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 Maribavir (cytomegalovirus infection (refractory to therapies))

of 1 June 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.

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 German Social Code, Book Five (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 for 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, No. 2 and 3 SGB V in conjunction with Chapter 5 Sections 5 et seq. 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. According to Section 35a, paragraph 1, sentence 12 SGB V, the pharmaceutical company must then, within three months of being requested to do so by the G-BA, submit evidence according to Chapter 5, Section 5, paragraphs 1–6 VerfO, in particular regarding the additional medical benefit in relation to the appropriate comparator therapy as defined by the G-BA according to Chapter 5, Section 6 VerfO and prove the additional benefit in comparison with the appropriate comparator therapy.

In accordance with Section 35a, paragraph 2 SGB V, the G-BA decides 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 its session on 15 March 2012 to the effect that, for orphan drugs, the G-BA initially no longer independently determines 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 its 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 threshold 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 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 relevant date for the start of the benefit assessment procedure was the first placing on the (German) market of the active ingredient maribavir on 1 December 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 24 November 2022.

Maribavir for the treatment of cytomegalovirus (CMV) infection and/or disease refractory (with or without resistance) to one or more prior therapies, including ganciclovir, valganciclovir, cidofovir or foscarnet, in adult patients who have undergone haematopoietic stem cell transplantation (HSCT) or solid organ transplantation (SOT), is approved as an orphan medicinal product for the treatment of rare diseases under Regulation (EC) No. 141/2000 of the European Parliament and of 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 approval studies by the G-BA.

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 1 March 2023 together with the IQWiG assessment on the website of the G-BA (www.g-ba.de), thus initiating the written statement procedure. In addition, an oral hearing was held.

The G-BA made its resolution on the basis of the pharmaceutical company's dossier, the dossier assessment carried out by the G-BA, the IQWiG assessment of treatment costs and patient numbers (IQWiG G22-41) and the statements made in the written statement and oral hearing procedure, as well of the amendment drawn up by the G-BA on the benefit assessment.

In order to determine the extent of the additional benefit, the G-BA has evaluated the studies relevant for the approval with regard to their therapeutic relevance (qualitative) in accordance with the criteria laid down in Chapter 5, Section 5, paragraph 7, sentence 1, numbers 1 – 4 VerfO. The methodology proposed by the IQWiG in accordance with the General Methods 1 was not used in the benefit assessment of maribavir.

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

1.1 Additional benefit of the medicinal product

1.1.1 Approved therapeutic indication of Maribavir (Livtencity) in accordance with the product information

LIVTENCITY is indicated for the treatment of cytomegalovirus (CMV) infection and/or disease that are refractory (with or without resistance) to one or more prior therapies, including ganciclovir, valganciclovir, cidofovir or foscarnet in adult patients who have undergone a haematopoietic stem cell transplantation (HSCT) or solid organ transplantation (SOT).

Therapeutic indication of the resolution (resolution of 1 June 2023):

see the approved therapeutic indication

1.1.2 Extent of the additional benefit and significance of the evidence

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

There is a hint for a minor additional benefit for adults who have undergone haematopoietic stem cell transplantation or solid organ transplantation with cytomegalovirus infection and/or disease refractory to one or more prior therapies (including ganciclovir, valganciclovir, cidofovir or foscarnet).

Justification:

For the benefit assessment, the pharmaceutical company submits data from the label-enabling, multicentre, unblinded, randomised-controlled phase III study SHP620-303, which compares maribavir against investigator-assigned anti-CMV therapy with the active ingredients ganciclovir, valganciclovir, foscarnet and cidofovir.

A total of 352 patients aged 18 years and older who had received haematopoietic stem cell transplantation (HSCT) or solid organ transplantation (SOT) and had a CMV infection that was refractory to the last therapy administered from the four anti-CMV therapies (ganciclovir, valganciclovir, foscarnet and cidofovir) were enrolled in the study.

It was randomised in a 2:1 ratio to the treatment arm with maribavir (N = 235) or the control arm (N = 117). The application of the medicinal products corresponded to the requirements in the product information. After three weeks of treatment, patients in the control arm had the option to switch to a maribavir rescue arm, where they were treated for up to eight weeks, if priori-defined criteria of non-response were met.

The primary endpoint was CMV infection control on week 8. In addition, further endpoints on morbidity, health-related quality of life and side effects were assessed.

The study consisted of a two-week screening phase, an eight-week treatment period and a follow-up of 12 weeks.

The results of the evaluable patient-relevant endpoints of the SHP620-303 study are discussed below.

Mortality

The endpoint of overall mortality was defined as death from any cause and was collected at all study visits from randomisation throughout the study duration.

There were no signs of statistically differences between the study arms.

Morbidity

Infection control

The endpoint of infection control on week 8 is the primary endpoint of the study. It was defined as a CMV DNA concentration of < 137 IU/ml in blood plasma, confirmed in two consecutive post-baseline samples at least five days apart.

In the present therapeutic indication, patients who have previously received HSCT or SOT and are therefore immunosuppressed are treated. Consequently, antiviral therapy should ideally be started before the onset of symptomatology, as CMV disease is a serious complication for this patient group.

Even though the CMV DNA concentration is a laboratory parameter that does not reflect the symptomatology and is therefore not directly patient-relevant, the endpoint of infection control is included in the benefit assessment due to the potentially life-threatening situation for the patients and the clinical relevance in the treatment decision.

As part of the study, the patients were subject to binary categorisation as responders or non-responders. Responders were those who achieved infection control exactly on week 8. In addition to this analysis at the end of week 8, maintenance of infection control was considered on weeks 12, 16 and 20. The response is considered maintained unless two consecutive CMV DNA readings are > 137 IU/ml on weeks 12, 16 and 20 after an infection control. The operationalisation of the endpoint is comprehensible.

For the endpoint of infection control on week 8 and maintenance of infection control on week 20, there is a statistically significant advantage of maribavir over the control arm.

Symptom control

The endpoint "symptom control" is a combined endpoint, which is assessed depending on the presence of symptomatology at baseline by assessing tissue-invasive CMV disease and CMV syndrome. Tissue-invasive CMV disease is a threatening symptom of CMV infection and is associated with symptoms that depend on the organ affected. The endpoint of CMV organ disease is directly patient-relevant. The chosen operationalisation of the CMV syndrome is based on symptoms and laboratory parameters that differ in their significance for the ill subject. The patient relevance of the endpoint CMV syndrome cannot be conclusively assessed in the present operationalisation.

The study recorded symptom control up to the end of week 8 and maintenance of effect up to weeks 12, 16 and 20 and evaluated post hoc.

Due to the overall unclear patient relevance as well as the unclear added value of the information on clinical relevance compared to the endpoint of infection control, the combined endpoint of symptom control is not used for the benefit assessment and is only presented additionally.

Graft endpoints

The graft endpoints included graft rejection or loss in patients with SOT and the occurrence of graft-versus-host disease (GVHD) in patients after HSCT.

The presence of a CMV infection or CMV disease is a serious complication after HSCT or SOT and significantly increases the risk of treatment failure. Therefore, rejection or loss of the graft as well as the occurrence of GVHD are considered directly patient-relevant.

In the study, the assessment of the graft by the investigator includes the status of graft function, whether episodes of acute rejection are present, or whether other relevant complications develop, and loss was clinically defined as irrevocable dysfunction. However, uncertainties remain regarding the exact definition of acute rejection and the criteria that had to be fulfilled for this. In addition, the corresponding study manual for the investigator was not submitted.
Acute and chronic GVHD should be diagnosed and classified by the investigator based on criteria from the 2015 NIH Consensus Conference and Harris et al. (2016), and recurrent GVHD was defined as an adverse event of special interest.

Due to the fact that purely descriptive data are available as well as the ambiguities in the operationalisation of the graft endpoints, these are only comprehensible to a limited extent and cannot be used to assess the additional benefit.

EQ-5D-VAS

The European Quality of Life 5-Dimension Visual Analogue Scale (EQ-5D-VAS) was collected to assess general health status via an electronic study diary. Due to low return rates (< 70%) and large differences (> 15%) between the study arms of the EQ-5D-VAS, no usable data are available for this endpoint.

Quality of life

As part of the study, health-related quality of life was assessed using the Short Form 36 Health Survey (SF-36). Due to low return rates (< 70%) and large differences (> 15%) between the study arms of the SF-36, no usable data are available regarding quality of life.

Side effects

The follow-up period planned a priori for all adverse events (AEs) should be up to 30 days after the last dose according to the study protocol. At this data collection time point, no statistical evaluation was submitted by the pharmaceutical company. The results are presented descriptively in the resolution.

In addition, time-to-event evaluations of the safety endpoints are presented post hoc as required by the G-BA for different observation durations in the study arms, which refer to the period during the 8-week treatment (median treatment duration 57 days with maribavir vs 34 days in the control arm) and the follow-up. The period begins with the intake of the study medication and ends 21 days after the end of treatment with cidofovir, 7 days after the end of treatment with all other anti-CMV therapies or from the start of rescue therapy or another CMV therapy.

This procedure was not justified by the pharmaceutical company even if a different follow-up period seems plausible in principle, e.g. due to different half-lives of the study therapies with different start dates of the follow-up therapies to be started promptly.

The operationalisation of the safety endpoints is basically comprehensible, but uncertainties arise due to the 30-day shortened follow-up period planned a priori and varying in duration depending on the study medication used, as well as due to ambiguities regarding the non-consideration of disease-related events.

In addition, there are uncertainties in the median observation period, which was 141 days in both study arms (range maribavir arm: 1-217; range of control arm: 1–286). Subjects from the control arm who switched to the rescue arm were also included in the duration of observation, but for safety they were only taken into account for the analyses until they switched to the rescue arm. Thus, the duration of observation for the safety data may not correspond to the duration of observation of the entire study.

Furthermore, there are differences in the median treatment duration (maribavir arm 57 days; control arm 34 days), which could result in a risk of bias to the disadvantage of maribavir. The differences may be due, among other things, to the switch to the rescue arm and the higher percentage of therapy discontinuations in the control arm.

The analyses presented showed a clear statistically significant advantage of maribavir for the endpoint "AE leading to discontinuation of study medication", which is also supported by the descriptive results over the entire study period. There was a statistically significant advantage of maribavir in the overall rates of severe AE within the treatment period, but this cannot be used due to the uncertainties of the results related to the lower magnitude of effect over the entire study period. In the overall rates of serious AEs, no statistically significant difference was detected between the study arms.

In addition, at the SOC level, there was a statistically significant advantage of maribavir for the blood and lymphatic system disorders (severe AEs and AEs) and the renal and urinary disorders (AEs), and a statistically significant disadvantage of maribavir for the endpoints of nervous system disorders (AEs) and skin and subcutaneous tissue disorders (AEs).

Despite the uncertainties described above, the overall assessment shows advantages for maribavir in the side effects category.

Overall assessment

For the benefit assessment of maribavir for the treatment of adults who have undergone haematopoietic stem cell transplantation or solid organ transplantation with cytomegalovirus infection and/or disease refractory to one or more prior therapies (including ganciclovir, valganciclovir, cidofovir or foscarnet), there are assessable mortality, morbidity and side effects results based on the SHP620-303 study.

In the mortality category, there were no statistically significant differences between treatment groups in the endpoint of overall mortality.

In the morbidity endpoint category, there was a statistically significant advantage of maribavir for the patient-relevant endpoints "infection control on week 8" and "maintenance of infection control on week 20". The endpoint of symptom control and the graft endpoints could not be used for the benefit assessment.

No usable data on health-related quality of life are available in the study.

In the endpoint category of side effects, despite remaining uncertainties, there was a statistically significant advantage of maribavir in the endpoint "AE leading to discontinuation of study medication". In detail, both advantages and disadvantages of maribavir were evident for the specific AEs. In the overall rates of "serious AEs" and "severe AEs", there was no advantage of maribavir in the overall assessment.

In the overall assessment of the available results, a minor additional benefit of maribavir is determined due to advantages in the endpoints "infection control" and "AE that led to discontinuation of study medication".

Significance of the evidence

For the SHP620-303 study, there is a high risk of bias at study level.

Due to the open-label study design chosen due to the different dosage forms of the medicinal products used, as well as uncertainties regarding the unrestricted possibility of switching to an alternative anti-CMV therapy at any time and the possibility of switching to a maribavir rescue arm after at least three weeks of the eight-week treatment, uncertainties arise in the significance of the evidence.

Furthermore, the risk of bias for all relevant endpoints in the morbidity category as well as for the safety analyses is also assessed as high. In addition, uncertainties remain with regard to the assessment and evaluation of the safety endpoints, which could not be clarified during the written statement procedure.

The reliability of data is therefore classified in the category "hint".

1.1.3 Summary of the assessment

The present assessment is the benefit assessment of the new medicinal product Livtencity with the active ingredient maribavir, which has been approved as an orphan drug for the treatment of cytomegalovirus (CMV) infection and/or disease refractory (with or without resistance) to one or more prior therapies, including ganciclovir, valganciclovir, cidofovir or foscarnet, in adults who have undergone HSCT or SOT.

For this therapeutic indication, the pharmaceutical company presents the label-enabling, multicentre, unblinded, randomised-controlled phase III study SHP620-303, in which maribavir was compared with medically prescribed anti-CMV therapy with the active ingredients ganciclovir, valganciclovir, cidofovir and foscarnet.

In the endpoint “overall mortality”, no statistically significant difference was detected between the study arms.

The endpoints "infection control on week 8" and "maintenance of infection control on week 20" showed a statistically significant advantage of maribavir.

In addition, no usable data were available for the graft endpoints and the endpoints of the health-related quality of life category.

The endpoint "AE leading to discontinuation of study medication" showed a statistically significant advantage of maribavir. In the overall rates of "serious AEs" and "severe AEs", there was no advantage of maribavir in the overall assessment.

Within the scope of the assessment of side effects, there are uncertainties regarding the different follow-up periods as well as the lack of clarity regarding the non-consideration of disease-related events.

Uncertainties remain at study level due to the open-label study design and the possibility of switching to a maribavir rescue arm.

In the overall assessment, a hint for a minor additional benefit of maribavir is identified.

2.1 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 takes into account the patient numbers stated in the pharmaceutical company's dossier, which, however, are overall fraught with uncertainty due to the neglect of CMV infections and CMV diseases occurring after one year after a transplantation, as well as the unclear data basis of the expert estimates on percentage values within a Delphi survey and the associated uncertainty as to what extent the estimates are representative.

2.2 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 Livtencity (active ingredient: maribavir) at the following publicly accessible link (last access: 15 May 2023):

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

Treatment with maribavir should be initiated and monitored by doctors experienced in the treatment of patients who have undergone solid organ transplantation or haematopoietic stem cell transplantation.

2.3 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 May 2023).

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 calculated on the basis of the costs per pack after deduction of the statutory rebates.

The recommended dosage of maribavir is 400 mg twice daily, i.e. a daily dose of 800 mg, for 8 weeks, according to the product information, although the treatment duration may be individualised depending on the patient's clinical situation. 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.

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				
Maribavir	2 x daily	56.0	1	56.0

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					
Maribavir	400 mg	800 mg	4 x 200 mg	56.0	224 x 200 mg

Costs:

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					
Maribavir 200 mg	56 FCT	€ 18,214.22	€ 2.00	€ 1,777.59	€ 16,434.63

LAUER-TAXE® last revised: 15 May 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.

No additionally required SHI services are taken into account for the cost representation.

2.4 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 Maribavir

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

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

The benefit assessment of the G-BA was published on 1 March 2023 together with the IQWiG assessment of treatment costs and patient numbers on the website of the G-BA (www.g-ba.de), thus initiating the written statement procedure. The deadline for submitting statements was 22 March 2023.

The oral hearing was held on 12 April 2023.

An amendment to the benefit assessment with a supplementary assessment was submitted on 4 May 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 23 May 2023, and the proposed resolution was approved.

At its session on 1 June 2023, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee Medicinal products	21 February 2023	Information of the benefit assessment of the G-BA
Working group Section 35a	5 April 2023	Information on written statements received; preparation of the oral hearing
Subcommittee Medicinal products	12 April 2023	Conduct of the oral hearing
Working group Section 35a	19 April 2023 10 May 2023 17 May 2023	Consultation on the dossier assessment by the G-BA, the assessment of treatment costs and patient numbers by the IQWiG, and the evaluation of the written statement procedure
Subcommittee Medicinal products	23 May 2023	Concluding discussion of the draft resolution
Plenum	1 June 2023	Adoption of the resolution on the amendment of Annex XII AM-RL

Berlin, 1 June 2023

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

Prof. Hecken