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) Olaparib (reassessment after the deadline: ovarian, fallopian tube or primary peritoneal cancer, BRCA-mutated, FIGO stages III and IV, maintenance treatment)

of 21 September 2023

Contents

1. Legal basis

According to Section 35a paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assesses the benefit of reimbursable medicinal products with new active ingredients. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the G-BA electronically, including all clinical trials the pharmaceutical company has conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. approved therapeutic indications,
2. medical benefit,
3. additional medical benefit in relation to the appropriate comparator therapy,
4. number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. treatment costs for the statutory health insurance funds,
6. requirements for a quality-assured application.

The G-BA may commission the Institute for Quality and Efficiency in Health Care (IQWiG) to carry out the benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment must be completed within three months of the relevant date for submission of the evidence and published on the internet.

According to Section 35a paragraph 3 SGB V, the G-BA decides on the benefit assessment within three months of its publication. The resolution is to be published on the internet and is part of the Pharmaceuticals Directive.

2. Key points of the resolution

The pharmaceutical company submitted a dossier for the early benefit assessment of the active ingredient olaparib (Lynparza) on 10 July 2019. For the resolution of 16 January 2020 made by the G-BA in this procedure, a limitation up to 1 April 2024 was pronounced. At the pharmaceutical company's request, this limitation was shortened until 1 April 2023 by the resolution of the G-BA of 19 January 2023.

In accordance with Section 4, paragraph 3, No. 5 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5 Section 8, paragraph 1, number 5 VerfO, the procedure for the benefit assessment of the medicinal product Lynparza recommences when the deadline has expired.

The pharmaceutical company submitted the final dossier to the G-BA in accordance with Section 4, paragraph 3, number 5 of the Ordinance on the Benefit Assessment of

Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 1, number 5 VerfO on 31 March 2023.

The G-BA commissioned the IQWiG to carry out the dossier assessment. The benefit assessment was published on the G-BA website (www.g-ba.de) on 3 July 2023, thus initiating the written statement procedure. An oral hearing was also held.

The G-BA came to a resolution on whether an additional benefit of olaparib 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 olaparib.

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 Olaparib (Lynparza) in accordance with the product information

Lynparza is indicated as monotherapy for the:

maintenance treatment of adult patients with advanced (FIGO stages III and IV) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.

Therapeutic indication of the resolution (resolution of 21.09.2023):

see the approved therapeutic indication

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Adult patients with advanced (FIGO stages III and IV) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy; maintenance treatment

Appropriate comparator therapy for olaparib as monotherapy:

Niraparib

1 General Methods, version 6.1 from 24.01.2022. 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 and Section 6 para. 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV):

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.

According to Section 6, paragraph 2, sentence 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the determination of the appropriate comparator therapy must be based on the actual medical treatment situation as it would be without the medicinal product to be assessed. According to Section 6, paragraph 2, sentence 3 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the G-BA may exceptionally determine the off-label use of medicinal products as an appropriate comparator therapy or as part of the appropriate comparator therapy if it determines by resolution on the benefit assessment according to Section 7, paragraph 4 that, according to the generally recognised state of medical knowledge, this is considered a therapy standard in the therapeutic indication to be assessed or as part of the therapy standard in the medical treatment situation to be taken into account according to sentence 2, and

1. for the first time, a medicinal product approved in the therapeutic indication is available with the medicinal product to be assessed,
2. according to the generally recognised state of medical knowledge, the off-label use is generally preferable to the medicinal products previously approved in the therapeutic indication, or
3. according to the generally recognised state of medical knowledge, the off-label use for relevant patient groups or indication areas is generally preferable to the medicinal products previously approved in the therapeutic indication.

An appropriate comparator therapy may also be non-medicinal therapy, the best possible add-on therapy including symptomatic or palliative treatment, or monitoring wait-and-see approach.

Justification based on the criteria set out in Chapter 5, Section 6, paragraph 3 VerfO and Section 6, paragraph 2 AM-NutzenV:

on 1. In addition to olaparib, medicinal products with the following active ingredients are approved in the present therapeutic indication:

Bevacizumab, carboplatin, cisplatin, cyclophosphamide, doxorubicin, epirubicin, niraparib, paclitaxel, treosulfan and melphalan.

on 2. Non-medicinal treatments are not considered.

on 3. The following resolutions and guidelines of the G-BA on medicinal treatments for the maintenance treatment of advanced ovarian cancer after platinum-based first-line chemotherapy are available:

Resolutions on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V:

- Olaparib: Resolution of 20 April 2023
- Olaparib: Resolution of 16 January 2020
- Niraparib: Resolution of 20 May 2021

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

Among the approved active ingredients listed under 1., only certain active ingredients named below will be included in the appropriate comparator therapy, taking into account the evidence on therapeutic benefit, the guideline recommendations and the reality of care.

According to current guidelines, chemotherapy with carboplatin in combination with paclitaxel is recommended as first-line therapy for advanced ovarian cancer.

Platinum-based first-line chemotherapy should be followed by additional maintenance treatment of advanced ovarian cancer.

According to current guidelines, PARP inhibitors, the active ingredient bevacizumab or the combination of a PARP inhibitor with bevacizumab can be considered.

According to the current S3 guideline, the combination of a PARP inhibitor with bevacizumab as maintenance treatment is recommended for patients after response and completion of platinum-based first-line chemotherapy in combination with bevacizumab whose tumour has a positive status of homologous recombination deficiency (HRD), defined by BRCA 1/2 mutation or/and genomic instability. In this regard, according to the S3 guideline, only data for the active ingredient olaparib are available so far.

Maintenance treatment with bevacizumab is indicated if the primary therapy also included the use of bevacizumab. According to the bevacizumab product information, in this case, bevacizumab monotherapy is used following bevacizumab-containing primary treatment.

According to the present therapeutic indication forming the basis of the resolution, olaparib is used as monotherapy in patients with a response (complete or partial) after platinum treatment as part of first-line chemotherapy regimen without bevacizumab.

Based on platinum-based first-line chemotherapy without the active ingredient bevacizumab, the available evidence for the maintenance treatment suggests that bevacizumab and the combination of bevacizumab with olaparib are not considered as an appropriate comparator therapy.

As a PARP inhibitor, in addition to olaparib as monotherapy for maintenance therapy in patients with advanced BRCA1/2-mutated, high-grade epithelial ovarian cancer (active ingredient to be assessed), niraparib (independent of BRCA mutation status) is approved.

By resolution of 20 May 2021, no additional benefit was determined for niraparib compared to the appropriate comparator therapy of monitoring wait-and-see approach, against the background that no complete study data were available for the benefit assessment.

According to the scientific-medical societies, the therapy standard in the first-line treatment of patients with advanced (FIGO stages III and IV) BRCA1/2-mutated, high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer, who have a response after completed platinum-based first-line chemotherapy, represents maintenance treatment using a PARP inhibitor (niraparib or olaparib), a PARP inhibitor in combination with bevacizumab (olaparib) as well as bevacizumab in case of contraindications to PARP inhibitors.

In the overall analysis of the available evidence, the G-BA determines the PARP inhibitor niraparib as the appropriate comparator therapy.

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

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

2.1.3 Extent and probability of the additional benefit

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

For maintenance treatment of adult patients with advanced (FIGO stages III and IV) BRCA1/2-mutated (germline and/or somatic), high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy, an additional benefit is not proven.

Justification:

For the renewed benefit assessment after the expiry of the limited period of validity of the resolution of 16 January 2020, the pharmaceutical company submits the results of the randomised, double-blind, placebo-controlled phase III SOLO-1 study.

The SOLO-1 study, which has been ongoing since August 2013, enrolled 391 adult patients with advanced (FIGO (Fédération-Internationale-de-Gynécologie-et- d'Obstétrique) stage III or IV) high-grade serous or high-grade endometrioid ovarian cancer and an ECOG-PS ≤ 1 who had responded (completely or partially) to a previous platinum-containing first-line chemotherapy in the main cohort at the start of the study. 375 (approx. 96%) of the patients had tumours of serous histology, 16 of the patients (approx. 4%) had tumours of non-serous histology. All patients had a mutation in the BRCA (Breast Cancer Susceptibility Gene) 1 or BRCA2 genes. Randomisation was 2:1 (olaparib N = 260; placebo N = 131) stratified by response to platinum-based first-line chemotherapy (complete/ partial).

The primary endpoint of the study is progression-free survival (PFS). Patient-relevant secondary endpoints are overall survival, health status, health-related quality of life, and adverse events.

Patients are treated until disease progression, unacceptable toxicity or withdrawal of consent, however, for a maximum of two years. At the principal investigator's discretion, patients may continue to be treated with the study medication under these conditions even after disease progression, provided that they continued to benefit from the treatment from the principal investigator's point of view and no other discontinuation criteria are present.

The decision on the type of subsequent therapy after therapy discontinuation is at the discretion of the principal investigator. Switching from the placebo arm to treatment with olaparib is not allowed according to the study design.

The SOLO-1 study is being conducted in 118 study sites across Australia, Asia, Europe, New Zealand, and North and South America.

For the benefit assessment, the data cut-off of 7 March 2022 (mortality, morbidity (except EQ-5D VAS) and side effects) and the data cut-off of 17 May 2018 (EQ-5D VAS and health-related quality of life) were submitted.

<u>On the implementation of the time-limit requirements and implementation of the appropriate comparator therapy</u>

According to the justification of the initial resolution of 16 January 2020, the limitation was that further clinical data from the SOLO-1 study are expected, which may be relevant for assessing the benefit of the medicinal product.

The initial resolution was based on the results of the data cut-off of 17 May 2018, in which the available data on the endpoint of overall survival were, however, still not very significant, particularly due to the low number of events that occurred at that time, and therefore could not be conclusively assessed.

For the new benefit assessment of olaparib after expiry of the period of validity of the resolution of 1 April 2024, the expected results from the final analysis on overall survival as well as on further patient-relevant endpoints used for the demonstration of additional benefit should be presented from the SOLO-1 study in the dossier.

The pharmaceutical company has informed the G-BA that the current SOLO-1 study results on overall survival have become available in the meantime.

These were the results of a pre-specified overall survival data cut-off at the time point 7 years after enrolment of the last study patient.

At the same time, the pharmaceutical company has explained that the event-driven final analysis on overall survival will occur later than originally expected.

In order to enable the inclusion of the new results on the pre-specified data cut-off on overall survival at the time point 7 years after enrolment of the last study patient of the SOLO-1 study for the renewed benefit assessment of the medicinal product according to Section 35a SGB V in due time, the period of validity of the resolution, which was originally limited to 1 April 2024, was changed to 1 April 2023 at the request of the pharmaceutical company.

For the new benefit assessment after expiry of the deadline, the SOLO-1 study results of the pre-specified data cut-off at the time point 7 years after enrolment of the last study patient

on overall survival as well as other patient-relevant endpoints should be submitted in the dossier.

For the reassessment after the deadline, the pharmaceutical company submits the SOLO-1 study results of the data cut-off at the time point 7 years after enrolment of the last study patient on overall survival as well as other patient-relevant endpoints. The pharmaceutical company thus complied with the conditions of the limitation.

Due to a change in therapy in the present therapeutic indication, niraparib was determined as the appropriate comparator therapy by the G-BA on the basis of the generally recognised state of medical knowledge for the present assessment after the deadline.

The SOLO-1 study submitted by the pharmaceutical company for the benefit assessment is a randomised, double-blind study in which olaparib is compared with placebo.

Due to the lack of comparison with the appropriate comparator therapy niraparib, the SOLO-1 study is unsuitable for assessing the additional benefit of olaparib and is therefore not used for the benefit assessment. Overall, the documents submitted by the pharmaceutical company for the benefit assessment do not show any evidence of an additional benefit compared to niraparib.

Conclusion

Overall, the data presented are unsuitable to demonstrate an additional benefit compared to the appropriate comparator therapy, which is why an additional benefit of olaparib as maintenance treatment in adult patients with advanced (FIGO stages III and IV) BRCA1/2-mutated (in the germline and/or somatic), high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who have a response (complete or partial) following completed platinum-based first-line chemotherapy.

2.1.4 Summary of the assessment

The present assessment is a new benefit assessment of the active ingredient olaparib due to the expiry of the limitation of the resolution of 16 January 2020. The therapeutic indication assessed here is as follows:

"Lynparza is indicated as monotherapy for the maintenance treatment of adult patients with advanced (FIGO stages III and IV) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy."

The G-BA determined niraparib as the appropriate comparator therapy.

For the benefit assessment, the pharmaceutical company submitted the results from the randomised, double-blind, placebo-controlled phase III SOLO-1 study, in which the treatment with olaparib as monotherapy was investigated.

Overall, the data presented are unsuitable to demonstrate an additional benefit compared to the appropriate comparator therapy, which is why an additional benefit of olaparib is not proven.

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

Adult patients with advanced (FIGO stages III and IV) BRCA1/2-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy; maintenance treatment

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

The resolution is based on the information from the dossier of the pharmaceutical company regarding the number of patients.
Compared to the initial assessment of olaparib as monotherapy, the adjusted derivation now available leads to a methodologically more suitable estimate of the number of patients in the SHI target population. However, this estimate is subject to uncertainties.

If the patient group with platinum-based first-line chemotherapy is included in the target population as a whole, irrespective of the simultaneous administration of bevacizumab, the number of eligible patients could almost double. However, the patient group is not included in the present therapeutic indication on which the resolution is based.

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 Lynparza (active ingredient: olaparib) at the following publicly accessible link (last access: 31 August 2023):

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

Treatment with olaparib should only be initiated and monitored by specialists in internal medicine, haematology, and oncology, specialists in gynaecology and obstetrics, and other specialists participating in the Oncology Agreement, all of whom are experienced in the treatment of patients with ovarian cancer.

Prior to treatment with Lynparza for first-line maintenance treatment of high-grade epithelial ovarian cancer (EOC), fallopian tube cancer (FTC) or primary peritoneal cancer (PPC), patients must have harmful or suspected harmful breast cancer susceptibility gene (BRCA) 1 or 2 mutations confirmed in the germline and/or tumour by a validated test method.

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: 1 September 2023).

Treatment period:

If no maximum treatment duration is specified in the product information, the treatment duration is assumed to be one year (365 days), even if the actual treatment duration varies from patient to patient and/or is shorter on average. The time unit "days" is used to calculate the "number of treatments/ patient/ year", time intervals between individual treatments and for the maximum treatment duration, if specified in the product information.

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
olaparib	Continuously, 2 x daily	365.0	1	365.0
Appropriate comparator therapy				
Niraparib	Continuously, 1 x daily	365.0	1	365.0

Consumption:

For the cost representation, only the dosages of the general case are considered. Patient-individual dose adjustments (e.g. because of side effects or co-morbidities) are not taken into account when calculating the annual treatment costs.

Designation of the therapy	Dosage/ application	Dosage/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed					
olaparib	300 mg	600 mg	4 x 150 mg	365.0	1,460 x 150 mg
Appropriate comparator therapy					
Niraparib	200 mg	200 mg	2 x 100 mg	365.0	730 x 100 mg

Costs:

In order to improve comparability, the costs of the medicinal products were approximated both on the basis of the pharmacy sales price level and also deducting the statutory rebates in accordance with Section 130 and Section 130a SGB V. To calculate the annual treatment costs, the required number of packs of a particular potency was first determined on the basis of consumption. Having determined the number of packs of a particular potency, the costs of the medicinal products were then calculated on the basis of the costs per pack after deduction of the statutory rebates.

Costs of the medicinal products:

Designation of the therapy	Packaging size	Cost (pharmacy discount price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates
Medicinal product to be assessed					
Olaparib 150 mg	112 FCT	€ 4,945.71	€ 2.00	€ 478.56	€ 4,465.15
Appropriate comparator therapy					
Niraparib 100 mg	84 FCT	€ 5,955.07	€ 2.00	€ 577.38	€ 5,375.69
Abbreviations: FCT = film-coated tablets					

LAUER-TAXE® last revised: 1 September 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.

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.

2.5 Designation of 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 the assessed medicinal product

According to Section 35a, paragraph 3, sentence 4, the G-BA designates all medicinal products with new active ingredients that can be used in a combination therapy with the assessed medicinal product for the therapeutic indication to be assessed on the basis of the marketing authorisation under Medicinal Products Act.

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

(AM-NutzenV), a medicinal product with a new active ingredient is considered to be a medicinal product with a new active ingredient for as long as there is dossier protection for the medicinal product with the active ingredient that was authorised for the first time.

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

3. Bureaucratic costs calculation

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

4. Process sequence

At its session on 28 March 2023, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 31 March 2023, the pharmaceutical company submitted a dossier for the benefit assessment of olaparib to the G-BA in due time in accordance with Chapter 5 Section 8, paragraph 1, number 5 VerfO.

By letter dated 3 April 2023 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 olaparib.

The dossier assessment by the IQWiG was submitted to the G-BA on 15 June 2023, and the written statement procedure was initiated with publication on the G-BA website on 3 July 2023. The deadline for submitting statements was 24 July 2023.

The oral hearing was held on 7 August 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 12 September 2023, and the proposed resolution was approved.

At its session on 21 September 2023, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee Medicinal products	28 March 2023	Determination of the appropriate comparator therapy
Working group Section 35a	2 August 2023	Information on written statements received; preparation of the oral hearing
Subcommittee Medicinal products	7 August 2023	Conduct of the oral hearing
Working group Section 35a	16 August 2023 6 September 2023	Consultation on the dossier assessment by the IQWiG, evaluation of the written statement procedure
Subcommittee Medicinal products	12 September 2023	Concluding discussion of the draft resolution
Plenum	21 September 2023	Adoption of the resolution on the amendment of the AM-RL

Berlin, 21 September 2023

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

Prof. Hecken