GBA
Gemeinsamer
Bundesausschuss

# Justification

for the Resolution of the Federal Joint Committee (GBA) on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Dupilumab (new therapeutic indication: chronic spontaneous urticaria (CSU), ≥ 12 years)

of 5 November 2026

**Contents**


**1. Legal basis ... 2**

**2. Key points of the resolution ... 2**

**2.1 Additional benefit of the medicinal product in relation to the appropriate comparator therapy ... 3**

2.1.1 Approved therapeutic indication of dupilumab (Dupixent) in accordance with the product information ... 3

2.1.2 Appropriate comparator therapy ... 3

2.1.3 Extent and probability of the additional benefit ... 6

2.1.4 Summary of the assessment ... 7

**2.2 Number of patients or demarcation of patient groups eligible for treatment ... 7**

**2.3 Requirements for a quality-assured application ... 8**

**2.4 Treatment costs ... 8**

**3. Bureaucratic costs calculation ... 11**

**4. Process sequence ... 12**


Courtesy translation – only the German version is legally binding.

## 1. Legal basis

According to Section 35a, paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (GBA) assess the benefit of all reimbursable medicinal products with new active ingredients. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the GBA electronically, including all clinical studies the pharmaceutical company have conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. approved therapeutic indications,
2. medical benefit,
3. additional medical benefit in relation to the appropriate comparator therapy,
4. number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. treatment costs for the statutory health insurance funds,
6. requirements for a quality-assured application.

The GBA may commission the Institute for Quality and Efficiency in Health Care (IQWiG) to carry out the benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment must be completed within three months of the relevant date for submission of the evidence and published on the internet.

According to Section 35a, paragraph 3 SGB V, the GBA decide on the benefit assessment 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

The active ingredient dupilumab (Dupixent) was listed for the first time on 1 December 2017 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

On 6 November 2025, dupilumab 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 from 12.12.2008, sentence 7).

On 1 September 2025, the pharmaceutical company submitted an application to merge the assessment procedures of dupilumab according to Section 35a, paragraph 5b SGB V. At their session on 16 October 2025, the GBA approved the merger application.



Courtesy translation – only the German version is legally binding.

On 5 May 2026, the pharmaceutical company submitted a dossier in due time in accordance with Section 4, paragraph 3, number 3 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 2 of the Rules of Procedure (VerfO) of the GBA on the active ingredient dupilumab.

The GBA came to a decision on whether an additional benefit of dupilumab compared with the appropriate comparator therapy could be determined on the basis of the dossier of the pharmaceutical company, the dossier assessment prepared by the IQWiG and the statements submitted in the written statement and oral hearing procedure. In order to determine the extent of the additional benefit, the GBA have evaluated the data justifying the finding of an additional benefit on the basis of their therapeutic relevance (qualitative), in accordance with the criteria laid down in Chapter 5, Section 5, paragraph 7 VerfO. The methodology proposed by the IQWiG in accordance with the General Methods[1] was not used in the benefit assessment of dupilumab.

In the light of the above, and taking into account the statements received and the oral hearing, the GBA have made the following assessment:

## 2.1 Additional benefit of the medicinal product in relation to the appropriate comparator therapy

### 2.1.1 Approved therapeutic indication of dupilumab (Dupixent) in accordance with the product information

"Dupixent is indicated for the treatment of moderate to severe chronic spontaneous urticaria in adults, adolescents and children (2 years and above) with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU."

**Therapeutic indication of the resolution (resolution of 05.11.2026):**

"Dupixent is indicated for the treatment of moderate to severe chronic spontaneous urticaria in adults and adolescents (12 years and above) with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU."

### 2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Adults and adolescents 12 years and above with moderate to severe chronic spontaneous urticaria with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU

Appropriate comparator therapy for dupilumab:

- Omalizumab, in combination with H1 antihistamines of the 2nd generation

[1] General Methods, version 8.0 from 19.12.2025. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.



Courtesy translation – only the German version is legally binding.

Criteria according to Chapter 5 Section 6 of the Rules of Procedure of the GBA and Section 6, paragraph 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV):

The appropriate comparator therapy must be an appropriate therapy in the therapeutic indication according to the generally recognised state of medical knowledge (Section 12 SGB V), preferably a therapy for which endpoint studies are available and which has proven its worth in practical application unless contradicted by the guidelines under Section 92, paragraph 1 SGB V or the principle of economic efficiency.

In determining the appropriate comparator therapy, the following criteria, in particular, must be taken into account as specified in Chapter 5, Section 6, paragraph 3 VerfO:

1. To be considered as a comparator therapy, the medicinal product must, principally, have a marketing authorisation for the therapeutic indication.
2. If a non-medicinal treatment is considered as a comparator therapy, this must be available within the framework of the SHI system.
3. As comparator therapy, medicinal products or non-medicinal treatments for which the patient-relevant benefit has already been determined by the GBA must be preferred.
4. According to the generally recognised state of medical knowledge, the comparator therapy must be part of the appropriate therapy in the therapeutic indication.

According to Section 6, paragraph 2, sentence 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the determination of the appropriate comparator therapy must be based on the actual medical treatment situation as it would be without the medicinal product to be assessed. According to Section 6, paragraph 2, sentence 3 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the GBA may exceptionally determine the off-label use of medicinal products as an appropriate comparator therapy or as part of the appropriate comparator therapy if they determine by resolution on the benefit assessment according to Section 7, paragraph 4 that, according to the generally recognised state of medical knowledge, this is considered a therapy standard in the therapeutic indication to be assessed or as part of the therapy standard in the medical treatment situation to be taken into account according to sentence 2, and

1. for the first time, a medicinal product approved in the therapeutic indication is available with the medicinal product to be assessed,
2. according to the generally recognised state of medical knowledge, the off-label use is generally preferable to the medicinal products previously approved for the therapeutic indication, or
3. according to the generally recognised state of medical knowledge, the off-label use for relevant patient groups or indication areas is generally preferable to the medicinal products previously approved for the therapeutic indication.

An appropriate comparator therapy may also be non-medicinal therapy, the best possible supportive therapy including symptomatic or palliative treatment, or monitoring wait-and-see approach.



Courtesy translation – only the German version is legally binding.

Justification based on the criteria set out in Chapter 5, Section 6, paragraph 3 VerfO and Section 6, paragraph 2 AM-NutzenV:

On 1. In addition to dupilumab, H1 antihistamines of the first generation (e.g. hydroxyzine) and of the second generation (e.g. cetirizine, fexofenadine, loratadine) are approved for the treatment of chronic spontaneous urticaria. Furthermore, the active ingredient omalizumab is indicated as an add-on therapy for the treatment of chronic spontaneous urticaria in adults and adolescents (12 years and above) with inadequate response to H1 antihistamines and the active ingredient remibrutinib is indicated for the treatment of chronic spontaneous urticaria (CSU) in adults with inadequate response to H1 antihistamines. Systemic glucocorticoids (e.g. prednisolone) are approved for acute treatment.

On 2. Non-medicinal treatment options are not considered in the present therapeutic indication as a rule.

On 3. No GBA resolutions are available for the therapeutic indication - chronic spontaneous urticaria.

On 4. The generally recognised state of medical knowledge was illustrated by a systematic search for guidelines as well as systematic reviews of clinical studies in the present indication and is presented in the "Research and synopsis of the evidence to determine the appropriate comparator therapy according to Section 35a SGB V".

The scientific-medical societies and the Drugs Commission of the German Medical Association (AkdÄ) were also involved in writing on questions relating to the comparator therapy in the present indication according to Section 35a, paragraph 7 SGB V (see "Information on Appropriate Comparator Therapy").

H1 antihistamines as well as the biologic agents omalizumab and remibrutinib are generally approved for the treatment of chronic spontaneous urticaria. Due to their marketing authorisation and side-effect profile, systemic glucocorticoids are only available for the acute treatment of acute exacerbation of chronic spontaneous urticaria. Consequently, these are ineligible as the appropriate comparator therapy for the long-term treatment of patients in the intended therapeutic indication.

The active ingredient remibrutinib is a new treatment option in the present therapeutic indication. The active ingredient was only recently approved (marketing authorisation on 23 April 2026). Based on the generally recognised state of medical knowledge, remibrutinib is not determined here as the appropriate comparator therapy.

Based on the evidence available in the therapeutic indication and the guidelines, H1 antihistamines of the 2$^{nd}$ generation are initially recommended for the treatment of chronic spontaneous urticaria. These should initially be administered at the standard dose (according to the marketing authorisation). If there is no response, dose escalation to up to four times the approved dose is recommended. If there is a continued inadequate response to antihistamines of the 2$^{nd}$ generation, a combination of H1 antihistamines of the 2$^{nd}$ generation and omalizumab is recommended.



Courtesy translation – only the German version is legally binding.

The use of H1 antihistamines at doses up to four times the approved dose is not consistent with the marketing authorisation. The S3 guideline on urticaria2 recommends dose escalation to up to four times the approved dose for the treatment of chronic urticaria if there is no response to a standard dose of H1 antihistamine of the 2nd generation. This recommendation is consensus- and evidence-based and has the highest possible level of recommendation (evidence basis: relevant RCTs3). This recommendation is also set out in the written statement issued by the German Dermatological Society as well as in international guidelines4,5. In accordance with current therapy recommendations and taking into account the written statement from the relevant scientific-medical society, dose escalation of H1 antihistamines of the 2nd generation to up to four times the approved dose is considered the therapy standard for the treatment of patients with chronic spontaneous urticaria who do not respond to a standard dose of an H1 antihistamine of the 2nd generation. Other therapy options approved for the therapeutic indication (omalizumab) are only recommended following the lack of a response to high-dose H1 antihistamines of the 2nd generation. In accordance with the generally recognised state of medical knowledge, it can be concluded in the overall assessment that the off-label use of H1 antihistamines of the 2nd generation at a dose up to four times the approved dose for the treatment of urticaria is the therapy standard in the therapeutic indication under assessment for patients with inadequate response to H1 antihistamines of the 2nd generation at the standard dose, and must generally be preferred to the use of the approved dose; Section 6, paragraph 2, sentence 3, number 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV).

Consequently, the appropriate comparator therapy for dupilumab for the treatment of moderate to severe chronic spontaneous urticaria in adults and adolescents (12 years and above) with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU is therefore determined to be the active ingredient omalizumab in combination with H1 antihistamines of the 2nd generation.

The findings in Annex XII do not restrict the scope of treatment required to fulfil the medical treatment mandate.

Any change to the appropriate comparator therapy requires a decision by the GBA based on a prior review of the criteria set out in Chapter 5, Section 6, paragraph 3 VerfO.

### 2.1.3 Extent and probability of the additional benefit

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

The additional benefit over the appropriate comparator therapy is not proven for the treatment of moderate to severe chronic spontaneous urticaria in adults and adolescents

[2] S3 guideline on the classification, diagnosis and treatment of urticaria; p. 43: "For patients with chronic urticaria who do not respond to a standard-dose H1 antihistamine of the 2nd generation, dose escalation up to four times* is recommended as a second-line therapy option prior to consideration of other treatments."

[3] Evidence report on the relevant S3 guideline: Reference to multiple RCTs, page 24 et seq.

[4] Caffarelli C, Paravati F, El Hachem M, Duse M, Bergamini M, Simeone G, et al. Management of chronic urticaria in children: a clinical guideline. Ital J Pediatr 2019;45(1):101.

[5] Sabroe RA, Lawlor F, Grattan CEH, Ardern-Jones MR, Bewley A, Campbell L, et al. British Association of Dermatologists guidelines for the management of people with chronic urticaria 2021. Br J Dermatol 2022;186(3):398-413.



Courtesy translation – only the German version is legally binding.

(12 years and above) with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU.

Justification:

In their dossier, the pharmaceutical company did not present any data for the assessment of the additional benefit of dupilumab compared with the appropriate comparator therapy.

Overall, no data are therefore available to enable an assessment of the additional benefit of dupilumab for the treatment of moderate to severe chronic spontaneous urticaria in adults and adolescents (12 years and above) with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU. An additional benefit is therefore not proven.

### 2.1.4 Summary of the assessment

The present assessment is the benefit assessment of a new therapeutic indication for the active ingredient dupilumab.

The therapeutic indication assessed here is as follows: "For the treatment of moderate to severe chronic spontaneous urticaria in adults and adolescents (12 years and above) with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU".

The appropriate comparator therapy was determined to be "Omalizumab, in combination with H1 antihistamines of the 2$^{nd}$ generation".

The pharmaceutical company did not present any data to prove the additional benefit of dupilumab compared to the appropriate comparator therapy. Consequently, an additional benefit of dupilumab is not proven for the treatment of moderate to severe chronic spontaneous urticaria in adults and adolescents (12 years and above) with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU.

## 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 information is based on the data provided by the pharmaceutical company in the dossier.

Definitive assessment of the estimate is not possible as it is subject to various uncertainties overall. There are uncertainties regarding routine data during the collection of prevalence data and pretreatment with H1 antihistamines, owing to the ICD codes used and over-the-counter availability of antihistamines, as well as regarding the operationalisation of severity based on an inadequate response to treatment with H1 antihistamines. The determination of the inadequate response is also subject to uncertainties due to different operationalisations as well as the fluctuating nature of the disease. It is not possible to make a definitive assessment of the presented estimate of the number of patients who are naive to anti-IgE antibodies.



Courtesy translation – only the German version is legally binding.

## 2.3 Requirements for a quality-assured application

The requirements in the product information are to be taken into account. The European Medicines Agency (EMA) provides the contents of the product information (summary of product characteristics, SmPC) for Dupixent (active ingredient: dupilumab) at the following publicly accessible link (last access: 21 September 2026):

https://www.ema.europa.eu/en/documents/product-information/dupixent-epar-product-information_en.pdf

Treatment with dupilumab must be initiated and monitored by specialists experienced in treating patients with chronic spontaneous urticaria.

## 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: 1 September 2026). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

In general, initial induction regimens are not taken into account for the cost representation, since the present indication is a chronic disease with a continuous need for therapy and, as a rule, no new titration or dose adjustment is required after initial titration.

Dupilumab is approved for the treatment of moderate to severe chronic spontaneous urticaria in adults and adolescents (12 years and above) and may be used in combination with H1 antihistamines. Omalizumab is used as an add-on therapy to H1 antihistamines. The use of H1 antihistamines of the 2nd generation at up to four times the approved dose is recommended.[2] For the treatment costs of H1 antihistamines, the range from the single dose up to four times the standard dose (OLU) is determined by a more cost-effective and a more cost-intensive therapy option.



Courtesy translation – only the German version is legally binding.

Adults and adolescents 12 years and above with moderate to severe chronic spontaneous urticaria with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU

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: | | | | |
| Dupilumab | Continuously, 1 x every 14 days | 26.1 | 1 | 26.1 |
| if applicable, in combination with H1 antihistamines of the 2nd generation: | | | | |
| Levocetirizine | Continuously, 1 x daily | 365.0 | 1 | 365.0 |
| Fexofenadine | Continuously, 1 x daily | 365.0 | 1 | 365.0 |
| Appropriate comparator therapy: | | | | |
| Omalizumab | Continuously, 1 x every 28 days | 13.0 | 1 | 13.0 |
| in combination with H1 antihistamines of the 2nd generation: | | | | |
| Levocetirizine | Continuously, 1 x daily | 365.0 | 1 | 365.0 |
| Fexofenadine | Continuously, 1 x daily | 365.0 | 1 | 365.0 |

Consumption:

For dosages depending on body weight (BW), the average body measurements from the official representative statistics "2025 Microcensus – body measurements of the population"[6] were used as a basis. The active ingredient dupilumab is dosed in children and adolescents according to body weight. Standard patients with an average body weight of 48.7 kg (for children aged 12 years) or 78.3 kg (for adults) are considered for the cost calculation. The dupilumab dosage recommendations for these body weights can be found in the product information.

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



Courtesy translation – only the German version is legally binding.

| 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: | | | | | |
| Dupilumab | 200 mg – 300 mg | 200 mg – 300 mg | 1 x 200 mg – 1 x 300 mg | 26.1 | 26.1 x 200 mg – 26.1 x 300 mg |
| if applicable, in combination with H1 antihistamines of the 2nd generation: | | | | | |
| Levocetirizine | 5 mg - | 5 mg - | 1 x 5 mg - | 365.0 | 365 x 5 mg - |
| | 20 mg | 20 mg | 4 x 5 mg | | 1,460 x 5 mg |
| Fexofenadine | 180 mg - | 180 mg - | 1 x 180 mg - | 365.0 | 365 x 180 mg |
| | 720 mg | 720 mg | 4 x 180 mg | | 1,460 x 180 mg |
| Appropriate comparator therapy: | | | | | |
| Omalizumab | 300 mg | 300 mg | 2 x 150 mg | 13.0 | 26 x 150 mg |
| in combination with H1 antihistamines of the 2nd generation: | | | | | |
| Levocetirizine | 5 mg - | 5 mg - | 1 x 5 mg - | 365.0 | 365 x 5 mg - |
| | 20 mg | 20 mg | 4 x 5 mg | | 1,460 x 5 mg |
| Fexofenadine | 180 mg - | 180 mg - | 1 x 180 mg - | 365.0 | 365 x 180 mg |
| | 720 mg | 720 mg | 4 x 180 mg | | 1,460 x 180 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.

Non-prescription medicinal products that are reimbursable at the expense of the statutory health insurance according to Annex I of the Pharmaceuticals Directive (so-called OTC exception list) are not subject to the current medicinal products price regulation. Instead, in accordance with Section 129 paragraph 5aSGB V, when a non-prescription medicinal product is dispensed and invoiced in accordance with Section 300, a medicinal product dispensing price in the amount of the dispensing price of the pharmaceutical company plus the surcharges in accordance with Sections 2 and 3 of the Pharmaceutical Price Ordinance in the version valid on 31 December 2003 applies to the insured.



Courtesy translation – only the German version is legally binding.

**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: | | | | | |
| Dupilumab 200 mg | 6 SFI | € 3,840.76 | € 1.77 | € 216.01 | € 3,622.98 |
| Dupilumab 300 mg | 6 SFI | € 3,840.76 | € 1.77 | € 216.01 | € 3,622.98 |
| Levocetirizine 5 mg | 100 FCT | € 21.98 | € 1.10 | € 3.89 | € 16.32 |
| Fexofenadine 180 mg[7] | 100 FCT | € 52.26 | € 1.77 | € 3.18 | € 47.31 |
| Appropriate comparator therapy: | | | | | |
| Omalizumab 150 mg | 10 SFI | € 4,172.95 | € 1.77 | € 234.98 | € 3,936.20 |
| Levocetirizine 5 mg | 100 FCT | € 21.98 | € 1.10 | € 3.89 | € 16.32 |
| Fexofenadine 180 mg[7] | 100 FCT | € 52.26 | € 1.77 | € 3.18 | € 47.31 |
| Abbreviations: FCT = film-coated tablets; SFI = solution for injection | | | | | |

LAUER-TAXE® last revised: 1 September 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.

Because there are no 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, no costs for additionally required SHI services had to be taken into account.

## 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.

[7] Fixed reimbursement rate



Courtesy translation – only the German version is legally binding.

## 4. Process sequence

The Subcommittee on Medicinal Products determined the appropriate comparator therapy at their session on 28 November 2023.

A review of the appropriate comparator therapy took place once the positive opinion was granted. At their session on 25 November 2025, the Subcommittee on Medicinal Products newly determined the appropriate comparator therapy.

On 5 May 2026, the pharmaceutical company submitted a dossier for the benefit assessment of dupilumab to the GBA in due time in accordance with Chapter 5, Section 8, paragraph 2 VerfO.

By letter dated 13 May 2026 in conjunction with the resolution of the GBA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefit of medicinal products with new active ingredients in accordance with Section 35a SGB V, the GBA commissioned the IQWiG to assess the dossier concerning the active ingredient dupilumab.

The dossier assessment by the IQWiG was submitted to the GBA on 7 August 2026, and the written statement procedure was initiated with publication on the GBA website on 17 August 2026. The deadline for submitting written statements was 7 September 2026.

The oral hearing was held on 21 September 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 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 and the oral hearing was discussed at the Subcommittee's session on 27 October 2026, and deliberation of the draft resolution was concluded.

At their session on 5 November 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

**Chronological course of consultation**

| Session | Date | Subject of consultation |
|---|---|---|
| Subcommittee on Medicinal Products | 28 November 2023 | Determination of the appropriate comparator therapy |
| Subcommittee on Medicinal Products | 25 November 2025 | New determination of the appropriate comparator therapy |
| Working group Section 35a | 16 September 2026 | Information on written statements received; preparation of the oral hearing |



Courtesy translation – only the German version is legally binding.

| | | |
|---|---|---|
| Subcommittee on Medicinal Products | 21 September 2026 | Conduct of the oral hearing |
| Working group Section 35a | 30 September 2026<br>14 October 2026 | Consultation on the dossier assessment by the IQWiG and evaluation of the written statement procedure |
| Subcommittee on Medicinal Products | 27 October 2026 | Concluding discussion of the draft resolution |
| Plenum | 5 November 2026 | Adoption of the resolution on the amendment of the Pharmaceuticals Directive |

Berlin, 5 November 2026

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

Dr Optendrenk



Courtesy translation – only the German version is legally binding.