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# Issue Brief

## Institute for Quality and Efficiency in Health Care: Germany

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INSTITUTE FOR QUALITY AND EFFICIENCY IN HEALTH CARE

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**ABSTRACT:** The Institute for Quality and Efficiency in Health Care (IQWiG) was established in 2004 to provide Germany's Federal Joint Committee with evidence-based evaluations of the benefits and cost benefits of health services, and functions in an advisory role. IQWiG reviews available evidence and produces recommendations after an extensive process of consultation with experts and stakeholders. IQWiG's recommendations are then considered by the Joint Committee in issuing coverage and payment directives. Under German law, insurance funds must cover any service that is medically necessary, which means that cost-effectiveness analysis can only be used to exclude a treatment from coverage if at least one equivalent alternative exists.

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### OVERVIEW

Most Germans receive health coverage through the Statutory Health Insurance (SHI) system of sickness funds. Decisions about reimbursement of pharmaceuticals and other medical services (therapeutic and diagnostic procedures) by the sickness funds are made by a Federal Joint Committee composed of provider, insurer, and patient representatives. The Institute for Quality and Efficiency in Health Care (IQWiG) was established in 2004 to provide the committee with evidence-based evaluations of the benefits and cost benefits of services, and functions in an advisory role. In other words, the analyses and the coverage decisions are split between IQWiG and the Federal Joint Committee, respectively. IQWiG and the Federal Joint Committee are funded through a system using revenues from surcharges on SHI payments to providers. In addition to reports on coverage recommendations, IQWiG produces health information for consumers and patients and working papers on methodological and other issues.

Requests for evaluation of specific health services may come from a variety of government sources and interested organizations. The Joint Committee identifies priority topics for IQWiG, which in turn conducts or commissions an evaluation on those topics. IQWiG reviews available evidence and

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produces recommendations after an extensive process of consultation with experts and stakeholders. The review process is transparent and public, and does not consider confidential commercial information that cannot be published. IQWiG's recommendations are then considered by the Joint Committee in issuing coverage and payment directives.

IQWiG studies focus on the evaluation of benefits and costs of a new service, defined in terms of improvement in patient-related outcomes. The cost-effectiveness component was further cemented on June 1, 2007, with the implementation of health care reform to develop methods for the cost-benefit evaluation of drugs to define a ceiling price. Under German law, the SHI funds must cover any service that is medically necessary. This means that cost-effectiveness analysis can only be used to exclude a treatment from coverage if at least one equivalent alternative exists. The Joint Committee may authorize conditional coverage while further data on a treatment are being collected. Sometimes its directives leave some options to sickness funds (e.g., to exclude a treatment or negotiate a discounted price).

A number of issues have emerged in the early years of IQWiG's operations. First, new drugs and inpatient medical services are covered by default and are assessed only if the Joint Committee requests an evaluation. Germany pays higher prices and covers more new drugs than other European countries; more rapid evaluations could alleviate this. Second, controversy has surrounded some recommendations because of limited time to raise public awareness of the value of evidence-based decision-making.

## **EVIDENCE-BASED POLICY-MAKING IN THE GERMAN HEALTH CARE SYSTEM: HISTORY AND CURRENT STATUS**

About 90 percent of the German people are covered by the statutory health insurance (SHI) system, which requires enrollment in privately operated sickness funds with legal responsibility and joint employer/individual financing. Most of the rest have private health insurance.<sup>1</sup> The growth in new drugs and technologies,

along with the decrease in the income of the health insurance funds, have led to debates over whether services such as lifestyle drugs or certain medical services like some dental procedures should be covered by the sickness funds. Measures in 1992 and afterwards provided for increased transparency and cost control in drug reimbursement and the use of health technology assessment to evaluate outpatient medical services. The health care reforms of 2003 established an evidence-based policy-making process to improve quality, provide transparency in coverage decisions, and promote patient participation.<sup>2,3</sup>

Decisions about coverage of pharmaceuticals and other medical services under the SHI are made by the Federal Joint Committee, which includes members from associations of physicians, hospitals, and sickness funds, along with patient representatives. (Patient representatives have no vote in the main committee, but participate actively in the main committee and subcommittees.) The committee is responsible for making evidence-based decisions about the exclusion of pharmaceuticals and lifestyle drugs from the SHI fund, inclusion and exclusion of other medical care services in outpatient care, and exclusion of medical services in hospital care. It also makes decisions about disease management programs for chronic illnesses, sets reference prices for medications, and conducts cost-effectiveness analyses and quality assurance of inpatient and outpatient care. The committee's directives are binding on sickness funds and providers.<sup>4,5,6</sup>

For an independent evaluation of intrinsic and incremental benefits of pharmaceuticals and other medical services, the 2003 legislation required the Federal Joint Committee to establish a nonprofit, non-governmental, independent private law foundation that has the legal capacity and is responsible to create and maintain the Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG). IQWiG was established on June 1, 2004, and is responsible for undertaking the evaluation of benefits and cost benefits of medical services, based on international standards of evidence-based medicine in a

transparent, scientific, inclusive, independent, and consistent way. In 2007, it was given the additional responsibility to develop methods for cost-benefit evaluation of drugs in order to define a ceiling price and further support competition between SHI providers (Gesundheitsreform 2007 “Gesetz zur Stärkung des Wettbewerbs in der gesetzlichen Krankenversicherung”).<sup>7,8</sup>

## **THE CURRENT PROCESS OF EVIDENCE-BASED POLICY-MAKING IN GERMANY**

The Federal Joint Committee appraises and uses comparative effectiveness to develop directives that are legally binding for the insurers, providers, and payers of health care.<sup>9</sup>

### **Reimbursement of Pharmaceuticals**

When drugs are approved for marketing, they are usually immediately reimbursable by the sickness funds, with minor exceptions such as cold remedies, over-the-counter drugs (except for specific age groups), and life-style drugs such as those for erectile dysfunction or obesity. While the Ministry of Health can exclude coverage of some drugs, such as those with unnecessary active ingredients,<sup>10</sup> on its own, the main process for exclusion of pharmaceuticals is through the Federal Joint Committee. (There is only a negative list of non-covered drugs; proposals for a positive coverage list have never been implemented.)

A request for evaluation of a drug may be made by any of the associations represented on the Joint Committee, by patient advocacy and self-help groups, or by the Ministry of Health or the Federal commissioner for patient affairs. The committee in turn may commission an evaluation by IQWiG, especially when coverage is controversial or preliminary review suggests that the evidence is inconclusive.<sup>11</sup> IQWiG submits evaluation results and a recommendation to the Joint Committee, which the committee uses to develop a directive that, once approved by the Ministry of Health, is binding on SHI funds.

The Joint Committee has several subcommittees, including one on pharmaceuticals (Arzneimittel

Unterausschuss). This subcommittee defines and composes maximum reimbursement amount clusters (“Festbetrag clusters”) for certain drugs (e.g., drugs with similar clinical efficacy and chemical composition), which it submits to the Joint Committee. In cases where the medications cost more than the maximum reimbursement rate in the market, the Joint Committee can decide that the patients need to pay for the extra costs of these drugs.<sup>12,13</sup>

### **Reimbursement of Nonpharmaceutical Medical Services**

As in the case of pharmaceuticals, the Joint Committee makes only *negative* determinations regarding coverage of medical services in hospitals; sickness funds cover any service not specifically excluded. For non-hospital services, however, the committee makes *positive* decisions: a new procedure or technology may be covered only if the committee has specifically decided to include it as a listed service. In making its evaluations, the committee considers not only the benefit of a service but also the feasibility of implementing coverage, considering, for example, necessary equipment and physician training and skills.

The current process of evidence-based policy-making in Germany is focused on reimbursement decisions. IQWiG is not commissioned to develop guidelines for medical practice, though the Federal Joint Committee can publish treatment recommendations for clinicians based on IQWiG reports. Physicians may still prescribe an excluded drug or treatment, but patients must usually pay the full cost, with some exceptions. A physician may provide an explanation of why a patient requires a specific excluded drug and request its reimbursement. Additionally, a constitutional court decision in 2005 has specified that, when a patient has a life-threatening disease for which no alternate treatment is available, the SHI fund must cover a treatment for which the chance of success is not entirely remote.

When evidence of the benefit of a health service is incomplete, the Joint Committee might decide to propose a conditional coverage scheme. The treatment

would be reimbursed for a set period, during which physicians are responsible to collect specific data needed for evaluation.<sup>14</sup>

### **THE STRUCTURE, SIZE, FUNDING, AND OUTPUTS OF IQWiG**

The Federal Joint Committee established the Foundation of the Institute for Quality and Efficiency in Health Care to establish and define the structure of IQWiG. The Foundation has two parts: the Foundation Council (Stiftungsrat), and a five-member Foundation Board of Directors (Vorstand). The Foundation Board of Directors has two members from the health insurance funds, two members from the health providers, and one representative from the Ministry of Health. Half of the members of the Foundation Council are from the National Confederations of Regional Associations of the Statutory Health Insurance funds and half are from provider organizations. The management of IQWiG is independent from the Foundation, and receives advice from two committees: the Board of Trustees (Kuratorium) and a Scientific Advisory Board. The Board of Trustees has 30 members and includes representatives from scientific societies, employers, pharmaceutical companies, and other groups.<sup>15</sup>

The current structure of IQWiG includes eight departments, along with an Institute Management Department. The departments are: 1) Pharmaceutical, 2) Medical Biometry, 3) Health Economics, 4) Health Information, 5) Quality of Healthcare, 6) Nondrug Interventions, 7) Communication, and 8) Administration. IQWiG staff has grown from 11 employees in 2004 to more than 90 employees at present. However, the work of the Institute is done in collaboration with a wider network of German and international experts who provide consultation and peer review and carry out analyses. The health information department receives feedback from focus groups of consumers at the Patient University of Hannover (an innovative program that provides self-help education for the chronically ill).

IQWiG is funded through surcharges on services reimbursed by SHI; the details are determined by the Federal Joint Committee. The budget has grown from €8 million in 2005 to a planned €15 million in 2009. This includes salaries, administrative costs, and costs for outside experts and consultants.

The products developed by IQWiG in response to Joint Committee commissions include full or rapid reports, assessing the benefit or cost benefit of medical interventions and health information for consumers and patients. IQWiG also produces working papers on its own initiative, on topics such as reviews of clinical

**Table 1. IQWiG Reports and Other Products**

<b>Topics</b>	<b>Example</b>
Screening	Screening for visual impairment in children younger than 6 years
Nonpharmacological procedure	Negative Pressure Wound Therapy
Health care management (Disease Management Program, DMP)	Systematic guideline search and evaluation, as well as extraction and comparison of relevant information on obesity, for the preparation of the DMP obesity module
Pharmaceuticals	Fixed combinations of corticosteroids and long-acting beta-2-receptor agonists for inhaled use in patients with asthma
Diagnostics	Positron emission tomography (PET) and PET/CT in malignant lymphoma
Quality of care	Relationship between provider volume and outcomes in the care of preterm infants and neonates with very low birth weight
Patient information	Production of an information leaflet for pregnant women to support medical counseling on HIV tests within the framework of the maternity guidelines of the Federal Joint Committee

guidelines, methodological studies, or evaluations of the quality of health services. The following table gives some examples of completed outputs.

## PRINCIPLES AND VALUES, AIMS AND OBJECTIVES

IQWiG is charged by law with the following tasks:

1. Research on, assessment, and presentation of current scientific evidence on diagnostic and therapeutic procedures for specific diseases;
2. Preparation of scientific reports and expert opinions on quality and efficiency issues for the SHI system, taking into account age, gender, and personal circumstances;
3. Appraisal of evidence-based clinical practice guidelines on the epidemiologically most important diseases;
4. Issuance of recommendations on disease management programs; and <sup>16,17</sup>
5. Provision of understandable evidence-based information for patients and public.

IQWiG operates under some general principles:

- *Inclusiveness:* The law requires that providers, experts, industry, and patient organizations have an opportunity to comment on IQWiG methods and recommendations. The draft report plans and reports are published online in the public domain and stakeholders and the general public are encouraged to submit their views and comments. IQWiG provides an email alert service notifying subscribers of the publication of draft reports and the opportunity to provide comments. Comments can be submitted through written correspondence or the submission of written documents and evidence.
- *Transparency:* All of the methods and processes used in developing IQWiG reports are made public, along with the evidence underpinning the guidance provided by the report. Unlike similar organizations elsewhere, IQWiG does

not accept confidential commercial information furnished by pharmaceutical companies and subject to publication restrictions. Instead, a standard contract negotiated with the pharmaceutical manufacturers' association specifies the types of information that companies should provide and permits IQWiG to publish any relevant data, so that third parties can understand and evaluate its processes and methods.

- *Independence:* The system of funding through levies on provider charges assures that IQWiG is independent of stakeholders or the appropriations process, and any individual involved in the reports has to declare their conflicts of interest. The commissioning bodies, the Joint Committee or Ministry of Health, clarify the scope of commissioned projects as stakeholders but do not have any direct involvement in the process of delivering the projects.
- *Scientific rigor and consistency:* IQWiG methods for evaluating the benefits of health services are based on internationally recognized standards of evidence-based medicine. The methods for benefit evaluation are set out in a methods paper, which is regularly revised by the methods group of IQWiG. Methods for cost-benefit evaluation are under development.<sup>18,19</sup>

## USING COMPARATIVE EFFECTIVENESS RESEARCH (CER) TO INFORM POLICY DECISIONS

The Federal Joint Committee, the main decision-making body of the self-administrated health care system, appraises and uses comparative effectiveness research (CER) prepared by IQWiG or other sources using a detailed evidence-based procedure (paragraph §92 of the Social code book V). The committee considers needs and costs to develop legally binding directives for the insurers, providers and payers of health care.<sup>20</sup> IQWiG is a producer of CER and undertakes synthesis of the available evidence to evaluate the benefits and cost benefit of drugs and healthcare services for

in- and outpatient care. The recommendations of IQWiG are only advisory and the Federal Joint Committee might decide to follow or not follow the recommendations. In the absence of evidence for the benefit of health care services, the Federal joint committee might decide to propose a conditional coverage scheme (“Modellvorhaben”). In the latter case, treatment would be reimbursed for a set period of time by the health insurance fund, while the physicians would be responsible for collecting the needed data to more fully evaluate the procedure.<sup>21</sup> The research institutes could also undertake clinical trials on these medical interventions and submit a request to the Federal Joint Committee that the medical intervention be reimbursed.

## **PROCESSES AND METHODS**

### **Process of Preparing Reports in IQWiG**

*Topic Selection:* As noted above, requests for evaluation of specific health services may come from a variety of government sources and interested organizations. These applications are considered and prioritized by the Joint Committee, taking into account the clinical relevance of the health service and the risk and costs associated with it. IQWiG is then commissioned to evaluate priority services. In addition, the committee has given IQWiG a general commission to regularly evaluate the current medical literature, monitor developments in medicine and their influence on the quality and efficiency of medical services, and undertake projects based on its own initiative that could provide useful information or recommendations for the improvement of medical services. In 2006, this general authorization was amended to specify that IQWiG could independently select topics for preparing understandable evidence-based health information for patients and public through a scientific process.

After IQWiG is commissioned to do an evaluation, an internal project group defines the scientific question in consultation with the commissioning agency and other relevant groups. A research protocol and report plan is prepared and finalized after an opportunity for public comment, after which a report and recommendations are developed based on

a literature search and evaluation and synthesis of available studies and finalized after public and stakeholder consultation. External experts are usually involved in the process, which includes several further stages of internal review.

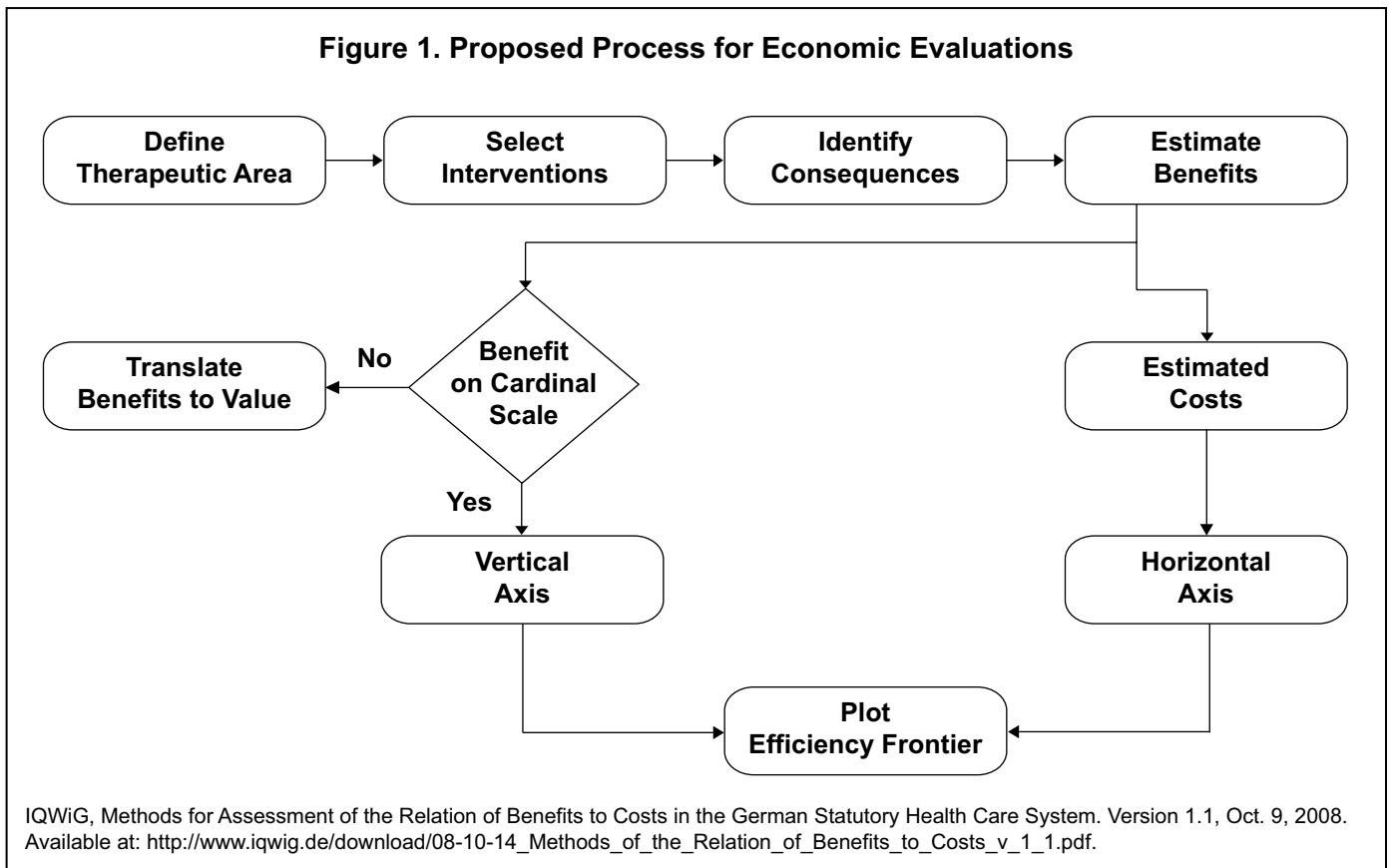
IQWiG also produces “rapid reports,” which do not inform directives by the Joint Committee, but are intended to provide up-to-date information on relevant health care developments, especially new medical technologies. They are subject to peer review but not extensive public consultation.

*Comments and Hearing:* IQWiG allows public and stakeholder comment on the report plans and preliminary reports done by the Institute. Each stakeholder and relevant governmental body is given the opportunity to comment or challenge the reports of IQWiG with written documents and evidence. Legal appeal cannot be made on IQWiG reports as the reports and their recommendation are not legally binding; however, if the directives based on the reports are developed, approved and implemented by the Federal Joint Committee, challenging the directives necessitates legal appeal.

### **Methods for Evaluating Patient-Relevant Benefit and Cost-Benefit Relationships in IQWiG**

SHI funds must reimburse any service that is necessary to diagnose or cure a disease, prevent worsening of the disease, or alleviate symptoms. Benefit assessments by IQWiG help to determine whether a service meets this definition of necessity, taking into consideration both positive and negative effects in comparison with other treatments, placebo, or no active treatment. IQWiG also assesses the cost-effectiveness of some treatments. Under the law, an effective treatment may not be excluded from coverage on the basis of its costs. However, cost-effectiveness analysis may be used to set a maximum reimbursement amount for the treatment.

IQWiG undertakes the assessment of the benefit and harm of medical services in terms of patient-relevant medical outcomes—that is, outcomes that reflect



how the patient feels, functions, or survives. Outcome measures considered in this context include mortality, morbidity (complaints and complications), health-related quality of life, effects on duration of the illness, adverse effects of the intervention, and patient satisfaction. Topic-specific outcomes to be measured are identified in consultation with affected individuals or patient organizations.

The latest working paper on cost-benefit evaluation methodology recommends that an “efficiency frontier” should be constructed for each therapeutic area to make it possible to compare the relative costs and benefits of alternative therapies. The plot has two axes, a horizontal one reflecting the total net costs per patient from the perspective of the insurers of the SHI funds, and a vertical one, which reflects health benefits assessed by IQWiG that can be parameterized with actual clinical measures. The benefit should always be established before the economic evaluation and should be derived from a rigorous assessment of patient-relevant outcomes. Hence, prior to any cost-effectiveness evaluation, a benefits evaluation is needed. For the

economic evaluation, IQWiG submits a budget impact analysis to the Joint Committee, which takes it into consideration along with other factors such as affordability. This method cannot be used for new drugs with no available alternative therapy, meaning sickness funds must continue to reimburse these as they do currently.<sup>22</sup>

**PATIENT INFORMATION**

IQWiG’s patient health information Web site (<http://www.informedhealthonline.org>) was launched in February 2006. It provides understandable health information for patients and the public to support informed decision-making about health issues and to improve public understanding of scientific concepts and evidence-based medicine. The content is based on scientific evidence, especially systematic reviews, and uses evidence-based techniques to communicate the information in nondirective and neutral language. Topics are identified through an internal horizon scanning process and are approved by the internal steering committee. Health information is developed through a

rigorous scientific process, which includes identifying and assessing the evidence, peer review, and a stakeholder consultation process.<sup>23,24</sup> The products can be in the form of feature articles, fact sheets and research summaries, patient narratives, interactive features, and animated films.<sup>25</sup>

### **THE MEDIA AND PUBLIC PERCEPTIONS**

Since the publication of the first draft reports, IQWiG has received intense media attention, critiquing or appraising the reports and patient information published by the Institute. The involvement of stakeholders and the general public in the process of preparing reports improves the transparency and inclusiveness of the reports but also causes debate, criticisms, and discussion. For example, pharmaceutical companies or associations have issued press releases during the process of preparing and publishing reports.

There are several reasons for the intense media coverage that IQWiG has received. German pharmaceutical policies allow reimbursement of most new drugs immediately after their marketing approval by licensing authorities. If the Federal Joint Committee then decides to commission IQWiG to evaluate a product, this represents a threat to the manufacturer, because a negative report could mean that its pharmaceutical or medical service might be excluded from SHI reimbursement. In addition to this, the Federal Joint Committee usually selects and prioritizes topics for evaluation that have a potential impact on health services in Germany, possibly resulting in new directives for the SHI funds, and for which primary literature search and evaluation indicates that the evidence base may be inconclusive or controversial.<sup>26,27</sup>

### **IMPACT ON POLICY AND PRACTICE: SELECTED CASE STUDIES AND OVERALL TRENDS**

The interrelated health care system in Germany facilitates the implementation of the recommendations of IQWiG reports in the system. Full reports from IQWiG are submitted to the Federal Joint Committee and the committee takes them into consideration as a basis for

developing directives for the health care system. These directives are mandatory for the SHI funds, but there can sometimes be opportunities, within the framework of a directive, for different sickness funds to adopt different coverage or payment options.<sup>28,29</sup>

For example, one of the first full reports produced by IQWiG was on rapid-acting insulin analogues for the treatment of diabetes mellitus type 2. The report found no additional benefit of insulin analogues compared with human insulin. On the basis of this finding, the Federal Joint Committee decided that these analogues would not be reimbursed by the SHI funds as long as they were more expensive than human insulin. Some SHI funds responded by excluding insulin analogues from coverage, while others negotiated discounts from the manufacturers.<sup>30</sup>

### **LESSONS LEARNED: A CRITICAL VIEW Earlier Benefit Assessment of Drugs and Medical Services**

The SHI funds allow immediate reimbursement of any pharmaceutical that has received marketing approval, at any price the producer sets. Similarly, the policy of having only a negative list of excluded procedures for inpatients means that nonpharmacy services provided in hospitals are covered by default. Assessment of the benefits of these medical services and pharmaceuticals is undertaken only when the Joint Committee decides to request an evaluation by IQWiG. Under current rules, Germany pays the highest prices for drugs in Europe and has more new drugs available than other European countries. An earlier benefit evaluation of drugs and medical services could prevent additional costs and the harm of medical services without a proof of benefit.

### **Limited Time to Raise Public Awareness**

The previous unlimited access to pharmaceuticals has made it difficult for the patient and public to accept the exclusion of some of the drugs from SHI coverage.<sup>31</sup> In addition, IQWiG was given a number of commissions immediately after its establishment, and was not provided with the time to raise awareness on the



need for a more evidence-based approach for deciding the inclusion or exclusion of medical services. This resulted into disputes and criticisms of the first IQWiG reports and discussions regarding the process of stakeholder consultation. The longer time period currently devoted to the development of cost-evaluation methods has provided more opportunities to discuss the way methods are developed, and may help different stakeholders get acquainted with the need for a more systematic approach for cost-benefit evaluation.

### **Need for More Targeted Primary Research**

In the first proposals to establish IQWiG in 2004, it was suggested that IQWiG should have its own trial coordination department, to help address the lack of primary studies for important clinical questions. The plan was that this IQWiG department would make recommendations on how necessary clinical trials should be designed and conducted. It would also coordinate and provide ongoing advice on the research work conducted in scientific institutions in Germany and abroad. This proposal was not implemented because of several issues:

1. The current budget of many clinical trials comes from the industry and there were concerns about the potential effects of collaboration between industry and an independent Institute in undertaking industry-funded trials. On the other hand, if industry was not to be considered as a main source for funding for clinical trials, there was a question of who should be funding necessary trials.
2. If the Institute was to be involved in coordinating primary trials, there was a possibility that the involvement would bias its assessment of those trials in the evidence-synthesis stage. Despite the need for collaboration between the evidence synthesis and primary research sectors, appropriate strategies would have had to be put in place to ensure the independence of the two sectors.

### **Need for Regulation to Access Unpublished Data**

IQWiG's access to unpublished data for benefit assessment of drugs and medical interventions is dependent on the willingness of pharmaceutical companies to provide these data; there is no regulation requiring that the companies do so. This can lead to publication bias in the benefit assessment of medical services, especially in cases when the published data are scarce. A regulation for obligatory availability of data for the benefit assessment of drugs and medical services might help in ensuring a more thorough assessment of the benefit and harm of medical services.

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