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Facts – Opinions – Background

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Executive Summary

1. Issue Monitoring

Another MDR corrigendum on its way

f.l.t.r: Dr. Meinrad Lugan, Günther Oettinger

The European Commission has decided to initiate another "corrigendum" that will amend or modify some parts of the EU Medical Device Regulation (MDR). The key issue is a transitional period that will be introduced for class I devices that are classified higher by the MDR, like class Ir. In this way the "hard deadline" in May 2020 could be avoided, a BVMed delegation headed by chairman Dr. Meinrad Lugan and CEO Dr. Marc-Pierre Möll confirmed after holding talks with the German EU Commissioner Günther Oettinger, the relevant EU Directorate General, and parliamentary staff as well as government experts in Brussels.

MDR is "not functioning"

Background to the ongoing discussions: As a regulatory framework, the MDR is still not functioning. Meanwhile, the analysis of the problems – lack of Notified Bodies; lack of staff; no transitional periods; absence of implementing acts, guidelines, and harmonized standards – is increasingly being understood not only in Berlin but in Brussels too. Experts fear that patient care will suffer if not all devices have been certified by the application date May 26, 2020.

f.l.t.r.: Dr. Meinrad Lugan, Günther Oettinger, Dr. Marc-Pierre Möll

Approval of EU Council, Commission, and Parliament needed

The European Council and the European Commission are now ready to introduce another corrigendum. A transitional period according to article 120 (3) MDR for class Ir devices is being discussed. The European Parliament will have to agree to the procedure. Moreover, further measures will have to be discussed, including "stop the clock" scenarios. "There must be a functioning regulatory framework in order to ensure that all devices can be certified in a timely manner," said BVMed CEO Dr. Marc-Pierre Möll.

"There must be a functioning regulatory framework in order to ensure that all devices can be certified in a timely manner."

Jens Spahn, CDU

Jens Spahn presents national law

In the meantime, the German Minister of Health Jens Spahn has presented a draft law for a "Medical Devices EU Amendment Act" (Medizinprodukte-Anpassungsgesetz-EU, MPAnpG-EU). It envisages a law to implement the requirements regarding medical devices provided for by EU law, the so-called Medical Devices Implementing Law (Medizinprodukte-Durchführungsgesetz, MDG). Legally speaking, the implementation of the MDR via the MDG is not required, because the MDR will come into force directly. As far as the new provisions of the MDR are emphasized by the MDG, e.g. new notification and reporting requirements for distributors and importers or the ban on counterfeiting and fraud, this is in the interest of legal clarity.

The medtech companies and BVMed regard the draft law as essentially positive and support especially the fact that tried and tested national provisions, such as that on the medical device consultant, are maintained. The regulation that gives enforcement powers to the higher federal authorities Federal Institute for Drugs and Medical Devices (BfArM) and Paul-Ehrlich-Institut (PEI; the federal agency for vaccines and biomedical drugs) is understandable but must be reviewed for feasibility.

Digital medical devices: “Gathering experience”

f.l.t.r.: Dr. Manfred W. Elff, Prof. Dr. Jörg Debatin, Natalie Gladkov, Prof. Dr. Dr. Christian Dierks, Dr. Marc-Pierre Möll

With the new approach for digital medical devices based on the Digital Care Law (DVG), “we now want to gain experience without delay and improve patient care.” These were the words of Prof. Dr. Jörg Debatin, head of the new “Health Innovation Hub” of the Federal Ministry of Health at BVMed’s first Digital Talk in Berlin.

Inclusion of classes IIb and III devices at a later stage

In terms of providing a starting point from where to ensure swift access to digital solutions, BVMed recognizes many valuable approaches in the Digital Care Law (DVG), though it proposes more comprehensive regulations with regard to the scope and support of telemedicine solutions, in particular, an extension to class IIb and III medical devices, said BVMed managing director Dr. Marc-Pierre Möll. In the discussion, Debatin viewed the limitation to classes I and IIa as justifiable, as small steps were easily implementable and would allow to gain experience with the new approach without delay. If the approach proves successful, Debatin is not opposed to an extension to include classes IIb and III.

Dr. Marc-Pierre Möll

In April 2019, Federal Health Minister Jens Spahn launched the Health Innovation Hub under the leadership of Prof. Dr. Jörg Debatin in order to actively search the digital scene for new ideas and solutions and thus to improve healthcare. The former head of the Hamburg-Eppendorf University Hospital (UKE) had consistently digitized the clinic during his time as medical director and chairman of the board.

Fast track procedure justified

Prof. Dr. Jörg Debatin

Consultant, lawyer, and general practitioner Prof. Dr. Dr. Christian Dierks gave an introduction to the Digital Care Law (DVG), which governs, among other things, the introduction of digital healthcare applications (diGA) into the reimbursement systems. According to Dierks, the DVG legislative procedure is set to “go through,” irrespective of the future of the grand coalition. The short product cycles of digital healthcare applications meant that a “fast track” procedure bypassing the Federal Joint Committee (G-BA) was justifiable. In its place, the Federal Institute for Drugs and Medical Devices (BfArM) decides on the inclusion based on a White List of “Benefit Criteria.”

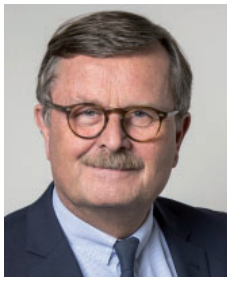
Concerns of medtech companies

Prof. Dr. Dr. Christian Dierks

In the discussion, representatives of the medical device industry called for an extension of the scope of the Digital Care Law (DVG) regulations beyond class I and IIa medical devices, given that a myriad of digital healthcare applications with medical devices, based on their main device classification “implant,” should be assigned a higher class. This applies, for example, to software or apps processing the data of a medical device and informing the physician or patient about the parameters of, for example, a pacemaker or insulin pump. Like the pacemaker, the app would be classified in class III and thus not be covered by the entitlement. Another concern of medtech companies focuses on the criteria governing the proof of benefit criteria, which are currently being compiled by the Federal Institute for Drugs and Medical Devices (BfArM).

Doctors revolt against the German DRG system

In a large-scale campaign published by the nationwide magazine "Stern," 30 organizations and individuals from the healthcare sector have called for fundamental changes in financing hospital services. The campaign is endorsed by the Association of the Scientific Medical Societies in Germany (AWMF), the Professional Association of German Doctors of Internal Medicine (BDI), the German Medical Students' Association (BVMD), the German Society of Surgery (DGCH), the German Society of Internal Medicine (DGIM), as well as 215 MDs, among them Professor Dr. Frank-Ulrich Montgomery, chairperson of the World Medical Association (WMA). They argue the enormous pressure on costs is massively damaging healthcare because the well-being of patients is being subordinated to economic factors.



Frank-Ulrich Montgomery

Fundamental criticism of the DRG system by doctors

Many doctors are facing unsolvable dilemmas, as the "diktat of economics" has led to a "de-humanization" of medical practice in the hospitals. The signatories claim that the DRG system by which hospitals are compensated for their services on the basis of flat rates per case offers many incentives to generate "profit through unnecessary activities to the detriment of patients." The reimbursement system rewards high-tech short-term medical interventions like catheter examinations or spine surgery, and penalizes the thoughtful employment of invasive measures.

The doctors' principal demands:

- Replace the DRG system or at least fundamentally reform it.
- Stop "financially driven and dangerous over-therapy on the one hand and shortcomings in patient care on the other." The authors accept the necessity of acting economically.
- The state must plan for hospitals to be located where they are really needed and equip them well. This requires a master plan and the courage to sometimes merge two or three hospitals into larger, more efficient centers that are better invested with staff.

Georg Baum

German Hospital Association skeptical of the campaign

The German Hospital Federation (DKG) is skeptical of the campaign. No one is treated without good medical cause in Germany, according to them. There are always multiple medical options on diagnostics and treatments to be decided on. Just like in the outpatient sector, it makes full sense to link the reimbursement of hospitals to the services they actually render and the costs they incur. "State-financed systems do not lead to better healthcare. Healthcare in socialist countries and the British healthcare system show this in abundance," said Georg Baum, managing director of the DKG federation. He warned of the possible consequences: long waiting lines, a rationing of services, and inferior technical equipment in general.

Call for reimbursement of remote monitoring

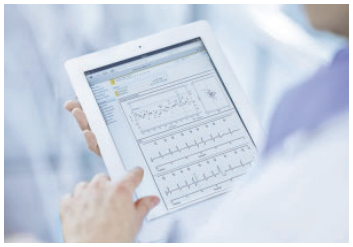
Dr. Marc-Pierre Möll

Cardiology companies in BVMed are calling for the reimbursement of continuous remote monitoring for patients with active cardiac implants. In view of the current recommendations on the remote monitoring of cardiac patients published by the "Telemonitoring" working group of the German Cardiac Society (DGK), it remains incomprehensible why continuous remote monitoring is denied reimbursement while the benefit assessment procedure with the Federal Joint Committee (G-BA) has been ongoing for more than three years, says BVMed CEO Dr. Marc-Pierre Möll. "The benefit has long been proven, clinical evidence is available. It is high time that remote monitoring is made routinely available to affected cardiac patients."

Detailed recommendations by cardiologists

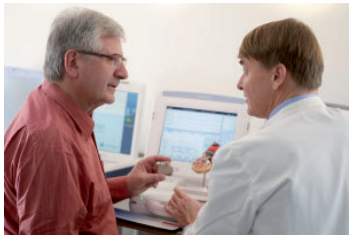
On August 13, 2019, the DKG working group published its recommendations on remote monitoring. In it, the expert group of cardiologists provides detailed guidance regarding the monitoring and therapy processes for patients with implants. Apart from technical requirements on monitoring systems, the paper provides standardized instructions on monitoring parameters and the evaluation of findings as well as detailed recommendations on how to approach selected constellations of findings. In doing so, the DGK experts once again underline that there is sufficient clinical evidence to support the benefits of remote monitoring of active patients with cardiac implants.

Benefit assessment procedure stuck in G-BA committee



The greatest obstacle to the widespread application of continuous remote monitoring for implant patients remains the absence of a regular billing code in the remuneration system. A benefit assessment procedure with the Federal Joint Committee (G-BA) in this regard has been pending for more than three years.

Reimbursement of remote monitoring shows significant gaps



Based on expert opinion, study results are so compelling that telecardiology was already included in the European treatment guidelines a few years ago. Still, cost reimbursement in Germany remains unsatisfactory. For instance, health insurance funds often do not even cover the costs of the necessary infrastructure such as the data transmission device for ICD patients. For patients with cardiac pacemakers, neither the medical monitoring services nor the technology costs are reimbursed.

Background

Over 600,000 patients are currently living with cardiac implants in Germany. Of these, approximately 470,000 are cardiac pacemakers, and approximately 130,000 are ICD and CRT systems. Going forward, a new implantation rate of approximately 100,000 pacemakers and around 50,000 ICD and CRT systems per year is assumed.

2. Documentation: FAZ article on MDR problems

FAZ.NET

Frankfurter Allgemeine Zeitung – FAZ
August 20, 2019, business section, page 24
Circulation: 250.857

https://www.faz.net/aktuell/wirtschaft/unternehmen/eu-verordnung-vorbereitung-hakt-durch-mangel-an-medizinprodukten-16341595.html

Ilka Kopplin

Scissors and scalpels threatened to become scarce

Medical technology is in turmoil: Soon an EU regulation will come into effect and preparations will be hampered. Supply bottlenecks could result.
By Ilka Kopplin

Not many people need a temporomandibular joint prosthesis. Cancer patients or accident victims are among them. “But if it is necessary, the people who depend on it are also happy to get such an implant,” says Marc Michel. He is managing director of the medium-sized prosthesis manufacturer Peter Brehm in Weisendorf near Erlangen. In Peter Brehm’s range of products, this prosthesis will no longer be offered in future.

PETER BREHM
Die Präzision in Titan
für den Menschen

The reason: The transition period for the new EU Medical Devices Regulation (MDR), according to which a large proportion of medical technology devices must then be certified, will end next May. Following various medical scandals, such as those thoroughly manipulated breast implants, politicians have reacted. The new regulations, which came into force in May 2017, are intended to significantly tighten the existing documentation requirements and ensure greater patient safety.

Marc Michel

However, implementation has been more than difficult over the past two years, as companies do not yet know in detail where or how to obtain certification. This is pushing the local industry, which is predominantly characterized by small and medium-sized companies, to its personnel and financial limits. According to the association (BVMed), more than 200,000 people are employed in this sector in Germany, generating a turnover of around 30 billion euros. Not only in the Swabian region of Tuttlingen, where a leading cluster of around 400 medical technology companies has established itself, people are sounding the alarm: their livelihoods are threatened and jobs are being cut.

The manufacturers are now revising their products and, like Brehm, are soon no longer offering some devices that are rarely used, for example. There are pragmatic reasons for this: On the one hand, the documentation requirements under the new regulation are in some cases so high that expenditure and yield are no longer in proportion – even if the companies do not express this so loudly in public. Thus, clinical study data must now also be available for implants, similar to that known in the pharmaceutical industry. Previously, it was often possible to refer to data on similar devices. Apart from additional costs, the question arises which hospital


Schere und Skalpell könnten knapp werden

should carry out such studies with prostheses, some of which have been on the market for decades. The gain in knowledge for researchers is rather limited.

On the other hand, the new regulation includes existing devices, many of which are rated higher in their risk class, others have to be certified for the first time. The latter applies to so-called reusable surgical instruments, such as scissors or scalpels, as well as software or material drugs such as nasal spray. All in all, this results in considerably greater costs for companies and regulators.

The topic has also long since arrived in politics. At the beginning of July, Federal Health Minister Jens Spahn (CDU) wrote a warning letter to the responsible EU commissioners to draw attention to the precarious situation a few months before the end of the transition period. It says, for example: It is estimated that more than 150,000 medical devices from around 4,000 manufacturers in Europe will require certification for the first time from the end of May 2020, according to surveys conducted by the authorities. It was clear that the capacities for certification were not sufficient. It was to be assumed that tens of thousands of devices would no longer be allowed to be brought onto the market after this date. “This means that massive supply bottlenecks are to be feared,” writes Spahn.


Jens Spahn, CDU

The problem already begins with the so-called “Notified Bodies,” i.e. the private companies that carry out such certifications. So far there are almost 60 of them in Europe. However, they must themselves be accredited according to the new regulation, which is done by various state bodies. So far, however, there are only two bodies in Europe – the British BSI and TÜV Süd – that have already received this seal. Around 40 other companies have submitted an application. Government circles say, however, that there will only be about 20 Notified Bodies in the coming months. “At the current pace of preparation, the new regulatory system will not be ready in time to absorb this additional workload,” the European umbrella association MedTech Europe stated in a letter to the EU Commission. Many practical questions have also not been clarified. According to the new regulation, for example, all devices will be gathered in the European database Eudamed. The only problem is that the database is not yet fully functional. “As a company, we still don’t know where, how, and in what form we should make the data available,” explains Michel.


Manufacturer Peter Brehm,
a common German medtech SME.

Many companies – including Peter Brehm – are now tackling an interim solution under which they can extend their certified devices, which are already on the market, until 2024 in accordance with the former Medical Device Directive. According to this directive, as well as the new regulations, the devices will be divided into different risk classes. For example, wheelchairs are classified in the lowest class. Implantable devices such as pacemakers and hip prostheses, on the other hand, fall into the highest class. According to the new regulation, there will then be additional subclasses with high requirements. However, this extension option does not exist by far for all devices, including tens of thousands of surgical instruments alone.

There is also another area where things are getting tight: qualified personnel. Notified Bodies and companies alike are courting employees for regulatory and quality management functions. The profit of the 160-employee company Peter Brehm is noticeably burdened by the additional costs, as Michel says. By the way, this also applies to the big players in the industry, such as the Melsungen-based B. Braun Group. For many devices, the family-owned company also takes a detour via the old directive. But only the subsidiary Aesculap, which manufactures prostheses and surgical instruments, has to have several thousand products recertified.

Dr. Meinrad Lugan

Until the introduction of the new regulation, B. Braun expects group-wide additional costs in the high double-digit millions. The time and effort required for new products to reach patients has increased due to the new clinical requirements and documentation obligations in an "unacceptable manner without any demonstrable benefit for safety or efficacy," warns B. Braun manager Meinrad Lugan. In Tuttlingen, necessity has made people inventive. The "Medical Mountains" cluster initiative in Tuttlingen has formed an expert table from various companies to help others.

Peter Brehm in Weisendorf is therefore also very busy. "We have to submit the updated technical documentation for all our devices on the market to the Notified Body by the end of August," says Michel explaining the recertification process. After all, for a knee endoprosthesis alone, there are about four binders with around 400 pages each. They contain instructions for use, design and production documents, as well as material overviews and risk reports that the Notified Body must work through. For Brehm it is now also time: Thus it says on the part of the Federal Government in its answer from July to a small inquiry of the FDP parliamentary group that it assumes at present that the recertification lasts between three and nine months. The deadline is May 26, 2020.

3. In Brief

MDR immediate aid program in Baden-Wuerttemberg

The Ministry of Economics in Baden-Wuerttemberg has made available an MDR immediate aid program in order to assist the medical technology industry in the federal state, which mostly consists of medium-sized businesses. The program's aim is to prepare for the implementation of the Medical Device Regulation (MDR). It has now been started with its first measure for product group specific collaborative projects. Baden-Wuerttemberg is the first federal state to do so. Read more at www.gesundheitsindustrie-bw.de/MDR-IVDR.

MDR portal: All the documents in one place

BVMed makes available important information and relevant documents regarding the implementation of the new EU Medical Device Regulation (MDR) through its MDR information portal at www.bvmed.de/mdr. The documents include flowcharts, publications, and links to relevant documents, guidelines, and implementation aids of the EU Commission as well as guidelines by various organizations.

Financial results of SHI funds for first half of 2019

In order to reduce their reserves, the Statutory Health Insurance funds have spent more money during the first half of 2019 than they have generated through contribution payments. Nevertheless, their financial reserves are still at around 20.8 billion euros, the Federal Ministry of Health reported regarding the half-yearly accounts of the health insurance funds. In total, the expenditure volume of the Statutory Health Insurance funds was at 125 billion euros in the first half of 2019, with a deficit of around 544 million euros. The income of the health insurance funds rose by 3.6 percent compared to the same period of the previous year, and the expenditure by 4.7 percent.

Hospitals forced to temporarily close intensive care beds

37 percent of all hospitals have had to close intensive care beds in order to stay within the limits for the minimum number of care staff in hospitals. For the same reason, 23 percent of the hospitals have had to close beds on general wards, and 29 percent even have had to temporarily block entire areas of care for emergency cases directed to them through the ambulance control centers. This is the result of a representative survey conducted by the German Hospital Institute (Deutsches Krankenhausinstitut, DKI) that has just been published.

BVMed: Avoiding sepsis through the prevention of infections

On the occasion of this year's World Sepsis Day on September 13, the BVMed sectoral interest group "Nosocomial Infections" has called on hospitals, care providers, and any other medical institution to prevent sepsis cases caused by infections through adequate prevention measures. More people worldwide suffer from sepsis, frequently known as "blood poisoning," than from colorectal cancer, breast cancer, and AIDS put together, the German Sepsis Society (Deutsche Sepsis-Gesellschaft, DSG) said. Many patients are left with serious disabilities after suffering from sepsis, or even die, if the symptoms are not recognized in time.

4. People

Claudia Bernhard, Left Party

Claudia Bernhard new Senator for Health in Bremen

Claudia Bernhard from the Left Party is the new Senator for Health, Women, and Consumer Protection in the federal state of Bremen. Andreas Bovenschulte (SPD) is the first state premier in a West German federal state to head a red-green-red coalition government of SPD, Green Party, and the Left Party. The three-party coalition has 49 of the 84 members of the Bremen parliament behind it. Ms. Bernhard succeeds Eva Quante-Brandt (SPD), who was the Senator for Science, Health, and Consumer Protection in Bremen between July 2015 and August 2019. Ms. Quante-Brandt remains a member of the Bremen state parliament.

Dr. Dirk Heinrich

Dr. Dirk Heinrich confirmed as SpiFa chairman

The general meeting of the Federal Association of German Specialist Physicians (Spitzenverband Fachärzte Deutschlands, SpiFa), held in Salzburg on August 30, 2019, confirmed Dr. Dirk Heinrich as its chairman for another 4 years. Board members Dr. Christian Albring, Dr. Hans-Friedrich Spies, and Dr. Axel Schroeder were also confirmed in office. In addition, the general meeting elected a fifth member to the board. Dr. Helmut Weinhart, treasurer of the Association of the Specialists in Orthopedics and Trauma Surgery, (Berufsverband für Orthopädie und Unfallchirurgie, BVOU), will strengthen the SpiFa board in its work with immediate effect.

Boris Velter, SPD

Boris Velter heads “Health City Berlin”

Boris Velter (SPD), most recently State Secretary for Health in Berlin, has assumed his new position as director of the office of “Gesundheitsstadt Berlin 2030” (“Health City Berlin 2030”). The office is being established by the Charité hospital and the hospital network Vivantes with the intention to support the Health City commission in the implementation of its recommendations for the future.

5. Events

10 - 12 October 2019

Cardiology Autumn Congress, Berlin
Autumn meeting of the German Cardiac Society
ht2019.dgk.org

10 - 12 October 2019

XPOMET Medicinale 2019, Berlin
Festival on the future of medicine
www.xpomet.com

22 - 25 October 2019

German Orthopedic Convention 2019, Berlin
Organizer: Joint annual convention of the German Society for Accident Surgery, the German Society for Orthopedics and Orthopedic Surgery, and the Professional Association of Orthopedic Specialists
www.dkou.de

27 - 29 October 2019

World Health Summit, Berlin
Science – innovation – policies
40 sessions – 200 speakers – more than 1,600 participants from over 80 countries
www.worldhealthsummit.org

8 - 9 November 2019

Diabetes & Obesity Conference, Leipzig
Autumn conference of the German Diabetes Association
Annual conference of the German Obesity Association
www.herbsttagung-ddg.de

18 - 21 November 2019

MEDICA & Compamed, Dusseldorf
The biggest medical trade show in the world
www.medica.de
High-tech solutions for medical technology
www.compamed.de

19 - 20 March 2020

National DRG Forum, Berlin
Conference and exhibition for decision makers and hospital managers
www.drg-forum.de

24 - 26 March 2020

Altenpflege 2020, Nuremberg
Leading exhibition for the care sector
www.altenpflege-messe.de

21 - 22 April 2020

DMEA – Connecting Digital Health, Berlin
Industry trade show, congress, and academy on healthcare IT
www.dmea.de

21 - 24 April 2020

German Surgeons' Congress, Munich
Congress of the German Surgeons' Association
www.chirurgie2020.de

24 - 27 April 2020	**Cardiology Congress, Mannheim** Annual meeting of the German Cardiac Society *https://jt2020.dgk.org/*
25 - 28 April 2020	**Internal Medicine Congress, Wiesbaden** Annual meeting of the German Internist Society *www.dgim2020.de*
5 - 7 May 2020	**T4M – Technology for Medical Devices, Stuttgart** Trade fair and congress "Technology for Medical Devices" *www.messe-stuttgart.de/t4m/*
May/June 2020	**Medtec Live, Nuremberg** Trade fair and congress – merger of MT Connect and Medtec Europe *www.medteclive.de*
17 - 19 June 2020	**Capital Congress "Medicine & Health", Berlin** Biggest German healthcare congress for decision makers (8,500 participants) *www.hauptstadtkongress.de*
23 - 26 September 2020	**Rehacare International, Dusseldorf** International trade show and congress on rehabilitation and technical aids *www.rehacare.de*
10 - 12 November 2020	**VISION, Stuttgart** World trade fair for vision technology *www.messe-stuttgart.de/vision/*

6. Abbreviations and Glossary

AOK	Allgemeine Ortskrankenkassen (Local Healthcare Funds)
AWMF	Arbeitsgemeinschaft der medizinisch-wissenschaftlichen Fachgesellschaften (Association of the Scientific Medical Societies)
BKK	Betriebskrankenkassen (Company Health Insurance Funds)
BMG	Bundesministerium für Gesundheit (Federal Ministry of Health)
BQS	Bundesgeschäftsstelle Qualitätssicherung (German National Institute for Quality Measurement in Healthcare)
BVMed	Bundesverband Medizintechnologie (German Medical Technology Association)
DIMDI	Deutsches Institut für Medizinische Dokumentation und Information (German Institute of Medical Documentation and Information)
DKG	Deutsche Krankenhausgesellschaft (German Hospital Federation)
DRG	Diagnosis Related Groups
EBM	Einheitlicher Bewertungsmaßstab (Uniform Evaluation Scale)
FPV	Fallpauschalenvereinbarung (Diagnosis Related Groups Agreement)
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
G-DRG	German Diagnosis Related Groups
GKV	Gesetzliche Krankenversicherung (Statutory Health Insurance)
HTA	Health Technology Assessment
ICD	International Statistical Classification of Diseases and Related Health Problems
IGeL	Individuelle Gesundheitsleistungen (Individual Healthcare Services)
IKK	Innungskrankenkassen (Craft Guild Health Insurance Funds)
InEK	Institut für das Entgeltsystem im Krankenhaus (Institute for the Hospital Remuneration System)
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Healthcare)
KHEntgG	Krankenhausentgeltgesetz (German Hospital Remuneration Law)
LKK	Landwirtschaftliche Krankenkassen (Agricultural Sickness Funds)
MDS	Medizinischer Dienst der Spitzenverbände der Krankenkassen (Medical Review Board of the Statutory Health Insurance Funds)
MPG	Medizinproduktegesetz (Medical Devices Act)
NUB	Neue Untersuchungs- und Behandlungsmethoden (New Examination and Treatment Methods)
OPS	Operationen- und Prozedurenschlüssel (Surgery and Procedure Code)
PKV	Private Krankenversicherung (Private Health Insurance)
SGB V	Social Security Code Book V (Sozialgesetzbuch, Fünftes Buch)
vdek	Verband der Ersatzkassen (Association of Employees' Health Insurances)