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
Pegcetacoplan (new therapeutic indication: primary immune-complex membranoproliferative glomerulonephritis, ≥ 12 years)

From 6 August 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 (G-BA) assess the benefit of all reimbursable medicinal products with new active ingredients.

For medicinal products for the treatment of rare diseases (orphan drugs) that are approved according to Regulation (EC) No. 141/2000 of the European Parliament and the Council of 16 December 1999, the additional medical benefit is considered to be proven through the grant of the marketing authorisation according to Section 35a, paragraph 1, sentence 11, 1st half of the sentence SGB V. Evidence of the medical benefit and the additional medical benefit in relation to the appropriate comparator therapy do not have to be submitted (Section 35a, paragraph 1, sentence 11, 2nd half of the sentence SGB V). Section 35a, paragraph 1, sentence 11, 1st half of the sentence SGB V thus guarantees an additional benefit of an approved orphan drug, although an assessment of the orphan drug in accordance with the principles laid down in Section 35a, paragraph 1, sentence 3, numbers 2 and 3 SGB V in conjunction with Chapter 5, Sections 5 et seqq. of the Rules of Procedure (VerfO) of the G-BA has not been carried out. In accordance with Section 5, paragraph 8 AM-NutzenV, only the extent of the additional benefit is to be quantified indicating the significance of the evidence.

However, the restrictions on the benefit assessment of orphan drugs resulting from the statutory obligation to the marketing authorisation do not apply if the turnover of the medicinal product with the SHI at pharmacy sales prices and outside the scope of SHI-accredited medical care, including VAT exceeds € 30 million in the last 12 calendar months. In accordance with Section 35a, paragraph 1, sentence 12 SGB V, the pharmaceutical company shall provide evidence - within three months of being requested to do so by the G-BA - in accordance with Chapter 5, Section 5, paragraphs 1 to 6 VerfO, in particular regarding the additional medical benefit in relation to the appropriate comparator therapy specified by the G-BA in accordance with Chapter 5, Section 6 VerfO, and in this evidence, demonstrate the additional benefit over the appropriate comparator therapy.

In accordance with Section 35a, paragraph 2 SGB V, the G-BA decide whether to carry out the benefit assessment itself or to commission the Institute for Quality and Efficiency in Health Care (IQWiG). Based on the legal requirement in Section 35a, paragraph 1, sentence 11 SGB V that the additional benefit of an orphan drug is considered to be proven through the grant of the marketing authorisation, the G-BA modified the procedure for the benefit assessment of orphan drugs at their session on 15 March 2012 to the effect that, for orphan drugs, the G-BA initially no longer independently determine an appropriate comparator therapy as the basis for the solely legally permissible assessment of the extent of an additional benefit to be assumed by law. Rather, the extent of the additional benefit is assessed exclusively on the basis of the approval studies by the G-BA indicating the significance of the evidence.

Accordingly, at their session on 15 March 2012, the G-BA amended the mandate issued to the IQWiG by the resolution of 1 August 2011 for the benefit assessment of medicinal products with new active ingredients in accordance with Section 35a, paragraph 2 SGB V to that effect that, in the case of orphan drugs, the IQWiG is only commissioned to carry out a benefit assessment in the case of a previously defined comparator therapy when the sales volume of the medicinal product concerned has exceeded the turnover limit according to Section 35a, paragraph 1, sentence 12 SGB V and is therefore subject to an unrestricted benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment by the G-BA 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 G-BA 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 pegcetacoplan (Aspaveli) was listed for the first time on 1 April 2022 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

On 15 January 2026, pegcetacoplan 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).

Pegcetacoplan for the treatment of primary immune-complex membranoproliferative glomerulonephritis, ≥ 12 years is approved as a medicinal product for the treatment of rare diseases under Regulation (EC) No 141/2000 of the European Parliament and the Council of 16 December 1999.

In accordance with section 35a, paragraph 1, sentence 11, 1st half of the sentence SGB V, the additional benefit is considered to be proven through the grant of the marketing authorisation. The extent of the additional benefit and the significance of the evidence are assessed on the basis of the marketing approval studies by the G-BA.

On 11 February 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 submitted 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 of the Rules of Procedure (VerfO) of the G-BA on the active ingredient pegcetacoplan with the new therapeutic indication "Aspaveli is indicated for the treatment of adult and adolescent patients aged 12 to 17 years with primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN) in combination with a renin-angiotensin system (RAS) inhibitor, unless RAS inhibitor treatment is not tolerated or contraindicated".

The G-BA carried out the benefit assessment and commissioned the IQWiG to evaluate the information provided by the pharmaceutical company in Module 3 of the dossier on treatment costs and patient numbers. The benefit assessment was published on 15 May 2026 together with the IQWiG assessment on the G-BA website (www.g-ba.de), 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 dossier of the pharmaceutical company, the dossier assessment carried out by the G-BA, the assessment of treatment costs and patient numbers (IQWiG G26-04) 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 G-BA have assessed the studies relevant to the marketing authorisation on the basis of their therapeutic relevance (qualitative), in accordance with the criteria laid down in Chapter 5, Section 5, paragraph 7,

sentence 1, numbers 1 to 4 VerfO. The methodology proposed by the IQWiG in accordance with the General Methods [1] was not used in the benefit assessment of pegcetacoplan.

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

## 2.1 Additional benefit of the medicinal product

### 2.1.1 Approved therapeutic indication of pegcetacoplan (Aspaveli) in accordance with the product information

Aspaveli is indicated for the treatment of adult and adolescent patients aged 12 to 17 years with C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN) in combination with a renin-angiotensin system (RAS) inhibitor, unless RAS inhibitor treatment is not tolerated or contraindicated.

**Therapeutic indication of the resolution (resolution of 6 August 2026):**

Aspaveli is indicated for the treatment of adult and adolescent patients aged 12 to 17 years with primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN) in combination with a renin-angiotensin system (RAS) inhibitor, unless RAS inhibitor treatment is not tolerated or contraindicated.

### 2.1.2 Extent of the additional benefit and significance of the evidence

In summary, the additional benefit of pegcetacoplan is assessed as follows:
Hint of non-quantifiable additional benefit since the scientific data does not allow quantification.

Justification:

For the benefit assessment, the pharmaceutical company submitted evaluations from the phase III VALIANT study. This is a multicentre, randomised, placebo-controlled, double-blind study designed to investigate the safety and efficacy of pegcetacoplan in adult and adolescent patients 12 years of age and older with C3G or IC-MPGN.

Subjects aged 12 years and older with C3G or primary IC-MPGN (with or without a previous kidney transplant) were enrolled if they met the following criteria: body weight ≥ 30 kg, evidence of active disease, proteinuria ≥ 1 g/day determined by 24-hour urine sample collection or a uPCR ≥ 1.0 g/g in at least 2 first-morning urine (FMU) samples during screening, and an eGFR ≥ 30 ml/min/1.73 m². In addition, patients had been receiving a stable treatment regimen as concomitant medication for C3G or IC-MPGN for at least 12 weeks prior to randomisation. This concomitant medication included Renin-Angiotensin System (RAS) inhibitors (e.g. Angiotensin-Converting Enzyme [ACE] inhibitors, Angiotensin II Receptor Blockers [ARB]) and/or sodium-glucose cotransporter-2 (SGLT2) inhibitors and/or immunosuppressants (e.g. MMF, cyclophosphamide) and/or prednisone or systemic corticosteroids (e.g. prednisone) up to a maximum of 20 mg/day.

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

Subjects were excluded if they had C3G/IC-MPGN as a secondary condition, had shown improvement of the renal disease within eight weeks prior to or during screening, or had experienced a kidney transplant rejection reaction requiring treatment if a baseline kidney biopsy was available.

Subjects were randomised in a 1:1 ratio to receive either pegcetacoplan (N = 63) or placebo (N = 61). Stratification was by post-transplant recurrence (yes vs no) and baseline renal biopsy (yes vs no). The study sub-population with IC-MPGN is examined below: Pegcetacoplan (N = 12) and placebo (N = 16).

The study comprised a 10-week screening phase, a 26-week double-blind, placebo-controlled study phase, a 26-week open-label, single-arm study phase and an 8-week safety follow-up.

Mortality

Deaths were surveyed as part of the safety assessment. There were no deaths in the analysed sub-population.

Morbidity

*Change in renal function, measured by proteinuria*

The "change in renal function, measured by proteinuria" endpoint, operationalised mainly as the change in the log-transformed FMU-uPCR at week 26 compared with baseline, was assessed as the primary endpoint of the study.

The endpoint is a laboratory parameter without direct reference to symptoms. Within the G-BA, opinions differ as to whether proteinuria constitutes a patient-relevant endpoint per se. Proteinuria – together with eGFR – is a relevant parameter for therapy management in this therapeutic indication.

For the present benefit assessment procedure, the pharmaceutical company did not submit any suitable investigations to validate proteinuria as a surrogate for a patient-relevant endpoint. A final assessment of any surrogate validation of proteinuria can therefore not be made on the basis of the documents submitted in this procedure. The endpoint of proteinuria is therefore only presented additionally. There was a statistically significant difference in favour of pegcetacoplan over placebo.

*Change in renal function, measured by eGFR*

The "change in renal function, measured by eGFR" endpoint was operationalised in the study as the change in eGFR from baseline to week 26.
The endpoint is a laboratory parameter without direct reference to symptoms. Within the G-BA, opinions differ as to whether renal function measured by eGFR constitutes a patient-relevant endpoint per se. The eGFR – together with proteinuria – is a relevant parameter for therapy management in this therapeutic indication.

For the present benefit assessment procedure, the pharmaceutical company did not submit any suitable investigations to validate the eGFR as a surrogate for a patient-relevant endpoint. A final assessment of any surrogate validation of the eGFR can therefore not be made on the basis of the documents submitted in this procedure. The eGFR endpoint is therefore only presented additionally. There was no statistically significant difference between the treatment arms.

*Fatigue (FACIT-Fatigue, Peds FACIT-F)*

The "Fatigue" endpoint was assessed in the study using the FACIT-Fatigue questionnaire for adults and the Peds FACIT-F questionnaire for children and adolescents aged 12 to 17 years.

The "Functional Assessment of Chronic Illness Therapy – Fatigue Scale" (FACIT-Fatigue) is a fatigue-specific module of the "Functional Assessment of Chronic Illness Therapy Measurement System" (FACIT). The FACIT-Fatigue and the "Paediatric Functional Assessment of Chronic Illness Therapy – Fatigue" (Peds FACIT-F), designed for children aged 8 to 17 years, assess the intensity/quality (adult version) and frequency (paediatric version) of fatigue, as well as its impact on everyday activities and functioning over the past week, using 13 items in each case.

The data for this endpoint are not assessable due to low return rates, some of which vary considerably.

*WPAI:SHP (question 6)*

The "Work Productivity and Activity Impairment Questionnaire: Specific Health Problem" (WPAI:SHP) is a tool for the disease-specific assessment of self-reported impairments in working life among adults; it also includes a question on impairments affecting other daily activities. The questionnaire comprises six questions covering overall work productivity (5 questions) and limitations in daily activities (1 question) over the past 7 days.

It is a tool for measuring the impairment of work productivity and daily activities. Unlike the other 5 questions, the question on how the disease impairs daily activities (question 6) addresses a patient-relevant aspect.

The data for this endpoint are not assessable due to low return rates.

*EQ-5D VAS*

In the study, the self-rated general health status was assessed using the "European Quality of Life 5-Dimension 5-Level" (EQ-5D-5L) questionnaire. The EQ-5D-5L visual analogue scale (EQ-5D VAS) used measures the current health status on a scale from 100 ("best conceivable health status") to 0 ("worst conceivable health status").

The data for this endpoint are not assessable due to low return rates.

*PGI-C*

The aim of this version of the "Patient Global Impression of Change" (PGIC) in the study is to assess the patient-reported change in general health status since the start of treatment.

Regardless of the suitability of the operationalisation, the return rates are too low, and the data for this endpoint are therefore not assessable.

<u>Quality of life</u>

*KDQOL-36*

The study used the "Kidney Disease Quality of Life Instrument – 36 items" (KDQOL-36; version 1) to assess quality of life. The KDQOL-36 comprises 24 disease-specific questions relating to

renal disease and 12 questions from the generic "SF-12 Health Survey" (SF-12). The disease-specific part of the questionnaire covers three of the eight domains of the KDQOL-SF:

- Symptoms and problems (12 items)
- Renal disease burden (4 items)
- Effects of renal disease on daily life (8 items)

The SF-12, as the generic part of the questionnaire, consists of the following two domains:

- Physical Component Summary (PCS) with 5 subdomains (7 items)
- Mental Component Summary (MCS) with 3 subdomains (5 items)

The data for this endpoint are not assessable as the percentage of subjects included in the analysis at week 26 was 41.7% (pegcetacoplan arm) and 81.3% (placebo arm).

Side effects

*Serious AEs (SAEs), severe AEs*

For the endpoints of SAEs and severe AEs, there was no statistically significant difference between the treatment arms in either case.

*Therapy discontinuation due to AEs*

There was no therapy discontinuation due to AEs in any of the treatment arms.

Overall assessment

Results from the randomised, double-blind VALIANT study, which compared pegcetacoplan with placebo, are available for the benefit assessment of pegcetacoplan in the treatment of adults and adolescents aged 12 to 17 years with IC-MPGN.

There were no deaths in the analysed sub-population.

The data on the endpoint categories of morbidity and quality of life are not assessable due to the very low and partly highly variable return rates.

In the endpoint category of side effects, neither advantages nor disadvantages of pegcetacoplan compared with placebo can be identified overall.

In the overall assessment of the available results on the patient-relevant endpoints, the G-BA classify the extent of the additional benefit of pegcetacoplan for the treatment of adults and adolescents aged 12 to 17 years with IC-MPGN on the basis of the criteria in Section 5, paragraph 8 in conjunction with Section 5, paragraph 7, sentence 1, numbers 1 to 4 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) as non-quantifiable since the scientific data does not allow quantification.

Significance of the evidence

This assessment is based on the results of the double-blind, randomised, placebo-controlled phase III VALIANT study.

The risk of bias is assessed as high at the study level. This is attributable to uncertainties regarding baseline imbalances, combined with the post hoc division into two sub-populations without stratification.

In the overall assessment, the significance of the evidence is categorised as a "hint" due to the uncertainties mentioned.

### 2.1.3 Summary of the assessment

The present assessment is the benefit assessment of a new therapeutic indication for the active ingredient pegcetacoplan. Aspaveli was approved under "exceptional circumstances" as an orphan drug. The new approved therapeutic indication is: "for the treatment of adult and adolescent patients aged 12 to 17 years with C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN)". This assessment covers only patients with IC-MPGN.

The benefit assessment is based on the results of the double-blind, randomised controlled trial VALIANT, which compared pegcetacoplan with placebo.

There were no deaths in the analysed sub-population.

No assessable data on the endpoint category of morbidity are available to determine an additional benefit. With regard to the endpoints presented additionally, a statistically significant difference in favour of pegcetacoplan was observed for the "proteinuria" endpoint, whereas no statistically significant differences were observed for the "eGFR" endpoint. These are laboratory parameters that have not undergone surrogate validation but are relevant for therapy management.

No assessable data were available in the endpoint category of health-related quality of life.

For the endpoints of severe or serious adverse events in the side effects category, there were no relevant differences for the benefit assessment. There were no cases of therapy discontinuation due to AEs in the study.

The risk of bias at the study level is considered high as there are uncertainties, in particular, regarding baseline imbalances, combined with the post-hoc division into two sub-populations without stratification. The significance of the data presented is therefore subject to uncertainty overall.

The overall assessment leads to a hint of non-quantifiable additional benefit of pegcetacoplan for the treatment of adults and adolescents aged 12 to 17 years with IC-MPGN since the scientific data does not allow quantification.

## 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 take into account the patient numbers stated in the pharmaceutical company's dossier, which are, however, subject to uncertainty due to various methodological aspects. Uncertainties also arise from the inclusion of patients with other glomerular diseases and from the unclear exclusion of potentially relevant patients who do not have an OPC code for a renal biopsy. Therefore, both the lower and upper limits are assessed as uncertain overall.

## 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 Aspaveli (active ingredient: pegcetacoplan) at the following publicly accessible link (last access: 12 March 2026):

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

Treatment with pegcetacoplan must be initiated and monitored by specialists who are experienced in the treatment of patients with renal diseases.

In accordance with the European Medicines Agency (EMA) requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material that contains information for medical professionals and patients (incl. patient identification card). The training material contains, in particular, informations and warnings of the increased risk of infection with encapsulated bacteria associated with the use of pegcetacoplan.

## 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 June 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.

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 | | | | |
| Pegcetacoplan | Continuously, 2 x every 7 days | 104.3 | 1 | 104.3 |

Consumption:

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.

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.

For dosages depending on body weight (BW) or body surface area (BSA), the average body measurements from the official representative statistics "2025 Microcensus – body measurements of the population" were applied (average body weight of 12-year-olds: 48.7 kg)[2].

| 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 | | | | | |
| Pegcetacoplan (12-year-olds) - | 810 mg - | 810 mg - | 1 x 810 mg – | 104.3 | 104.3 x 810 mg - |
| Pegcetacoplan (adults) | 1,080 mg | 1,080 mg | 1 x 1,080 mg | 104.3 | 104.3 x 1,080 mg |

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

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.

**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 | | | | | |
| Pegcetacoplan 1,080 mg | 8 INF | € 29,481.74 | € 1.77 | € 1,683.11 | € 27,796.86 |
| Abbreviations: INF = infusion solution | | | | | |

LAUER-TAXE® last revised: 1 June 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.

## 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 11 February 2026, the pharmaceutical company submitted a dossier for the benefit assessment of pegcetacoplan to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 2 VerfO.

The benefit assessment of the G-BA was published on 15 May 2026 together with the IQWiG assessment of treatment costs and patient numbers on the G-BA website (www.g-ba.de) together with IQWiG's assessment of treatment costs and

patient numbers, thus initiating the written statement procedure. The deadline for submitting written statements was 5 June 2026.

The oral hearing was held on 22 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 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 28 July 2026, and the draft resolution was conclusively discussed.

At their session on 6 August 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

**Chronological course of consultation**

| Session | Date | Subject of consultation |
|---|---|---|
| Subcommittee on Medicinal Products | 12 May 2026 | Information of the benefit assessment of the G-BA |
| Working group Section 35a | 16 June 2026 | Information on written statements received; preparation of the oral hearing |
| Subcommittee on Medicinal Products | 22 June 2026 | Conduct of the oral hearing |
| Working group Section 35a | 1 July 2026<br>15 July 2026 | Consultation on the dossier evaluation by the G-BA, the assessment of treatment costs and patient numbers by the IQWiG, and the evaluation of the written statement procedure |
| Subcommittee on Medicinal Products | 28 July 2026 | Concluding discussion of the draft resolution |
| Plenum | 6 August 2026 | Adoption of the resolution on the amendment of the Pharmaceuticals Directive |

Berlin, 6 August 2026

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

Dr Optendrenk