Gemeinsamer Bundesausschuss

Justification

for 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
Eravacycline (new therapeutic indication: complicated intra-abdominal infections (cIAI), ≥ 12 to < 18 years, ≥ 50 kg)

From 16 July 2026

Contents

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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 its publication. 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 21 April 2022, 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 Xerava with the active ingredient eravacycline according to Section 35a, paragraph 1, sentence 3, numbers 2 and 3 SGB V, since the medicinal product Xerava with the active ingredient eravacycline for the treatment of bacterial infections is a reserve antibiotic within the meaning of Section 35a, paragraph 1c, sentence 1 SGB V.

By the key date of 21 January 2026, i.e. at the latest within four weeks of informing the pharmaceutical company about the approval for a new therapeutic indication, the pharmaceutical company did not submit a dossier 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 Rules of Procedure (VerfO) concerning the active ingredient eravacycline, with the new therapeutic indication

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(complicated intra-abdominal infections (cIAI), 12 to < 18 years, ≥ 50 kg). The assessment procedure began on 1 February 2026.

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 carried out an assessment of patient numbers and treatment costs. 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 website (www.g-ba.de) together with G-BA's assessment, thus initiating the written statement procedure. In addition, an oral hearing was held.

The G-BA have adopted their resolution on the basis of 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 G-BA's assessment of treatment costs and patient numbers and the statements submitted in the written statement and oral hearing procedure.

2.1 Additional benefit of the medicinal product

2.1.1 Approved therapeutic indication of Eravacycline (Xerava) in accordance with the product information

Xerava is indicated in adolescents from the age of 12 years weighing at least 50 kg for the treatment of complicated intra-abdominal infections (cIAI).

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Therapeutic indication of the resolution (resolution of 16 July 2026):

See the approved therapeutic indication

2.1.2 Extent of the additional benefit and significance of the evidence

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

Adolescents aged 12 to < 18 years weighing ≥ 50 kg with complicated intra-abdominal infections (cIAI)

The additional benefit is considered proven.

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Justification:

For the medicinal product Xerava with the active ingredient eravacycline, 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 21 April 2022, 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 is the benefit assessment of a new therapeutic indication for the active ingredient eravacycline. The therapeutic indication assessed here is as follows: Xerava is indicated in adolescents from the age of 12 years weighing at least 50 kg for the treatment of complicated intra-abdominal infections (cIAI).

The additional benefit of eravacycline is deemed to be proven for adolescents from the age of 12 years weighing at least 50 kg with complicated intra-abdominal infections (cIAI).

For the medicinal product Xerava with the active ingredient eravacycline, 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 21 April 2022, 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). Since the requirements for a quality-assured application for eravacycline result in restrictive use, and on the other hand other alternative therapy options are available for Gram-positive pathogens (especially MRSA), use is predominantly for infections with Gram-negative organisms.

This enables an approximately analogous calculation of adult patient numbers as in the resolution on cefiderocol (resolution of the G-BA of 5 May 2022) in the therapeutic indication "infections caused by aerobic Gram-negative organisms for which only limited treatment options are available" (see resolution on eravacycline from 19 January 2023). Consequently, the figures (approximately 2,600 – 6,600 adult patients) from the resolution on cefiderocol were used as the basis for presenting the patient numbers for the therapeutic indication of eravacycline. The calculation was made there using two different approaches based on data from the RKI and the HISS (Hospital Infection Surveillance System) - pathogen surveillance,

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respectively, for 2019. These patient numbers are also to be assessed as uncertain overall. Due to the limited therapeutic indications of eravacycline (only complicated intra-abdominal infections) compared to cefiderocol, there is additional uncertainty.

According to the Federal Statistical Office[1], adolescents aged between 12 and under 18 years account for 5.6% of the total population. Based on the percentage of adults (83.4%) and the patient numbers from the resolution on eravacycline or cefiderocol, this results in 175 - 440 adolescent patients. However, differences in incidence between adolescents and adults are not taken into account.

An overall lower number of patients in the SHI target population may result particularly against the background of the restrictive use of eravacycline 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 G-BA and the statement of the RKI, which was prepared in agreement with the BfArM. The statements made in the written statement and oral hearing procedure were taken into account.

About the notes on application

Reference is made to the specifications of the marketing authorisation.

The requirement that eravacycline may only be used for the treatment of infections mentioned in the therapeutic indication 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.

According to the field of expertise, qualified consultation takes place with a specialist in the field of infectiology (internal medicine and infectiology, microbiology, virology and epidemiology of infectious diseases or additional qualification in infectiology) or, if not available, with a specialist from other disciplines who must have appropriate experience in the treatment of infectious diseases with multidrug-resistant pathogens.

About the notes on pathogen detection

In principle, eravacycline should not be used as part of a calculated (empirical) therapy. The strict 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 eravacycline should be as short as possible.

[1] Federal Statistical Office. Statistical report: Population projections for 2025 based on the 2022 census (reference date: 31.12.2025). https://www-genesis.destatis.de/datenbank/online/statistic/12411/table/12411-0005

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About the notes on 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 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.

For this reason, the participation of clinics using eravacycline in these systems should be sought.

The reporting of consumption and resistance data on eravacycline 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 requirements of the product information and the information listed in the LAUER-TAXE® (last revised: 15 May 2026). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

Eravacycline is listed in the LAUER-TAXE®, but is only dispensed as a clinic pack. Accordingly, the active ingredient is currently not subject to the Pharmaceutical Price Ordinance (Arzneimittelpreisverordnung) and no rebates according to Section 130 or Section 130a SGB V apply. The calculation is based on the purchase price of the clinic pack plus 19% value added tax, in deviation from the LAUER-TAXE® data usually taken into account.

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Adolescents aged 12 to < 18 years weighing ≥ 50 kg with complicated intra-abdominal infections (cIAI)

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				
Eravacycline	2 x daily	1	4 – 14	4 – 14

Consumption:

The active ingredient eravacycline is dosed according to body weight (BW). For dosages depending on body weight, the average body measurements from the official representative statistics "2025 Microcensus – body measurements of the population"[2] were used as a basis (average body weight of adolescents from the age of 12 years: 48.7 kg and average body weight of adolescents 17 to below 18 years of age: 67.9 kg; according to the marketing authorisation of eravacycline, a body weight of 50 kg is necessary).

The 2025 Microcensus was published on the Federal Health Reporting website (www.gbe-bund.de) and will be used for procedures with LAUER-TAXE® as of 15 May 2026 or later.

For the cost representation, only the dosages of the general case are considered. Patient-individual dose adjustments (e.g. because of side effects or comorbidities) are not taken into account when calculating the annual treatment costs.

The reconstituted eravacycline solution may be stored (at 2°C to 8°C) in the refrigerator for up to 72 hours.

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					
Eravacycline	1 mg/kg BW 50.0 mg – 67.9 mg	2 x 50.0 mg – 2 x 67.9 mg	1 x 100 mg – 1 x 100 mg + 1 x 35.8 mg	4 – 14	4 x 100 mg – 20 x 100 mg

Costs:

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

[2] Federal Health Reporting. Average body measurements of the population (2025, both sexes), www.gbe-bund.de

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particular potency, the costs of the medicinal products were then calculated on the basis of the costs per pack plus value added tax.

Costs of the medicinal products:

Designation of the therapy	Packaging size	Costs (clinic purchase registry)	Value added tax (19%)	Costs of the medicinal product
Eravacycline 100 mg	10 PCI	€ 1,250.00	€ 237.50	€ 1,487.50
Abbreviations: PIC = powder for the preparation of an infusion solution concentrate				

LAUER-TAXE® last revised: 15 May 2026

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 additional SHI services required are taken into account for the cost representation.

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.

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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 data from the product 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

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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.

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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 statutory 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:

Adolescents from the age of 12 years weighing at least 50 kg with complicated intra-abdominal infections (cIAI)

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 have 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

The pharmaceutical company did not submit any benefit assessment dossier at the relevant time.

The draft of the G-BA's requirements for a quality-assured application was published on the G-BA website (www.g-ba.de) on 4 May 2026 together with the G-BA's assessment of treatment costs and patient numbers, thus initiating the written statement procedure. The deadline for submitting written statements was 26 May 2026.

The oral hearing was held on 8 June 2026.

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

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by the leading organisations of the care providers, the members nominated by the SHI umbrella organisation, and the representatives of the patient organisations. Representatives of the IQWiG also participate in the sessions.

The evaluation of the written statements received and the oral hearing were discussed at the Subcommittee's session on 7 July 2026, and the draft resolution was conclusively discussed.

At their session on 16 July 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Working group Section 35a	17 February 2026 14 April 2026	Consultation on the draft requirements for a quality-assured application
Subcommittee on Medicinal Products	24 February 2026	Draft requirements for a quality-assured application; notification of the RKI and BfArM
Subcommittee on Medicinal Products	28 April 2026	Draft requirements for a quality-assured application, taking into account the statement of the RKI
Working group Section 35a	2 June 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	8 June 2026	Conduct of the oral hearing
Working group Section 35a	16 June 2026 1 July 2026	Consultation on the G-BA's draft requirements for a quality-assured application, the G-BA's assessment of treatment costs and patient numbers, and the evaluation of the written statement procedure
Subcommittee on Medicinal Products	7 July 2026	Concluding discussion of the draft resolution
Plenum	16 July 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 16 July 2026

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Dr Optendrenk

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