment and healthcare research. It discusses methodological approaches to benefit assessment schemes of medical technologies and accompanies the implementation process of benefit assessment as part of the procedure for new examination and treatment methods.

Sectoral interest group “Mechanical Thrombosis Prophylaxis” (FBMT)
FBMT is concerned with all matters of physical thrombosis prophylaxis. Its focus is on public relations work. The members updated the brochure on physical thromboembolism prophylaxis in hospital and ambulatory care. Moreover, they are in regular dialog with physicians and nursing staff. This exchange is aimed at maintaining the care situation in the area of thrombosis prophylaxis in the medium- and long-term.

Sectoral interest group “Modern Wound Care” (FBMW)
The aim of FBMW is the improvement of access to the care for chronic wounds. To this end, the sectoral interest group has commissioned an independent institute with a data analysis in order to generate valid data on wound care. These data will serve as a basis for discussions with all stakeholders in the healthcare system and will have an impact on the public relations work of FBMW. With the first wound dialog on the issue of the need for action among payers and physicians to ensure best practice for improved care structures, “Best Practice für verbesserte Versorgungsstrukturen – Handlungsbedarf bei Kostenträgern und Ärzten,” the sectoral interest group has also created a platform for discussing and advancing joint solutions for the improvement of the current situation of wound care in Germany with all those concerned. Moreover, FBMW has revised and published the information card on the prescribability and reimbursability of wound care products, “Verordnungs-
Cardiology: Cardiac pacemaker, implantable defibrillators and telecardiology monitoring of patients with pacemakers

Sectoral interest group “Peripheral Vascular Medicine” (FBPG)

FBPG is concerned with medical technologies used in the peripheral circulatory system, e.g., PTA technologies, drug-coated stents, stent grafts, and intercranial systems for stroke therapy. The activities at specialist congresses are coordinated together with the professional medical societies through an exhibitors’ advisory council. In addition, FBPG coordinates register projects as well as initiatives for the further development of the DRG system in cooperation with the professional societies.

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

FBI-H plays a significant role in taking a critical look at the care and contract situation for absorbing incontinence products. The sectoral interest group was actively involved in political discussions. It developed solutions, and discussed with politicians and payers how patient-oriented and medically necessary care can be improved and assured in the long term. Its activities are based on its own position papers and the information brochure “Aufsaugende Inkontinenzhilfsmittel,” which presents data, facts, and background information about absorbent incontinence aids in Germany. With regard to the topic of quality, FBI-H contributed a statement to the current update of product group 15 of the register of medical technical aids.

Sectoral interest group “Renal Replacement Therapy” (FBNE)

The members of FBNE are the suppliers of dialysis technology devices. FBNE aims to inform the public about the importance of these life-saving medical technologies and the conditions necessary to make them available.

Sectoral interest group “Nosocomial Infections” (FBNi)

Despite their different ranges of products, the active members of FBNi are united by a common ambition: the prevention of hospital infections. They contribute to this goal through their own website “Infektionen vermeiden – Bewusst Handeln” (“Avoiding Infections – Acting Sensibly” at www.krankenhausinfektionen.info), and the “Hygiene Forum” of BVMed, which takes place once a year as a platform for dialog. On its website, FBNi presents a visualization of the most common ways of infection and describes how infections can be prevented. In 2015, the information offered was extended to the norovirus, and it will be expanded further. Over and above these means of communication, the manufacturers’ devices help to prevent infections in their different ways.

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

FB STRI represents the interests of the suppliers of implants for soft tissue reinforcement. The sectoral interest group’s aim is the discussion of the joint interests and needs for this type of product as well as the coordination of the 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 dealing with hernia and biological implants (Herniamed).
Sectoral interest group “Spine Surgery” (FBSC)

FBSC, which represents medical technologies for the spine, supports the establishment and appropriate representation of medical technologies for the spine within the classification and remuneration catalogs, as well as the development of patterns for health services research. In cooperation with the German Spine Society (Deutsche Gesellschaft für Wirbelsäulenchirurgie, DWG), FBSC is involved in the development and design of the German spine register. FBSC alsocoordinates the further training activities together with the professional societies.

Sectoral interest group “Sterile Materials Care” (FBSV)

FBSV is concerned with the exchange on issues concerning the requirements of sterile devices and devices that must be used in a low-germ environment. Specific topics are considered in the sub-working groups “Ethylene Oxide Sterilization” (AGEO) and “Radiosterilization” (AGS). The stricter requirements for sterilization with ethylene oxide have been particularly focused on. This traces back specifically to the decision made by the French health authority ANSM about medical devices sterilized with ethylene oxide that are to be used for premature and newborn babies and infants.

Sectoral interest group “Ostomy / Incontinence Care” (FBSI)

FBSI focuses on the topic of quality-assurance in ostomy and draining incontinence help care. It has developed a suggestion for the definition of nationwide standards of care and made it available to the Federal Association of the Statutory Health Insurance Funds, GKV-Spitzenverband. It was also involved in the current update of product group 15 of the register of medical technical aids. In order to strengthen the rights of patients, FBSI has also developed general and targeted patient information cards, which are available for download from www.bvmed.de/infokarten.

Sectoral interest group “Therapeutic Apheresis” (FBTA)

The members of FBTA are companies that offer technologies for extracorporeal blood cleansing. The member companies support the German Lipidapheresis Register (Deutsches Lipidaphereseverregistr, DLAR), which will compile a systematic documentation of lipidapheresis procedures. The DLAR registry aims to substantiate known positive results with the help of a wide range of data, thus securing established forms of therapy.

Sectoral interest group “Tracheotomy / Laryngectomy” (FBTL)

In 2015, FBTL developed a position paper on its priority issues and goals. The main focus is on assuring quality of care. To this end, FBTL updates the brochure “Empfehlung für die Versorgung tracheotomierter Patienten” (“Recommendations for the Care for Patients Who Have Undergone a Tracheotomy”) and develops a proposal for the definition of Germany-wide standards of care in this area. Moreover, it continues with its targeted public relations work, e.g. via interviews with experts in specialized journals. FBTL also strives for increasing exchange of information with the other professional associations concerned.

Sectoral interest group “Abbreviated Supply Channel” (FBVV)

FBVV aims to ensure that patients have access to medically necessary high-quality hearing aids through an abbreviated supply channel. To this end, it has started the quality initiative “Verkürzter Versorgungsweg” (Abbreviated Supply Channel, www.hörgeräte-qvv.de). The initiative guarantees that patients are equipped with high-quality hearing aids straight at ENT specialists, as the latter work closely together with hearing aid acousticians. This venture is based on jointly defined quality features and a compliance codex, which is obligatory for the members. The program is accompanied by a website, which provides information about the abbreviated supply channel. Moreover, FBVV conducted a round table talk on this issue with medical experts as well as representatives of the health insurance funds.
Medical care for premature babies has constantly improved over the last 30 years thanks to the progress of medical technology.

**PROJECT GROUPS**

**Decubitus Forum (DF)**
DF supported the Federal Association of the Statutory Health Insurance Funds (GKV-Spitzenverband) in the revision of product group 11 (devices for the prevention of decubitus) of the register of medical technical aids. To this end, DF provided an expert statement that defines service criteria for this product group. As part of its ongoing public relations work, DF has published a patient information leaflet on the avoidance and early recognition of decubitus and the treatment with appropriate medical technical aids. The DF platform [www.dekubitus-forum.de](http://www.dekubitus-forum.de) complements the public relations activities of the project group.

**Project group “Neurostimulation”**
The project group brings together the manufacturers of implantable medical technologies in the field of neurostimulation, e.g. deep brain stimulation or procedures used for epilepsy and migraine. Its key topics are the promotion of the appropriate representation of the technologies in the reimbursement systems as well as the development of patient information materials.

**Project group “Rehabilitation Technology” (PG Reha)**
Rehabilitation technology helps to preserve mobility and makes the provision of ambulatory care easier through specific medical technical aids. The BVMed project group unites service providers with a focus on rehabilitation technologies. It aims to create awareness of the important role of rehabilitation technologies in ambulatory care and to assure a high quality of care.

**Project group “Occupational Safety” (PGAG)**
The focus of PGAG is on field staff working in distribution, service, and application support. PGAG has thoroughly updated the “return documents” of BVMed and developed recommendations regarding returns for the staff of medical institutions as well as sample procedural instructions for companies.

**Project group “Intermittent Self-Catheterization” (PG ISK)**
The project group aims to guarantee high quality of care in the field of intermittent self-catheterization. In this respect, it works closely with the German-language Paraplegia Association (Deutschsprachige Medizinische Gesellschaft für Paraplegie e. V., DMGP), e.g. in its planned patient survey. The activities are accompanied by the targeted public relations work of the campaign “Faktor Lebensqualität” (Quality of Life Factor, [www.faktor-lebensqualitaet.de](http://www.faktor-lebensqualitaet.de)).

**Project group “Medical Care and Remuneration” (PG MVV)**
PG MVV issues the newsletter “MedTech ambulant” ([www.bvmed.de/medtech-ambulant](http://www.bvmed.de/medtech-ambulant)), which is published quarterly. It addresses in particular practice-based physicians by looking at issues and topics that are specific and relevant for them. The issues dealt with in 2015 were lipedema, hernia operations, ambulatory lymphological care, as well as compression therapy in ambulatory care. Moreover, PG MVV is updating the brochure on the legal framework for ambulatory surgery in the Statutory Health Insurance system.

**Project group “Re-Use” (PG Re-Use)**
PG Re-Use is the group that deals with the reprocessing and reuse of medical devices. For some time, its activities have been focused on the different proposals by the European Union institutions for a common European regulation for reprocessing medical devices, including single-use devices, through the planned Medical Device Regulation. Basically, only those medical devices should be reprocessed and reused whose reprocessing has been proved and validated with regard to safe reuse.

**Project group “Tissues” (PGT)**
PGT is the body for the discussion of products that are manufactured using animal or human tissue, cells or blood.
The copies of BVMed's new "Body Pride" campaign ("Körperstolz", bvmed.de/koerperstolz)
BVMed: Our Services for You

The German Medical Technology Association (BVMed) is an industry association that represents around 230 medical technology industry and trade companies. Among the members of the association are 20 of the largest medical device manufacturers worldwide in the consumer goods sector. The scope of BVMed’s members comprises the entire sector of medical dressings, medical 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, applications of nanomedicine and biotechnology procedures, such as tissue engineering (tissue replacement), 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. The services of BVMed can be subdivided into four sectors:

1. **Organization**
BVMed carries out the joint formation of opinion in more than 50 committees covering specific subjects. Further information can be found in this report starting on page 13. An up-to-date list of the BVMed working committees can be found at www.bvmed.de/mitglieder.

2. **Consultancy**
The experts of BVMed are ready to offer accurate advice to members on such diverse topics as the Medical Devices Law, reimbursement for medical devices in hospital and ambulatory care, the Law on Advertising in the Healthcare System, standardization projects or ordinances.

3. **Information**
BVMed offers a wide range of information through its internal as well as external communications, e.g.:

**INTERNAL COMMUNICATIONS**
General circulars to all members, specific circulars for the individual expert committees, weekly newsletters, weekly chartpool, monthly report, extranet for member companies.

**EXTERNAL COMMUNICATIONS**
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 and radio service with film material, background discussions with the media, and social media channels (Youtube, Facebook, Twitter).

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 join BVMed?**
The terms and conditions for membership of BVMed are stated in article 3 of the BVMed statutes, which can be found on the website (www.bvmed.de/satzung) or by contacting BVMed. Applications for membership must be submitted in a letter to the managing director of BVMed. Please contact us. We look forward to helping you!
As of April 2016: 232 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 GmbH & Co. KG, Abbott Diabetes Care (ADC)
Abbott Vascular Deutschland GmbH
Abena GmbH
Abiomed Europe GmbH
Acandis GmbH & Co. KG
Aesculap AG
ALCON PHARMA GmbH
alloPlus GmbH
AMO Abbott Medical Optics Germany GmbH
AMPLITUDE GmbH
Andreas Fahl Medizintechnik-Vertrieb GmbH
AngioDynamics Inc. Germany
Ansell GmbH
ArjoHuntleigh GmbH
ATMOS MedizinTechnik GmbH & Co. KG
Attends GmbH
auric Hörsysteme GmbH & Co. KG
B. Braun Melsungen AG
Bausch & Lomb GmbH
Baxter Deutschland GmbH
Becton Dickinson GmbH
B. Braun Melsungen AG
BGS Beta-Gamma-Service GmbH & Co. KG
bionet Biomedical Technology GmbH
Biomet Deutschland GmbH
BIOTRONIK SE & Co. KG
BONESUPPORT GmbH
Boston Scientific Medizintechnik GmbH
Bracco Imaging Deutschland GmbH
BSN medical GmbH
BTG International Germany GmbH
C. R. Bard International GmbH
Cardinal Health Germany 507 GmbH
CARDIONOVUM GmbH
CareFusion Germany 318 GmbH
Carl Zeiss Meditec Vertriebsgesellschaft mbH, Vertrieb Ophthalmo-Chirurgie
CeramTec GmbH
cerbomed GmbH
Chemische Fabrik Kreussler & Co. GmbH
Coloplast GmbH
Coltène / Whaledent GmbH + Co. KG
ConvaTec (Germany) GmbH
COOK Deutschland GmbH
CORIN GSA GmbH
Corinon GmbH
Covidien Deutschland GmbH
CPR GmbH
curasan AG
curea medical GmbH
Dansac GmbH
DEWE + Co. Verbandstoff-Fabrik Dr. Wüsthoff
dFine Europe GmbH
DiabetikExpress GmbH
DIAMED Medizintechnik GmbH
Dr. Ausbittel & Co. GmbH
Eckert & Ziegler BEBIG GmbH
Edwards Lifesciences Services GmbH
EMKA Verbandstoffe GmbH & Co. KG
curacon GmbH
FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH
Fidia Pharma GmbH
FOR LIFE GmbH
Franz Kalff GmbH
Fresenius SE & Co. KGaA
Freudenberg Medical Europe GmbH
Fuhrmann GmbH
Fumedica Medizintechnik GmbH
Gambror Dialysatoren GmbH
GerroMed Pflege- und Medizintechnik GmbH
Gesundheitsteam GmbH Bayern
GHD GesundHeits GmbH Deutschland
GID Germany GmbH
Globus Medical Germany GmbH
HAEMONETICS GmbH
HANS HEPP GmbH & Co. KG
HEIMOMED Heinze GmbH & Co. KG
Helm Medical GmbH
Henry Schein Medical GmbH
Heraeus Medical GmbH
Hollister Incorporated Niederlassung Deutschland
Holthaus Medical GmbH & Co. KG
HOMANN – MEDICAL GmbH u. Co. KG
Hörkonzepthe Vertriebs GmbH & Co. KG
Hospira Deutschland GmbH
HOYA Surgical Optics GmbH
Ilneseer Hospitailia GmbH
implantcast GmbH
Impulse Dynamics Germany GmbH
Integra GmbH
Intrinsic Therapeutics, Inc.
Intuitive Surgical Deutschland GmbH
JenaValve Technology GmbH
Johnson & Johnson Medical GmbH
Juka Pharma GmbH
Kaneka Pharma Europe N.V. German Branch
Karl Beese (GmbH & Co. KG)
KARL OTTO BRAUN GmbH & Co. KG
KCI Medizinprodukte GmbH / An Acelity Company
Kettenbach GmbH & Co. KG
Kramer MT GmbH & Co. KG
KRAUTH medical KG (GmbH & Co. KG)
KREWI Medical Produkte GmbH
KUBIVENT GmbH
LDR Medical
Leina-Werke GmbH
Licher MT GmbH
Lohmann & Rauscher International GmbH & Co. KG
Ludwig Bertram GmbH
MagForce AG
mamedis GmbH
Mammotome Devicor Medical Germany GmbH
Maquet Cardiopulmonary GmbH
Mathys Orthopadie GmbH
medac Gesellschaft für klinische Spezialpräparate mbH
Diverse professions in medical-technology: The industry employs over 190,000 people, ranging from development engineer and designer to production worker.