Gemeinsamer Bundesausschuss

This English version is a courtesy translation only. Only the German version is legally binding.

Chapter 5: Benefit Assessment of pharmaceuticals according to s. 35a SGB V

Table of contents

Part 1: Scope and definitions

Section 1 Scope

(1) Based on the Regulation for Early Benefit Assessment of New Pharmaceuticals (AM-NutzenV), this chapter governs the procedure for assessing reimbursable pharmaceuticals with new active ingredients according to s. 35a para. 1 and 6 SGB V, in particular the advice, the requirements for the evidence necessary to prove the benefit (dossier), the procedure of the hearings, and the implementation of the benefit assessment in the Pharmaceuticals Directive.

(2) The benefit assessment according to s. 35a para. 1 and 6 SGB V is implemented for reimbursable pharmaceuticals with new active ingredients and new combinations of active ingredients,

1. Which are made available on the market for the first time after 01 January 2011, insofar as this is the first time a pharmaceutical with this active ingredient is made available on the market,
2. Which are made available on the market for the first time after 01 January 2011 and which after 01 January 2011 receive a new therapeutic indication according to s. 2 para. 2,
3. If the Federal Joint Committee orders a new assessment according to s. 16,
4. If the Federal Joint Committee orders a new assessment according to s. 13 on the basis of new scientific findings,
5. Upon request from the pharmaceutical company according to s. 14,
6. For which the Federal Joint Committee has decided on a benefit assessment with a time limit, as soon as the period has expired, and
7. For pharmaceuticals which were made available on the market before 01 January 2011 and which receive a new therapeutic indication after 01 January 2011 according to s. 2 para. 2, insofar as the If the Federal Joint Committee has ordered a benefit assessment for the pharmaceutical according to s. 16.

(3) The provisions of Chapter 4 rules of procedure shall remain unaffected hereby.

Section 2 Pharmaceuticals with new active ingredients

(1) [1]Pharmaceuticals with new active ingredients are pharmaceuticals which contain active ingredients, whose effects are not generally known in medical science upon their first market authorisation. [2]A pharmaceutical with new active ingredients is considered a pharmaceutical with a new active ingredient for as long as there is data exclusivity for the pharmaceutical with the active ingredient that has been authorised for the first time. [3] Fixed combinations of active ingredients are also deemed to be pharmaceuticals as defined in sentence 1, insofar as they contain at least one new active ingredient.

(2) [1]A new therapeutic indication is a therapeutic indication, for which a new authorisation is issued according to s. 29 para. 3 No. 3 German Pharmaceutical Act (AMG), or which is classified as a major variation of Type II according to Annex 2 No. 2 lit. a of the Commission Directive (EU) No 1234/2008 of 24 November 2008 regarding the examination of variations to the terms of market authorisations for human and veterinary pharmaceuticals (OJ L 334 of 12 December 2008, p. 7). [2]A therapeutic indication is new compared to the previously authorised therapeutic indication if, in particular

- The indications refer to a group of patients, which differs from the previously authorised therapeutic indication,
- An indication is added, which is attributed to a different therapeutic area (treatment, diagnosis of prophylaxis), or
- The indication is moved to a different therapeutic area (treatment, diagnosis of prophylaxis).

Section 3 Benefit and additional benefit

(1) The benefit of a pharmaceutical is the patient-relevant therapeutic effect, in particular in respect of the improvement in the state of health, the reduction of the duration of the disease, longer survival, the reduction in side-effects, or an improvement in the quality of life.

(2) The additional benefit of a pharmaceutical is a benefit according to para. 1, which is qualitatively or quantitatively higher than the benefit of the appropriate comparator.

Section 4 Responsibility for conducting the benefit assessment

(1) [1]The Pharmaceuticals Subcommittee is responsible for conducting the assessment procedure. [2]To this end, it establishes working groups that can be tasked, in particular, with carrying out the following tasks:

1. Preparing the advice,
2. Creating a benefit assessment, unless regulated otherwise by s. 17,
3. Appraisal of the statements,
4. Preparing the decision.

(2) [1]A “Summary documentation” is drawn up about the execution of the benefit assessment. [2]The “Summary documentation” includes:

1. Description of the procedure,
2. Underlying benefit assessment and dossier,
3. Statements received from the written and verbal hearings,
4. Appraisal of the arguments submitted,
5. Assessment of the additional benefit the Federal Joint Committee.

(3) [1]The subcommittee advises on the basis of a report from the working group and submits the results of its assessment and a draft resolution to the plenary.

Part 2: Proof of the additional benefit and definition of the comparator

Section 5 Requirements for the proof of the additional benefit by the pharmaceutical company

(1) [1]The additional benefit must be proven by the pharmaceutical company in the dossier according to s. 9. [2]The Federal Joint Committee has no obligation to examine ex officio.

(2) [1]For reimbursable pharmaceuticals with new active ingredients, which are comparable in pharmacological-therapeutic terms with reference price

pharmaceuticals, the additional medical benefit must be proven as a therapeutic improvement corresponding to s. 35 para. 1 b sent. 1 to 5 SGB V. [2]The proof of a therapeutic improvement is provided on the basis of a Summary of Product Charateristics (SPC) and through assessment of clinical studies according to the international standards of evidence-based medicine. [3]Clinical studies are preferred, in particular direct comparison studies with other pharmaceuticals of this reference price group with patient-relevant endpoints, in particular mortality, morbidity, and quality of life have to be taken into account.

(3) [1]For pharmaceuticals with new active ingredients, which do not fulfil the requirements of para. 2, the proof of additional benefit is provided indication-specific compared to the appropriate comparator identified according to s. 6 on the basis of documents about the benefit of the pharmaceutical in the authorised therapeutic indication. [2]The basis here is formed by market authorisation under pharmaceutical law, the officially approved SPC and announcements by authorisation agencies, as well as the appraisal of clinical studies according to the international standards of evidence-based medicine. [3]Insofar as it is impossible or inappropriate to carry out or demand studies at the highest level of evidence, proof from the best available evidence level must be submitted, along with a specific justification from the pharmaceutical company. [4]In addition, the pharmaceutical company must also explain to what extent the best available evidence submitted by the company is appropriate as proof for an additional benefit. [5]However, acknowledgement of the additional benefit based on documents from a lower evidence level requires a justification all the more the further there is a deviation from evidence level I.

(4) [1]The dossier must state the probability with which and the extent to which an additional benefit exists, stating the validity of the evidence; with regard to probability, it must explain the certainty with which a statement concerning the existence of an additional benefit can be made (result certainty). [2]This information about the validity of the results should be made both with regard to the number of patients and with regard to the extent of the additional benefit.

(5) [1]For pharmaceuticals according to para. 3, the additional benefit compared to the appropriate comparator is identified as an improvement in the effect of

patient-relevant endpoints compared to the benefits according to s. 3 para. 1. [2]Preferred proof of the additional benefit are randomised, blinded, and controlled direct comparison studies, whose methods correspond to the international standards of evidence-based medicine and which are carried out on populations or under conditions, which are representative of and relevant for the usual treatment situation, and which have been conducted compared to an appropriate comparator according to s. 6. [3]If there are no direct comparable studies for the new pharmaceutical compared to the appropriate comparator, or if these do not provide information about the additional benefit, available clinical studies, preferably randomised, blind and controlled studies, can be used as the appropriate comparator, which are suitable for an indirect comparison of the pharmaceutical with new active ingredients, and thus as evidence of an additional benefit by indirect comparison. [4]If, at the time of the assessment, there are no valid data about patient-relevant endpoints, the assessment is performed on the basis of the best available evidence taking into account the study quality, with information about the probability of the proof of an additional benefit.

(6) [1]The validity of the evidence must be presented taking into account the quality of the study, the validity of the endpoints applied, the evidence level, and the probability of and the extent to which there is an additional benefit must be assessed; paragraph 4 sent. 1 clause. 2. shall apply correspondingly. [2]The studies submitted are assessed in respect of the quality of their planning, implementation and evaluation, and in respect of their validity regarding the relevance of the additional benefit. [3]The dossier must explain the evidence level at which all submitted documents are provided. The following evidence levels apply:

1. I a Systematic reviews of studies of evidence level I b
2. I b Randomised clinical studies
3. II a Systematic reviews of studies of evidence level II b
4. II b Prospective comparative cohort studies
5. III Retrospective comparative studies
6. IV Case series and other non-comparative studies

7. V Associative observations, pathophysiological considerations, descriptive representations, single case reports, opinions from recognised experts not proven with studies, consensus conferences and reports from expert committees.

(7) [1]For pharmaceuticals according to para. 3, the extent of the additional benefit and the therapeutic importance of the additional benefit compared to the appropriate comparator must be quantified as follows, taking into account the severity of the disease:

1. There is a major additional benefit if a sustained and large improvement in the therapy-relevant benefit as defined in s. 3 para. 1 is achieved, which has not previously been achieved compared to the appropriate comparator, in particular a recovery from the disease, a considerable increase in life, long-term freedom from severe symptoms or extensive avoidance of severe side-effects according to s 4 para. 13 AMG and Chapter 4 s. 23 para. 1 rules of procedure of the Federal Joint Committee.

2. There is a considerable additional benefit if a significant improvement in the therapy-relevant benefit as defined in s. 3 para. 1 is achieved, which has not previously been achieved compared to the appropriate comparator, in particular a lessening of severe symptoms, a moderate extension in life, an easing of the disease, which is noticeable to the patients, a relevant avoidance of severe side-effects or a significant avoidance of other side-effects.

3. There is a minor additional benefit if a moderate and not merely slight improvement in the therapy-relevant benefit as defined in s. 3 para. 1 is achieved, which has not previously been achieved compared to the appropriate comparator, in particular a reduction in non-severe symptoms of the disease or a relevant avoidance of side-effects.

4. There is an additional benefit, which is not quantifiable however, because the scientific base data do not permit this.

5. There is no additional benefit.

6. The benefit of the pharmaceutical being assessed is less than the benefit of the appropriate comparator.

Section 6 Appropriate comparator

(1) Appropriate comparator is the therapy, whose benefit is compared against the benefit of a pharmaceutical with new active ingredients for the benefit assessment according to s. 35a SGB V.

(2) [1]The appropriate comparator typically has to be identified according to benchmarks deriving from the international standards of evidence-based medicine. [2]If there are several alternatives, the more economic therapy is selected, preferably a therapy, for which there is a reference price.

(3) [1]The appropriate comparator must be an appropriate therapy in the therapeutic indication according to the generally accepted state of medical knowledge (s. 12 SGB V), preferably a therapy for which are there endpoint studies and which has been proven in practical use, unless guidelines according to s. 92 para. 1 SGB V or the efficiency principle prevent this. [2]When identifying the appropriate comparator, the following criteria in particular have to be considered:

1. Insofar as a medical therapeutic indication is considered as the comparator, the pharmaceutical must be authorised for the therapeutic indication.

2. Insofar as a non-medicinal treatment is considered as the comparator, this must be deliverable within the framework of the statutory health insurance.

3. Medical therapeutic indications or non-pharmaceutical treatments are preferred as comparator, whose patient-relevant benefit has already been determined by the Federal Joint Committee.

4. The comparator should belong to the appropriate therapy in the therapeutic indication according to the generally accepted state of medical knowledge.

5. If there are several alternatives, the more economic therapy is selected, preferably a therapy, for which there is a reference price.

(4) [1]For pharmaceuticals of an active ingredient class, the same appropriate comparator must be used, taking into account para. 3, in order to guarantee a uniform assessment. [2]The appropriate comparator must also be suitable for assessing pharmaceuticals upon request from the Federal Joint Committee according to s. 35a para. 6 SGB V, which were made available on the market before 01 January 2011.

Section 7 Advice

(1) [1]The Federal Joint Committee shall advise the pharmaceutical company on the basis of a written request based on the submitted documents according to sentence 6, in particular about the tangible content of the documents and studies to be submitted and about the appropriate comparator. [2]Advice about the content of completed procedures and pending legal proceedings is excluded in principle. [3]Data will not be pre-checked with regard to a submission of a dossier in the future. [4]The form according to Annex I (Application form) must be used for the request. [5]In the Application form (Annex I), the questions to be discussed in the advice meeting must be sent in German. [6]The pharmaceutical company shall send the Federal Joint Committee the documents and information important for the creation of a dossier concerning the benefit assessment, which it holds at this time, in German or English. [7]The advice meetings shall be held within eight weeks of submission of the documents. [8]If the pharmaceutical company does not send the documents and information required for the advice meeting, the Federal Joint Committee can refuse an advice meeting. [9]The advice meeting shall be held at the offices of the Federal Joint Committee, unless it decides otherwise. [10]The advice meeting can take place before the start of the Phase III market authorisation studies with the participation of the Federal Institute for Pharmaceutical and Medical Devices or the Paul-Ehrlich-Institut.

(2) [1]The information provided within the framework of the advice meeting must be treated as confidential. [2]The pharmaceutical company shall receive minutes of the advice meeting. [3]The Federal Joint Committee can conclude agreements with the pharmaceutical company regarding the subjects discussed in the advice meeting. The information provided by the Federal Joint Committee

within the framework of the advice meeting about the subjects according to para. 1 sent. 1 is not binding.

(3) [1]For benefit assessments according to s. 16, an advice meeting must be offered before the Federal Joint Committee requests that the pharmaceutical company submit a dossier. [2]The advice meeting shall be conducted in German.

(4) [1]Fees shall be charged for the advice meeting. [2]Further details about the amount of the fees are contained in the Fees Regulations.

Part 3: Assessment procedure

Section 8 Start of the assessment procedure

The assessment procedure by the Federal Joint Committee starts at the following times:

1. For pharmaceuticals with new active ingredients, which are made available on the market for the first time after 01 January 2011, the first time they are made available on the market. The applicable time for the first time it is made available on the market is the inclusion of the pharmaceutical in the Large German Specialities-Tariff (known as the "Lauer-Taxe").
2. For pharmaceuticals receiving a new therapeutic indication according to s. 2 para. 2, if a benefit assessment has been carried out for the pharmaceutical according to this procedure, within 4 weeks after authorisation for the new therapeutic indication or after notification of the pharmaceutical company of approval for a change in Type II according to Annex 2 No. 2 lit. a of Directive (EU) 1234/2008.
3. For pharmaceuticals made available on the market before 01 January 2011, within three months after request of the dossier by the Federal Joint Committee.
4. For pharmaceuticals, for which a benefit assessment has already been decided and for which the pharmaceutical company has applied for a new benefit assessment no earlier than one year after the decision, within three months of the request by the Federal Joint Committee.

5. For pharmaceuticals, for which there is a limited decision regarding the benefit assessment, on the day the period expires.

6. For pharmaceuticals according to sections 12-15, within three months of the request from the Federal Joint Committee for a dossier to be submitted.

Section 9 Requirements for the dossier

(1) [1]The dossier serves the assessment of the benefit of the pharmaceutical. [2]The dossier must be submitted in German, unless regulated otherwise according to the requirements for the dossier. [3]In the dossier, the pharmaceutical company must prove the additional benefit of the pharmaceutical compared to the appropriate comparator according to the requirements of s. 5 and the requirements in para. 2. [4]To this end, it must contain the following information:

1. Authorised therapeutic indication,
2. Medical benefit,
3. Medical additional benefit in relation to the appropriate comparator,
4. Number of patients and patient groups, for whom there is a therapeutically important additional benefit,
5. Costs of the therapy for the statutory health insurance fund,
6. Requirement for a quality-assured therapeutic indication.

(2) [1]The dossier template in Annex II must be used for the composition of the dossier. [2]The data according to paragraphs 1, 4 to 8 must be prepared and submitted corresponding to the requirements defined in modules 1 to 5. [3]Modules 1 to 4 contain the foundations, on which the assessment is based, and are published on the website of the Federal Joint Committee. [4]Documents containing operating and business secrets must be marked as such in module 5 by the pharmaceutical company.

(3) [1]Even if the pharmaceutical company refers to s. 10 and objects to publication of documents in module 5, it must guarantee, however, that all information about the study methods and results are provided in full for publication in the dossier in module 1 to 4 according to the provisions of paragraph 2 sentence 2. [2]If the dossier does not correspond to these requirements, the proof of the additional benefit cannot be considered to have been provided.

(4) [1]For the pharmaceutical to be assessed, the pharmaceutical company shall submit the market authorisation studies in the dossier, including the study reports and the assessment report from the authorisation agency, as well as all studies which have been transferred to the authorisation agency. [2]In addition, all results, study reports and study protocols of studies are sent with the pharmaceutical, for which the company was the sponsor, along with all available information about current and cancelled studies with the pharmaceutical, for which the company is the sponsor or otherwise financially participated, and corresponding information about studies by third parties, insofar as this is available.

(5) The dossier should also contain the market authorisation number, the date of authorisation, the market authorisation holder, the central pharma number, the allocation to the anatomical-therapeutic-chemical (ATC) classification and the name of the pharmaceutical.

(6) [1]For the appropriate comparator, the pharmaceutical company sends all available results of clinical studies in the dossier, including study protocols, which are suitable for reaching conclusions about the additional benefit of the pharmaceutical being assessed. [2]If there are no clinical studies for a direct comparison with the pharmaceutical being assessed, or if these do not provide sufficient information about the additional benefit, indirect comparisons can be made in the dossier.

(7) [1]The pharmaceutical company has to send the costs for the statutory health insurance, according to the pharmacy retail price and the actual costs incurred by the health insurance funds. [2]The costs are stated both for the pharmaceutical to be assessed and for the appropriate comparator. [3]The direct costs of the statutory health insurance over a specific period apply here. [4]If, when using the pharmaceutical corresponding to the SPC or package leaflet, there are regular differences when using medical treatment or when prescribing other services between the pharmaceutical to be assessed and the appropriate comparator, the associated costs differences for determining the costs actually incurred by the health insurance funds must be taken into account.

(8) In module 1, the dossier contains a summary of the main information, which is the basis of an agreement according to s. 130b SGB V.

Section 10 Publication

(1) [1]The dossier shall be published simultaneously with the benefit assessment according to s. 18 para. 4 on the website of the Federal Joint Committee, unless this is prevented as a result of operating and business secrets, protection of intellectual property or protection of personal details. [2]The publication shall contain the foundations, on which the assessment is based.

(2) [1]The pharmaceutical company shall mark operating and business secrets in the dossier; s. 9 para. 2 and 3 shall remain unaffected. [2]This marking may not prevent publication of the results of the studies.

(3) The Federal Joint Committee can settle the details by agreement with the relevant associations of the pharmaceutical industry and with pharmaceutical companies.

Section 11 Submission of the dossier

(1) [1]The dossier must be sent by the deadline stated in s. 8 at the latest. [2]The Federal Joint Committee only has to consider documents submitted on time. [3]Documents from authorisation agencies, which the pharmaceutical company has not received in time for a timely submission, must be taken into account, insofar as this does not delay the benefit assessment.

(2) [1]The pharmaceutical company can also send the dossier to the Federal Joint Committee before the times stated in s. 8. [2]If the pharmaceutical company submits the dossier to the Federal Joint Committee three weeks before the respective deadline, the office of the Federal Joint Committee shall conduct a formal advance check that the dossier is complete. [3]If the dossier is incomplete, the office of the Federal Joint Committee shall typically inform the pharmaceutical company within two weeks, stating which additional information is required. [4]This shall not affect the check of the content of the dossier.

(3) [1]The Federal Joint Committee shall request that the respective pharmaceutical company submits the dossier on time and complete. [2]The Federal Joint Committee can also request that the pharmaceutical company submits a complete dossier on time after an advice meeting according to s. 7.

Section 12 Requirements for the dossier for orphan pharmaceuticals

For orphan pharmaceuticals authorised according to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan pharmaceutical products (orphan pharmaceuticals), the provisions of this Article apply with the following conditions:

1. The medical additional benefit according to s. 35a para. 1 sent. 3 No. 2 and 3 SGB V is considered to be proven as a result of the market authorisation; evidence according to s. 5 para. 1 to 6 does not have to be provided. Section 5 para. 7 remains unaffected hereby; the extent of the additional benefit must be proven for the number of patients and patient groups, for whom there is a therapeutically important additional benefit.
2. If the sales of the orphan pharmaceutical with the statutory health insurance at pharmacy retail prices, including VAT, in the last twelve calendar months exceed the amount of Euro 50 million, the pharmaceutical company must send evidence according to s. 5 para. 1 to 6 within three months of request from the Federal Joint Committee and this must prove the additional benefit compared to the appropriate comparator. Sales are calculated on the basis of the information according to s. 84 para. 5 sent. 4 SGB V.

Section 13 Request by the Federal Joint Committee for a dossier because of new scientific findings

(1) [1]Upon request from its members or from the organisations and institutions named in s. 139b para. 1 sent. 2 SGB V, the Federal Joint Committee can demand a new benefit assessment of a pharmaceutical assessed according to the provisions of this Article because of new scientific findings, no earlier than

one year after requiring a benefit assessment according to s. 20. [2]This shall also apply if the pharmaceutical's therapeutic indication has been restricted by the responsible authorisation agencies. Section 16 para. 2 shall apply accordingly.

(2) The pharmaceutical company will be informed about the reasons for the benefit assessment upon service of the decision.

Section 14 Requirement to submit a dossier as a result of a request from the pharmaceutical company for a new benefit assessment because of new scientific findings

(1) [1]One year after publication of the decision according to s. 20 at the earliest, the pharmaceutical company can apply to the Federal Joint Committee for a new benefit assessment if it demonstrates the requirement because of new scientific findings.

(2) [1]The Federal Joint Committee shall decide on the request within three months. [2]If the Federal Joint Committee finds the request to be justified, it shall demand that the pharmaceutical company sends the evidence necessary for the benefit assessment according to the provisions of this Article. [3]The dossier must be submitted to the Federal Joint Committee by the pharmaceutical company within three months after the decision has been served.

Section 15 Exemption from benefit assessment according to s. 35a para. 1a SGB V

(1) [1]No later than three months before the deadline according to s. 8, the pharmaceutical company can apply to the Federal Joint Committee for exemption from the obligation to submit evidence according to s. 4 to exempt the pharmaceutical from the benefit assessment according to the provisions of this Article (in particular s. 11 and 13), if it is expected that the statutory health insurance funds will only incur insignificant costs for the pharmaceutical. [2]The evaluation of insignificance shall be made on the basis of costs expected to be incurred by the health insurance funds as defined in s. 9 para. 8 and on the

expected sales of the pharmaceutical with the statutory health insurance. As long as the expected costs do not exceed Euro 1,000,000 within twelve calendar months, they are deemed to be insignificant.

(2) The pharmaceutical company has to demonstrate the reasons for the exemption according to para. 1. It shall provide the Federal Joint Committee with sufficient information for an evaluation of the insignificance.

(3) The Federal Joint Committee shall decide on the application within eight weeks.

(4) If the sales of the pharmaceutical to the statutory health insurance at pharmacy retail prices, including VAT, exceed the amount of Euro 1,000,000 within twelve calendar months, the pharmaceutical company must send evidence according to s. 5 para. 1 to 6 within 3 months of request from the Federal Joint Committee and this must prove the additional benefit compared to the appropriate comparator. Sales are calculated on the basis of the information according to s. 84 para. 5 sent. 4 SGB V.

Section 16 Requirement for a dossier for pharmaceuticals in the existing market according to s. 1 para. 2 No. 3

(1) [1]Upon request from its members or from the organisations and institutions named in s. 139b para. 1 sent. 2 SGB V, the Federal Joint Committee can demand a new benefit assessment according to the provisions of this Article for authorised and marketed pharmaceuticals. [2]Pharmaceuticals are preferably assessed, which are important for care or which compete with pharmaceuticals, for which a decision according to s. 20 has been made.

(2) The pharmaceutical company must submit the dossier to the Federal Joint Committee within three months after the decision has been served.

Section 17 Decision to conduct a benefit assessment

(1) [1]The Federal Joint Committee checks whether the pharmaceutical company has fulfilled obligations regarding the timely submission of a complete dossier according to the law. [2]If the pharmaceutical company has not submitted the

dossier by the deadlines stated in s. 8 at the latest, or not in full, despite reminder, the Federal Joint Committee shall find that the pharmaceutical's additional benefit has not been proven; the assessment of the benefit of the pharmaceutical shall not be affected by this. [3]This shall apply accordingly if the dossier is incomplete at the deadlines stated in s. 8 despite notification according to s. 11 para. 2 sent. 3.

(2) The Federal Joint Committee shall decide whether to execute the benefit assessment itself or through the IQWiG of third parties.

(3) Insofar as assessment of the benefit of the pharmaceutical shall be carried out on the basis of an assessment by the IQWiG or by third parties, the assignment must be combined with the measure that

1. The benefit assessment is to be conducted on the basis of the principles outlined in this rules of procedure, and
2. The completed benefit assessment must be sent to the Federal Joint Committee two working days before expiration of the period according to s. 18 para. 4 for publication.

Section 18 Benefit assessment

(1) [1]During the benefit assessment, a check is performed as to whether an additional benefit is proven compared to the appropriate comparator, which additional benefit is proven for which patient groups and to what extent, how the existing evidence is to be assessed and with what probability the proof is provided. [2]The benefit assessment is conducted on the basis of the dossier.

(2) [1]The benefit assessment checks the validity and completeness of the information in the dossier. [2]Here the documents are evaluated in respect of their planning, implementation and assessment quality regarding their validity for probability and extent of the additional benefit in respect of the information about the therapy costs. [3]The benefit assessment also includes a summary of the main information as an assessment of the information in the dossier according to s. 9 para. 1. [4]The benchmark for the assessment is

the generally accepted state of medical knowledge. [5]The foundations are the international standards of evidence-based medicine and health economics.

(3) [1]For the first assessment according to s. 35a SGB V at the time of introduction to the market, the market authorisation studies are generally applied as the basis for the assessment of pharmaceutical with new active ingredients. [2]If the market authorisation studies are not sufficient, the Federal Joint Committee can demand additional evidence.

(4) [1]If valid data about patient-relevant endpoints are not yet available at the time of the assessment, the assessment is performed on the basis of the best available evidence, taking into account the quality of the studies and stating the probability of proof of an additional benefit. [2]If valid data about patient-relevant endpoints are required for the proof of an additional benefit, the Federal Joint Committee can set a deadline in its decision according to s. 20, by when these data should be provided.

(5) [1]The benefit assessment is completed and published on the Internet within three months of the deadlines according to s. 8.

Section 19 Statutory hearing procedure

(1) [1]With the publication of the benefit assessment on the website of the Federal Joint Committee, the experts of medical and pharmaceutical science and practice, and the umbrella organisations of the pharmaceutical companies formed to safeguard economic interests, the relevant pharmaceutical company, the professional representatives of the pharmacists and the relevant umbrella organisations of doctors' associations for special therapies at the federal level are given the opportunity to respond in writing to the benefit assessment of the pharmaceutical, using the templates in Annex III. [2]The hearing period is three weeks.

(2) [1]Following the written hearing procedure and before a decision is made regarding the benefit assessment according to s. 92 para. 1 sent. 2 No. 6 SGB V, the Federal Joint Committee gives the authorised persons according to para. 1 the opportunity to respond to the benefit assessment verbally as

well. [2]Insofar they have submitted a written response according to para. 1, the experts and a maximum of up to two representatives of each of the organisations and relevant companies authorised to respond according to paragraph 1 can participate in the verbal hearing. [3]The verbal hearing does not replace the response submitted according to paragraph 1. [4]In particular, it serves to

1. comment on aspects regarding the benefit assessment, in particular new scientific findings which have been concluded after submission of the dossier, and

2. respond to the possibilities of a decision regarding the benefit assessment according to s. 92 para. 1 sent. 2 No. 6 SGB V in accordance with the principles specified in this procedure.

(3) [1]The written and verbal responses submitted according to paragraph 1 and 2 are included in the decision regarding the benefit assessment according to S. 92 para. 1 sent. 2 No. 6 SGB V. [2]Article 1 s. 10 para. 4 rules of procedure shall apply to the assessment of the responses.

Part 4: Decision and implementation of the benefit assessment in the Pharmaceutical Directive

Section 20 Decision regarding the benefit assessment

(1) [1]The Federal Joint Committee shall decide on the benefit assessment within three months of its publication. [2]The decision is published on the Internet. [3]It is part of the Pharmaceutical Directive according to s 92 para. 1 sent. 2 No. 6 SGB V and is published in the Federal Gazette. [4]Section 94 para. 1 SGB V does not apply.

(2) The decision is the basis for negotiations for all pharmaceuticals with the active ingredient according to s. 130b SGB V regarding the reimbursement and for determining the requirements of appropriateness, quality and cost-effectiveness of the prescription and for acknowledgement as a medical practice feature or for the allocation of pharmaceuticals without additional benefits to a reference price group according to s. 35 SGB V.

(3) With the decision according to s. 35a para. 3 SGB V, the Federal Joint Committee defines specifications in the Pharmaceuticals Directive on the basis on the benefit assessment regarding the economic prescription process for the pharmaceutical, in particular

1. Regarding the additional benefit of the pharmaceutical compared to the appropriate comparator,
2. Regarding the number of patients or the definition of the patient groups to be considered for the treatment,
3. Regarding the requirements for a quality-assured therapeutic indication, and
4. Regarding the therapy costs, also compared to the appropriate comparator.

Section 21 Pharmaceutical without additional benefit

If the benefit assessment shows that a therapy-relevant additional benefit according to the generally accepted state of medical knowledge is not proven for the pharmaceutical with the new active ingredient, a check is conducted according to the provisions of Nos. 1 and 2 as to whether the pharmaceutical can be allocated to a reference price group according to s. 35 para. 1 SGB V:

1. Pharmaceuticals with a new active ingredient, which according to s. 35 para. 1 sent. 2 No. 2 SGB V are pharmacologically-therapeutically comparable to pharmaceuticals, for which there is a reference price group, are allocated by the decision to the reference price group.
2. If allocation of the pharmaceutical with a new active ingredient to an existing reference price group according to s. 35 para. 1 sent. 2 No. 3 SGB V is possible, the Federal Joint Committee specifies this in the decision according to s. 35a para. 3 SGB V.
3. In all other cases, the Federal Joint Committee checks whether it is possible to form a reference price group according to s. 35 para. 1 sent. 2 No. 2 or No. 3 SGB V and Chapter 4, Sections 20 et.seq. rules of procedure.

Section 22 Pharmaceutical with additional benefit

If the benefit assessment shows that an additional benefit is proven according to the generally accepted state of medical knowledge for the pharmaceutical, the Federal Joint Committee specifies this in a decision according to s. 35a para. 3 SGB V in the Pharmaceutical Directive with information about the extent of the additional benefit.