Verband Forschender
Arzneimittelhersteller e.V.

VFA Position Paper
"Requirements for a health economic assessment in Germany"

It is the objective of this position paper to specify the legal requirements for the health economic assessment in Germany with a methodological and procedural proposal that is in line with international standards. Therefore, the VFA commissioned Prof. Dr. Graf von der Schulenburg, health economist from Leibniz University, Hanover, to develop an expert report which identifies international methods of health economic assessment that have been proven practicable and make them applicable in the German system. The VFA's procedural proposal is based on this report.

In the German terminology and in the German law the term cost-benefit assessment (CBA) is used as summary term for all kinds of health economic assessments. The term CBA will be used in this paper in its German meaning - as summary term.

Summary of the VFA's basic position on the cost-benefit assessment methods:

1. There are international standards for cost-benefit assessment (CBA) methods that all assessments must be based on, pursuant to the SHI Competition Enhancement Act (GKV-WSG).
2. The legislation makes a distinction between the benefit assessment (BA) and the cost-benefit assessment (CBA). Since these are two different concepts, a CBA cannot be based on a BA.
3. The metrics to measure benefits must be adequately selected depending on the question. These can also be clinical intermediate endpoints and aggregate effect measures.
4. Both clinical and health economic results are subject to uncertainty that must be determined and taken into account using appropriate methodology.
5. Analogue to other countries, the CBA should always be conducted from a societal perspective also in Germany.
6. Health-economic modelling is the basic technique for the CBA and is to be used as a standard.
7. The data basis shall consist of studies of all levels of evidence.
8. The Institute for Quality and Efficiency in Health Care (IQWiG) can be commissioned to conduct assessments, but it is not authorized to determine ethical, moral and societal values.

Hausvogteiplatz 13
10117 Berlin
Telefon 030 20604-0
Telefax 030 20604-222
www.vfa.de

Hauptgeschäftsführerin
Cornelia Yzer

Summary of the VFA's position on the process of cost-benefit assessment:

1. The integration of the parties to be involved according to the legislation should begin as part of a scoping workshop at the start of the process. All parties will jointly define the following:
    a. The decision problem to be reviewed;
    b. The comparative therapies to be selected;
    c. The patient-relevant benefits and outcomes; and
    d. The methodology to be applied.
2. The scoping workshop will be chaired by an independent external moderator.
3. IQWiG assigns the assessments to external experts, the commissions are publicly put out to tender. Selection criteria must be publicly disclosed.
4. During the literature search, the pharmaceutical company is to be systematically involved from the outset. Manufacturers have the right to submit study data and health economic analyses. The researched and submitted data must be integrated into the assessment process. A justification must be provided in case such data are not taken into consideration.
5. The judgment of applicability of existing models or the definition of a model to be potentially developed will be made by a clearing institution that is yet to be established (e.g. the German Institute for Medical Documentation and Information (DIMDI), the Robert Koch Institute (RKI) or a university institution). This institution will also fulfill the task of an arbitration body for any disputes.
6. Each procedure includes an internal and external review.
7. With the submission of the final report, the manufacturer is provided with an opportunity to submit final comments to the contracting entity of the procedure (Federal Joint Committee (G-BA) or Federal Ministry of Health (BMG)) (appeal).

Objective of the position paper

As of April 1, 2007, the legislature stipulates in the Act for the Enhancement of Competition in Statutory Health Insurance (SHI Competition Enhancement Act) that the Institute for Quality and Efficiency in Health Care (IQWiG) can be commissioned with evaluations of the benefits or cost-benefit ratio of pharmaceuticals. In doing so, the Institute must apply international standards of evidence-based medicine and health economics. Furthermore, it must publish the employed methods and criteria on the Internet and must ensure high procedural transparency as well as appropriate participation of the parties named in the legislation, including patient representatives and the pharmaceutical industry. It is the objective of this position paper to specify the legal requirements for the cost-benefit assessment in Germany with a procedural proposal that is in line with customary international standards.

This position paper is exclusively concerned with the new instrument of health economic assessment and not with the "benefit assessment" previously conducted by the IQWiG. This procedure still meets with comprehensive criticism. Especially, the arbitrary selection of studies and data including the regularly practiced exclusion of all non-randomized studies is in contradiction to the international standards, including the standard of evidence-based medicine.

Introduction – Legal framework and methodological requirements of the legislation

With the SHI Competition Enhancement Act (GKV-WSG), the legislature stipulated in the revised Section 35b para. 1 of the German Social Code V that the Institute for Quality and Efficiency in Health Care (IQWiG) can be commissioned with the assessment of benefits or the cost-benefit ratio of pharmaceuticals. Pursuant to Section 31 para. 2a of the German Social Code V, the cost-benefit assessment must be used to stipulate maximum reimbursement amounts for pharmaceuticals.

Introduction - Section 35b para. 1 of the German Social Code V:

"(1) Pursuant to Section 139b para. 1 and 2, the Institute for Quality and Efficiency in Health Care can be commissioned with the assessment of the benefits or cost-benefit ratio of pharmaceuticals. […] The assessment is made in comparison with other pharmaceuticals or treatment forms in consideration of the additional therapeutic benefit for the patients in relation to the costs. […] The Institute makes commission-related decisions on

the methods and criteria for the development of assessments pursuant to clause 1 based on the international standards of evidence-based medicine and health economics acknowledged by the respective expert circles. For the commission-related development of methods and criteria and the development of assessments, the Institute guarantees high procedural transparency and an appropriate participation of the parties named in Section 35 para. 2 and Section 139a para. 5. The Institute shall publish the respective methods and criteria on the Internet. […]"

Pursuant to Section 139a of the German Social Code V, the IQWiG must ensure that the assessment of the medical benefit is made in accordance with internationally recognized standards of evidence-based medicine. The economic assessment must be made analogously to the internationally acknowledged procedures relevant for economic evaluations. The legislature expressly mentioned health economics in this context.

Introduction – Section 139a para. 4 and 5 of the German Social Code V:

"(4) The Institute must ensure that the assessment of the medical benefit is made based on internationally acknowledged standards of evidence-based medicine and that the economic evaluation is made based on the relevant internationally recognized standards, especially of health economics. At regular intervals, the Institute must publicly report on the work processes and results including its basis for decision-making."

"(5) In all important segments of the assessment procedure, the Institute must provide an opportunity for comment to the experts of medical, pharmaceutical and health economic science and practice, to pharmaceutical companies and the relevant organizations representing the interests of patients and the self-help organizations for chronically ill and disabled people, as well as the German government's commissioner for patient concerns. The comments must be included in the decision."

During the benefit assessment, also as part of the CBA, the legislature demands that the additional therapeutic benefit for the patients has to be taken into account. The legislature particularly stipulated that the following aspects are to be considered in assessing patient benefits:

- Improvement of the state of health;
- Shortening the duration of illness;
- Extension of the duration of life;
- Reduction of side effects; and
- Improvement in the quality of life.

These legal provisions and tasks require more detailed development based on operationalisable methods. Especially the benefit aspect from the patients' point of view requires appropriate representation in the methods to be applied. Specifically, the quoted sections of the German Social Code V result in the following requirements that must be observed for the methods to be applied:

- The methods of the IQWiG must not deviate from the internationally accepted methods and procedures. Due to the demand of the legislature to generate commission-related methods based on a fundamental methodological paper, close cooperation during the determination of the respective sets of methods must be ensured between the contracting entity, the IQWiG and the parties to be involved that are named in the legislation.
- The legislation stipulates the implementation of both benefit assessment and cost-benefit assessments. An alleged simplification of the procedure based on the application of a two-stage procedure (first the benefit assessment, then the cost-benefit assessment based on the benefit assessment result) does not fulfil the requirements for health economics analyses and does not correspond to the requirements of the legislature. On the other hand, the legislature specified that a cost-benefit ratio must be determined, i.e. a quotient from costs and benefits. This is only possible, if both the numerator and the denominator are each calculated in a cardinal measure. For the numerator, i.e. the costs, aggregation to the Euro dimension is the obvious suggestion.
- Due to different criteria in the benefit definition and its operationalisation in the past, benefit assessment of the IQWiG and the deviating health economic benefit concept, it is methodologically impossible to integrate any "benefit" into the health economic evaluation that the IQWiG has determined or excluded during benefit assessment procedures. Instead, for methodological reasons, an integrated approach of simultaneous assessment of costs and economically evaluated benefit must be pursued.
- With regard to the denominator, i.e. the benefit, the benefit measures given by the legislature must be included. If the key additional benefit of a pharmaceutical compared to its comparative therapy is a binary variable (e.g. relapse, no relapse), it can be used in the form of a mean frequency. If the benefit simultaneously has several degrees of manifestation (e.g. different pain intensities) or dimensions (e.g. the burden due to several different side effects), the different dimensions must be aggregated into one metric with the help of validated

methods. If no validated method is available, it must be expressly explained how the aggregation was performed and what influence the specifically selected method of aggregation has on the results.

Internationally established standards in health economics
in the various international health care systems, given their context and specific decision problems, country-specific regulatory frameworks exist, however grounded in common health economic methodology At this point, a clear distinction must be made between the scientifically based health economic methods on the one hand (e.g. study forms, modelling types) and the societal or political framework (e.g. threshold value of cost effectiveness) on the other hand. For Germany, the discussion of the methods to be applied must take place publicly and with the involvement of the parties and groups mentioned in the legislation. Decisions regarding inclusion and exclusion criteria by the Federal Joint Committee (G-BA) require parliamentary control.

As a result, no individual or selected country-specific regulations should be analyzed in search of "international standards in health economics." Instead, the scientifically-based methods of health economics must be applied. International standards of health economics are not the sum of all methods applied in other health care systems but instead the methodological concepts developed by international health economic research in order to be able to conduct such assessments that have, in turn, also formed the basis for reimbursement decisions in many countries.

Benefit and its operationalisation

In accordance with the broad, comprehensively designed benefit definition of the legislation, the benefit must be operationalised depending on the decision problem resulting in variety of effect measures. Examples include mortality, morbidity, patient-reported outcomes (incl. improved quality of life, increased patient satisfaction and higher utility values), improved compliance and reduced side effects.

When it comes to the health economic assessment, the selection of effect measures reflects the basic question. Examples include costs per improved relevant medical progression parameter, costs per prevented event, costs per life year gained, etc.

A special role have highly aggregated effect measures that facilitate the economic comparison of various interventions and in different therapeutic areas. Internationally, the QALY concept is viewed as an option (the concept of quality-adjusted life years). With QALYs or by means of other utility measures, effects on the

duration of life and the quality of life perceived by the patient can be represented simultaneously in a single effect measure.

The basic idea is that an additional year spent in good health has a greater value for the patient than a year spent in poor health. In accordance with the benefit concept stipulated in the legislation and dependent on the context and perspective taken, the utility measures to be used must be defined specifically for each decision problem as part of a scoping process (scoping workshop) in accordance with the defined process.

Handling the uncertainty

One basic problem in benefit assessments and health economic evaluations is the fact that there is only a limited quantity of study data compared to a potentially infinite number of issues (effectiveness in diverse subgroups, different benefit dimensions, long-term effects, etc.). As a result, the corresponding evaluations are associated with a certain degree of uncertainty and it is the aim to apply appropriate methods accounting for uncertainty, or at least quantify its existence.

Modelling as a basic technique

One important technique is health economic modelling, which allows the evaluation of data in a new context, so that e.g. long-term data can be extrapolated from intermediate endpoints early on. Modelling is necessary, if:

- Clinical, epidemiological, monetary and quality-of-life data are being combined;
- Data originate from international studies and must be adapted to the German context;
- Data that are necessary for external validity and can not be generated through clinical studies must be linked with the available clinical data;
- Clinical studies represent shorter time periods than is necessary for an appropriate evaluation of costs and benefits;
- Long-term data that may be required for product evaluation are naturally unavailable, especially for new, innovative products.

Accordingly, decision-analytical models are among the international standards of health economic evaluations. During the past few years, a very high quality standard has been achieved in health economic modelling.

Quality criteria of the standard technique in modelling include:

- Transparency (detailed representation of the model, the underlying theory and assumptions as well as the methodology of literature identification and weighting of data);
- Internal consistency (the combination of the individual parameters must be without contradiction in themselves);
- Interpretability (the results must be assignable to the previously clearly defined problem);
- Validation: A complete external validation, i.e. a comparison of the model to empirical data is not regularly possible, because it was the non-availability of such data that made modelling necessary. On the other hand, partial aspects are validated as much as possible (e.g. the comparison of a model-generated mean life expectancy with relevant published life expectancy data);
- Analysis of uncertainties (critical factors for the result must be identified and discussed in sensitivity analyses).

To ensure appropriate decisions with regard to the models to be taken into account, the evaluation of existing models and the selection of parameters during a potential generation of a new model should be prepared and run by an independent clearing institution that should be newly established. For example, this could be performed by the DIMDI, RKI or a university institution. The involvement of the clearing institution must be a firm component of the cost-benefit assessment processes.

Analysis type

For the health economic evaluation, it must be clearly stated which study form was chosen and why. Since the legislature speaks of the assessment in terms of a cost-benefit ratio, the following internationally customary study forms are possible in addition to the cost-benefit analysis (used here as international term) and the cost-consequence analysis:

- Cost-effectiveness analysis (CEA) (used here as international term), when the therapeutic benefit that is relevant for the study can be expressed in a cardinally measurable medical unit. The aggregation of various benefit dimensions must be methodologically sound.
- Cost-utility analysis (CUA). The CUA is a sub form of the CEA and should be chosen when the benefit manifests itself predominantly in an improvement in the patient's quality of life.
- Cost comparison or cost minimization analysis. This analysis form is only of limited importance, because - for methodological reasons – it can only be applied in the

rarest cases when the benefit of the interventions to be compared is identical.
- A simple (disease) cost analysis, on the other hand, is not a suitable evaluation method, since it neither compares therapies nor puts costs and benefits in relation. Nevertheless, this study form can also include valuable data for subsequent evaluation studies.

Perspective

It follows from Section 35b of the German Social Code V that the legislature basically views the internationally established societal perspective as a cost assessment benchmark for the determination and evaluation of costs. As a result, all costs (and cost reductions analogously) must be recorded, no matter who or which institution within society absorbs them. This means both costs associated directly with therapy and indirectly caused costs of the disease must be recorded.

In addition, the legislative text requires that the "appropriateness and reasonableness of cost absorption by the community of insured patients" also has to be taken into account (Section 35b para. 1 clause 4 of the German Social Code V). From this wording, we can derive the wish of the legislature to also consider the payer perspective, apart from the international standard (perspective of society or the national economy). This additional assessment from the payer's point of view must be made whenever additional costs arise due to the use of the intervention to be assessed that seem unreasonable for the community of insured patients.

Costs

The costs to be considered depend on the health economic perspective:

Based on the requirement of the overall societal perspective, all relevant costs and cost savings that are achieved through the therapy to be assessed must be recorded. Direct and indirect costs as well as intangible effects must be taken into account accordingly. If the reasonableness of a burden for the community of insured patients is to be reviewed additionally, the consideration of partial aspects from the viewpoint of social security insurers can be made in addition to the societal perspective.

Data basis

The following data sources, all of which correspond to the international standard, are regularly used in economic evaluation studies:

- Clinical efficacy data from clinical studies;
- Resource consumption data (quantity vector) from targeted surveys including clinical studies;
- Cost data (price vector), usually from separate studies;
- Data from non-interventional studies (NIS) or health economic cohort studies that represent routine practice over longer periods of time;
- Registry data that provide both medical effectiveness and epidemiological data;
- Data from surveys specially conducted for the economic evaluation to reflect routine practice pattern and the epidemiology of the disease;
- Data from expert surveys; they provide important information e.g. for actual treatment processes outside of studies ("real-life setting"). As with all surveys, it must be ensured that the form of survey methodology is represented transparently and reproducibly;
- Incidence and/or prevalence data, usually from epidemiological studies and/or data from statutory health insurances.

Discounting

To allow decision-makers an objective assessment basis, overcoming the potential time-related discrepancy of costs and benefits is a key objective of the economic analysis (e.g. costs at the start of therapy with the benefit manifesting itself at a later time). For these reasons, it must be indicated whether discounting was applied and at which rate. The selected discount rate must be chosen in accordance with the problem at hand and justified in a reproducible manner.

Procedural proposal for a cost-benefit assessment based on international standards, as far as they are relevant according to the requirements of the SHI Competition Enhancement Act

1. Process description

The process of a cost-benefit assessment can be represented in two sequential steps:

(1) Generation of a reporting plan that defines the comparative interventions, target criteria, assessment methods and mandatory schedule to be included; and
(2) Implementation of the actual cost-benefit assessment.

2. Development of the reporting plan

The generation of the reporting plan is divided into four steps:

(1) Commission through the Federal Joint Committee (G-BA) or the Federal Ministry of Health (BMG).
(2) Specification of the problem and the project schedule.
(3) Implementation of the scoping workshop with the involvement of the parties mentioned in Section 139a para. 5 to determine the
    a) Problems to be analyzed;
    b) Comparative therapies to be selected;
    c) Patient-relevant benefits and outcomes; and
    d) Methodology to be applied.
(4) Determination of the final reporting plan and schedule.

3. Award of the commission by the Federal Joint Committee (G-BA) or the Federal Ministry of Health (BMG)

Pursuant to Section 139b para. 1 and 2 of the German Social Code V, the commission for the cost-benefit assessment is awarded by the Federal Joint Committee or the Federal Ministry of Health.

As part of the transparency requirement, which is based on Section 35b para. 1 of the German Social Code V and the EC Transparency Directive, the commissions and the preliminary subject draft must be published by the contracting entity as well as the IQWiG at the time the commission is awarded.

3.1. Specification of the problem and the project schedule

After the commission is awarded, the IQWiG will establish a project team with the goal of an initial subject specification. The Steering Committee of the Institute integrates the subject into the list of priorities of the Institute and, as a result, determines the project schedule. The revised and operationalised problem is submitted to the contracting entity together with the preliminary project schedule for review and revised if necessary.

After approval by the contracting entity, the IQWiG will publish the specified problem and project schedule. Within eight weeks after publication, the parties mentioned in Section 139a para. 5 of the German Social Code V have an opportunity to submit written comments. The comments should include suggestions in reference to the problem, comparative therapy, economic objectives as well as patient-relevant benefits and methodology to be applied. All comments are part of the reporting plan, which can be accessed on the Internet, and the final report.

3.2. Implementation of the scoping workshop

The legislation demands commission-related decisions regarding methods and criteria for the development of assessments with the involvement of the respective expert circles. The logical result is the performance of a scoping workshop. The submitted comments must be evaluated by the scoping project team and commented on individually with regard to their evidentiary content. Within four weeks after deadline expiration, the commenting parties as well as representatives from the contracting entity will be invited to the scoping workshop.
This workshop has the following objectives:

- To evaluate and, if required, propose a revision of the problem to be addressed;
- To suggest clinically relevant comparative therapies;
- To propose economically relevant objectives and patient-relevant benefits; as well as
- To suggest a commission-related methodology including inclusion and exclusion criteria for the selection of the literature to be included.

The scoping workshop will be headed by an independent moderator appointed by the respective contracting entity of the IQWiG. The moderator has the special task of serving as a neutral mediator between the positions of the workshop participants. The most important goal of the workshop is to create a broad consensus with regard to the aforementioned objectives. A word-for-word transcript must be generated for the workshop, which will be part of the reporting plan accessible over the Internet and the final report.

3.3. Development of the reporting plan and schedule

The suggestions of the participants of the scoping workshop must be evaluated by the project team and commented on individually. Based on the relevant suggestions, the project group will develop the reporting plan and update the suggested schedule for the implementation of the cost-benefit assessment, if necessary. No later than four weeks after the workshop was held, the reporting plan and the schedule must be published and made accessible on the Internet. This will be followed by a commenting procedure for the reporting plan with subsequent scientific hearing.

4. Implementation of the cost-benefit assessment

The implementation of the cost-benefit assessment is divided into five clearly defined steps that follow the development of the reporting plan:

4.1. Tender procedure and award of commission

Pursuant to Section 139b para. 3 of the German Social Code V, the Institute must assign scientific research commissions for the implementation of the cost-benefit assessment to external experts. Even if the IQWiG represents a foundation under private law, it is of a quasi-public nature with regard to its mandate. Furthermore, the type of financing (contributions from statutory health insurance patients) and the legal requirements (establishment and financing are legally stipulated) substantiate the character of a public contracting entity. It is for this reason that all commissions should be publicly tendered in the Federal Law Gazette. It is not planned for the IQWiG to conduct cost-benefit assessments.

The following criteria apply to the selection of external experts:

- Scientific expertise in the implementation of systematic cost-benefit or health technology assessments;
- Scientific expertise in the critical evaluation of applied study methods in health economics.

Scientific expertise can be demonstrated based on comparable projects for the indication under review that were conducted in the past as well publications in national and international journals with peer-review procedures. In principle, based on these criteria, all commissions for the cost-benefit assessment of pharmaceuticals must be assigned to external experts. To ensure a high degree of procedural transparency, the names and institutions of the experts must be indicated in the preliminary and final report. Furthermore, the number of applicants for the respective tender must be documented in the preliminary and final report. The contracting entity will perform random checks with regard to award criteria.

4.2. Literature search and assessment

A search strategy will be generated based on the reporting plan. The objective of the literature search is a comprehensive representation of the existing findings for the health economic assessment of the respective pharmaceutical and comparative therapies at the time of the search.

Parallel to the literature search, the IQWiG will inform the affected pharmaceutical companies of the implementation of the cost-benefit assessment and ask them to provide information on relevant published and unpublished studies within four weeks. When it comes to the submission of studies and data, the sample confidentiality agreement ratified by the IQWiG and the German Association of Research-based Pharmaceutical Companies (VFA) can be used to protect operative and business secrets of the pharmaceutical companies.

In addition to submitting other data sources, the pharmaceutical manufacturers have the opportunity to submit health economic analyses and models in accordance with the parameters stipulated in the reporting plan (indication, comparative intervention, defined benefit, time period under review, costs to be taken into account, etc.).

All publications identified in the literature search and submitted by the pharmaceutical companies will be independently examined by two scientists with regard to subject relevance by using the title and abstract information. All selected articles will be evaluated in their full text version. Subsequently, for all publications that are rated relevant, the reason for inclusion or exclusion must be documented individually. As part of this evaluation, the included publications must be briefly summarized with regard to their content and rated in terms of their methodological quality.

Decision regarding the modelling of the cost-benefit ratio

To meet the requirements of the legislation, it is necessary to determine the cost-benefit ratio of the pharmaceutical in relation to comparable therapies. The commissioned experts must examine whether an appropriate model or analysis is already available. Otherwise, a separate model must be developed in accordance with the formulated principles as part of the cost-benefit assessment or existing models must be modified. The various models should be appraised and the selection of a model be based on transparent criteria, conducted by a neutral clearing institution such as DIMDI, RKI or a university institution.

4.3. Internal and external review of the preliminary report

After the conclusion of the evidence assessment and the development of a decision-analytical model (if necessary), the IQWiG will conduct an internal review of the work results up to that point, during which especially compliance with the formal requirements of the reporting plan will be verified. Parallel, the content-related conclusions and the quality of the study assessments are evaluated by external experts who were not chosen by the IQWiG. The anonymised internal and external review procedure is implemented to support the IQWiG project team. Upon conclusion of the final report, the review reports are forwarded to the contracting entity. There are no plans for publication of these reports.

Preliminary report with commenting procedure and oral hearing

The preliminary report must simultaneously be sent to the contracting entity and be published for access over the Internet. As

described above, the parties mentioned in Section 139a para. 5 of the German Social Code V must be provided with an opportunity for written comment within eight weeks after publication.

The submitted comments should refer to the consistency of the criteria previously stipulated in the reporting plan compared to the subsequent implementation in the preliminary report as well as to a summary assessment of the model for evaluation of the cost-benefit ratio. The authors of the comment must disclose any potential conflict of interest to the Institute. The received comments are to be judged by the commissioned experts and commented on individually with regard to their relevance and to the gain of knowledge. The external experts of the preliminary report must also be provided with an opportunity for comment. All comments must be published on the Internet for convenient access.

Within eight weeks after the expiration of the deadline, the representatives who submitted the comments as well as representatives from the contracting entity will be invited to an hearing. The essence of the hearing is the scientific discussion of facts in dispute with the goal of improving the quality and acceptance of the assessment. The hearing will be chaired by a neutral moderator appointed by the contracting entity. A word-for-word transcript must be generated of the hearing, which will be part of the final report accessible over the Internet.

Revision of the preliminary report and publication of the final report

Based on the commented statements and the verbal contributions during the hearing, the preliminary report is revised and the final report is generated. At this time, the parties mentioned in the legislation have a final opportunity for comment (appeal). Following the completion and submission of the final report, the contracting entity has four weeks to verify the results of the cost-benefit assessment and the submitted appeals and to make initial conclusions. After expiration of the four-week embargo, the final report will be published for public access on the Institute's website.

Decision regarding a necessary update

As already governed in Section 35b para. 2 clause 2 and 3 of the German Social Code V, the legislation provides for an institutional update in terms of a regular examination of the assessment results for their validity. In addition, the parties mentioned in Section 139 of the German Social Code V have the right to petition for an update. The Federal Joint Committee must decide on the applications. The decision and its justification must be published for public access on the website of the Federal Joint Committee.

The overall process of the working steps presented in this position paper can be downloaded at the following address:
http://www.vfa.de/Ablauf-KNB

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