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 Ivacaftor (new therapeutic indication: cystic fibrosis, combination regimen with Ivacaftor/ Tezacaftor/ Elexacaftor, 6 to 11 years (heterozygous for F508del and other or unknown mutations))

of 4 August 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 is part of the Pharmaceuticals Directive.

2. Key points of the resolution

The active ingredient ivacaftor (Kalydeco) was listed for the first time on 15 August 2012 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

Kalydeco is approved as a 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.

Within the previously approved therapeutic indications, the sales volume of ivacaftor with the statutory health insurance at pharmacy sales price including value-added tax exceeded € 50 million. Evidence must therefore be provided for ivacaftor in accordance with Section 5, paragraph 1 through 6 VerfO, and the additional benefit compared with the appropriate comparator therapy must be demonstrated.

On 7 January 2022, Kalydeco received marketing authorisation for a new therapeutic indication to be classified as a major type 2 variation as defined according to Annex 2 number 2 letter a to Regulation (EC) No. 1234/2008 of the European 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, 12.12.2008, p. 7).

On 3 February 2022, i.e. no later than four weeks after the pharmaceutical company has been notified of the authorisation for a new therapeutic indication, the pharmaceutical company has submitted a dossier in due time 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 ivacaftor with the new therapeutic indication (cystic fibrosis; combination regimen with ivacaftor/ tezacaftor/ elexacaftor, 6 to 11 years (heterozygous for F508del and other or unknown RF mutation)).

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 16 May 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 ivacaftor 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. 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 ivacaftor.

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 Ivacaftor (Kalydeco) in accordance with the product information

Kalydeco tablets are indicated in a combination regimen with ivacaftor/ tezacaftor/ elexacaftor tablets for the treatment of adults, adolescents and children aged 6 years and older with cystic fibrosis (CF) who have at least one F508del mutation in the CFTR gene.

Therapeutic indication of the resolution (resolution of 4 August 2022):

Kalydeco tablets are indicated in a combination regimen with ivacaftor/ tezacaftor/ elexacaftor tablets for the treatment of children aged 6 to 11 years with cystic fibrosis, who are heterozygous for the F508del mutation in the CFTR gene and carry a mutation on the second allele that is not a minimal function, gating (including R117H) or residual function mutation, or the mutation on the second allele is unknown (other mutations).

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

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Children aged 6 to 11 years with cystic fibrosis, who are heterozygous for the F508del mutation in the CFTR gene and carry a mutation on the second allele, which is not a minimal function, no gating (including R117H) and no residual function mutation, or the mutation on the second allele is unknown (other mutations)

Appropriate comparator therapy for ivacaftor in combination with Ivacaftor/ Tezacaftor/ Elexacaftor:

Best supportive care

Best Supportive Care (BSC) is defined as the therapy that ensures the best possible, patient-individual optimised, supportive treatment to alleviate symptoms and improve the quality of life (in particular antibiotics for pulmonary infections, mucolytics, pancreatic enzymes for pancreatic insufficiency, physiotherapy (as defined in the Remedies Directive), making full use of all possible dietary measures).

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 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. The following medicinal products are approved for the symptomatic therapy of CF:

aztreonam, carbocisteine[2], ceftazidime, ciprofloxacin, colistimethate, dornase alfa, Meronem, pancreatin, tobramycin.

[2] currently off the market

on 2. In the treatment of CF, nutritional measures, support of the respiratory function and physiotherapy (in the sense of the Remedies Directive) are basically considered as non-medicinal treatment.

on 3. There are no resolutions for the patient group to be considered in the present therapeutic indication *"Children aged 6 to 11 years with cystic fibrosis, who are heterozygous for the F508del mutation in the CFTR gene and show a mutation on the second allele, which is not a minimal function, no gating (including R117H) and no residual function mutation, or the mutation on the second allele is unknown (other mutations)*".

For adolescents aged 12 years and older and adults, a resolution dated 19 November 2021 is available for ivacaftor in combination with ivacaftor/ tezacaftor/ elexacaftor for the present mutation.

on 4. The generally recognised state of medical knowledge was illustrated by a search for guidelines as well as systematic reviews of clinical studies and is presented in the "Research and synopsis of the evidence to determine the appropriate comparator therapy according to Section 35a SGB V". 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.

According to the current state of medical knowledge, there is no specific standard therapy for children aged 6 to 11 years with cystic fibrosis, who are heterozygous for the F508del mutation in the CFTR gene and show a mutation on the second allele, which is not a minimal function, gating (including R117H) or residual function mutation, or the mutation on the second allele is unknown ("other mutations"). For children aged 6 to 11 years with CF, the above-mentioned medicinal and non-medicinal treatment options are available for symptomatic therapy. These are recommended in the present evidence for symptomatic therapy of CF, especially antibiotic therapy of pulmonary infections (ceftazidime, colistimethate, tobramycin), inhaled medicinal products (dornase alfa), enzyme substitution for pancreatic insufficiency (pancreatin), nutritional therapy and support of respiratory function and physiotherapy. Thus, CF treatment is patient-individual in order to alleviate symptoms and improve quality of life in the sense of Best Supportive Care (BSC).

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 ivacaftor in combination with ivacaftor/ tezacaftor/ elexacaftor is assessed as follows:

Children aged 6 to 11 years with cystic fibrosis, who are heterozygous for the F508del mutation in the CFTR gene and carry a mutation on the second allele, which is not a minimal function, no gating (including R117H) and no residual function mutation, or the mutation on the second allele is unknown (other mutations)

An additional benefit is not proven.

Justification:

The pharmaceutical company did not present any study data on the assessment of the additional benefit of ivacaftor in combination with ivacaftor/ tezacaftor/ elexacaftor for the treatment of children aged 6 to 11 years with cystic fibrosis, who are heterozygous for the F508del mutation in the CFTR gene and carry a mutation on the second allele, which is not a minimal function, no gating (including R117H) and no residual function mutation, or the mutation on the second allele is unknown (other mutations).

Even though the marketing authorisation for the present therapeutic indication was granted by the EMA on the basis of data from children aged 6 to 11 years with heterozygous F508del mutation and minimal function mutation or homozygous F508del mutation (VX19-445-116[3] and VX18-445-106[4] studies), assuming that the functionality of the chloride channels is mainly modulated by the large effect on the F508del mutation in the CFTR gene, no transfer of an additional benefit identified in the present benefit assessment procedure can be made from children aged 6 to 11 years with heterozygous F508del mutation and minimal function mutation to children of the same age who are heterozygous for the F508del mutation and have a other/unknown mutation on the second allele, as not all prerequisites are fulfilled that would justify a recognition of an additional benefit.

In its dossier for the present therapeutic indication to be assessed, the pharmaceutical company does not present any studies or other information on the course of the disease under BSC. In addition, it does not adequately address the extent to which children aged 6 to 11 years, who have a heterozygous F508del mutation and different mutations on the second allele, are comparable with each other with respect to their clinical picture.

A transfer of the additional benefit of ivacaftor from the population of children aged 6 to 11 years with heterozygous F508del mutation and minimal function mutation to the population of children aged 6 to 11 years with heterozygous F508del mutation and different/unknown mutation to be considered here is not justified due to the insufficiently certain comparability of the pathophysiology as well as the lack of data for the patient population to be assessed.

In the present benefit assessment procedure, it is also not possible to transfer an additional benefit for subjects aged 12 years and older with heterozygous F508del mutation and different/unknown mutation, because no additional benefit was identified in the benefit assessment procedure[5] for this patient population (resolution date: 19 November 2021) due to the absence of data. The recognition of an additional benefit for children aged 6 to 11 years on the basis of results in older subjects aged 12 years and older is therefore not possible.

Overall, for the present therapeutic indication, the pharmaceutical company did not present any study that would have been suitable for the assessment of the additional benefit of

[3] Benefit assessment procedure for the active ingredient ivacaftor (new therapeutic indication: cystic fibrosis, combination regimen with ivacaftor/ tezacaftor/ elexacaftor, from 6 to ≤ 11 years (heterozygous for F508del and MF mutations)) https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/800/

[4] Benefit assessment procedure for the active ingredient ivacaftor (new therapeutic indication: Cystic fibrosis, combination regimen with ivacaftor/ tezacaftor/ elexacaftor, from 6 to ≤ 11 years (homoozygous for F508del)) https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/801/

[5] Benefit assessment procedure for the active ingredient ivacaftor (new therapeutic indication: Cystic fibrosis, combination regimen with ivacaftor/ tezacaftor/ elexacaftor, from 12 years of age (heterozygous for F508del and other or unknown mutation https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/699/

ivacaftor in combination with ivacaftor/ tezacaftor/ elexacaftor compared with the appropriate comparator therapy.

An additional benefit of ivacaftor in combination with ivacaftor/ tezacaftor/ elexacaftor versus the appropriate comparator therapy is therefore not proven.

Taking into account the available evidence on the medical benefit of ivacaftor in combination with ivacaftor/ tezacaftor/ elexacaftor, the disease progression, and the statements of the scientific-medical societies on the current reality of care, ivacaftor in combination with ivacaftor/ tezacaftor/ elexacaftor can be a relevant treatment option for children aged 6 to 11 years, who are heterozygous for the F508del mutation in the CFTR gene and show other/unknown mutation on the 2nd allele for individual patients.

2.1.4 Summary of the assessment

The present assessment is the early benefit assessment of a new therapeutic indication for the active ingredient ivacaftor in combination with ivacaftor/ tezacaftor/ elexacaftor. Ivacaftor (invented name: Kalydeco) was approved as an orphan drug but has exceeded the EUR 50 million turnover limit.

The present resolution refers to the therapeutic indication “in a combination regimen with ivacaftor/ tezacaftor/ elexacaftor tablets for the treatment of children aged 6 to 11 years with cystic fibrosis, who are heterozygous for the F508del mutation in the CFTR gene and carry a mutation on the second allele that is not a minimal function, no gating (including R117H) and no residual function mutation, or the mutation on the second allele is unknown (other mutations)”.

The G-BA determined Best Supportive Care (BSC) to be the appropriate comparator therapy.

Overall, for the present therapeutic indication, the pharmaceutical company did not present any study that would have been suitable for the assessment of the additional benefit of ivacaftor in combination with ivacaftor/ tezacaftor/ elexacaftor compared with the appropriate comparator therapy.

An additional benefit of ivacaftor in combination with ivacaftor/ tezacaftor/ elexacaftor versus the appropriate comparator therapy is therefore not proven.

Taking into account the available evidence on the medical benefit of ivacaftor in combination with ivacaftor/ tezacaftor/ elexacaftor, the disease progression, and the statements of the scientific-medical societies on the current reality of care, ivacaftor in combination with ivacaftor/ tezacaftor/ elexacaftor can be a relevant treatment option for children aged 6 to 11 years, who are heterozygous for the F508del mutation in the CFTR gene and show other/unknown mutation on the 2nd allele, for individual patients.

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

In order to ensure consistent consideration of the patient numbers taking into account the most recent resolutions on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V in the therapeutic indication of cystic fibrosis, the G-BA uses the following derivation of the patient numbers:

The information on the number of patients is based on the target population in statutory health insurance (SHI).

Altogether, it is assumed that there are currently about 8,000 patients with cystic fibrosis in Germany[6].

This amount differs from the calculation of the pharmaceutical company in the dossier, which assumes 6,648 patients with cystic fibrosis in the total population. However, this figure is subject to uncertainties and is underestimated, as those patients without process data and without a current informed consent form were not taken into account here. In addition, there is currently no evidence that the overall patient population has changed meaningfully since the 2012 reporting volume (8,042 patients ever reported and alive at the time. This figure has already been adjusted for multiple responses according to the information in the report volume).

Therefore, the number of 56 patients in the SHI target population calculated by the pharmaceutical company especially represents an underestimation in the overall assessment.

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 Kalydeco (active ingredient: ivacaftor) at the following publicly accessible link (last access: 17 May 2022):

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

Treatment with ivacaftor should only be initiated and monitored by doctors experienced in the therapy of children with cystic fibrosis.

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 July 2022).

[6] Mukoviszidose e.V. - Federal Association for Cystic Fibrosis (CF) Website Mukoviszidose e.V.

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.

For the cost representation only the dosages of the general case are considered. If the treatment duration is not limited, initial induction schemes are not considered for the cost representation. Patient-individual dose adjustments (e.g., because of side effects or comorbidities) are not taken into account when calculating the annual treatment costs.

For dosage depending on body weight, the average body measurements from the official representative statistics “Microcensus 2017 – body measurements of the population” were applied. The average body weight of 6-year-olds is 23.6 kg and that of 11-year-olds 42.1 kg. The dosage of ivacaftor/ tezacaftor/ elexacaftor recommended for children varies depending on body weight. According to the product information, children up to a body weight of 30 kg receive 1 x daily 2 tablets of 37.5 mg/ 25 mg/50 mg ivacaftor/ tezacaftor/ elexacaftor and 1 x daily 1 tablet of 75 mg ivacaftor. Above a body weight of 30 kg, children receive 1 x daily 2 tablets of 75 mg/ 50 mg/ 100 mg ivacaftor/ tezacaftor/ elexacaftor and 1 x daily 1 tablet of 150 mg ivacaftor.

Patients in the present therapeutic indication receive the best supportive care. The costs for a best supportive care therapy are different from patient to patient. Because best supportive care has been determined as an appropriate comparator therapy, this is also reflected in the medicinal product to be assessed. The type and scope of best supportive care can vary depending on the medicinal product to be assessed and the comparator therapy.

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				
Ivacaftor	continuously, 1 x daily	365	1	365
Ivacaftor/ tezacaftor/ elexacaftor	continuously, 1 x daily	365	1	365
Best supportive care	Different from patient to patient			
Appropriate comparator therapy				
Best supportive care	Different from patient to patient			

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					
Ivacaftor	75 mg - 150 mg	75 mg - 150 mg	1 x 75 mg - 1 x 150 mg	365	365 x 75 mg - 365 x 150 mg
Ivacaftor/ tezacaftor/ elexacaftor	75 mg/ 50 mg/ 100 mg - 150 mg/ 100 mg/ 200 mg	75 mg/ 50 mg/ 100 mg - 150 mg/ 100 mg/ 200 mg	2 x 37.5 mg/ 25 mg/ 50 mg - 2 x 75 mg/ 50 mg/ 100 mg	365	730 x 37.5 mg/ 25 mg/ 50 mg - 730 x 75 mg/ 50 mg/ 100 mg
Best supportive care	Different from patient to patient				
Appropriate comparator therapy					
Best supportive care	Different from patient to patient				

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					
Ivacaftor 75 mg	28 FCT	€ 6,751.63	€ 1.77	€ 384.99	€ 6,364.87
Ivacaftor 150 mg	56 FCT	€ 13,492.83	€ 1.77	€ 769.98	€ 12,721.08
Ivacaftor 37.5 mg/ tezacaftor 25 mg/ elexacaftor 50 mg	56 FCT	€ 12,738.95	€ 1.77	€ 726.93	€ 12,010.25
Ivacaftor 75 mg/ tezacaftor 50 mg/ elexacaftor 100 mg	56 FCT	€ 12,738.95	€ 1.77	€ 726.93	€ 12,010.25

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
Best supportive care	Different from patient to patient				
Appropriate comparator therapy					
Best supportive care	Different from patient to patient				
Abbreviations: FCT = film-coated tablets					

LAUER-TAXE® last revised: 15 July 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.

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. 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 11 January 2022, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 3 February 2022, the pharmaceutical company submitted a dossier for the benefit assessment of ivacaftor to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 2, sentence 2 VerfO.

By letter dated 8 February 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 ivacaftor.

The dossier assessment by the IQWiG was submitted to the G-BA on 12 May 2022, and the written statement procedure was initiated with publication on the website of the G-BA on 16 May 2022. The deadline for submitting written statements was 7 June 2022.

The oral hearing was held on 27 June 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 26 July 2022, and the proposed resolution was approved.

At its session on 4 August 2022, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee Medicinal products	11 January 2022	Determination of the appropriate comparator therapy
Working group Section 35a	21 June 2022	Information on written statements received; preparation of the oral hearing
Subcommittee Medicinal products	27 June 2022	Conduct of the oral hearing
Working group Section 35a	6 July 2022 20 July 2022	Consultation on the dossier assessment by the IQWiG, assessment of the written statement procedure
Subcommittee Medicinal products	26 July 2022	Concluding discussion of the draft resolution
Plenum	4 August 2022	Adoption of the resolution on the amendment of Annex XII AM-RL

Berlin, 4 August 2022

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

Prof. Hecken