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 Anifrolumab (systemic lupus erythematosus)

of 6 October 2022

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 on the internet and forms part of the Pharmaceuticals Directive.

2. Key points of the resolution

The relevant date for the first placing on the (German) market of the active ingredient anifrolumab in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 of the Rules of Procedure of the G-BA (VerfO) is 1 April 2022. 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 24 March 2022.

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on the website of the G-BA (www.g-ba.de) on 1 July 2022, 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 anifrolumab 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, the statements

submitted in the written statement and oral hearing procedure, and the addendum to the benefit assessment prepared by IQWiG. 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 anifrolumab.

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 Anifrolumab (Saphnelo) according to product information

Saphnelo is indicated as an add-on therapy for the treatment of adult patients with moderate to severe, active autoantibody-positive systemic lupus erythematosus (SLE), despite standard therapy.

Therapeutic indication of the resolution (resolution of 15 September 2022):

See therapeutic indication according to marketing authorisation.

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Adults with moderate to severe, active autoantibody-positive systemic lupus erythematosus (SLE), despite standard therapy

Appropriate comparator therapy for anifrolumab as add-on therapy:

- Belimumab

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

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.

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

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 (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. For the treatment of systemic lupus erythematosus (SLE), non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, indomethacin), systemic glucocorticoids, azathioprine, anti-malarial active ingredients (chloroquine and hydroxychloroquine) and belimumab may be used.

on 2. A non-medicinal treatment is unsuitable in the therapeutic indication.

on 3. In the therapeutic indication under consideration here, the following resolutions of the G-BA are available:

Belimumab (resolution according to Section 35a SGB V of 02.08.2012)

on 4. The generally recognised state of medical knowledge on which the resolution of the G-BA is based, was illustrated by a systematic search for guidelines as well as 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 originally presented therapeutic indication according to Section 35a paragraph 7 SGB V.

The evidence search revealed that no uniform therapy algorithm exists now. Patients with SLE are treated on a patient-individual basis, taking into account the affected organ, any prior therapy and the prevailing disease activity.

Patients are usually first put on optimised treatment with glucocorticoids, antimalarials (hydroxychloroquine and chloroquine) followed by symptomatic treatment with NSAIDs. Immunosuppressants (such as azathioprine) are used in case of an inadequate response to glucocorticoids. Belimumab is indicated as an add-on therapy in case of persistent high disease activity (e.g., positive test for anti-dsDNA antibodies and low complement) despite standard therapy. Belimumab should be used upon failure of standard or conventional therapy (hydroxychloroquine, chloroquine, non-steroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, azathioprine).

Change of the appropriate comparator therapy

Originally, the appropriate comparator therapy was determined as patient-individual standard therapy according to the wording of the German marketing authorisation "for the treatment of adult patients with moderate to severe, active autoantibody-positive systemic lupus erythematosus (SLE), who have already been receiving a standard therapy". After the product was placed on the market, the competent national regulatory authority (PEI) was contacted due to the deviating English wording of the original marketing authorisation "for the treatment of adult patients with moderate to severe, active autoantibody-positive systemic lupus erythematosus (SLE), despite

standard therapy". Taking into account the EPAR and the feedback from the PEI, it is clear that the present treatment setting relates to a failure of standard therapy and it is to be assessed in the line of therapy analogous to the therapeutic indication of belimumab.

Since the planned therapeutic indication exclusively involves patients who have active SLE despite standard therapy, belimumab is determined as the appropriate comparator therapy. In this treatment setting, a continuation of an inadequate therapy is not appropriate and therefore does not correspond to the specific appropriate comparator therapy.

Belimumab is given in addition to standard therapy. In principle, it is assumed that the possibility of a patient-individual standard therapy is used for all patients, taking into account the affected organ, the prior therapy and the disease activity. The following active ingredients can be used for this purpose: Hydroxychloroquine, chloroquine, non-steroidal anti-inflammatory drugs (NSAIDs), glucocorticoids and azathioprine.

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

2.1.3 Extent and probability of the additional benefit

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

The additional benefit is not proven for adults with moderate to severe, active autoantibody-positive systemic lupus erythematosus (SLE), despite standard therapy.

Justification:

For adults with chronic, moderate to severe autoantibody-positive systemic lupus erythematosus (SLE), despite standard therapy, there are no direct comparator studies of anifrolumab versus belimumab as an appropriate comparator therapy. The pharmaceutical company therefore presents three adjusted indirect comparisons via the bridge comparator placebo + standard therapy. For anifrolumab, it draws on the TULIP-1, TULIP-2 and MUSE studies. On the side of the comparator therapy belimumab, the pharmaceutical company includes the BLISS-52 and BLISS-76 studies.

The TULIP-1, TULIP-2 and MUSE studies are pivotal, double-blind, randomised, 52-week studies comparing anifrolumab as add-on therapy to standard therapy with placebo + standard therapy in adults with chronic, moderate to severe autoantibody-positive SLE according to ACR criteria[2] under stable previous therapy. Inclusion criteria for screening were a SLEDAI-2K score[3] ≥ 6, a "clinical" SLEDAI-2K score ≥ 4, a BILAG-2004[4] A assessment in ≥ 1 organ system(s) or BILAG-2004 B assessment in ≥ 2 organ systems, and a PGA[5] ≥ 1.0. The prior therapy consisted of at least one preparation or a combination of antimalarials, immunosuppressants or oral corticosteroids.

[2] American College of Rheumatology

[3] Systemic Lupus Erythematosus Disease Activity Index – Revised Version

[4] British Isles Lupus Assessment Group 2004

[5] Physician's Global Assessment

The BLISS-52 and BLISS-76 studies are pivotal, double-blind, randomised studies with 52-week and 76-week treatment durations, respectively, comparing belimumab as add-on therapy to standard therapy in adults with SLE according to ACR criteria. The inclusion criteria for screening were a SELENA-SLEDAI score[6] ≥ 6, positive antinuclear and/or anti-dsDNA antibodies at 2 different time points and stable basic therapy ≥ 30 days prior to randomisation.

The pharmaceutical company submits a total of three adjusted indirect comparisons that include the same studies on the intervention and comparison side, but differ in the respective study populations enrolled.

In the first adjusted indirect comparison, the pharmaceutical company uses the total populations of the studies with anifrolumab (meta-analysis of the TULIP-1, TULIP-2 and MUSE studies) and the studies with belimumab (meta-analysis of the BLISS-52 and BLISS-76 studies). However, the total population of the belimumab studies is not restricted to the patient population of the approved therapeutic indication of belimumab (high disease activity, e.g., positive test for anti-dsDNA antibodies and low complement). In addition, the standard therapy in all five studies of this indirect comparison also contains active ingredients that are not approved for the treatment of SLE in Germany. In addition, the study pool on the comparator side is potentially incomplete, as further studies are available when taking into account the total population (no limitations regarding concomitant medication approved in Germany as well as disease activity based on serological markers).

In the second adjusted indirect comparison, the pharmaceutical company uses the sub-population of patients who have only received medicinal products approved in Germany on the intervention side and the sub-population of patients who have only received medicinal products approved in Germany and have high disease activity (anti-ds-DNA-AK positive, low complement C3/C4) on the comparison side.
In the third adjusted indirect comparison, the pharmaceutical company uses the sub-population of patients who have only received medicinal products approved in Germany and have high disease activity (anti-ds-DNA-AK positive, low complement C3/C4) on both the intervention and comparison sides.
For both the second and the third adjusted indirect comparison, there is no sufficient similarity between the sub-populations considered, especially with regard to patient characteristics. On the one hand, a significant difference can be observed in the percentage of patients with 1 BILAG A or 2 BILAG B assessments. On the other hand, patients in the studies with anifrolumab predominantly show organ manifestations, whereas patients in the studies with belimumab are more characterised by serologically active disease. In addition, there are differences in the duration of the disease and the ancestry of the patients. The differences in the duration of the disease are even more pronounced in the third adjusted indirect comparison; in addition, further differences in the SLEDAI and PGA scores are shown here.
There are also differences in the study characteristics. The guidelines for standard therapy were significantly more restrictive in the studies with anifrolumab than in the studies with belimumab. The PGA score and BILAG A or BILAG B assessments were defined as inclusion criteria in the anifrolumab studies only. The differences in the versions of the SLEDAI (SLEDAI-2K vs SELENA-SLEDAI) and BILAG (2004 vs classic) used in the anifrolumab and belimumab studies should also be noted.

Conclusion

[6] Safety of Oestrogens in Lupus Erythematosus National Assessment – Systemic Lupus Erythematosus Disease Activity Index

In the overall assessment, the three adjusted indirect comparisons presented are considered unsuitable for the assessment of the additional benefit of anifrolumab compared to the appropriate comparator therapy.

The first adjusted indirect comparison is not suitable for deriving conclusions on the additional benefit of anifrolumab, in particular due to the lack of restriction to the approved therapeutic indication of belimumab on the comparison side, the use of active ingredients not approved in Germany for the treatment of SLE in the context of standard therapy, and the incomplete study pool. The sub-populations of the studies considered in the second and third adjusted indirect comparisons are not sufficiently similar with regard to the study characteristics and especially with regard to the patient characteristics to derive conclusions on the additional benefit of anifrolumab on the basis of these comparisons.

Therefore, no data relevant for the benefit assessment of anifrolumab are available, so an additional benefit is not proven.

2.1.4 Summary of the assessment

The present assessment concerns the benefit assessment of the new medicinal product Saphnelo with the active ingredient anifrolumab. Anifrolumab is approved as an add-on therapy for the treatment of adult patients with moderate to severe, active autoantibody-positive systemic lupus erythematosus (SLE), despite standard therapy.

The G-BA determined belimumab as appropriate comparator therapy.

Due to the lack of direct comparator studies, the pharmaceutical company submits three adjusted indirect comparisons with placebo + standard therapy as a bridge comparator for the benefit assessment. For anifrolumab, it draws on the TULIP-1, TULIP-2 and MUSE studies. On the side of the comparator therapy belimumab, the pharmaceutical company includes the BLISS-52 and BLISS-76 studies.

However, the three adjusted indirect comparisons presented are not suitable for deriving conclusions about the additional benefit of anifrolumab compared to belimumab. In the first adjusted indirect comparison, it has not been restricted to the approved therapeutic indication of belimumab on the comparison side, the standard therapy used contains active ingredients not approved in Germany for the treatment of SLE and the study pool is incomplete. In the second and third adjusted indirect comparisons, the sub-populations considered are not sufficiently similar in terms of study characteristics and especially in terms of patient characteristics.

Therefore, no data relevant for the benefit assessment of anifrolumab are available, so an additional benefit is not proven.

2.2 Number of patients or demarcation of patient groups eligible for treatment

The number of patients is the target population in statutory health insurance (SHI). The information is based on the pharmaceutical company's data from the dossier, taking into account the latest dossier assessment[7] in the therapeutic indication of belimumab for adults with systemic lupus erythematosus.

Uncertainties in the range given by the pharmaceutical company exist on the one hand with regard to the unclear change in prevalence in the past 20 years, as the prevalence data originate from 2002. In addition, there are uncertainties regarding the percentage values for disease activity (chronically active, relapsing-remitting or mild course) as well as the percentage values for disease severity (moderate to severe SLE), which vary depending on the operationalisation using M-SLEDAI or PGA and are based on data from 1987 to 2014.

As both the range given by the pharmaceutical company for anifrolumab (4,819 to 18,473 patients) and the range estimated in the dossier assessment of belimumab (4,600 to 14,800 patients) are subject to uncertainty, the uncertainty can be partially accounted for in the absence of further data by estimating a total range of approximately 4,600 to 18,500 patients.

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 Saphnelo (active ingredient: anifrolumab) at the following publicly accessible link (last access: 30 June 2022):

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

Treatment with anifrolumab should only be initiated and monitored by doctors experienced in SLE therapy.

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 September 2022).

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.

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 patient-individual and/or is shorter on average. The time unit "days" is used to calculate the "number

[7] IQWiG dossier assessment (A12-05)

of treatments/ patient/ year", time intervals between individual treatments and for the maximum treatment duration, if specified in the product information.

For the calculation of the consumption of medicinal products to be dosed according to weight, the G-BA generally uses non-indication-specific average weights as a basis. For the bodyweight (KG), the average weight of the German population from the official representative statistics "Microcensus 2017 - body measurements of the population" is therefore used[8] as a basis (average body weight: 77.0 kg).

Anifrolumab is approved as an *add-on* therapy to a standard therapy for the treatment of adult patients with moderate to severe, active autoantibody-positive systemic lupus erythematosus. The active ingredient of the appropriate comparator therapy can also be used as an add-on therapy to a standard therapy in patients with active, autoantibody-positive systemic lupus erythematosus. Thus, if applicable, the corresponding costs of standard therapy are incurred both for the medicinal product under assessment and for the appropriate comparator therapy and are therefore not listed separately.

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				
Anifrolumab	continuously, 1 x every 28 days	13.0	1	13.0
Appropriate comparator therapy				
Belimumab	continuously, 1 x every 28 days	13.0	1	13.0

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					
Anifrolumab	300 mg	300 mg	1 x 300 mg	13.0	13.0 x 300 mg
Appropriate comparator therapy					
Belimumab	10 mg/kg = 770 mg	770 mg	1 x 400 mg + 3 x 120 mg	13.0	13.0 x 400 mg + 39.0 x 120 mg

[8] Federal Statistical Office, Wiesbaden 2018: http://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					
Anifrolumab 300 mg	1 CIS	€ 1,708.53	€ 1.77	€ 94.28	€ 1,612.48
Appropriate comparator therapy					
Belimumab 120 mg	1 PIC	€ 175.72	€ 1.77	€ 0.00	€ 173.95
Belimumab 400 mg	1 PIC	€ 559.37	€ 1.77	€ 0.00	€ 557.60
Abbreviations: CIS = concentrate for the preparation of an infusion solution, PIC = powder for the preparation of an infusion solution concentrate					

LAUER-TAXE® last revised: 15 September 2022

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.

For the use of anifrolumab, costs are regularly incurred for examining for both active and inactive ("latent") tuberculosis infections. The costs presented are a blood test (quantitative determination of an in vitro interferon-gamma release after ex vivo stimulation with antigens specific for Mycobacterium tuberculosis-complex (except BCG)) and a chest radiograph. The tuberculin skin test is not presented due to lack of sensitivity and specificity as well as the possibility of "sensitisation".

Designation of the therapy	Designation of the service	Number	Unit cost	Costs/ patient/ year
Medicinal product to be assessed				
Anifrolumab	Quantitative determination of an *in vitro* interferon-gamma release after *ex vivo* stimulation with antigens (at least ESAT-6 and CFP-10) specific for Mycobacterium tuberculosis-complex (except BCG) (GOP 32670)	1	€ 58.00	€ 58.00
	Chest radiograph (GOP 34241)	1	€ 16.45	€ 16.45

Other SHI services:

The special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe) (Sections 4 and 5 of the Pharmaceutical Price Ordinance) from 01.10.2009 is not fully used to calculate costs. Alternatively, the pharmacy sales price publicly accessible in the directory services according to Section 131 paragraph 4 SGB V is a suitable basis for a standardised calculation.

According to the currently valid version of the special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe), surcharges for the production of parenteral preparations containing cytostatic drugs a maximum amount of € 81 per ready-to-use preparation, and for the production of parenteral solutions containing monoclonal antibodies a maximum of € 71 per ready-to-use unit are to be payable. These additional other costs are not added to the pharmacy sales price but rather follow the rules for calculating in the Hilfstaxe. The cost representation is based on the pharmacy retail price and the maximum surcharge for the preparation and is only an approximation of the treatment costs. This presentation does not take into account, for example, the rebates on the pharmacy purchase price of the active ingredient, the invoicing of discards, the calculation of application containers, and carrier solutions in accordance with the regulations in Annex 3 of the Hilfstaxe.

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 25 May 2021, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

The appropriate comparator therapy determined by the G-BA was reviewed. The Subcommittee on Medicinal Products determined the appropriate comparator therapy at its session on 15 March 2022.

On 24 March 2022, the pharmaceutical company submitted a dossier for the benefit assessment of anifrolumab to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 VerfO.

By letter dated 30 March 2022 in conjunction with the resolution of the G-BA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefits 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 anifrolumab.

The dossier assessment by the IQWiG was submitted to the G-BA on 28 June 2022, and the written statement procedure was initiated with publication on the website of the G-BA on 1 July 2022. The deadline for submitting written statements was 22 July 2022.

The oral hearing was held on 8 August 2022.

By letter dated 9 August 2022, the IQWiG was commissioned with a supplementary assessment. The addendum prepared by IQWiG was submitted to the G-BA on 16 September 2022.

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 6 September 2022, and the proposed resolution was approved.

At its session on 06 October 2022, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee Medicinal products	25 May 2021	Determination of the appropriate comparator therapy
Subcommittee Medicinal products	8 June 2022	New determination of the appropriate comparator therapy
Working group Section 35a	3 August 2022	Information on written statements received; preparation of the oral hearing
Subcommittee Medicinal products	8 August 2022	Conduct of the oral hearing, Commissioning of the IQWiG with the supplementary assessment of documents

Working group Section 35a	17.08.2022; 21.09.2022	Consultation on the dossier assessment by the IQWiG, assessment of the written statement procedure
Subcommittee Medicinal products	27 September 2022	Concluding discussion of the draft resolution
Plenum	6 October 2022	Adoption of the resolution on the amendment of Annex XII AM-RL

Berlin, 6 October 2022

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

Prof. Hecken