Gemeinsamer Bundesausschuss

Justification

of 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
Faricimab (Neovascular age-related macular degeneration)

of 6 April 2023

Contents

1. Legal basis

According to Section 35a paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assesses the benefit of 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 G-BA electronically, including all clinical trials the pharmaceutical company has 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 G-BA 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 G-BA decides on the benefit assessment within three months of its publication. The resolution is to be published online 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 faricimab on 15 October 2022 in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 of the Rules of Procedure (VerfO) of the G-BA. The pharmaceutical company submitted the final dossier to the G-BA in accordance with 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 VerfO on 13 October 2022.

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 16 January 2023 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 came to a resolution on whether an additional benefit of faricimab 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 G-BA has 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 faricimab.

In the light of the above, and taking into account the statements received and the oral hearing, the G-BA has come to 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 Faricimab (Vabysmo) in accordance with the product information

Vabysmo is indicated for the treatment of adult patients with:

- neovascular (wet) age-related macular degeneration (nAMD),
- visual impairment due to diabetic macular oedema (DME).

Therapeutic indication of the resolution (resolution of 6 April 2023):

Vabysmo is indicated for the treatment of adult patients with neovascular (wet) age-related macular degeneration (nAMD).

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

<u>Adults with neovascular (wet) age-related macular degeneration (nAMD)</u>

Appropriate comparator therapy for faricimab:

- Aflibercept or ranibizumab

<u>Criteria according to Chapter 5, Section 6 of the Rules of Procedure of the G-BA:</u>

The appropriate comparator therapy must be an appropriate therapy in the therapeutic indication in accordance with 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.

1 General Methods, version 6.1 from 24.01.2022. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

3. As comparator therapy, medicinal products or non-medicinal treatments for which the patient-relevant benefit has already been determined by the G-BA 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.

Justification based on the criteria set out in Chapter 5, Section 6, paragraph 3 VerfO:

on 1. In addition to the marketing authorisation for faricimab, there is also a marketing authorisation for aflibercept, brolucizumab and ranibizumab in the present therapeutic indication. The active ingredient verteporfin is approved for the "treatment of adults with exudative (wet) age-related macular degeneration (AMD) with predominantly classic subfoveal choroidal neovascularisation". Pegaptanib is no longer approved in the EU.

on 2. The following non-medicinal treatment options are available in the present therapeutic indication: Photodynamic therapy (PDT), photocoagulation by laser, proton therapy for age-related macular degeneration (resolution of 17 September 2009) and photodynamic therapy (PDT) with verteporfin for age-related wet macular degeneration with subfoveolar classic choriodal neovascularisation (resolution of 21 February 2006).

on 3. The following resolutions of the G-BA on the benefit assessment according to Section 35a SGB V are available for the present therapeutic indication:
- Aflibercept (resolution of 6 June 2013)
- Brolucizumab (resolution of 3 September 2020)

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 therapeutic indication. 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.

Based on the aggregated evidence, it can be stated that according to the guideline recommendations, the standard therapy for the targeted treatment setting consists of treatment with a *vascular endothelial growth factor* (VEGF) inhibitor, without a clear superiority of a specific inhibitor available in Germany being shown. Aflibercept, brolucizumab and ranibizumab are approved in the relevant therapeutic indication.

No data were available for brolucizumab in the benefit assessment according to Section 35a SGB V. An additional benefit compared to the appropriate comparator therapy is not proven. In addition, against the background of an ongoing, direct comparator study, a reassessment of brolucizumab versus a VEGF inhibitor is currently still pending. Therefore, the significance of brolucizumab cannot be assessed, so that overall, in the view of the G-BA, brolucizumab cannot be considered as an appropriate comparator therapy.

The significance of non-medicinal interventions is considered lower than the VEGF inhibitors established in neovascular (wet) AMD against the background of the aggregated evidence in the indication.

On the basis of the available aggregated evidence and on the basis of the authorisation status, the G-BA considers it justified to specify aflibercept or ranibizumab as the appropriate comparator therapy for the treatment of adults with neovascular (wet) AMD.

The appropriate comparator therapy determined here includes several therapeutic alternatives. These therapeutic alternatives are equally appropriate for the comparator therapy.

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

A change in the appropriate comparator therapy requires a resolution by the G-BA linked to the prior review of the criteria according to Chapter 5, Section 6, paragraph 3 Rules of Procedure.

2.1.3 Extent and probability of the additional benefit

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

For adults with neovascular (wet) age-related macular degeneration (nAMD), the additional benefit of faricimab is not proven.

Justification:

No assessable data are available for the assessment of the additional benefit of faricimab compared with the appropriate comparator therapy.

The pharmaceutical company identifies the two randomised controlled trials (RCT) TENAYA and LUCERNE in the present therapeutic indication. Both studies are double-blind, multicentre RCTs comparing faricimab versus aflibercept in patients aged 50 years and older with neovascular age-related macular degeneration.

According to the product information, therapy with aflibercept should be initiated with 3 consecutive monthly injections. Subsequently, the treatment interval should be extended to 2 months. Based on the functional and/or morphological findings, the 2-month treatment interval can be maintained or further extended in 2 to 4-week increments according to a "*Treat and Extend*" dosing scheme on a patient-individual basis or shortened accordingly in case of deterioration.

In the TENAYA and LUCERNE studies, aflibercept was administered after initiation with 3-monthly injections according to a fixed schedule every 8 weeks over a total study period of 2 years. The individual adjustment of the treatment interval envisaged by the product information was thus not possible in the comparator arms of the studies. In the intervention arm, on the contrary, a flexible dosing scheme with patient-individual treatment intervals of up to 16 weeks, depending on disease activity, was used in both studies according to the faricimab product information 20 or 24 weeks after treatment initiation.

As the flexibilisation, which is possible according to the product information for aflibercept, was not provided for in either study, both studies are not considered for the present benefit assessment due to the resulting inequality between the treatment arms, in accordance with the pharmaceutical company's approach in the dossier.

2.1.4 Summary of the assessment

The present assessment concerns the benefit assessment of the new medicinal product Vabysmo with the active ingredient faricimab.

Faricimab is used to treat adults with neovascular (wet) age-related macular degeneration (nAMD).

The G-BA determined aflibercept or ranibizumab as the appropriate comparator therapy.

For the assessment of the additional benefit, the pharmaceutical company presents the two RCTs TENAYA and LUCERNE, in each of which faricimab was compared with aflibercept.

In both studies, aflibercept was administered after initiation with 3-monthly injections according to a fixed schedule every 8 weeks over a total study period of 2 years. In the intervention arm, on the contrary, a flexible dosing scheme with patient-individual treatment intervals of up to 16 weeks was used in both studies in accordance with the product information of faricimab. As the flexibilisation, which is possible according to the product information for aflibercept, was not provided for in either study, both studies are not considered for the present benefit assessment due to the resulting inequality between the treatment arms, in accordance with the pharmaceutical company's approach in the dossier.

An additional benefit of faricimab compared to the appropriate comparator therapy is therefore not proven.

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 patient numbers presented by the pharmaceutical company in the dossier are subject to uncertainties. Despite the methodological weaknesses, the wider range in the previous procedure in the same therapeutic indication for the active ingredient brolucizumab seems more appropriate to account for the existing uncertainty. The resolution is therefore not based on the figures presented in the dossier, but on the figures from the resolution on brolucizumab of 3 September 2020 in the same therapeutic indication.

The derivation of the patient numbers in the dossier for the active ingredient brolucizumab is basically comprehensible and lies in a plausible order of magnitude. Due to the uncertain data basis for the estimation of the SHI target population, the specification of a range is fundamentally appropriate despite methodological weaknesses and thus takes this uncertainty into account.

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 Vabysmo (active ingredient: faricimab) at the following publicly accessible link (last access: 17 January 2023):

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

Treatment with faricimab should only be initiated and monitored by doctors experienced in the therapy of neovascular (wet) age-related macular degeneration.

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 patients. In particular, the training material contains information and warnings about infective endophthalmitis and intraocular inflammation.

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 March 2023).

In the present case, the treatment duration, consumption and costs shown refer to the first year of treatment on the one hand and to the subsequent years on the other; whole injection solutions consumed within the first year were rounded up for the first year of treatment.

In the present case, the treatment duration, consumption and costs shown refer to the first year of treatment on the one hand and to the subsequent years on the other.

Due to the possible patient-individual approach regarding the adjustment of the treatment intervals according to the product information, the possible upper and lower limits of the costs are presented in the present resolution for the following years.

Patient-individual dose adjustments, e.g. because of side effects or comorbidities, are not taken into account when calculating the annual treatment costs.

On faricimab: According to the specifications in the product information, the treatment is initiated with four injections at intervals of 4 weeks. After 20 and/or 24 weeks, a treatment check-up is suggested, on the basis of which the physician can individually determine the treatment intervals based on the disease activity. In patients without disease activity, administering faricimab every 16 weeks is to be considered. For patients with disease activity, treatment every 8 weeks or 12 weeks is to be considered.

On aflibercept: Treatment with aflibercept is initiated with three consecutive monthly injections; followed by a treatment interval of two months. Subsequently, this treatment interval can be maintained or extended in a "Treat & Extend" dosing scheme in 2 or 4-week increments. Treatment intervals longer than 4 months were not investigated. This has no effect on the cost calculation, as prolongation of the dosing interval beyond 4 months is still possible according to the product information. If the functional and/or morphological findings deteriorate, the treatment interval should be shortened accordingly. Treatment intervals below 4 weeks were not studied. To calculate the upper limit of treatments, the 2-month treatment interval achieved according to the fixed initial scheme is taken as a basis.

On ranibizumab: Treatment in adults starts with one injection per month until maximum visual acuity is achieved and/or there are no more signs of disease activity. Initially, three or more injections may be necessary. Finally, patients can be treated according to a "treat & extend" regimen, whereby the treatment interval can be extended by up to 2 weeks at a time.

The information on treatment costs refers to the application on one eye. Treatment of the second eye is possible.

<u>Treatment period:</u>

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 varies 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 the maximum treatment duration, if specified in the product information.

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Faricimab 1st year	1 x every 28 days for 4 applications	4	1	7.0 - 9.0
	then, 1 x after 28 days and every 56 days thereafter up to then, 1 x after 56 days and every 112 days thereafter	5 - 3		
Faricimab Subsequent years	Then, every 56 to 112 days	6.5 - 3.3	1	3.3 - 6.5
Appropriate comparator therapy				
aflibercept 1st year	1 x monthly[2] for 3 applications and 1 x every 2 months[2] for an application,	3 1	1	6.0 - 7.0
	Then, 1 x every 2 months[2] until Treat & Extend (30.4 days)[3]	3 - 2		
aflibercept Subsequent years	1 x every 2 months[2] until Treat & Extend (30.4 days)[3]	6 - 0	1	0 - 6.0
Ranibizumab 1st year	1 x monthly[2] for 3 applications,	3	1	6.0 - 12.0
	Then, 1 x monthly[2] until Treat & Extend (30.4 days)[4]	9 - 3		
Ranibizumab subsequent years	1 x monthly[2] until Treat & Extend (30.4 days)[4]	12 - 0	1	0 - 12.0

[2] One month corresponds to 30.4 days.
[3] To calculate the lower limit: The treatment interval is prolonged by one month for each treatment.
[4] To calculate the lower limit: The treatment interval is prolonged by half a month for each treatment.

Consumption:

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed					
Faricimab 1st year	6 mg	6 mg	1 x 6 mg	7.0 - 9.0	7.0 x 6 mg - 9.0 x 6 mg
Faricimab Subsequent years	6 mg	6 mg	1 x 6 mg	3.3 - 6.5	3.3 x 6 mg - 6.5 x 6 mg
Appropriate comparator therapy					
Aflibercept 1st year	2 mg	2 mg	1 x 2 mg	6.0 - 7.0	6.0 x 2 mg - 7.0 x 2 mg
Aflibercept Subsequent years	2 mg	2 mg	1 x 2 mg	0 - 6.0	0 x 2 mg - 6.0 x 2 mg
Ranibizumab 1st year	0.5 mg	0.5 mg	1 x 0.5 mg	6.0 - 12.0	6.0 x 0.5 mg - 12.0 x 0.5 mg
Ranibizumab subsequent years	0.5 mg	0.5 mg	1 x 0.5 mg	0 - 12.0	0 x 0.5 mg - 12.0 x 0.5 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.

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					
Faricimab	1 SFI	€ 1,136.52	€ 2.00	€ 106.80	€ 1,027.72
Appropriate comparator therapy					
Aflibercept	1 SFI	€ 1,099.38	€ 2.00	€ 103.28	€ 994.10
Ranibizumab	1 SFI	€ 1,263.26	€ 2.00	€ 118.83	€ 1,142.43
Abbreviations: SFI = solution for injection					

LAUER-TAXE® last revised: 15 March 2023

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.

Additionally required SHI services when using the medicinal product to be assessed and the appropriate comparator therapy according to the product information and package information leaflet are given by the treatment costs of the intravitreal injections and the necessary postoperative checks.

All three active ingredients are applied by intravitreal injection. For intravitreal injections, GOPs of the EBM are available [GOP 31371 / 36371 (right eye), GOP 31372 / 36372 (left eye) or GOP 31373 / 36373 (both eyes)].

Visual acuity checks are included in the basic specialist flat rate.

The product information for faricimab, aflibercept and ranibizumab recommends setting the treatment interval based on disease activity as determined by morphological parameters and/or visual acuity or functional findings.

The check-up interval should be determined by the attending physician, this can be more frequent than the injection interval.

Costs are incurred for the check-ups carried out for all treatment options. Among others, there are GOPs of the EBM for optical coherence tomography (OCT) for therapy control [GOP 06338 (right eye) or GOP 06339 (left eye)]. The frequency and type of examination used can vary from patient to patient. Due to the individual specification of the control intervals by the attending physician, the costs incurred cannot be quantified.

Type of service	Cost/ service	Number/ year	Cost/ year
Medicinal product to be assessed			
Faricimab			
Intravitreal administration of the medicinal product to the left or right eye (EBM 31372/ 36372 or 31371/ 36371)	€ 89.40 - € 191.33	1st year: 7 - 9 Subsequent years: 3.3 - 6.5	1st year: € 625.80 - € 1,721.97 Subsequent years: € 295.02 - € 1,243.65
Postoperative treatment (EBM 31717 or 31716)	€ 19.19 - € 26.78	1st year: 7 - 9 Subsequent years: 3.3 - 6.5	1st year: € 134.33 - € 241.02 Subsequent years: € 63.33 - € 174.07
Optical coherence tomography (EBM 06338 or 06339)	€ 46.43	Varies from patient to patient	non-quantifiable

Type of service	Cost/ service	Number/ year	Cost/ year
Further check-ups	non-quantifiable	Varies from patient to patient	non-quantifiable
Appropriate comparator therapy			
Aflibercept			
Intravitreal administration of the medicinal product to the left or right eye (EBM 31372/ 36372 or 31371/ 36371)	€ 89.40 - € 191.33	1st year: 6 - 7 Subsequent years: 0 - 6	1st year: € 536.40 - € 1,339.31 Subsequent years: € 0 - € 1,147.98
Postoperative treatment (EBM 31717 or 31716)	€ 19.19 - € 26.78	1st year: 6 - 7 Subsequent years: 0 - 6	1st year: € 115.14 - € 187.46 Subsequent years: € 0 - € 160.68
Optical coherence tomography (EBM 06338 or 06339)	€ 46.43	Varies from patient to patient	non-quantifiable
Further check-ups	non-quantifiable	Varies from patient to patient	non-quantifiable
Ranibizumab			
Intravitreal administration of the medicinal product to the left or right eye (EBM 31372/ 36372 or 31371/ 36371)	€ 89.40 - € 191.33	1st year: 6 - 12 Subsequent years: 0 - 12	1st year: € 536.40 - € 2,295.96 Subsequent years: € 0 - € 2,295.96
Postoperative treatment (EBM 31717 or 31716)	€ 19.19 - € 26.78	1st year: 6 - 12 Subsequent years: 0 - 12	1st year: € 115.14 - € 321.36 Subsequent years: € 0 - € 321.36
Optical coherence tomography (EBM 06338 or 06339)	€ 46.43	Varies from patient to patient	non-quantifiable
Further check-ups	non-quantifiable	Varies from patient to patient	non-quantifiable

2.5 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 Faricimab

According to Section 35a, paragraph 3, sentence 4, the Federal Joint Committee shall 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.

In accordance with Section 2, paragraph 1, sentence 1 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), only medicinal products containing active ingredients whose effects are not generally known in medical science at the time of initial marketing authorisation are to be considered within the framework of the designation of medicinal products with new active ingredients that can be used in a combination therapy. According to Section 2, paragraph 1, sentence 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), a medicinal product with a new active ingredient is considered to be a

medicinal product with a new active ingredient for as long as there is dossier protection for the medicinal product with the active ingredient that was authorised for the first time.

The designation of the combination therapies is based solely on the specifications according to Section 35a, paragraph 3, sentence 4. The G-BA does not conduct a substantive review based on the generally recognised state of medical knowledge. Thus, the designation is not associated with a statement as to the extent to which a therapy with the designated medicinal product with new active ingredient in combination with the medicinal product to be assessed corresponds to the generally recognised state of medical knowledge.

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 its session on 7 April 2021, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 13 October 2022, the pharmaceutical company submitted a dossier for the benefit assessment of faricimab to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 VerfO.

By letter dated 14 October 2022 in conjunction with the resolution of the G-BA 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 G-BA commissioned the IQWiG to assess the dossier concerning the active ingredient faricimab.

The dossier assessment by the IQWiG was submitted to the G-BA on 12 January 2023, and the written statement procedure was initiated with publication on the G-BA website on 16 January 2023. The deadline for submitting written statements was 6 February 2023.

The oral hearing was held on 20 February 2023.

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 session of the subcommittee on 28 March 2023, and the proposed resolution was approved.

At its session on 6 April 2023, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	7 April 2021	Determination of the appropriate comparator therapy
Working group Section 35a	15 February 2023	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	20 February 2023	Conduct of the oral hearing
Working group Section 35a	1 March 2023 15 March 2023 22 March 2023	Consultation on the dossier assessment by the IQWiG, assessment of the written statement procedure
Subcommittee on Medicinal Products	28 March 2023	Concluding discussion of the draft resolution
Plenum	6 April 2023	Adoption of the resolution on the amendment of Annex XII AM-RL

Berlin, 6 April 2023

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

Prof. Hecken