Gemeinsamer Bundesausschuss

Justification

of the Resolution of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V Sucroferric oxyhydroxide (New Therapeutic Indication: serum phosphorus level control in chronic kidney disease, 2 to < 18 years)

of 3 June 2021

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:

1st Approved therapeutic indications,

2nd Medical benefit,

3rd Additional medical benefit in relation to the appropriate comparator therapy,

4th Number of patients and patient groups for whom there is a therapeutically significant additional benefit,

5th Treatment costs for statutory health insurance funds,

6th 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 is part of the Pharmaceuticals Directive.

2. Key points of the resolution

The active ingredient sucroferric oxyhydroxide (Velphoro) was listed for the first time in the Great German Specialty Tax (Lauer Tax) on 1 October 2014.

On 16 November 2020, sucroferric oxyhydroxide received marketing authorisation for a new therapeutic indication to be classified as a major variation of type 2 according to Annex 2 number 2a 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, 12 December 2008, p. 7).

On 11 December 2020, i.e. at the latest within four weeks after informing the pharmaceutical company about the approval for a new therapeutic indication , the pharmaceutical company has 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 sucroferric oxyhydroxide with the new therapeutic indication (serum phosphorus level control in chronic kidney disease, 2 to < 18 years).

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on the G-BA website (www.g-ba.de) on 15 March 2021, 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 sucroferric oxyhydroxide 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 sucroferric oxyhydroxide.

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 Sucroferric oxyhydroxide (velphoro) in accordance with the product information

Velphoro is used to control serum phosphorus levels in paediatric patients 2 years of age and older with CKD stages 4 - 5 (defined by a glomerular filtration rate < 30 mL/min/1.73 m²) or with CKD on dialysis.

Therapeutic indication of the resolution (resolution of 3/06/2021):

see approved therapeutic indication

2.1.2 Appropriate comparator therapy

Paediatric patients 2 years of age and older with CKD stages 4 -5 (defined by a glomerular filtration rate < 30 mL/min/1.73 m²) or with CKD on dialysis.

- Therapy according to the doctor's instructions.

[1] General Methods, version 6.0 from 5.11.2020. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

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.
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 established by the Federal Joint Committee 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 hyperphosphataemia in paediatric and adolescent patients with chronic renal failure, only the active ingredient sevelamer carbonate is approved for patients > 6 years of age and with a body surface area > 0.75 m².

on 2. A non-medicinal treatment cannot be considered as a comparator therapy in this therapeutic indication.

on 3. The following decisions on the benefit assessment according to § 35a SGB V are available:

Resolution on the benefit assessment of sucroferric oxyhydroxide (adult patients) of 19 March 2015.

In addition, the guideline of the Joint Federal Committee on the prescription of drugs in the Pharmaceuticals Directive (Arzneimittel-Richtlinie, AM-RL) lists in Annex 1 under No. 37 “Phosphate binders only for the treatment of hyperphosphatemia in chronic renal insufficiency and dialysis”.

on 4. The generally recognised state of medical knowledge was illustrated by a search for guidelines as well as systematic reviews of clinical studies in the present indication.

Guidelines recommend calcium-containing phosphate binders (alone or in combination) and sevelamer carbonate to lower phosphate levels in children and adolescents with chronic kidney disease.

However, calcium-containing phosphate binders are not approved for use in children and adolescents in the present indication. Sevelamer carbonate is approved for the treatment of hyperphosphatemia in paediatric and adolescent patients (> 6 years of age and with a body surface area [BSA] of > 0.75 m²) with chronic renal insufficiency. Therefore, there is a discrepancy between drugs approved in the indication and drugs used in health care/recommended in guidelines.

Within the framework of a therapy according to the doctor's instructions, the following active ingredients or classes of active ingredients can therefore be considered as comparators: Calcium-containing phosphate binders and sevelamer carbonate. Appropriate therapy of the underlying disease and chronic renal insufficiency is assumed.

For the implementation of the therapy according to the doctor's instructions in a direct comparator study, it is expected that the study physician will have a choice of several treatment options (multicomparator study). It can be assumed that not only one active ingredient is equally suitable as a therapy option for all patients. In this respect, a selection and, if necessary, restriction of treatment options must be justified. The patient-individual therapy decision regarding the comparator therapy at baseline should be made prior to group assignment (e.g. randomisation).

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 sucroferric oxyhydroxide is assessed as follows:

For paediatric patients aged 2 years and older with CKD stages 4-5 (defined by a GFR < 30 ml/ min/ 1.73 m^2) or CKD on dialysis, the additional benefit of sucroferric oxyhydroxide compared with the appropriate comparator therapy is not proven.

Justification:

For the benefit assessment, the pharmaceutical company submits the PA-CL-PED-01 study, which justifies the extension of the marketing authorisation. This is a multicentre, open-label randomised study comparing sucroferric oxyhydroxide with calcium acetate for control of serum phosphate levels in children and adolescents with CKD. Children and adolescents aged 2 to < 18 years with hyperphosphataemia due to stage 4 or 5 CKD were included in the PA-CL-PED-01 study. CKD had to be stage 4 or 5 (estimated glomerular filtration rate < 30 ml/min/1.73m^2) or stage 5D (≥ 2 months of sufficient maintenance haemodialysis or peritoneal dialysis before enrolment). A total of 85 children and adolescents were randomly assigned to their treatment stratified by age group, 66 children and adolescents to the sucroferric oxyhydroxide arm and 19 children and adolescents to the calcium acetate arm.

The study design consisted of a titration phase of up to 10 weeks (phase 1) and a maintenance phase of 24 weeks (phase 2). The children and adolescents could switch from the titration phase to the maintenance phase if they had been treated for at least 4 weeks and the serum phosphate concentration was within the age-specific target range. This results in a minimum treatment duration of 28 weeks and a maximum treatment duration of 34 weeks.

Treatment in the intervention arm was in accordance with the product information of sucroferric oxyhydroxide. The active ingredient calcium acetate used in the control arm is not approved for children and adolescents; however, it is recommended in guidelines and had been named by the G-BA as a possible comparator in the context of therapy according to doctor's instructions in a clinical study. Its dosage in the study is in accordance with information in guidelines, moreover, an adequate therapy of the underlying disease was given. Comparator data against other phosphate binders are not submitted by the pharmaceutical company.

The primary study endpoint was the course of serum phosphate concentration in the intervention arm until the end of the titration phase. Secondary endpoints were the comparison of serum phosphate concentrations between the intervention and control arms and side effects (including deaths). Patient-individual endpoints on morbidity or health-related quality of life were not collected.

As discussed below, the data presented for the PA-CL-PED-01 study are inappropriate to answer the present research question for several reasons.

Data from only 39% of children and adolescents treated with sucroferric oxyhydroxide and 10% of those treated with calcium acetate were available for evaluation after the treatment period specified in the study protocol. Based on the data on the discontinuation rate in both arms and phases (titration and maintenance), it can be estimated that less than half of the randomised participants in the intervention arm and less than a quarter in the comparator arm were treated for the duration of at least 24 weeks required for chronic diseases. What is certain is that the treatment duration in the control arm was 7 weeks or less in 50% of patients.

The most common cause of premature discontinuation of treatment with the study medication were adverse events, which occurred in 12 children and adolescents in the intervention arm (≙ 18%) and 6 children and adolescents in the comparator arm(≙ 32%). Furthermore, lack of adherence or withdrawal of consent led to discontinuation in 16 children and adolescents in the intervention arm (≙ 24%) and 6 children and adolescents in the comparator arm(≙ 32%). As the study protocol only envisaged a final data collection at 2 weeks after treatment discontinuation, no information is available on the time course over at least 24 weeks. In addition, 11 children and adolescents in the intervention arm(≙ 17%) and 4 children and adolescents in the comparator arm(≙ 21%) underwent renal transplantation as definitive therapy for the underlying disease; for this group, there was no longer an indication for phosphate binder treatment and further observation after transplantation was not reasonable.

In addition, only endpoints on laboratory values and side effects were collected in the study presented, but no data on symptomatology, health-related quality of life or other patient-relevant endpoints. This does not allow a conclusion on the potential additional benefit of sucroferric oxyhydroxide compared with calcium acetate in the treatment of children and adolescents with CKD and hyperphosphatemia.

Regardless of the suitability of the submitted study for the benefit assessment, the included study population does not fully represent the target population in the new therapeutic indication. How large the proportion of the target population is that is not represented by the study population remains unclear. For instance, children and adolescents with hypercalcaemic values in the screening laboratory were excluded from study enrolment because a calcium-containing phosphate binder would have been contraindicated for them as intended therapy in the comparator arm. However, it cannot be assumed that only one active ingredient is equally suitable as a therapeutic option for all children and adolescents.

2.1.4 Summary of the assessment

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

The therapeutic indication assessed here is as follows: “Velphoro is indicated for the control of serum phosphorus level in pediatric patients 2 years of age and older with CKD stages 4-5 (defined by a glomerular filtration rate < 30 mL/min/1.73 m²) or with CKD on dialysis.”

The Federal Joint Committee determined the appropriate comparator therapy to be a therapy according to the doctor's instructions.

For this patient group, the pharmaceutical company presents the PA-CL-PED-01 study, in which sucroferric oxyhydroxide was compared with calcium acetate. However, the study data cannot be used for the benefit assessment in the present therapeutic indication for several reasons.

In the PA-CL-PED-01 study, there was a high rate of early treatment discontinuation, which differed between the intervention and comparator arms, so that overall significantly less than 50% of the children and adolescents included could be treated and evaluated over the period of at least 24 weeks which is required for chronic diseases. The reasons for the high rate of therapy discontinuations were in particular the occurrence of adverse events.

In addition, no patient-relevant endpoints on morbidity or quality of life were collected in the study presented.

Furthermore, due to the single comparator design with calcium acetate, the target population of the new therapeutic indication is not fully represented.

Overall, the G-BA therefore comes to the conclusion that an additional benefit of sucroferric oxyhydroxide compared to the appropriate comparator therapy is not proven. Based on the available data, statements on the additional benefit are only possible in relation to calcium acetate.

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 G-BA bases its decision on the estimate of patient numbers derived by the pharmaceutical company in the dossier. Overall, the data determined by the pharmaceutical company are subject to uncertainties due to missing data and methodological limitations.

For example, it is unclear how the ranges for the incidence and prevalence of CKD were determined, to which age group(s) they refer and to what extent they differ currently and for Germany. Moreover, the data obtained refer exclusively to children and adolescents with CKD stages 4-5. However, the target population also includes children and adolescents with CKD requiring dialysis, regardless of CKD stage, for whom serum phosphate level control is indicated.

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 Velphoro (active ingredient: sucroferric oxyhydroxide) at the following publicly accessible link (last access: 26 April 2021):

https://www.ema.europa.eu/en/documents/product-information/velphoro-epar-product-information_de.pdf

Initiation and monitoring of treatment with sucroferric oxyhydroxide should be carried out by specialists experienced in the treatment of children and adolescents with chronic kidney disease.

2.4 Treatment costs

The treatment costs are based on the information of the product information as well as the information in the Lauer-Taxe® (status: 15 May 2021).

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

Sucroferric Oxyhydroxide chewable tablets should only be used after the age of 6 and with a total daily dose of 1,000 mg or more, according to the product information. Sucroferric oxyhydroxide 125 mg powder in sachet is not currently on the market (as of Lauer-Taxe: 15 May 2021). For the cost calculation, the daily starting doses and the daily maximum doses specified in the product information for the age groups were used.

In the product information for sevelamer carbonate, only a starting dose is given for children and adolescents, which can be increased or decreased in single-dose increments of 0.4 g or 0.8 g, respectively. No information is given on a standard maintenance or maximum dose, therefore twice the starting dose (corresponding to the dosage after two increments) was used as the upper limit of the maintenance dose for the cost calculation.

The active ingredient sevelamer carbonate is dosed depending on the body surface area. For the calculation of the consumption of medicinal products to be dosed according to weight, the G-BA generally uses non-indication-specific average values as a basis. Therefore, an average body weight of 26.6 kg and a height of 1.28 m is assumed for children aged 7, and an average body weight of 67 kg and a height of 1.74 m for adolescents aged 17. This results in a body surface area of 0.98 m² for 7-year-olds and 1.81 m² for 17-year-olds (calculated according to Du Bois 1916; data from the Federal Statistical Office[2]).

Treatment duration:

Name of therapy	Treatment mode	Number of treatments/patient/year	Treatment duration/treatment (days)	Days of treatment/patient/ Year
Medicinal product to be assessed				
Sucroferric oxyhydroxide	Continuously, several times a day, divided between meals	365	1	365
Appropriate comparator therapy				
Therapy according to the doctor's instructions				

[2] Health Reporting of the Federal Government, Wiesbaden 2018 at www.gbe-bund.de

Name of therapy	Treatment mode	Number of treatments/patient/year	Treatment duration/treatment (days)	Days of treatment/patient/ Year
Sevelamer carbonate [a] (> 6 years and with a KOF > 0.75 m²)	continuously, 3x per day	365	1	365

[a] Costs are presented only for the active ingredient sevelamer carbonate, which is approved for paediatric and adolescent patients (> 6 years of age and with a BS > 0.75 m²) with chronic renal insufficiency and hyperphosphataemia. In addition to sevelamer carbonate, calcium-containing phosphate binders (alone or in combination) also represent suitable comparators for the present benefit assessment in the context of therapy according to the doctor's instructions. However, these medicinal products are not approved in the present therapeutic indication, and therefore no costs are presented for these medicinal products.

Consumption:

Name of therapy	Dosage/ Application [a]	Dosage/patient/days of treatment	Consumption according to active strength/treatment day	Costs/patient/year	Average annual consumption by potency
Medicinal product to be assessed					
Sucroferric Oxyhydroxide - powder in sachet [b]					
≥ 2 to <6 years of age	125 mg - 500 mg	500 mg - 1,250 mg	4 - 10 x 125 mg	365	1,460 - 3,650 x 125 mg
≥ 6 <9 years of age	250 mg - 875 mg	750 mg - 2,500 mg	6 - 20 x 125 mg	365	2,190 - 7,300 x 125 mg
≥ 9 <12 years of age	250 mg - 1,000 mg	1,000 mg - 3,000 mg	8 - 24 x 125 mg	365	2,920 - 8,760 x 125 mg
Sucroferric Oxyhydroxide - Chewable tablets					
≥ 6 <9 years of age	500 mg	1,000 mg - 2,500 mg	2 - 5 x 500 mg	365	730 - 1,825 x 500 mg
≥ 9 <12 years of age	500 mg - 1,000 mg	1,000 mg - 3,000 mg	2 - 6 x 500 mg	365	730 - 2,190 x 500 mg
≥ 12 <18 years of age	500 mg - 1,000 mg	1,500 mg - 3,000 mg	3 - 6 x 500 mg	365	1,095 - 2,190 x 500 mg
Appropriate comparator therapy					
Therapy according to the doctor's instructions [c]					
Sevelamer carbonate (patients > 6 years and with a BS > 0.75 m²)					
> 6 years and BS > 0.75 to < 1.2m^2	0.8 g - 1.6 g	2.4 g - 4.8 g	3 - 6 x 0.8 g	365	1,095 - 2,190 x 0.8 g
< 18 years and BS ≥ 1.2m^2	1.6 g - 3.2 g	4.8 g - 9.6 g	6 - 12 x 0.8 mg	365	2,190 - 4,380 x 0.8 g

[a] According to the product information, the dose per treatment day is divided into three doses at mealtimes. This may result in different dosages per application, which are covered by the range shown in the column (e.g. taking 125 mg - 250 mg - 125 mg results in a daily dose of 500 mg or taking 875 mg - 875 mg - 750 mg results in a daily dose of 2,500 mg).

[b] Sucroferric oxyhydroxide 125 mg powder in sachet is currently not available on the German market.

[c] Costs are presented only for the active ingredient sevelamer carbonate, which is approved for paediatric and adolescent patients (> 6 years of age and with a BS > 0.75 m²) with chronic renal insufficiency and hyperphosphatemia. In addition to sevelamer carbonate, calcium-containing phosphate binders (alone or in combination) also represent suitable comparators for the present benefit assessment in the context of therapy according to the doctor's instructions. However, these medicinal products are not approved in the present therapeutic indication, and therefore no costs are presented for these medicinal products.

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 Sections 130 and 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 product:

Name of therapy	Packaging size	Costs (pharmacy sales price)	Rebate § 130 SGB V	Rebate § 130a SGB V	Costs after deduction of statutory rebates
Medicinal product to be assessed					
Sucroferric oxyhydroxide powder in sachet [a]	-	-	-	-	-
Sucroferric oxyhydroxide 500 mg	90 CT	€ 184.76	€ 1.77	€ 9.62	€ 173.37
Appropriate comparator therapy					
Sevelamer carbonate 800 mg	90 POS	€ 156.21	€ 1.77	€ 6.89	€ 147.55

Abbreviations: CT = Chewable tablets, POS = Powder for oral suspension.

[a] Sucroferric Oxyhydroxide 125 mg powder in sachet is currently not available on the German market, therefore a cost representation is not possible.

LAUER-TAXE® last revised: 15 May 2021

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. Bureaucracy cost 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 08 July 2014, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

A review of the appropriate comparator therapy defined by the G-BA took place. The Subcommittee on Medicinal Products determined the appropriate comparator therapy at its session on 24 November 2020.

On 11 December 2020, the pharmaceutical company submitted a dossier for the benefit assessment of sucroferric oxyhydroxide 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 December 2020 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 sucroferric oxyhydroxide.

The dossier assessment by the IQWiG was submitted to the G-BA on 11 March 2021, and the written statement procedure was initiated with publication on the G-BA website on 15 March 2021. The deadline for submitting written statements was 6 April 2021.

The oral hearing was held on 26 April 2021.

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 session of the subcommittee on 25 May 2021, and the proposed resolution was approved.

At its session on 3 June 2021, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee Medicinal products	8 July 2014	Determination of the appropriate comparator therapy
Subcommittee Medicinal products	24 November 2020	Implementation of the appropriate comparator therapy
Working group Section 35a	21 April 2021	Information on written statement procedures received; preparation of the oral hearing
Subcommittee Medicinal products	26 April 2021	Conduct of the oral hearing
Working group Section 35a	5 May 2021 19 May 2021	Consultation on the dossier evaluation by the IQWiG, evaluation of the written statement procedure
Subcommittee Medicinal products	25 May 2021	Concluding consultation of the draft resolution
Plenum	3 June 2021	Adoption of the resolution on the amendment of Annex XII AM-RL

Berlin, 3 June 2021

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

Prof. Hecken