

Positions of the
VDGH on the future
developments in the
healthcare systems

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VDGH

Verband der Diagnostica-Industrie

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VDGH

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Preface



Matthias Borst



Dr. Martin Walger

The diagnostics industry is part of the healthcare sector, one of the largest branches of industry in Germany. In 2016, the healthcare sector generated 12 percent of the German gross domestic product. It is also an employment powerhouse. With a total of 7 million employees, one in six employees works in a health-related occupation. As a part of the overall healthcare sector, the industrial healthcare sector particularly strengthens the effectiveness and efficiency of the healthcare system. It is characterized by its export strength, high work productivity and high R&D intensity. In the diagnostics industry, about 11 percent of the domestic turnover flows into research and development. The value is, therefore, clearly above that of other industrial sectors.

The VDGH represents about 100 member companies that produce in vitro diagnostics (IVD) and products for research in the life sciences. The companies represent 90 percent of the domestic sales of diagnostics. The VDGH is committed to basic conditions that are research-friendly and innovation-friendly in Germany. These are necessary so that modern laboratory diagnostics can develop their medical benefits for patients and their economic benefits for our social systems. Both aspects are neglected if laboratory diagnostics are considered only as a cost factor in the healthcare system. Besides, the modern methods of laboratory diagnostics offer excellent opportunities: from the early diagnosis of disease to personalized medicine, from the process optimization and quality improvement in medical care to the demonstrable reduction in costs for the healthcare system. At the same time, the investment in production, research and development provides economic added value and qualified jobs.

Germany has good health care. We can and want to make it even more precise and efficient. Hence, VDGH would like to invite policy and all partners of our healthcare system to discuss the value of laboratory diagnostics.

Berlin, April 2017

A handwritten signature in black ink, appearing to be 'M. Borst'.

Matthias Borst
Chairman of the VDGH

A handwritten signature in black ink, appearing to be 'Dr. Martin Walger'.

Dr. Martin Walger
Managing Director VDGH

Overview

1 Ensuring and accelerating access to laboratory innovations

The inclusion of laboratory innovations in the standard care of the statutory health insurance (GKV) requires clear procedural rules, transparency about the consultation process, as well as defined time spans for decision-making. Cooperation possibilities for the industry, patient organizations and representatives from the scientific field are to be improved.

2 Adequate remuneration ensures the value of laboratory diagnostics

Diagnostics and therapy are equivalent cornerstones of medicine. Adequate remuneration ensures safe and precise diagnostics for the benefit of patients. It must be designed in such a way that laboratory diagnostics are preserved as a medical service all over the country. For the diagnostics manufacturers, adequate remuneration provides a suitable incentive to investigate and develop new tests.

3 Making better use of the potential for early diagnosis of illness

The early diagnosis investigations for children, adolescents and adults are to be checked regularly and adapted to the latest state of medical knowledge. In particular the medical health check-up ("Check-up 35") should be modernized and also cover health risks and exposures. The degree of familiarity and the use of health screening, as well as other early diagnosis programs of the GKV, can be improved by accompanying measures.

4 Upgrading infection protection – targeted use of diagnostics reduces antibiotic resistance

The dynamics of infection events are large. Therefore, the legal framework for the prevention and fight against infectious diseases has to be developed on a regular basis, taking into account epidemiological findings. Other remuneration items for the screening of dangerous pathogens in hospitals and for diagnostics in the field of contract medicine are to be agreed. In order to promote targeted antibiotic administration and to counteract antibiotic resistance efficiently, the use of diagnostics must be promoted, in particular for contractual medical care through suitable incentive structures.

5 Laboratory diagnostics are the key to personalized medicine

In personalized medicine, diagnostic tests have a key function. They determine genetic or molecular characteristics of a patient and thus allow the selection of the best drug for the treatment. This is the unique benefit of these companion diagnostics. The reimbursement conditions of the tests in contractual medical care and in hospitals are to be further improved. In this context, the digitalization of the health care system must also be advanced in order to make better use of care data and to support meaningful diagnostic applications.

6 Diabetes self-management – More than just a measuring value

In view of the continuing increase of charges in relation to diabetes mellitus for the health system and society as a whole, the disease must be given a higher priority. For this, prevention, early diagnosis and the ability for self-management of the handling by diabetic patients should be the focus of a national diabetes strategy. The blood glucose self-measurement is a central component of effective therapy. The one-sided focus of the cost carriers on the price of a test strip is not appropriate for the dimension of the disease and neglects the quality of care.

7 Further development of regulatory requirements for in vitro diagnostics

The VDPG advocates a supranational system for the marketing of in vitro diagnostics. The new European IVD regulation has rightly refused to switch to a state licensing system, because this would not increase patient safety. It is important that the transition period of five years is also used in the national implementation so that manufacturers can continue to operate in a functioning system. In the conformity assessment procedures, adjustments are necessary in order to guarantee functioning that is free from problems.

8 Tax support for research stimulates growth and high-tech jobs

In order to strengthen Germany as a location for research and development, to stimulate growth and to maintain the innovation strength of companies, tax support for R&D should be introduced in addition to the existing project support, e.g. as a "tax credit" in the form of a percentage deduction of R&D expenses from the tax liability. In order to adequately take into account research companies of all size classes, the support should vary as applicable according to size classes.

9 For ideology-free handling of individual health services

The so-called Individual Health Services (IGeL) are often stigmatized as medically superfluous. This goes past the supply reality. All responsible politicians and the statutory health insurance schemes are called on to open a constructive dialog. Mature citizens are also able to act independently as GKV-insured persons. An important prerequisite for this is detailed factual information about the service content by the treating doctor.

1

Ensuring and accelerating access to laboratory innovations

The inclusion of laboratory innovations in the standard care of the statutory health insurance (GKV) requires clear procedural rules, transparency about the consultation process, as well as defined time spans for decision-making. Cooperation possibilities for the industry, patient organizations and representatives from the scientific field are to be improved.

The key quality feature of developed healthcare systems is that patients are given rapid access to medical innovations. In spite of the diverse legal requirements that are aimed at this goal, the situation for the range of laboratory diagnostics remains deficient. In contractual medical care, the inclusion of laboratory innovations has almost come to a complete standstill in the GKV catalog of services.

The safety, quality and performance of an IVD are demonstrated by an elaborate conformity assessment procedure. After successful CE marking, the product is then accessible throughout Europe. A benefit assessment is also required in Germany for being able to bill new laboratory services at the expense of the GKV.

The evaluation committee of KBV and GKV-Spitzenverband is responsible for the inclusion of new laboratory services in the EBM (Uniform assessment scale). The discussions there continue to be like a "black box". Transparency about the decision-making processes and the people acting is desirable, not only for the industry, but also for patients and insured people. Furthermore, appropriate timetables should be established for the assessment procedures. The procedures that take significantly longer than the product lifecycle of a laboratory test miss the goal. The legislature has recognized this problem and has reacted with the GKV Care strengthening law of 2015. The assessment committee was obliged to include within its rules of procedure also deadlines concerning the consultations and decision-making process on the inclusion of new laboratory services and human-genetic services in the EBM. This requirement would not be implemented by self-management. Hence, the legislature remains encouraged to pursue and control the implementation of the political will. Explicit requirements are necessary

for self-management until the rules of procedure are adopted and which consultation periods in the actual procedure are appropriate from the point of view of the legislature.

Within the competence of the Joint Federal Committee (G-BA), the testing of examination and treatment methods in accordance with §137e SGB V was introduced with the GKV Care structure law of 2011. Neither the basic idea of an innovation in testing nor the hope for an acceleration of the innovation assessment have so far proved to be true in practice. Therefore, the testing regulation should be further developed by the G-BA, if necessary accompanied by legal clarifications. The budgetary reserves of the G-BA must not become a bottleneck for tests. Furthermore, the positive assessment of the potential by the G-BA should result in a legal entitlement to initiate the method assessment or the provisional inclusion in the GKV catalog of services.

For the benefit assessment under the responsibility of the G-BA, a basic discussion is stimulated about which assessment methods are suitable for in vitro diagnostics. The concept of clinical benefit in IVD differs fundamentally from that with medicaments or therapeutic medical products. It is also questionable whether the lack of explicit evidence of use required by the IQWiG and G-BA could lead to the conclusion that the corresponding investigation method has no benefit. Today procedures remain like genetic expression analysis or "Liquid Biopsy" (cancer diagnosis from the blood) that are withheld from the GKV insured people, while they are medically approved services in health care systems outside Germany.

Science and industry drive inventions to become marketable innovations – patients benefit from this. It is difficult to understand the fact that precisely these groups are excluded from the assessment of innovations by the assessment committee and/or the G-BA. Their competence should be included in the cooperation possibilities that exist only in the approach (application and voting rights).

Did you know?

In 2003, the Federal Association of Guild Health Insurance Schemes presented a proposal to examine the introduction of the HPV test as a laboratory diagnostic method for the early diagnosis of cervical cancer. In 2013, the legislature introduced appointments and deadlines with the early cancer diagnosis administration and registration law of self-management. In 2017, self-management will continue to provide the details for the implementation of screening programs.

2

Adequate remuneration ensures the value of laboratory diagnostics

Diagnostics and therapy are equivalent cornerstones of medicine. Adequate remuneration ensures safe and precise diagnostics for the benefit of patients. It must be designed in such a way that laboratory diagnostics are preserved as a medical service all over the country. For the diagnostics manufacturers, adequate remuneration provides a suitable incentive to investigate and develop new tests. The reimbursement of laboratory services in contractual medical care must not become a game because there is a fee policy resource allocation conflict.

Laboratory investigations are an inalienable cross-section task of modern medicine. They are produced by nearly all medical professional guilds. Laboratory diagnostics is the basis for two thirds of all clinical diagnoses. It strengthens prevention, because diseases are recognized before the appearance of typical symptomatology. With objective and exact diagnostic results, it forms the basis for specific therapy and allows – within the scope of the therapy control – an immediate adaptation of the treatment to the respective healing success. With this, processes of treatment are individualized and optimized, with the result of a medical as well as an economic effectiveness increase. The comprehensive use of the laboratory diagnostics must be remunerated appropriately.

The remuneration of in-patient and out-patient laboratory services must, furthermore, be calculated in such a way that they can be sufficiently produced as a medical service, also hence smaller setups and medical practices. Currently, the remuneration system is constructed – in particular in the contract-medical area – to be rather laboratory-hostile. Laboratory reimbursements in the EBM are lowered inclusively (quoted). The doctor's groups which may settle accounts for certain laboratory services with the permission of the Statutory Health Insurance Physicians (KV) are, in addition, subject to case value related budgeting. In the form of the so-called economic efficiency bonus, more than 13 percent of the fee volume of laboratory-medical services are used for the non-performance of laboratory-medical services. This provides false incentives. The economic efficiency bonus should be reduced and be abolished in the long term. Means thus freed up are to be used for the financing of laboratory-diagnostic innovations or better remuneration of existing laboratory services in the EBM.

The reforms of the tariff system for doctors (GOÄ) remain on the health-political agenda. The calculation of the single fees should occur clearly and on the basis of understandable representative data. It is to be considered that the GOÄ results in its main features from the early 80s and does not illustrate the cost increases that have appeared since then and neither the technical progress. The basic idea of support of the "speaking medicine" justifies neither the decrease of laboratory reimbursements nor the restacking of means from the laboratory into other areas. The purely technical service of a laboratory figure in the GOÄ amounts to only 20 percent; the big remainder is for the medical service.

Did you know?

Since 1999, the share of laboratory expenditures in total health care expenditure has declined from 3.09 percent to 3.00 percent, thus remaining at a consistently low level for more than 15 years. At the same time, the number of laboratory tests carried out has significantly increased.

3

Making better use of the potential for early diagnosis of illness

The early diagnosis investigations for children, adolescents and adults are to be checked regularly and adapted to the latest state of medical knowledge. In particular the medical health check-up ("Check-up 35") should be modernized and also cover health risks and exposures. The degree of familiarity and the use of health screening, as well as other early diagnosis programs of the GKV, can be improved by accompanying measures.

The demographic development and the change of the illness spectrum to chronic-degenerative and psychic illnesses requires effective health promotion and disease prevention. Early diagnosis investigations can serve to delimit the progress of an illness and to avoid, in particular, expensive sequelae. The earlier an illness is recognized, the more promising, faster and cheaper it can be treated, if necessary even cured. Early diagnosis with laboratory diagnostics offers concrete and objective investigation results here so that behavioral updates can be caused efficiently and/or therapeutic measures implemented.

Before this background, the services of the GKV for the early diagnosis of illnesses are hence to be continuously developed further. During the last few years welcome settings of the course have been carried out here with the early diagnosis of cancer of the intestine and cervical cancer. Need for action further exists with the medical health examination according to § 25 section 1 SGB V, the so-called Check up 35. This examination is very all-inclusive in the current arrangement and stands for the outdated approach of "one size fits all". Thus offers for the older population correspond to those for the younger one. This is not goal-oriented. The service catalogue and the circle of the claim beneficiaries should be structured anew according to the legal requirements and be differentiated concerning the contents so that a contemporary care specific to the target group of the population is guaranteed.

The VDGH has compiled – on the basis of present studies and guidelines as well as findings from medical practice – a "proposal for a revised version of the health examination directives". This singles out population-medically significant illnesses such as, for example, diabetes, cardiovascular or rheumatic diseases. On this basis, beginning with the 18th year and sex-specific differentiated, different extensive screening modules are defined.

To increase the value and exploitation of early diagnosis all together, the updating of the health examination should hence be flanked according to § 25 paragraph 1 SGB V by the following further measures:

- The health examination is combined with an active address, e.g. with an organized invitation procedure. In this case, measures to reach people at work should also be provided.
- Attention for the health investigation should be accompanied by appropriate systematic public relations. The involvement of the services of the Federal central office for health education is suggested.
- For insured people, bonuses can be planned, e.g., in the form of refunds or additional payment exemptions.
- As a systematic assessment is lacking in the current "Check up 35", an evaluation of the "new" health examination should be carried out on the basis of the collected data, e.g. after six years.

Did you know?

The current service catalog of the "Check up 35" is essentially from the year 1989, and major content adjustments have not been carried out since then. The aging of medical knowledge is currently occurring with a half-life of five years.

4

Upgrading infection protection – targeted use of diagnostics reduces antibiotic resistance

The dynamics of infection events are large. Therefore, the legal framework for the prevention and fight against infectious diseases has to be developed on a regular basis, taking into account epidemiological findings. Other remuneration items for the screening of dangerous pathogens in hospitals and for diagnostics in the field of contract medicine are to be agreed.

In order to promote targeted antibiotic administration and to counteract antibiotic resistance efficiently, the use of diagnostics must be promoted, in particular for contractual medical care through suitable incentive structures.

With the amendment of the Infection Protection Act, the legislature had already set important impulses in 2011. Thus self-management was obligated to create remuneration figures for the diagnosis and therapy of MRSA-settled or infected patients in the contractual medical remuneration. Nevertheless, epidemiology shows that new dangers are appearing. In spring 2017, the World Health Organization (WHO) published a global list of resistant bacterial pathogens, which are currently the greatest threat to human health. And pathogens do not stop at sector borders. Therefore, on the one hand, further diagnostic remuneration figures must be created for hospitals and contract doctors who are following the threat situation. On the other hand, the reporting obligations must be comprehensive and sector-wide, with the inclusion of other facilities. Provisions and deadlines by the legislature have proved their worth.

The avoidance of treatment-related infections must remain on the political agenda and be accompanied by the assessment of the initiation and testing of further measures. Effective protection against infection is a true quality indicator of healthcare facilities. Therefore, the quality assurance activities of the hospitals and medical practices, as well as the quality of the results, should be made more visible, especially in the facilities and sector-wide quality assurance, as well as in the structured quality reports of the hospitals in accordance with SGB V. In in-patient care, long-term efforts are necessary to strengthen protection against infection. In addition to hygienic measures, this includes targeted screening procedures during admission and discharge, as well as comprehensive diagnostics in the event of treatment. The remuneration for such measures must be guaranteed.

The fight against antibiotic resistance is a social task of the first rank. With the GKV Drug Supply Enhancement Act of 2017, the legislature has addressed the idea that an immediate diagnosis of infectious pathogens is the basis for quick, effective and appropriate antibiotic therapy. The self-management has to examine the extent to which diagnostics can be used for fast and quality-ensured antibiotic therapy in contractual medical care. Appropriate adjustments must be made in the EBM.

This new regulation is welcomed by the VDGH. Appropriate tests have been available for several years in Germany and are increasingly being developed for use in the doctor's laboratory or as patient-oriented diagnostics. The precise distinction between a viral and a bacterial infection can already significantly improve the targeted use of antibiotics in medical practice. Tests are also available to identify pathogens (individual tests, panel tests) and to determine the resistance of individual pathogens. Their reluctant use is not due to the lack of market availability, but to the reimbursement conditions in contractual medical care. There are no EBM compensation figures for important tests, like, for example, for the inflammation parameter Procalcitonin, which has long been used extensively and successfully in hospitals. And under the prevailing conditions, the contract doctor who tests their patient before deciding on an antibiotic therapy is burdening their laboratory budget and may not calculate the diagnostic service themselves under any circumstances. Hence, diagnostic medical services for antibiotic therapy should generally be financed off-budget (outside the total morbidity-oriented remuneration). In addition, incentives for testing before antibiotic treatment are to be provided in general medical care. At least the exclusion diagnostics must also be available and billable by the family doctor.

Did you know?

The cost for antibiotic resistance is estimated at 1.5 billion euros a year in the European Union. Costs are expected to increase in the coming decades.

5

Laboratory diagnostics are the key to personalized medicine

In personalized medicine, diagnostic tests have a key function. They determine genetic or molecular characteristics of a patient and thus allow the selection of the best drug for the treatment. This is the unique benefit of these companion diagnostics. The reimbursement conditions of the tests in contractual medical care and in hospitals are to be further improved. In this context, the digitalization of the health care system must also be advanced in order to make better use of care data and to support meaningful diagnostic applications.

Drugs are increasingly being developed and approved where the use of which is linked to the preceding testing of the patient. With the help of suitable laboratory tests, it can be excluded before the administration of the drug that, e.g., on account of specific genetic characteristics of the patient, the drug remains ineffective or leads to severe side effects. Already today, about 50 active ingredients are listed for available drugs where, in Germany, before their application, a (genetic) test is mandatory or recommended according to Medicinal Product Information. The use of a diagnostic agent and drug is inextricably linked.

The medically necessary coupling of a diagnostic agent and drug must also be present in the case of reimbursement by the GKV. While drugs can be prescribed immediately after their licensing at the cost of the legal health insurance, this is not the case with the laboratory tests as accompanying diagnostics (Companion Diagnostics). With the reorganizations of the Drug Supply Enhancement Act, the reimbursement of the companion diagnostics is better regulated and should occur at the same time as the decision about the benefit assessment of a medicinal product. This important step is welcomed by the VDGH. Nevertheless, the coupling should also be valid for companion diagnostics whose application is not formulated as being absolutely necessary. As the information for professionals of the drug does not always clearly express the need for the companion diagnostics even if the scientific proofs are given. For the patient it is furthermore vital to be able to also take up the offer of the companion diagnostics during the time phase between the licensing of the drug and the decision of the evaluation committee. Hence, a temporary reimbursement possibility should be created for this time phase.

Currently, oncology is the main sector of application of personalized medicine; other areas are being researched intensively and are moving up. So that the potential of personalized medicine can be used with lasting effect, the concurrent enhancement of corresponding medical competence is essential. A stronger consideration of relevant contents in medical training, continuing education, and advanced training is desirable.

The possibility to be able to treat and diagnose patients more individually and more exactly in future goes along with the degree of the digitalization of our health service. Big Data applications open up new diagnosis possibilities. Before this background, the VDGH stimulates an exchange about the chances of the digitalization, the current implementation status and the short-term and medium-term development perspectives. The Federal Ministry of Health could establish a platform for this. The relevant industry sectors should be included as essential partners.

Did you know?

The average efficacy of medicinal products amounts to approx. 25 percent for cancer cases and up to 60 percent for asthma and diabetes, with respect to the treated patient population. Companion Diagnostics can increase the degree of efficacy.

6

Diabetes self-manage- ment – More than just a measuring value

In view of the continuing increase of charges in relation to diabetes mellitus for the health system and society as a whole, the disease must be given a higher priority. For this, prevention, early diagnosis and the ability for self-management of the handling by diabetic patients should be the focus of a national diabetes strategy.

The blood sugar self-measurement is a central component of effective therapy. The one-sided focus of the cost carriers on the price of a test strip is counterproductive. It is not appropriate for the dimension of the disease and neglects the quality of care. Conventional measurement methods are now supplemented by new methods of glucose self-measurement developed by the industry and where the patient use is considerable.

According to the figures of the German Health Survey of 2012, 7.2 percent of the population in Germany has known diabetes and, in addition, up to 2.1 percent undiscovered diabetes (a total of 9.3 percent). This corresponds to about 7.5 million people affected. Today, diabetes is the most expensive chronic illness. The total expenses for the treatment of diabetes amount to about 20 percent of the total health care expenses of the statutory health insurance. In particular, the high costs for diabetes-related complications and sequelae are responsible for this.

In view of this challenge, everything speaks for implementing a national diabetes strategy. Experts agree about the fact that of the society-political challenge of diabetes mellitus can be met, above all, with measures of primary prevention and – based on an untimely diagnosis – with a lifestyle change (exercise, food). For the early diagnosis of diabetes, dependable laboratory tests are available. Those already ill receive immediate feedback about how their own behavior affects their blood glucose.

To guarantee this and to guarantee the therapy success, the patient must have enough freedom of choice with regard to the choice of the suitable blood glucose measuring system that is right for them, in consultation with the treating doctor. Not only does this mean a precise, readily available measurement value, the successful application depends rather on the safe, familiar or practiced handling by the patient of their blood glucose meter. Training and service programs should be available for this. In this respect, the blood glucose measuring system is not just any, readily interchangeable product.

Frequently, the attention of the health insurance companies, Statutory Health Insurance Physicians and associations of pharmacists is unilaterally on the costs of the blood glucose monitoring, whether by legally inadmissible calls for tender for test strips, or by setting quotas and trapping bonuses for the change-over of patients to measuring systems of a lower price class. Necessary quality criteria for the patient threaten to be avoided by this. Economic constraints for this do not exist. The existing competitive structures have already, for many years, been managing the decreasing prices of blood glucose test strips through price negotiations and the existence of different distribution channels.

Did you know?

The third most populous country in the world after China and India is “Diabetes-Land”. According to figures published by the International Diabetes Federation, some 415 million people worldwide suffer from diabetes.

7

Further development of regulatory requirements for in vitro diagnostics

The VDGH advocates a supranational system for the marketing of in vitro diagnostics. The new European IVD regulation has rightly refused to switch to a state licensing system, because this would not increase patient safety. It is important that the transition period of five years is also used in the national implementation so that manufacturers can continue to operate in a functioning system. In the conformity assessment procedures, adjustments are necessary in order to guarantee functioning that is free from problems before the end of the transition period. The same regulatory requirements apply to products produced within a health care facility (in-house production) as for industrially-produced products.

In vitro diagnostics are never in contact with the human body but rather are used to examine samples in a test tube (in vitro). The potential risk is, therefore, far less than with products that are introduced into the body. This is the reason why IVD have their own legal bases within the medical device law.

The objective of regulatory demands for in vitro diagnostics is to guarantee the safety and efficiency of the products and to customize the regulations for the purposes of patient safety with regard to new developments. At the same time, the scientific and technical progress is to be evaluated without delaying or preventing innovations needlessly.

So that in vitro diagnostics can be put on the market, they must meet the agreed standards of safety, quality assurance and effectiveness. With the CE marking of its products, the manufacturer documents the complete conformity with these regulations whose observance ensures a high degree of health protection, effectiveness and safety. Depending on the level of risk associated with the in vitro diagnostic product, a notified body must be involved to assess conformity, to test and certify the quality management system, to evaluate the product design, and to provide external monitoring. These quality and safety requirements should apply not only to industrially manufactured products but also to products manufactured within a healthcare institution (in-house).

After several years of political discussion, the new European IVD Regulation enters into force in 2017. It is positive that the application of the regulatory framework is being more prominently harmonized across the EU. However, the new legal framework will make the development and production of in vitro diagnostics much more complex, since the regulatory framework conditions have been markedly tightened. Something that is still open is how the immense additional staff requirements can be covered. Not only do companies need more staff, it is also a major challenge for the notified bodies and the supervisory authorities to find experts for the implementation of the increased system requirements.

The VDPGH supports the establishment of a National Working Group for the implementation of the new IVD regulation by the Federal Ministry of Health and actively participates there. It is important for the manufacturers that no additional bureaucratic hurdles are introduced nationally and that the necessary adaptations in the medical product legislation and its regulations are consistent. The enormously increased reporting obligation should be bundled and de-bureaucratized. The transitional period of five years must be used in such a way as to make the conversion to the new legal framework as free of friction as possible.

Did you know?

Under the IVD Directive 98/79/EC, about 20 percent of the IVDs have been under the supervision of notified bodies up to now. The upcoming IVD regulation will put over 85 percent of all IVDs under the supervision of notified bodies. Therefore, this requires good resource planning by the notified bodies and the supervisory authorities.

8

Tax support for research stimulates growth and high-tech jobs

In order to strengthen Germany as a location for research and development, to stimulate growth and to maintain the innovation strength of companies, tax support for R&D should be introduced. This should be in addition to the existing project support and should be designed as a "tax credit" in the form of a percentage deduction of R&D expenses from the tax liability. In order to adequately take into account research companies of all size classes, the support should vary as applicable according to size classes.

Unlike most OECD and EU countries, Germany does not have any system of tax incentives to promote research. It is high time such incentives were introduced. The countries that invest the most in their innovativeness are among the most successful in economic terms. Tax incentives are becoming increasingly urgent in life science research, since project support from the Federal Ministry of Education and Research (BMBF) has been dwindling for two years.

As regards regulatory policy, tax-driven support for R&D makes good sense, because it leaves companies the freedom to choose the area of research, it can be organized simply and unbureaucratically, and it does not give preferential treatment to any particular industry or company. Tax-based support for research will result in higher corporate research spending and in greater affluence for the economy as a whole. Every euro thus spent by the state generates additional corporate R&D spending of 1.25 euros, according to estimates by economists. At the same time, the gain for the German economy through higher tax revenues and the exploitation of technical progress would come to approx. 750 million euros a year; in other words, the return on investment for the public purse would be very rapid.

Most OECD countries have such tax credits ranging anywhere from 8 to 20 percent. Germany should take a lead from this. The system could be introduced gradually by focusing first on small and medium-size enterprises (e.g. tax credits of 30 percent instead of 10 percent) and by setting off half of the granted project support funding against tax incentives. The introduction of tax credits for innovative companies must not result in a reduction of the volume of current project support.

Did you know?

Almost 12 percent of employees in the diagnostics and life sciences industry work in research and development. This is the highest figure of any branch of industry.

9

For ideology-free handling of individual health services

The so-called Individual Health Services (IGeL) are often stigmatized as medically superfluous. This goes past the supply reality. All responsible politicians and the statutory health insurance schemes are called on to open a constructive dialog. Mature citizens are also able to act independently as GKV-insured persons. An important prerequisite for this is detailed factual information about the service content by the treating doctor.

Individual healthcare services are medical services that go beyond the list of SHI-approved services currently defined by the joint self-administration parties and, therefore, must be paid for by the SHI insureds themselves. There is a wide spectrum of such services. The range of services that are outside the benefits provided by the SHI (e.g. medical ability to travel, sport diving tests) or services explicitly requested by the patient, but without any medical objective (e.g. cosmetic surgery). Individual healthcare services, however, also include examination and treatment methods for which the Federal Joint Committee (G-BA) has not yet made a positive benefit assessment, or services authorized by the G-BA in the hospital but not for SHI-accredited doctors (e.g. Procalcitonin, gene expression test).

This very diversity disproves the claim that individual healthcare services are a waste of money, or, even worse, harmful. The diversity demonstrates, above all, also that insured patients have different wishes and preferences. This freedom should be respected because it is an expression of the patient's sovereign status. Nowadays, patients have an impressive array of information opportunities at their fingertips that they use extensively. That is why an approach that would prevent or make it as difficult as possible for the treating physician to provide individual healthcare services must seem anachronistic and patronizing.

What is needed, on the other hand, is comprehensive, objective, and balanced information that is based on a written agreement between the patient and the treating physician. This would include a statement of the costs of the measure that the patient has to pay and would have to be furnished before the service is provided. This approach strengthens the bond of trust between doctor and patient and enables the patient to make an informed and responsible decision.

The evaluation of new laboratory-diagnostic procedures for the admission into the reimbursement of the GKV often extends for a period of ten years and longer. In view of that, IGeL are a usual way to allow access to innovative laboratory tests for the patient. In this respect, IGeL can constitute a preliminary stage of a later GKV service. Altogether, the range of medical possibilities keeps growing, partly also faster than the contribution income and resources of the GKV. Without individual healthcare services, the healthcare system based on collective funding would be stretched to its limits even sooner.

Did you know?

An individual healthcare service once looked down upon is now a recognized SHI benefit: since July 1, 2008, screening for skin cancer is provided nationwide and paid for by the health insurer. Every insured person over the age of 35 is entitled to such an examination once every two years.

Der VDPGH

The German Diagnostics Industry Association (VDGH) is the trade association of the manufacturers of in vitro diagnostics (IVD) and life science research firms active in Germany. In vitro diagnostics are medical products or devices used exclusively to examine bodily fluids and tissues outside the human body.

The VDGH represents about 100 member companies. They research, develop, manufacture and sell these laboratory analytical products and their precursors as well as products for patient self-testing. In vitro diagnostics can help discover health risks, identify illnesses, gauge the effectiveness of medicines before they are administered, and draw up therapeutic plans. The products of the life science research companies are instruments, reagents, test systems, and consumables that serve research in the life sciences.

The companies in the VDGH represent about 90 percent of domestic sales of diagnostics. Two thirds of the companies are engaged in research and development and have production sites in Germany.

The diagnostics industry employs about 13 percent of its workforce in the area of research and development. This research commitment puts diagnostics companies well ahead of all other branches of industry in Germany.

