

ACCESS TO MEDICINES 2025

From prescription to joint treatment decisions



IN BRIEF

Health is the central basic need of people. In the future the empowered patient will become more engaged in his own health care and participate independently and actively in his individual healing and health maintenance process. In a society that is changing due to the demographic and subsequent structural changes, the desire for more self-determination provides an opportunity to maintain the high level of the health care system. On the one hand, the patient can be entrusted to perform more self-medication for minor diseases – using the warranty instances physician and pharmacist under his own responsibility. On the other hand, the patient can support the doctor by enabling him to assess his needs better. Nevertheless, the doctor will continue to take the decisions about necessary treatments and their prescription.

Medical and technological progress is opening up more and more individual treatment options. A good health care system of the future will offer the patient not only a medical treatment that is adapted to him, but also give him orientation and an empathetic appeal, and thus the basis for a good quality of life and the preservation of his health.

In order to maintain the performance of the health system and to ensure a high quality of access to medicines, the BAH is committed to the evolution of the framework conditions of the health care system. This includes the evaluation and re-assessment of the handling of innovative medicines and their reimbursement. It is obvious that this can only be achieved by an integrative approach involving all relevant stakeholders.

The BAH is ready to provide their expertise to policymakers, in order to create appropriate framework conditions for a sustainable access to medicines, in recognition of the described challenges and potentials. New approaches should ensure that everybody in this country has access to the care that is best for him and is able to assume responsibility for his health.

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INTRODUCTION

Germany will change in the years and decades to come. The key development is demographic change which will further transform the work and living environment of people. Additional factors are the advancing digitalisation as well as new treatment opportunities generated by medical and technological progress. The health care system must remain powerful, affordable and human. Health care must be adapted to people's altered living environments and accommodate medical progress.

The German Medicines Manufacturers' Association (BAH) wants to impart its expertise for further development of health care in the future, focusing on medicinal products. The aim and commitment of the BAH is to maintain the high level of the health care system, including comprehensive protection and access to innovations as well as financial viability for the community of solidarity. At the very heart of this commitment is the individual as an informed patient with personal responsibility who will be critically involved in decisions on his individual health care.

UNDERSTANDING OF THE PRESCRIPTION AND REIMBURSEMENT OF MEDICINES

The BAH would like to initiate a discussion regarding the future access to prescription medicines (Rx drugs). The topics “prescription of medicines” and “reimbursement of medicines” are directly connected with patient care. Both are considered a valuable asset in care that should basically be adhered to. Therefore, the BAH’s understanding of the two terms shall be set out first.

Prescription of medicines

The prescription of medicines or prescribing makes the physician the key decision maker regarding treatment with medicines. Compared to the past, the share of co-decision by patients or payers has gained enormous importance. Despite this development, all those involved still attribute the position of the “gate keeper” to the physician because of his professional competence. Prescription has been and still remains an important pillar of care, ensuring the quality of medical treatment.

Reimbursement of medicines

The reimbursement of prescription medicines is an important anchor of the German jointly-funded health system. Regardless of the financial capacity of the individual, all those insured have access to high-quality treatment. In order to avoid overstraining of the solidarity-based system, the entitlement to benefits is limited to services which are deemed to be “sufficient, appropriate, economical and necessary” (Social Security Code, Book V, Section 12). This principle essentially also applies to the reimbursement by private health insurance. ■

THESES FOR GERMANY 2025

Consequences of the aging society for health care

Low birth rates and reduced mortality will lead to an aging society in Germany. This poses great challenges for the health care of tomorrow. Chronic diseases and age-related impairments will come to the forefront. The number of patients needing treatment for several diseases at the same time will increase. The majority of the population will become aware of health as a valuable asset, requiring individual decisions to be made. Patients will increasingly adopt a market-oriented behaviour. This applies to a lesser extent to the purchase of goods than to the choice of the providers of care and insurance providers.

The importance of prevention will grow: The burden of chronic diseases on the population can only be reduced by reinforced efforts.¹ In order to use the available resources efficiently, there is a need for all stakeholders of the health care system to expand their prevention and information services. With a view to the higher age of patients, secondary and tertiary prevention will especially play a greater role.

Structural changes to the disadvantage of rural regions

Within the regions of Germany big differences in the age structure of the population are emerging. These differences are further promoted by the imbalances in workforce demand and supply. Urbanisation disadvantages the rural regions of Germany.² The respective municipalities will be forced to reduce their infrastructural supply which will also produce major challenges for health care.

People living in rural areas will have to put up with longer distances to access physicians, pharmacies, educational institutions, shopping opportunities and work places.

In order to provide care to people in structurally weak regions, new options must be created, e.g. by the use of telemedicine solutions. As the resources of physicians will be restricted, for patients with minor ailments, e.g. infections, the consultation of a physician should no longer be obligatory (e.g. for obtaining a certificate of disability). Alternatively, the competence of on-site pharmacies could be used more extensively.

Transformation of the working environment

In the course of the demographic change less middle aged people will be in employment. Concomitantly, it will be necessary and desirable from companies' and many people's point of view that older people also continue working. Absentee times are longer for the older working population, and in general everybody should be free to work according to his individual needs.³ This situation poses challenges on health care.

Another factor leading to transformation of the existing labor and living environment is the increasing digitalisation. Employers and employees will have to be more flexible. Good quality of health care will help to improve the quality of life and organisation of everyday family and labor issues.

Digitalisation

The importance of the internet as a medium of information and commerce is increasing. The internet offers an abundance of information on all questions concerning prevention, diagnosis and treatment of diseases. The patient has greater access to his personal health data and medical information. He becomes more informed and empowered, and increasingly the manager of his own health. The patient changes from a "health customer" to a "health partner". However, the quantity and quality of the information provided often overtax people.

Advice provided by physicians and pharmacists as the guarantors for appropriate care remains essential – and also increasingly for verification of the retrieved information. Physicians and pharmacists can provide orientation and a feeling of safety. Also in this context, information and communication technologies open up new options for care. There will be increasing numbers of informed patients asking their physicians explicitly for available treatment options. This will confront physicians with the new role of a moderator.

When giving advice, information will have to be placed into the individual context of the respective person. Further development of systems that use intelligent crosslinking of information, data and stakeholders will be crucial for the improvement of the quality of health care.

Individualisation of living environments

People are increasingly loosening traditional relationships with their families and surrounding neighbours. The reasons for this are urbanisation and the aging of society. Last but not least the wish for independence leads to many people in smaller households. Whereas family members, cohabitants or neighbours may provide advice and support in case of illness, less social cohesion requires a higher degree of individual responsibility.

In this context physicians and pharmacists will assume a new role – also making use of information and communication technologies. In this scenario, understanding the needs of the patient will play a central role.

Changes in health care

In the next few years the number of retiring physicians practicing in clinics or in the community will exceed the number of younger successors. More often than their predecessors young physicians seek an even work-life balance.⁴ To date a significant increase in employed physicians in ambulatory care has been recorded. Employee contract physicians typically work fewer hours than those self-employed. This will also affect the time which the physicians dedicate to their patients – at a time of rising demand of patients for medical services.⁵

Therefore, the average amount of time a patient spends at the physician office will be further reduced. As a consequence, measures must be taken so that more time is

available for those patients for whom a physician consultation is indicated. While for patients with mild disorders, such as infections, alternative treatments – for example self-medication – should be made available.

Shift of competence in the EU

The uniform European process for the approval of medicines by the European Medicines Agency (EMA) has proven itself. With the increasing harmonisation of European standards, the topic of benefit assessment of medical treatments will also evolve further at the European level. Since 2006 the EU project EUnetHTA (European network for Health Technology Assessment) has coordinated the systematic, evidence-based assessment of medical procedures with regard to their effects on the health of the individual, the health care system and Society in 27 countries. The goal of this institution is the networking of regional and national HTA institutions, research institutions and health ministries to facilitate an effective exchange of information and support.

A further institutionalisation of this organisation is to be expected. In many other areas the organisation of health care has already been harmonised in favour of uniform EU standards, for example the marketing authorisation of medicinal products.

Medical progress

Medical and technological progress lead to a paradigm shift. Improved and more targeted therapies often go hand in hand with a significant individualisation of treatment. Illness will in the future less be looked at as an organic disease, but rather in dimensions of molecular genetics. This leads to ever-smaller patient groups being given specific treatments up to individual therapies. By this, treatment becomes clearly more targeted. Linked to this are better and faster processes of healing and relief, less restrictions and a higher quality of life.

The classical development path of a pharmaceutical product will lose relevance in the future and must be supplemented by new processes. It will no longer be possible to recruit sufficiently large patient groups for studies within an ethically justifiable period of time. In addition, new technologies will allow for faster innovation cycles. Innovations can quickly reach patients, if the conditions allow it. The evidence which is necessary for marketing

authorisation must in the future be complemented by new data. All the more important is a quality assured usage of these treatments, which at the same time enables a continuous generation of evidence from care.

Growing digitalisation and well-informed patients open up new opportunities in the area of the safety of medicinal

therapy (medication safety) as an integral part of the access to medicines. Medication safety considers a medicine as a process and no longer as a mere product. The prerequisites for medication safety are quality-assured structures with a growing basis of individual digital data. It further involves health professionals, the acceptance of a treatment and the patients' understanding about a treatment. ■

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Changes in health care and access to medicines: summary

Demographic changes, rural-urban migration, medical progress, increases in age-related diseases – all these factors pose special challenges on health infrastructure and require (financial) resources. Cost pressure in the health care system and competition for the allocation of budgets will further increase. The health system of the future must deal more efficiently with existing resources. The informed patient who gets actively involved must be understood as an opportunity in this regard.

The players in the health care sector will create appropriate offerings and incentives to meet the demands. The networking of those involved must be optimised using digital solutions. In addition to any aspects of efficiency, future health care must take account of the new realities of life and at the same time remain human. A human access to medicines must respect and reflect the individual needs and treatment preferences of the patient.

The medicinal therapy of the future must continue to be effective, safe and quickly available. In order to meet the individual treatment preferences of patients, a variety of medicines must also be accessible in the future.

THE VALUE OF PATIENT-CENTERED ACCESS TO MEDICINES AND REFUNDING FOR THE INDIVIDUAL

The informed patient with his increased health awareness will change the use of medical services noticeably. He is informed and knows which treatment options are available or may be available for his concerns in the future. Self-management of diseases will be clearly more pronounced. The patient requires the right and best medication for him. He wants to have access to well-established as well as to innovative medicines and therapies. This includes also personalised medicine with the best possible personalised treatment.

The patient wishes to be entitled to a wide variety of available treatments, with the treatment suitable for him being completely funded by his health insurance. Physicians and pharmacists have to meet the increased demands of their “health partners” and involve the patient in the treatment decision. Despite increased self-responsibility of the patient, the physician as a health partner will ensure the quality of medical treatment by assuming unchanged responsibility for decisions on treatments and their prescription.

Only through this can the physician enable the patient to develop as his own health manager and prevent him

from succumbing to the trials and temptations of “digital quackery”. However, the empowered patient will choose those health partners who suit his needs best.

Diverse medicinal therapies for individual patients also comprise medicines which are based on further development of known active ingredients. It is not only structural changes to the active substance itself which may bring added value for the patient. This includes both innovative dosage forms or application systems as well as modified doses and extended indications. Such incremental patient- and application-relevant developments can contribute to improved therapeutic success and better quality of life for patients, as well as to higher safety of use. The concrete benefits can present as a reduction of side effects, an extended treatment spectrum, simplified form of administration, new and age-appropriate dosage forms (e.g. for children and the elderly), as well as adherence and compliance-enhancing developments. This form of innovation also means progress because it can be of great relevance for the patient and the health care system. The patient will not tolerate any loss of performance, but require at least the level of supply he is familiar with. ■

THE VALUE OF PATIENT-CENTERED ACCESS TO MEDICINES FOR SOCIETY

Despite certain weaknesses, the German health care system is one of the best in the world⁶. Almost the entire population is fully protected by statutory health insurance or private health insurance (or other backup systems). Also, with regard to the above challenges, it should be the aim and desire of all stakeholders to keep our health care system at a high level with comprehensive protection and to develop it accordingly. It is of particular importance to maintain the nationwide and comprehensive access to innovations in health care.

A patient-oriented health care system, putting the individual and his needs at the centre, can ensure that our economy remains powerful. Patients receive therapies enabling them to maintain or improve their health, supporting them to get back to work quickly. Older workers have the opportunity to work beyond the retirement age, if they wish to do so. High wages, minimal work losses and the employment of older people ensure that the statutory health insurance funds receives sufficient contributions to guarantee a high level of care. Besides this, the innovative power of our health care system is further reinforced by a strong health economy which offers more jobs than any other industry.

Fair health care that follows the principle of solidarity and preserves the “contract of generations” also helps to ensure social peace in Germany.

The challenges of an aging society with all its implications, and the desire of the individual for individualised medicinal treatment, are at first glance contradictory to sustainable financing of health care. It will be described hereafter how more efficiency, the expansion of self-medication of minor illnesses, personalised and thus more effective therapies, as well as the new opportunities of digitalisation, will lead to alleviating effects. ■

PREREQUISITES FOR A HIGH QUALITY ACCESS TO MEDICINES

The health care of the future must – despite all aspects of efficiency – take new life realities into account and at the same time remain human. As much freedom as possible and as much regulation as necessary. This corresponds to the credo of the social market economy which is significant for our country. In order to successfully meet future societal changes and taking medical and technological progress into account, appropriate framework conditions should be developed at an early stage. Respective concepts should place high-quality care at the centre, taking into account that people who are informed about health issues will assume an even more self-determining role in the future.

Preservation and extension of diversity and choice for patients

The responsible informed patient would like to have diverse options for treatment and reimbursement, and the chance to make his own choice. This offers opportunities for a cost-conscious design of the health system, because people set different priorities. It requires the diversity in the insurance landscape to be maintained, as well as free choice for the doctor and pharmacy, and to ensure more flexibility and different refunding models.

Against the background of limited resources, a social discourse must be led regarding which services should be funded by the solidarity system and which of them should be excluded and financed in other ways, e.g. through supplementary insurance. For this, fundamental political decisions are to be taken with regard to the legitimacy of self-administration and their control systems.

Further development of health structures

Demographic trends, the necessary treatment of complex and chronic diseases, as well as increased literacy and awareness of the patient, will change the usage pattern of medical services. These changes require the following measures:

- increased interdisciplinary cooperation
- overcoming of sectoral boundaries for supply and reimbursement
- promotion of new and age-adjusted approaches to treatment

- promotion of innovation, in particular in diseases with high treatment costs and so far untreatable diseases
- extension of prevention
- better coordination of the use of medical services through digital networking (e.g. to avoid multiple examinations)
- use of the possibilities of digitalisation for better diagnostics, efficient control of treatment and improvement of adherence
- solutions for care for the population in regions with a poor infrastructure, e.g. by more flexibility in the social systems.

Innovation as an opportunity for efficient care

The progress in medical technology and digitalisation will open up completely new approaches and concepts for efficient diagnosis, treatment and prevention. Therefore, it is necessary to come to a new understanding of the value of innovation and to adapt the relevant framework conditions. The aim must be to provide efficient treatment for the patient, suitable to his personal situation.

The importance of each situation must be considered from the perspective of the whole society. For example, it is an advantage if the performance of a person in paid work is preserved or can be restored. Furthermore, any potential costs incurred for an alternative or no therapy, should also be included. The measure must be the benefit for patients and society in the respective situation.

Besides completely new developments, innovations through further development can also result in a great impact and

benefit for the patient. These include the improvement of known active ingredients as well as dosage forms of well-known medicines. However, numerous control instruments of social law impede such developments. This has negative consequences for the access of patients to medicinal products. At the moment, the applicable social law-related regulations do not appreciate incremental improvements properly. Therapy- and patient-related developments need to be rewarded adequately in the future. All stakeholders involved should be committed to the promotion and financing of such patient-relevant developments.

Re-assessment of the benefit of medicines

Due to the move towards specific forms of therapy it is no longer possible in every case to perform the obligatory randomised, controlled trials (RCTs) with high numbers of patients for market approval. This also questions the methods that have been used so far for the assessment of the additional benefit of medicines in Germany. Randomised controlled trials including high numbers of patients, with mortality and morbidity as study endpoints, have served as criteria for assessing the benefit of a medicine and subsequently for the decision on the amount of reimbursement. The sole use of such data will no longer be suitable for the medicinal treatments of the future.

The assessment of the performance of a medicinal treatment cannot be based on a simplistic evaluation. The definition of the benefit of medicines must be designed in a significantly wider sense in the future, taking into consideration the individual perspective of the patient. Patient relevance and social relevance go hand in hand with this. As a consequence, the applied evaluation must be changed. Evidence will increasingly be generated from other data sources, including registers or retrospective insured persons data from social insurance institutions. Completely new forms of registers may emerge with increasing digitalisation. This produces new forms of evidence, which can complement the classical randomised controlled trials and need to be brought into line with them. Existing data can be merged, evaluated and modeled by means of a digital infrastructure. This will also bring new insights for improved medication safety.

Basically, new, flexible reimbursement and market access models can be derived from this and important findings for therapy and care be obtained. A precondition is that the benefit assessment is freed from a dogmatic understanding of evidence. If extensive evidence is only generated in the

course of the supply, payers and companies must make optimal use of it for the benefit of patients and society and incorporate it into supply decisions.

Definition of national and European responsibilities

The centralisation of procedures and responsibilities at European level has proved itself in many areas. Likewise, the development of a uniform European benefit assessment (Health Technology Assessment HTA) makes sense. The assessment must however be patient-relevant and sufficiently flexible, and must not be carried out simplistically. Basically, enough room must be left for national decision-making bodies to take local realities of care into account. Decisions on pricing and reimbursement should remain at the national level. This can already be justified by the varying performances of the European economies, as well as in the expectations of the respective populations regarding medical treatment. Last but not least, the Lisbon Treaty regulates the national responsibility in this area. Market access, pricing and reimbursement of medicinal products should be oriented to national frameworks, in order to allow broad and unhindered access of patients to appropriate medicinal treatments as far as possible.

Role of physicians and pharmacists

Physicians and pharmacists need to meet the increased expectations of their “health partners” and involve the patient in treatment decisions. Irrespective of an extended self-responsibility of the patient, the physician will continue to ensure the quality of medical treatment by assuming unchanged responsibility for decisions on treatments and their prescription. ■

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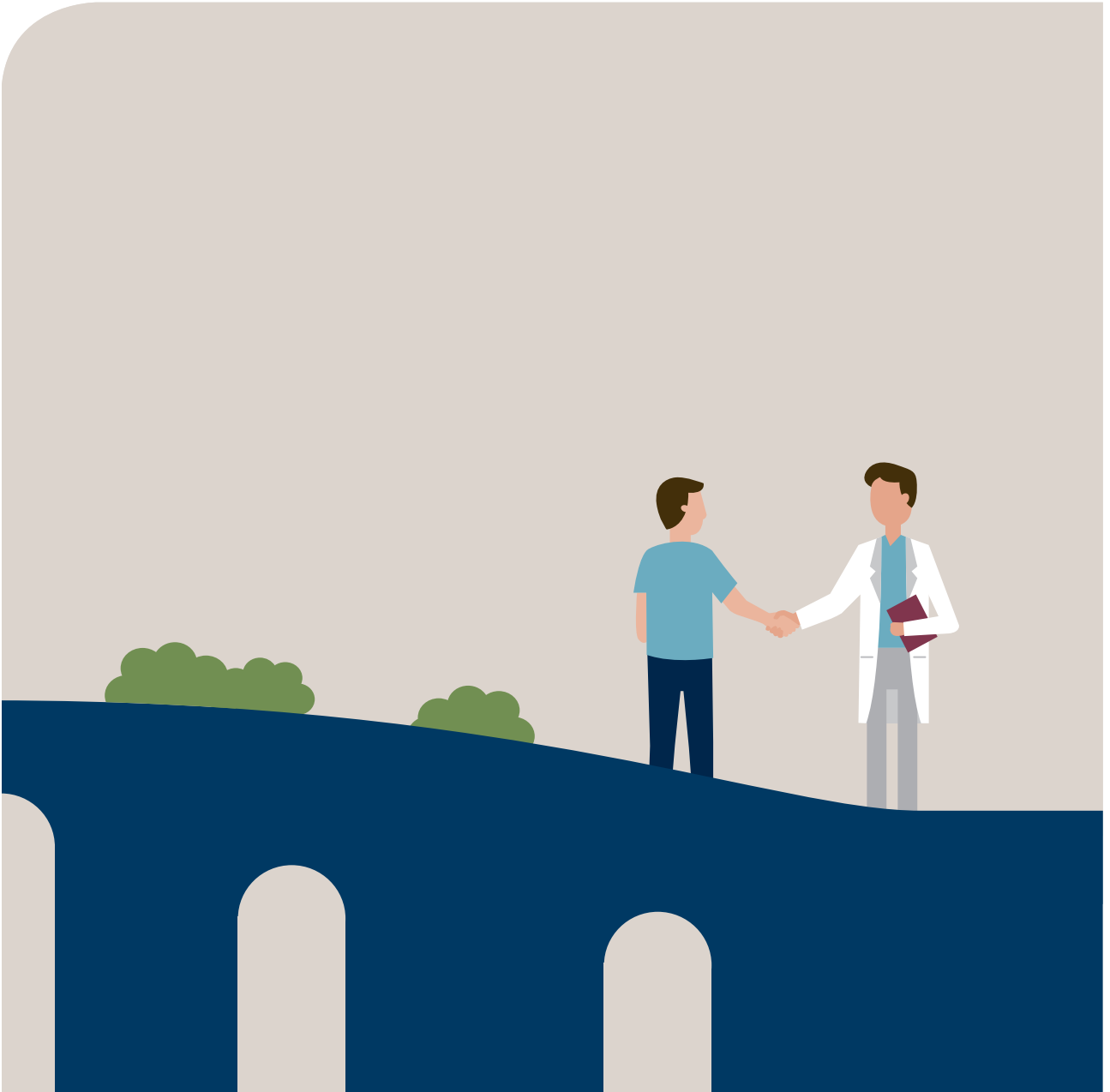
Local pharmacies are gaining higher significance as a low-threshold counselling and guarantor instance. They provide orientation in an increasingly flexible health world and will assume a piloting function.

CONCLUSION

Health is the central basic need of the human being. In the future, the empowered patient will want to engage more and will independently and actively participate in his individual healing and health maintenance process. In a society that is changing due to the demographic and subsequent structural changes, the desire for more self-determination provides an opportunity to preserve the high level of the health care system. On the one hand, the patient can be entrusted with more self-medication of minor diseases, making independent use of the support offered by the guarantors of appropriate care, the physician and pharmacist. On the other hand, the patient can support the doctor by enabling him to assess his needs better. Nevertheless, the physician will continue to take the decision about appropriate treatments and their prescription.

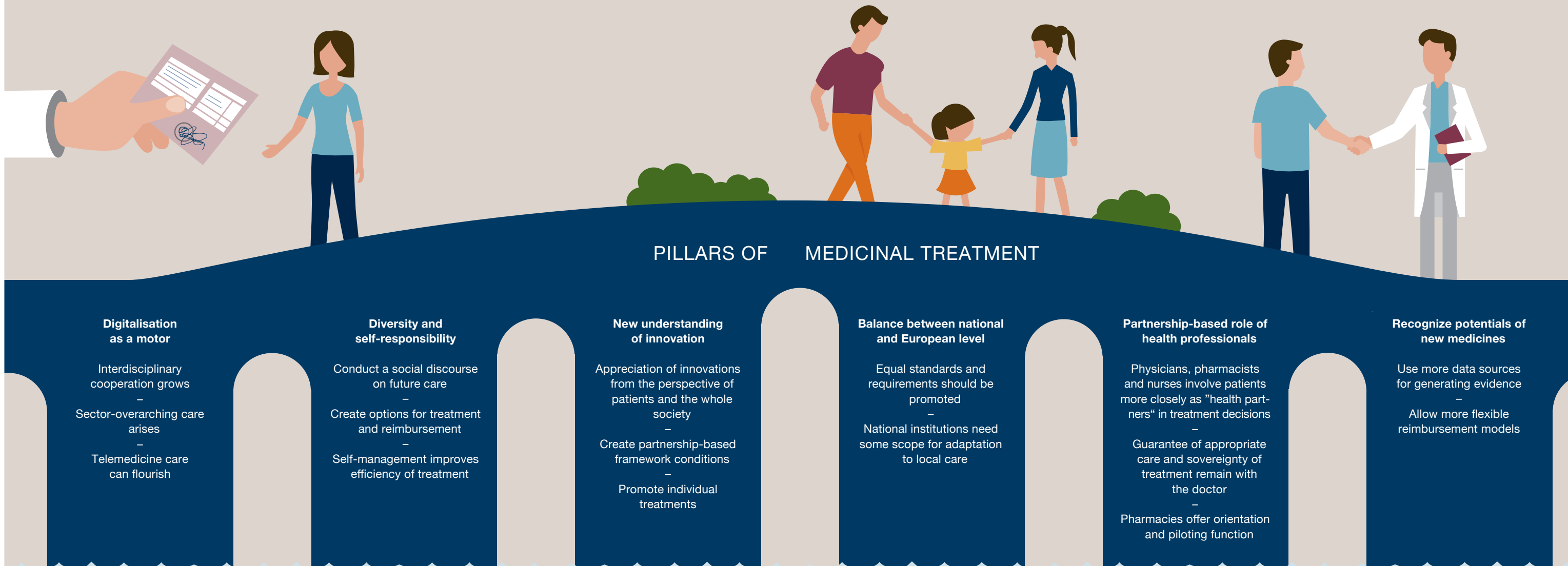
The progress of medical technology allows increasingly individual treatment options. Besides a medicine tailored to his needs, a good health care system of the future offers the patient orientation and understanding of his needs – and by this the basis for a good quality of life and the preservation of his health.

In order to maintain the performance of the health system and ensure a high quality of access to medicines, the BAH is committed to the evolution of the framework conditions of the health system. This includes an evaluation and re-assessment of the handling of innovative medicines and their reimbursement. It is obvious that this can only be achieved by an integrative approach with the participation of all relevant stakeholders. The BAH is ready to provide his expertise to policymakers, in order to create appropriate framework conditions for a sustainable access to medicines, in recognition of the described challenges and potentials. New concepts should pave the way, so that everyone in this country can have access to the best care for him and accept responsibility for his health.



PATIENT AT THE CENTRE

From prescription to joint treatment decision



DEVELOPMENTS AND INFLUENCES OF SOCIETY

Individualisation

- Smaller households
- Loosening of traditional relationships

Medical progress

- Treatment gets more targeted and more individual
- Faster innovation cycles due to new technologies

Shift of competence in the EU

- Greater harmonisation and coordination, e.g. regarding the benefit assessment of medicinal products

Structural change and aging

- Rural-urban migration and urbanisation
- More chronic and multiple diseases
- Wish of the people to do more for their own health and to stay healthy longer

Change of health care

- Shortage of physicians
- More medical care centers, more salaried physicians
- Longer journeys to physicians, hospitals, etc.

Digitalisation

- Information management brings new challenges for care providers
- Danger of overload due to information flood
- Request for verified information
- New opportunities in the area of medication safety

Access to medicines 2025

What manufacturers do

Medicines manufacturers make an essential contribution to an individualized access to medicines and by this to the health of people. This contribution ranges from targeted therapies for cancer up to patient-friendly dosage forms for known active ingredients. For this, the manufacturers need a partnership-based framework. Only on such a basis can they offer further innovative products in the future and ensure high-quality medicinal treatments.

The value of a patient-centred access to medicines for the individual:

- Patient-relevant developments help to improve the adherence, outcomes, quality of life and safety for the individual.
- Personal responsibility and self-management increase therapeutic success and thus the efficiency of treatment.
- This leads to the release of resources and helps to stabilize insurance fees and to maintain equal access and nationwide care for the individual.

The value of a patient-centred access to medicines for the company:

- The innovative strength of the health care system is reinforced by a powerful health care industry.
- Reduced work losses, good wages and the increased employment of older people ensure stable insurance finances and thus the level of health care.
- Contributes to the social peace of the society through an equitable health coverage.
- More efficiency, more self-medication of minor health problems, personalised treatments and digitalisation lead to alleviating effects.

CONCLUSION

From medicine prescription to joint treatment decision.

DO YOU WANT TO SHAPE THE FUTURE OF THE ACCESS TO MEDICINES WITH US?

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ABOUT US

By company membership the German Medicines Manufacturers' Association (BAH) is the leading trade organisation of the pharmaceutical industry in Germany. It represents the interests of more than 420 member companies which create about 80,000 jobs in Germany. Globally operating medicines manufacturers are as involved in the manifold activities of the association as the broadly represented medium-sized businesses. BAH caters for both pre-prescription medicines ('Rx') and non-prescription medicines ('OTC'), as well as substance-based medical devices.



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