Gemeinsamer Bundesausschuss

Justification

to the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Dalbavancin (new therapeutic indication: acute bacterial skin and skin structure infections (ABSSSI), from birth to < 3 months)

of 20 November 2025

Contents

1. Legal basis

According to Section 35a paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assess the benefit of all reimbursable medicinal products with new active ingredients.

Pursuant to Section 35a, paragraph 1c, sentence 1 SGB V, the Federal Joint Committee shall exempt the pharmaceutical company from the obligation to submit the evidence pursuant to Section 35a, paragraph 1, sentence 3, numbers 2 and 3 SGB V (medical benefit and additional medical benefit in relation to the appropriate comparator therapy) upon request, if it is an antibiotic that is effective against infections caused by multidrug-resistant bacterial pathogens with limited treatment options and the use of this antibiotic is subject to a strict medical assessment of the therapeutic indication (reserve antibiotic).

The additional benefit is deemed to be proven if the Federal Joint Committee have decided on an exemption for a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V; the extent of the additional benefit and its therapeutic significance are not to be assessed by the Federal Joint Committee.

In the resolution according to Section 35a, paragraph 3, sentence 1 SGB V, the Federal Joint Committee shall specify the requirements for a quality-assured application of the reserve antibiotic pursuant to Section 35a, paragraph 1c, sentence 8 SGB V, taking into account the effects on the resistance situation. Pursuant to Chapter 5 Section 20, paragraph 6, sentence 3 of the Rules of Procedure (VerfO) of the G-BA, the Federal Joint Committee may lay down restrictive requirements for the use of the antibiotic in order to ensure a strict medical assessment of the therapeutic indication, if this is necessary to maintain the reserve status of the medicinal product. With regard to these requirements for a quality-assured application of the reserve antibiotic, the Federal Joint Committee shall obtain a statement from the Robert Koch Institute (RKI), which shall be prepared in agreement with the Federal Institute for Drugs and Medical Devices (BfArM).

Pursuant to Section 35a, paragraph 3 SGB V, the G-BA pass a resolution on the benefit assessment, taking into account the requirements for a quality-assured application according to Section 35a, paragraph 1c, sentence 8 SGB V, within three months of publication of the resolution. The resolution is to be published on the internet and is part of the Pharmaceuticals Directive.

2. Key points of the resolution

By resolution of 20 April 2023, the Federal Joint Committee decided that the pharmaceutical company is exempted from the obligation to submit evidence in the benefit assessment procedure for the medicinal product Xydalba with the active ingredient dalbavancin according to Section 35a, paragraph 1, sentence 3, numbers 2 and 3 SGB V, since the medicinal product Xydalba with the active ingredient dalbavancin for the treatment of bacterial infections is a reserve antibiotic within the meaning of Section 35a, paragraph 1c, sentence 1 SGB V.

On 2 May 2025, dalbavancin received marketing authorisation for a new therapeutic indication to be classified as a major type 2 variation as defined according to Annex 2, number 2, letter a to Regulation (EC) No. 1234/2008 of the Commission of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, sentence 7).

On 27 May 2025, i.e. at the latest within four weeks after informing the pharmaceutical company about the approval for a new therapeutic indication, the pharmaceutical company have submitted a dossier in due time in accordance with Section 4, paragraph 3, number 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5 Section 8, paragraph 1, number 2 of the Rules of Procedure (VerfO) of the G-BA on the active ingredient dalbavancin with the new therapeutic indication.

In this, the pharmaceutical company submitted evidence pursuant to Section 35a, paragraph 1, sentence 3, numbers 1, 4 and 5 SGB V and evidence on the requirements for a quality-assured application of the reserve antibiotic, taking into account the effects on the resistance situation (Chapter 5 VerfO Annex II. 1 Section 1.4). The assessment procedure started on 1 June 2025.

The additional benefit is deemed to be proven if the Federal Joint Committee have decided on an exemption for a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V; the extent of the additional benefit and its therapeutic significance are not to be assessed by the Federal Joint Committee. In the resolution according to Section 35a, paragraph 3, sentence 1 SGB V, the Federal Joint Committee shall specify requirements for a quality-assured application of the reserve antibiotic, taking into account the effects on the resistance situation.

A draft of the requirements for a quality-assured application of the reserve antibiotic was made available to the RKI for drafting a statement in agreement with the BfArM in accordance with Section 35a, paragraph 1c SGB V.

The G-BA commissioned the IQWiG to assess the information provided by the pharmaceutical company in Module 3 of the dossier on treatment costs and patient numbers.

The draft of the requirements for a quality-assured application as well as the RKI statement drafted in agreement with the BfArM were published on the G-BA's website (www.g-ba.de) together with IQWiG's assessment of treatment costs and patient numbers, thus initiating the written statement procedure. The oral hearing has been dispensed with since all assessment experts who submitted written statements waived their right to make an oral statement.

The G-BA have adopted their resolution on the basis of the dossier of the pharmaceutical company, the draft of the requirements for a quality-assured application prepared by the G-BA taking into account the joint statement of RKI/BfArM, the IQWiG's assessment of treatment costs and patient numbers (IQWiG 25- 19) and the statements submitted in the written statement procedure.

2.1 Additional benefit of the medicinal product

2.1.1 Approved therapeutic indication of Dalbavancin (Xydalba) in accordance with the product information

Xydalba is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults and paediatric patients from birth.

Therapeutic indication of the resolution (resolution of 20 November 2025):

Xydalba is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in paediatric patients from birth up to the age of 3 months.

2.1.2 Extent of the additional benefit and significance of the evidence

In summary, the additional benefit of dalbavancin is assessed as follows:

Children from birth to < 3 months with acute bacterial skin and skin structure infections (ABSSSI)

The additional benefit is considered proven.

Justification:

For the medicinal product Xydalba with the active ingredient dalbavancin, an exemption from the obligation to submit the evidence according to Section 35a, paragraph 1, sentence 3, number 2 and 3 SGB V was granted by resolution of 20 April 2023, as it is a reserve antibiotic within the meaning of Section 35a, paragraph 1c, sentence 1 SGB V. The additional benefit is deemed to be proven if the Federal Joint Committee have decided on an exemption for a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V; the extent of the additional benefit and its therapeutic significance are not to be assessed by the Federal Joint Committee.

2.1.3 Summary of the assessment

The present assessment concerns the new medicinal product Xydalba with the active ingredient dalbavancin. The new therapeutic indication is:

"Xydalba is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in paediatric patients from birth up to the age of 3 months."

For the medicinal product Xydalba with the active ingredient dalbavancin, an exemption from the obligation to submit the evidence according to Section 35a, paragraph 1, sentence 3, numbers 2 and 3 SGB V was granted by resolution of 20 April 2023, as it is a reserve antibiotic within the meaning of Section 35a, paragraph 1c, sentence 1 SGB V.

The additional benefit is deemed to be proven if the Federal Joint Committee have decided on an exemption for a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V; the extent of the additional benefit and its therapeutic significance are not to be assessed by the Federal Joint Committee.

In the resolution according to Section 35a, paragraph 3, sentence 1 SGB V, the Federal Joint Committee specified the requirements for a quality-assured application of the reserve antibiotic pursuant to Section 35a, paragraph 1c, sentence 8 SGB V, taking into account the effects on the resistance situation.

2.2 Number of patients or demarcation of patient groups eligible for treatment

The information on the number of patients is based on the target population in statutory health insurance (SHI).

The G-BA base their resolution on the patient numbers stated by the pharmaceutical company in the dossier. The calculation of patient numbers was based on the assumption that the target population mainly comprises pathogens with limited treatment options - operationalised via the presence of methicillin-resistant Staphylococcus aureus (MRSA). The calculation of the target population is also based on the assumption that no paediatric patients from birth up to the age of 3 months with ABSSSI and MRSA receive outpatient treatment if intravenous therapy is required.

The patient numbers given are subject to uncertainty. With regard to the ICD-10 codes used, there is uncertainty regarding the extent to which non-ABSSSI cases were collected and ABSSSI cases were not collected. Cases in which there was only colonisation with MRSA may also have been collected. The lower limit does not include cases with a secondary diagnosis of ABSSSI. A lower number of patients in the SHI target population may also result against the background of the restrictive use of dalbavancin within the framework of a quality-assured application as a reserve antibiotic.

2.3 Requirements for a quality-assured application

In the resolution according to Section 35a, paragraph 3, sentence 1 SGB V, the Federal Joint Committee shall specify requirements for a quality-assured application of the reserve antibiotic, taking into account the effects on the resistance situation. The requirements for a quality-assured application are based on the draft prepared by the Federal Joint Committee and the statement of the RKI, which was prepared in agreement with the BfArM. The statements made in the written statement procedure were taken into account.

<u>About the notes on application:</u>

Reference is made to the specifications of the marketing authorisation.

The requirement that dalbavancin may only be used if only limited treatment options are available is determined in the present resolution within the framework of the requirements for a quality-assured application in order to ensure the strict medical assessment of all therapeutic indications pursuant to Section 35a, paragraph 1c SGB V.

Dalbavancin is approved for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults and paediatric patients from birth. The present resolution relates to the patient population of paediatric patients from birth up to the age of 3 months.

Dalbavancin may only be used if there is evidence or, in exceptional cases, strong suspicion that the infection is caused by methicillin-resistant Staphylococcus aureus (MRSA) and only limited treatment options are available.

The qualified consultation occurs according to the subject expertise with a specialist with an additional qualification in infectiology, a specialist in internal medicine and infectiology, or a specialist in microbiology, virology and epidemiology of infectious diseases. In case of unavailability of the above-mentioned groups of specialists at the time of use, a specialist with appropriate experience in the treatment of infectious diseases with multidrug-resistant pathogens must be consulted.

About the notes on pathogen detection:

In principle, dalbavancin should not be used as part of a calculated (empirical) therapy. The strict medical assessment of the therapeutic indication as a reserve antibiotic requires knowledge of the pathogen. Even in the exceptional cases mentioned, infection with a multidrug-resistant pathogen from the pathogen list of the RKI is at least probable. If the pathogen detection reveals that the pathogen is sensitive to other antibiotics (without reserve status), the therapy must be de-escalated accordingly to avoid unnecessary use of the reserve antibiotic. Empirical therapy with dalbavancin should be as short as possible.

About the instructions for implementation:

Outpatient implementation:

For the appropriate handling of MRSA infections and the corresponding requirements in the practice, please refer to the current recommendations of the RKI.

The use of a uniform system is necessary for the future assessment of the resistance situation. The RKI's ARS system aggregates data on antibiotic resistance throughout Germany and also forms the basis for Germany's participation in international surveillance systems.[1] For this reason, the laboratory supporting the medical practice should endeavour to participate in this system.

Inpatient implementation:

In order to implement the requirements for a quality-assured application, it is necessary that they are taken into account in the hospital's internal regulations/ processes.

The respective Drug Commission is responsible for integration into the processes. Evidence-based antibiotic stewardship teams (see S3 guideline: strategies to ensure rational antibiotic use in hospitals, update 2018) are particularly suitable for implementation.

Pursuant to Section 23 paragraph 4 Infection Protection Act, the treatment facility is obliged to carry out consumption and resistance surveillance, whereby there is no specification of the systems to be used. The use of a uniform system is necessary for the future assessment of the resistance and consumption situation. The RKI's ARS, AVS and ARVIA systems aggregate Germany-wide data on antibiotic resistance and consumption. ARS also forms the basis for Germany's participation in international surveillance systems.[1] For this reason, the hospitals in which dalbavancin is used should endeavour to participate in these systems.

[1] For further information, please visit https://ars.rki.de/.

The reporting of consumption and resistance data on dalbavancin to the above-mentioned systems should be ensured within six months of the entry into force of this resolution. Until participation in the mentioned systems, consumption and resistance situation must be ensured via the existing systems.

2.4 Treatment costs

The treatment costs are based on the contents of the product information and the information listed in the LAUER-TAXE® (last revised: 15 September 2025). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

The single doses recommended in the product information were used as the calculation basis. The use of dalbavancin is limited to one application.

For the cost representation, only the dosages of the general case are considered.
For dosages depending on body weight, the reference percentiles of the Robert Koch Institute from the "German Health Interview and Examination Survey for Children and Adolescents (KiGGS)"[2] were used for the age group under consideration. The average body weights of boys and girls result in an average body weight of 3.46 kg for neonates and 5.22 kg for infants aged two months (as an approximation to < 3 months).

[2] Contributions to Federal Health Reporting. Reference percentiles for anthropometric measures and blood pressure from the German Health Interview and Examination Survey for Children and Adolescents (KiGGS) (2013, both sexes, from birth), https://edoc.rki.de/handle/176904/3254

Children from birth to < 3 months with acute bacterial skin and skin structure infections (ABSSSI)

Treatment period:

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Dalbavancin	Single dose	1	1	1

Consumption:

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed					
Dalbavancin	From birth to < 3 months: 22.5 mg/kg = 77.9 mg – 117.5 mg	77.9 mg – 117.5 mg	1 x 500 mg	1.0	1 x 500 mg

Costs:

In order to improve comparability, the costs of the medicinal products were approximated both on the basis of the pharmacy sales price level and also deducting the statutory rebates in accordance with Section 130 and Section 130a SGB V. To calculate the annual treatment costs, the required number of packs of a particular potency was first determined on the basis of consumption. Having determined the number of packs of a particular potency, the costs of the medicinal products were then calculated on the basis of the costs per pack after deduction of the statutory rebates. Any reference prices shown in the cost representation may not represent the cheapest available alternative.

Costs of the medicinal products:

Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates
Medicinal product to be assessed					
Dalbavancin 500 mg	1 PIC	€ 972.19	€ 1.77	€ 53.20	€ 917.22
Abbreviation: PIC = powder for the preparation of an infusion solution concentrate					

LAUER-TAXE® last revised: 15 September 2025

Costs for additionally required SHI services:

Only costs directly related to the use of the medicinal product are taken into account. If there are regular differences in the necessary use of medical treatment or in the prescription of other services in the use of the medicinal product to be evaluated and the appropriate comparator therapy in accordance with the product information, the costs incurred for this must be taken into account as costs for additionally required SHI services.

Medical treatment costs, medical fee services, and costs incurred for routine examinations (e.g. regular laboratory services such as blood count tests) that do not exceed the standard expenditure in the course of the treatment are not shown.

No additionally required SHI services are taken into account for the cost representation.

Other SHI services:

The special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe) (Sections 4 and 5 of the Pharmaceutical Price Ordinance) from 1 October 2009 is not fully used to calculate costs. Alternatively, the pharmacy sales price publicly accessible in the directory services according to Section 131 paragraph 4 SGB V is a suitable basis for a standardised calculation. According to the currently valid version of the special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe), surcharges of a maximum of € 39 per ready-to-use unit are incurred for the preparation of
infusion solutions containing antibiotics and virustatics. These additional other costs are not added to the pharmacy sales price but rather follow the rules for calculating in the Hilfstaxe. The cost representation is based on the pharmacy retail price and the maximum surcharge for the preparation and is only an approximation of the treatment costs. This presentation does not take into account, for example, the rebates on the pharmacy purchase price of the active ingredient, the invoicing of discards, the calculation of application containers, and carrier solutions in accordance with the regulations in Annex 3 of the Hilfstaxe.

2.5 Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

According to Section 35a, paragraph 3, sentence 4, the G-BA designate all medicinal products with new active ingredients that can be used in a combination therapy with the assessed medicinal product for the therapeutic indication to be assessed on the basis of the marketing authorisation under Medicinal Products Act.

Basic principles of the assessed medicinal product

A designation in accordance with Section 35a, paragraph 3, sentence 4 SGB V requires that it is examined based on the product information for the assessed medicinal product whether it can be used in a combination therapy with other medicinal products in the assessed therapeutic indication. In the first step, the examination is carried out on the basis of all sections of the currently valid product information for the assessed medicinal product.

If the assessed medicinal product contains an active ingredient or a fixed combination of active ingredients in the therapeutic indication of the resolution (assessed therapeutic indication) and is approved exclusively for use in monotherapy, a combination therapy is not considered due to the marketing authorisation under Medicinal Products Act, which is why no designation is made.

A designation is also not considered if the G-BA have decided on an exemption as a reserve antibiotic for the assessed medicinal product in accordance with Section 35a, paragraph 1c, sentence 1 SGB V. The additional benefit is deemed to be proven if the G-BA have decided on an exemption for a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V; the extent of the additional benefit and its therapeutic significance are not to be assessed by the G-BA. Due to the lack of an assessment mandate by the G-BA following the resolution on an exemption according to Section 35a, paragraph 1c, sentence 1 SGB V with regard to the extent of the additional benefit and the therapeutic significance of the reserve antibiotic to be assessed, there is a limitation due to the procedural privileging of the pharmaceutical companies to the effect that neither the proof of an existing nor an expected at least considerable additional benefit is possible for exempted reserve antibiotics in the procedures according to Section 35a paragraph 1 or 6 SGB V and Section 35a paragraph 1d SGB V. The procedural privileging of the reserve antibiotics exempted according to Section 35a, paragraph 1c, sentence 1 SGB V must therefore also be taken into account at the level of designation according to Section 35a, paragraph 3, sentence 4 SGB V in order to avoid valuation contradictions.

With regard to the further examination steps, a differentiation is made between a "determined" or "undetermined" combination, which may also be the basis for a designation.

A "determined combination" exists if one or more individual active ingredients which can be used in combination with the assessed medicinal product in the assessed therapeutic indication are specifically named.

An "undetermined combination" exists if there is information on a combination therapy, but no specific active ingredients are named. An undetermined combination may be present if the information on a combination therapy:

- names a product class or group from which some active ingredients not specified in detail can be used in combination therapy with the assessed medicinal product, or
- does not name any active ingredients, product classes or groups, but the assessed medicinal product is used in addition to a therapeutic indication described in more detail in the relevant product information, which, however, does not include information on active ingredients within the scope of this therapeutic indication.

Concomitant active ingredient

The concomitant active ingredient is a medicinal product with new active ingredients that can be used in combination therapy with the assessed medicinal product for the therapeutic indication to be assessed.

For a medicinal product to be considered as a concomitant active ingredient, it must be classified as a medicinal product with new active ingredients according to Section 2 paragraph 1 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with the corresponding regulations in Chapter 5 of the Rules of Procedure of the G-BA as of the date of the present resolution. In addition, the medicinal product must be approved in the assessed therapeutic indication, whereby a marketing authorisation is sufficient only for a sub-area of the assessed therapeutic indication.

Based on an "undetermined combination", the concomitant active ingredient must be attributable to the information on the product class or group or the therapeutic indication according to the product information of the assessed medicinal product in the assessed therapeutic indication, whereby the definition of a product class or group is based on the corresponding requirements in the product information of the assessed medicinal product.

In addition, there must be no reasons for exclusion of the concomitant active ingredient from a combination therapy with the assessed medicinal product, in particular no exclusive marketing authorisation as monotherapy.

In addition, all sections of the currently valid product information of the eligible concomitant active ingredient are checked to see whether there is any information that excludes its use in combination therapy with the assessed medicinal product in the assessed therapeutic indication under marketing authorisation regulations. Corresponding information can be, for example, dosage information or warnings. In the event that the medicinal product is used as part of a determined or undetermined combination which does not include the assessed medicinal product, a combination with the assessed medicinal product shall be excluded.

Furthermore, the product information of the assessed medicinal product must not contain any specific information that excludes its use in combination therapy with the eligible concomitant active ingredient in the assessed therapeutic indication under marketing authorisation regulations.

Medicinal products with new active ingredients for which the G-BA have decided on an exemption as a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V are ineligible as concomitant active ingredients. The procedural privileging of the reserve antibiotics exempted according to Section 35a, paragraph 1c, sentence 1 SGB V also applies accordingly to the medicinal product eligible as a concomitant active ingredient.

Designation

The medicinal products which have been determined as concomitant active ingredients in accordance with the above points of examination are named by indicating the relevant active ingredient and the invented name. The designation may include several active ingredients, provided that several medicinal products with new active ingredients may be used in the same combination therapy with the assessed medicinal product or different combinations with different medicinal products with new active ingredients form the basis of the designation.

If the present resolution on the assessed medicinal product in the assessed therapeutic indication contains several patient groups, the designation of concomitant active ingredients shall be made separately for each of the patient groups.

Exception to the designation

The designation excludes combination therapies for which - patient group-related - a considerable or major additional benefit has been determined by resolution according to Section 35a, paragraph 3, sentence 1 SGB V or it has been determined according to Section 35a, paragraph 1d, sentence 1 SGB V that at least considerable additional benefit of the combination can be expected. In this context, the combination therapy that is excluded from the designation must, as a rule, be identical to the combination therapy on which the preceding findings were based.

In the case of designations based on undetermined combinations, only those concomitant active ingredients - based on a resolution according to Section 35a, paragraph 3, sentence 1 SGB V on the assessed medicinal product in which a considerable or major additional benefit had been determined - which were approved at the time of this resolution are excluded from the designation.

Legal effects of the designation

The designation of combinations is carried out in accordance with the legal requirements according to Section 35a, paragraph 3, sentence 4 and is used exclusively to implement the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The designation is not associated with a statement as to the extent to which a therapy with the assessed medicinal products in combination with the designated medicinal products corresponds to the generally recognised state of medical knowledge. The examination was carried out exclusively on the basis of the possibility under Medicinal Products Act to use the medicinal products in combination therapy in the assessed therapeutic indication based on the product information; the generally recognised state of medical knowledge or the use of the medicinal products in the reality of care were not the subject of the examination due to the lack of an assessment mandate of the G-BA within the framework of Section 35a, paragraph 3, sentence 4 SGB V.

The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

Justification for the findings on designation in the present resolution:

Children from birth to < 3 months with acute bacterial skin and skin structure infections (ABSSSI)

- No designation of medicinal products with new active ingredients that can be used in combination therapy in accordance with Section 35a, paragraph 3, sentence 4 SGB V, as the G-BA has decided to exempt the assessed medicinal product as a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V.

3. Bureaucratic costs calculation

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

4. Process sequence

On 27 May 2025, the pharmaceutical company submitted a dossier for the benefit assessment of dalbavancin to the G-BA in due time.

The draft of the G-BA's requirements for a quality-assured application was published on the G-BA's website (www.g-ba.de) on 1 September 2025 together with the IQWiG's assessment of treatment costs and patient numbers, thus initiating the written statement procedure. The deadline for submitting statements was 22 September 2025.

The oral hearing has been dispensed with since all assessment experts who submitted written statements waived their right to make an oral statement.

In order to prepare a recommendation for a resolution, the Subcommittee on Medicinal Products commissioned a working group (Section 35a) consisting of the members nominated by the leading organisations of the care providers, the members nominated by the SHI umbrella organisation, and representatives of the patient organisations. Representatives of the IQWiG also participate in the sessions.

The evaluation of the written statements received was discussed at the session of the subcommittee on 11 November 2025, and the draft resolution was approved.

At their session on 20 November 2025, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Working group Section 35a	18 June 2025	Consultation on the draft requirements for a quality-assured application
Subcommittee on Medicinal Products	24 June 2025	Draft requirements for a quality-assured application; notification of the RKI and BfArM
Subcommittee on Medicinal Products	26 August 2025	Draft requirements for a quality-assured application, taking into account the statement of the RKI
Working group Section 35a	19 August 2025	Information on statements received
Working group Section 35a	14 October 2025 4 November 2025	Consultation on the G-BA's draft requirements for a quality-assured application, the IQWiG's assessment of treatment costs and patient numbers, and the evaluation of the written statement procedure
Subcommittee on Medicinal Products	11 November 2025	Concluding discussion of the draft resolution
Plenum	20 November 2025	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 20 November 2025

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken