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
Depemokimab (chronic rhinosinusitis with nasal polyps)

of 1 October 2026

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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 relevant date for the start of the benefit assessment procedure was the first placing on the (German) market of the active ingredient depemokimab on 1 April 2026 in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 of the Rules of Procedure of the GBA (VerfO). Pursuant to Section 4, paragraph 3, number 1 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 1, number 1 of the Rules of Procedure (VerfO), the pharmaceutical company submitted the final dossier to the GBA on 30 March 2026.

The GBA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 1 July 2026 on the GBA website (www.g-ba.de), thus initiating the written statement procedure. In addition, an oral hearing was held.

The GBA came to a resolution on whether an additional benefit of depemokimab 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

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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 depemokimab.

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 Depemokimab (EXDENSUR) in accordance with the product information

Chronic rhinosinusitis with nasal polyps (CRSwNP)

EXDENSUR is indicated as an add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control.

Therapeutic indication of the resolution (resolution of 01.10.2026):

See the approved therapeutic indication

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Adults with severe chronic rhinosinusitis with nasal polyps (CRSwNP) for whom therapy with systemic corticosteroids, and/or surgery do not provide adequate disease control

Appropriate comparator therapy for depemokimab as an add-on therapy to intranasal corticosteroids:

- Dupilumab or mepolizumab or omalizumab, each in combination with intranasal corticosteroids (budesonide or mometasone furoate)

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

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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 shall be preferred.
4. According to the generally recognised state of medical knowledge, the comparator therapy should 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.

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

On 1. Corticosteroids are approved for the treatment of CRSwNP (therapeutic indication): the active ingredients budesonide and mometasone furoate as intranasal (topical) corticosteroids (INCS) as well as oral corticosteroids (OCS). Antibiotics and analgesics are also approved for short-term intervention on demand. In addition, besides depemokimab, the biologic agents dupilumab, mepolizumab, omalizumab and tezepelumab are approved for the treatment of CRSwNP following an inadequate response to systemic corticosteroids and/or surgical intervention.

On 2. Non-medicinal treatment alone is not considered in the therapeutic indication. Surgical measures represent an intervention on demand.

On 3. With regard to chronic rhinosinusitis with nasal polyposis (CRSwNP), there are resolutions of the GBA on the benefit assessment of medicinal products with new active ingredients - according to Section 35a of SGB V - of 14 May 2020 for the active

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ingredient dupilumab, of 19 May 2022 for the active ingredient mepolizumab, and of 7 May 2026 for the active ingredient tezepelumab.

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 therapeutic indication according to Section 35a, paragraph 7 SGB V. According to the available aggregated evidence, use of the biologic agents dupilumab, mepolizumab or omalizumab as an add-on therapy to INCS maintenance treatment is recommended for adults with chronic rhinosinusitis with nasal polyps for whom therapy with systemic corticosteroids and/or surgery do not provide adequate control of the CRSwNP disease. The active ingredient tezepelumab is a new treatment option in the present therapeutic indication. The active ingredient was only recently approved (marketing authorisation on 20 October 2025). According to the generally recognised state of medical knowledge, tezepelumab is not determined as an appropriate comparator therapy for the present resolution.

Furthermore, the use of saline nasal rinses is recommended on the basis of evidence. According to the recommendations, invasive treatment methods may also be an option in individual cases.

Oral corticosteroids (OCS) are approved in the present therapeutic indication, but the evidence for the long-term use of OCS for standard or maintenance treatment of nasal polyps - especially beyond flare therapy - is to be regarded as rather low; consistently positive recommendations for long-term OCS use are not available on the basis of the aggregated evidence. Antibiotics as well as analgesics are not considered as standard or maintenance treatment, as these are only indicated for short-term treatment on demand (in case of complications, infections). Based on these considerations, the GBA assume that patients in both arms receive further supportive measures (e.g. nasal rinses) as well as an appropriate, on-label therapy for complications (if applicable, short-term antibiotics, short-term systemic corticosteroids as part of a flare therapy).

In the overall assessment, the GBA conclude that the biologic agents dupilumab or mepolizumab or omalizumab, each in combination with intranasal corticosteroids (budesonide or mometasone furoate), are considered appropriate for depemokimab as add-on therapy to intranasal corticosteroids in adults with inadequately controlled chronic rhinosinusitis with nasal polyps. The appropriate comparator therapy determined here includes several alternative therapy options. The above-mentioned options dupilumab, mepolizumab and omalizumab are considered equally appropriate for the add-on therapy; within the intranasal corticosteroids, budesonide and mometasone furoate are equally appropriate therapeutic alternatives. The additional benefit over one of the biologic agents mentioned, each in combination with intranasal corticosteroids (budesonide or mometasone furoate) can be proven.

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.

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2.1.3 Extent and probability of the additional benefit

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

The additional benefit of depemokimab as an add-on therapy to intranasal corticosteroids is not proven for adults with severe chronic rhinosinusitis with nasal polyps (CRSwNP) for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control.

Justification:

No direct comparator data between depemokimab and the appropriate comparator therapy are available.

In the dossier, the pharmaceutical company presented the data from the 52-week, placebo-controlled ANCHOR-1 and ANCHOR-2 studies. Both studies were carried out at the same time. Adult patients who, on a scale of 0 to 8, had a nasal polyp score (NPS) ≥ 5 (≥ 2 for each nostril), severe symptoms of nasal polyps, and at least 2 symptoms of chronic rhinosinusitis for more than 12 weeks were enrolled in the studies. In addition, at the time of screening, the patients met at least one of the following criteria: intake of systemic corticosteroids (SCS) on at least 3 consecutive days within the last 2 years for the treatment of nasal polyps; medical contraindication to SCS; undergone previous surgery for nasal polyps.

In both studies, treatment with depemokimab was carried out in accordance with the product information. In the ANCHOR-1 study, a total of 276 patients were randomised in a 1:1 ratio to receive either depemokimab (N = 143) or placebo (N = 133). The ANCHOR-2 study involved a total of 264 patients, of which N = 132 patients (depemokimab vs placebo) were respectively allocated to each treatment arm. Treatment with the biologic agents of the appropriate comparator therapy – dupilumab, mepolizumab or omalizumab – was prohibited both prior to enrolment in the study and during the study. The studies are thus unsuitable for deriving an additional benefit of depemokimab compared to the appropriate comparator therapy.

In the overall assessment, an additional benefit of depemokimab over the appropriate comparator therapy is therefore not proven for adults with severe chronic rhinosinusitis with nasal polyps (CRSwNP) for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control.

2.1.4 Summary of the assessment

The present assessment concerns the benefit assessment of the new medicinal product EXDENSUR with the active ingredient depemokimab. The therapeutic indication assessed here is: "as add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control".

The GBA determined the biologic agents dupilumab or mepolizumab or omalizumab, each in combination with the intranasal corticosteroids (INCS) budesonide or mometasone furoate, as the appropriate comparator therapy.

For the assessment of the additional benefit of depemokimab, the pharmaceutical company presented data from the randomised ANCHOR-1 and ANCHOR-2 studies comparing depemokimab with placebo. Due to the lack of comparison with the appropriate comparator therapy, the data presented are therefore unsuitable for deriving an additional benefit.

In the overall assessment, an additional benefit of depemokimab over the appropriate comparator therapy is therefore not proven for adults with severe chronic rhinosinusitis with

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nasal polyps (CRSwNP) for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control.

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 resolution is based on the information provided by the pharmaceutical company in the benefit assessment dossier. The pharmaceutical company initially referred to the calculation set out in the dossier on mepolizumab[2] for the same therapeutic indication, thereby following the routine data analysis. However, the criteria for identifying patients with severe CRSwNP and inadequate disease control set out in this dossier on depemokimab are broader in scope and are therefore within a broadly plausible range. However, the data remain subject to uncertainties, partly due to the chosen time interval of four quarters between the last documented diagnosis and a previous sinus surgery.

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 Exdensur (active ingredient: depemokimab) at the following publicly accessible link (last access: 8 July 2026):

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

Treatment with depemokimab should only be initiated and monitored by specialists experienced in treating patients with CRSwNP.

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 July 2026).

The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

If no maximum treatment duration is specified in the product information, the treatment duration is assumed to be one year (365 days), even if the actual treatment duration is different from patient to patient and/or is shorter on average. The time unit "days" is used to calculate the "number of treatments/ patient/ year", time intervals between individual treatments and for the maximum treatment duration, if specified in the product information.

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.

[2] Resolution of 19.05.2022

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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.

Adults with severe chronic rhinosinusitis with nasal polyps (CRSwNP) for whom therapy with systemic corticosteroids, and/or surgery do not provide adequate disease control

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				
Depemokimab	Continuously, 1 x every 6 months	2.0	1	2.0
In combination with intranasal corticosteroids				
Budesonide	Continuously, 2 x daily	365.0	1	365.0
Mometasone	Continuously, 1 x daily	365.0	1	365.0
Appropriate comparator therapy				
Dupilumab or omalizumab or mepolizumab, each in combination with intranasal corticosteroids (budesonide or mometasone furoate)				
Dupilumab	Continuously, 1 x every 14 days	26.1	1	26.1
Mepolizumab	Continuously, 1 x every 28 days	13.0	1	13.0
Omalizumab	Continuously, 1 x every 14 days - 1 x every 28 days	13.0 – 26.1	1	13.0 – 26.1
In each case, in combination with intranasal corticosteroids				
Budesonide	Continuously, 2 x daily	365.0	1	365.0
Mometasone	Continuously, 1 x daily	365.0	1	365.0

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Consumption:

For the calculation of omalizumab consumption based on dosages depending on body weight (BW), the average body measurements from the official representative statistics "2025 Microcensus – body measurements of the population" were applied (average body height: 1.73 m, average body weight: 78.3 kg)[3].

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					
Depemokimab	100 mg	100 mg	1 x 100 mg	2.0	2 x 100 mg
In combination with intranasal corticosteroids					
Budesonide	0.1 mg – 0.2 mg	0.2 mg – 0.4 mg	4 x 0.05 mg – 8 x 0.05 mg	365.0	1,460 puffs, each 0.05 mg – 2,920 puffs, each 0.05 mg
Mometasone	0.1 mg – 0.4 mg	0.1 mg – 0.4 mg	2 x 0.05 mg – 8 x 0.05 mg	365.0	730 puffs, each 0.05 mg – 2,920 puffs, each 0.05 mg
Appropriate comparator therapy					
Dupilumab or omalizumab or mepolizumab, each in combination with intranasal corticosteroids (budesonide or mometasone furoate)					
Dupilumab	300 mg	300 mg	1 x 300 mg	26.1	26.1 x 300 mg
Mepolizumab	100 mg	100 mg	1 x 100 mg	13.0	13 x 100 mg
Omalizumab	150 mg – 600 mg	150 mg – 600 mg	1 x 150 mg – 4 x 150 mg	13.0 – 26.1	13 x 150 mg – 104.4 x 150 mg
In each case, in combination with intranasal corticosteroids					
Budesonide	0.1 mg – 0.2 mg	0.2 mg – 0.4 mg	4 x 0.05 mg – 8 x 0.05 mg	365.0	1,460 puffs, each 0.05 mg – 2,920 puffs, each 0.05 mg

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

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Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Mometasone	0.1 mg – 0.4 mg	0.1 mg – 0.4 mg	2 x 0.05 mg – 8 x 0.05 mg	365.0	730 puffs, each 0.05 mg – 2,920 puffs, each 0.05 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					
Depemokimab 100 mg	1 SFI	€ 9,998.86	€ 1.77	€ 567.70	€ 9,429.39
Budesonide 0.05 mg[4]	2 MNS (2 x 200 puffs)	€ 31.64	€ 1.77	€ 1.55	€ 28.32
Mometasone 0.05 mg[4]	2 SNS (2 x 140 puffs)	€ 27.11	€ 1.77	€ 1.19	€ 24.15
Appropriate comparator therapy					
Dupilumab 300 mg	6 SFI	€ 3,895.26	€ 1.77	€ 219.12	€ 3,674.37
Mepolizumab 100 mg	3 SFI	€ 3,732.70	€ 1.77	€ 0.00	€ 3,730.93
Omalizumab 150 mg	10 SFI	€ 4,172.95	€ 1.77	€ 234.98	€ 3,936.20
Budesonide 0.05 mg[4]	2 MNS (2 x 200 puffs)	€ 31.64	€ 1.77	€ 1.55	€ 28.32
Mometasone 0.05 mg[4]	2 SNS (2 x 140 puffs)	€ 27.11	€ 1.77	€ 1.19	€ 24.15
Abbreviations: SFI = solution for injection; SNS = standard nasal spray; MNS = metered-dose nasal spray					

LAUER-TAXE® last revised: 15 July 2026

[4]Fixed reimbursement rate

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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.

4. Process sequence

At their session on 25 February 2025, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 30 March 2026, the pharmaceutical company submitted a dossier for the benefit assessment of depemokimab to the GBA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 VerfO.

By letter dated 1 April 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 depemokimab.

The dossier assessment by the IQWiG was submitted to the GBA on 26 June 2026, and the written statement procedure was initiated with publication on the GBA website on 1 July 2026. The deadline for submitting written statements was 22 July 2026.

The oral hearing was held on 10 August 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 were discussed at the Subcommittee's session on 22 September 2026, and deliberation of the draft resolution was concluded.

At their session on 1 October 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

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Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	25 February 2025	Determination of the appropriate comparator therapy
Working group Section 35a	5 August 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	10 August 2026	Conduct of the oral hearing
Working group Section 35a	19 August 2026 2 September 2026	Consultation on the dossier assessment by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	22 September 2026	Concluding discussion of the draft resolution
Plenum	1 October 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 1 October 2026

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

Dr Optendrenk

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