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)

Rucaparib (reassessment after the deadline: ovarian cancer, fallopian tube cancer or primary peritoneal cancer, maintenance treatment)

of 21 September 2023

Contents

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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 for the active ingredient (rucaparib) to be assessed for the first time on 26 February 2019. For the resolution of 15 August 2019 made by the G-BA in this procedure, a limitation up to 1 April 2023 was pronounced. 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 rucaparib recommences when the deadline has expired.

The pharmaceutical company did not submit a complete dossier to the G-BA at the relevant time, but no later than the date of expiry of the deadline, 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.

The pharmaceutical company has therefore not submitted the required evidence to the G-BA for the benefit assessment according to Section 35a SGB V. The legal consequence stipulated in Section 35a, paragraph 1, sentence 5 SGB V is that an additional benefit is considered unproven.

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In its benefit assessment, the G-BA made findings on the appropriate comparator therapy, the number of patients in the target population, the requirements for a quality-assured application and the treatment costs. The benefit assessment was published on the G-BA website (www.g-ba.de) on 3 July 2023, thus initiating the written statement procedure. In addition, an oral hearing was held.

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 Rucaparib (Rubraca) in accordance with the product information

Rubraca is indicated as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to 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:

Maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy

Appropriate comparator therapy for rucaparib as monotherapy:

Patient-individual therapy with selection of:

- olaparib,
- niraparib and
- monitoring wait-and-see approach (only for patients who have already received a PARP inhibitor);

taking into account prior therapy with a PARP inhibitor

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.

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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 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.

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

on 1. In terms of authorisation status, the active ingredients available are bevacizumab, cisplatin, carboplatin, cyclophosphamide, doxorubicin, liposomal doxorubicin (PLD), epirubicin, etoposide, gemcitabine, melphalan, niraparib, olaparib, paclitaxel, topotecan, trabectedin and treosulfan.

on 2. Non-medicinal treatments are not considered.

on 3. Resolutions on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V:
- Olaparib: Resolution of 6 December 2018
- Niraparib: Resolution of 15 July 2021

In the therapeutic indication ";Maintenance treatment of adult patients with platinum-sensitive, relapsed, high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy", the resolution on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V for rucaparib dated 15 August 2019 is available and is replaced by the present resolution.

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on 4. 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 health care provision.

The generally accepted state of medical knowledge for the indication was established by means of a search for guidelines and systematic reviews of clinical studies.

It is assumed that a platinum-sensitive relapsing ovarian cancer is based on a response to platinum-containing pretreatment with a relapse-free interval of at least six months. This includes partially platinum-sensitive ovarian cancers with a recurrence between six and twelve months after completion of platinum-containing chemotherapy.

According to the current S3 guideline (2022[1]), patients with a relapse of high-grade ovarian cancer should be offered maintenance treatment with a PARP inhibitor after a response to platinum-containing combination therapy. In addition to the PARP inhibitor rucaparib to be assessed here, the PARP inhibitors olaparib and niraparib have a corresponding marketing authorisation.

The PARP inhibitor olaparib was initially approved for the maintenance treatment of adult patients with platinum-sensitive relapse of BRCA-mutated (germline and/or somatic) high-grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer who respond to platinum-based chemotherapy. Subsequently, olaparib was approved as "monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy". By resolution of 6 December 2018, the G-BA determined a hint for a minor additional benefit in the benefit assessment of olaparib in this therapeutic indication. Compared to the appropriate comparator therapy with monitoring wait-and-see approach, treatment with olaparib led to a moderate prolongation of overall survival with concomitant adverse events.

The PARP inhibitor niraparib was approved for maintenance treatment in adult patients with relapse of a platinum-sensitive, poorly differentiated serous cancer of the ovaries, fallopian tubes or primary peritoneal carcinomatosis who are in response to platinum-based chemotherapy. In the reassessment after the deadline, it was determined that an additional benefit was not proven for niraparib compared to the appropriate comparator therapy "olaparib" (resolution of 15 July 2021).

Bevacizumab is approved for treatment of adult patients with first relapse of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer. Bevacizumab is used either in combination with carboplatin and gemcitabine over six to ten treatment cycles or in combination with carboplatin and paclitaxel over six to eight treatment cycles and then as maintenance treatment as monotherapy until disease progression. Since bevacizumab maintenance treatment requires a bevacizumab-containing primary therapy and this, however, is not a prerequisite for maintenance treatment with rucaparib in the present therapeutic indication, bevacizumab is not determined as an appropriate comparator therapy from this point of view.

In accordance with the guidelines, the scientific-medical societies explained the high value of PARP inhibitors in the context of maintenance treatment during the written statement procedure for this benefit assessment. Patients with a relapse should be

1 S3 guideline Diagnostics, therapy and after-care of malignant ovarian tumours, version 5.1-May 2022, AWMF-registration number: 032/035OL.

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offered maintenance treatment with a PARP inhibitor following platinum-containing relapse therapy. However, the evidence does not show that one PARP inhibitor is regularly preferable to the other PARP inhibitors. Therefore, both PARP inhibitors - olaparib and niraparib - are considered in the determination of the appropriate comparator therapy.

Rucaparib is used in the present therapeutic indication for maintenance treatment in the treatment setting after a relapse. It can be assumed that a relevant percentage of patients in the present therapeutic indication have already received previous treatment with a PARP inhibitor as maintenance treatment with a PARP inhibitor is a standard in the previous treatment setting (after first-line chemotherapy) according to the current state of medical knowledge. With regard to renewed therapy with a PARP inhibitor, no explicit recommendations are currently available. Therefore, for patients who have already received a PARP inhibitor, monitoring wait-and-see approach is considered an appropriate comparator therapy in the present therapeutic indication.

For these reasons, the G-BA determines a patient-individual therapy as the appropriate comparator therapy overall, selecting olaparib, niraparib and monitoring wait-and-see approach (only for patients who have already received a PARP inhibitor); taking into account prior therapy with a PARP inhibitor.

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

Change of the appropriate comparator therapy:

Originally, the appropriate comparator therapy was determined as follows:

The appropriate comparator therapy for rucaparib as monotherapy for the maintenance treatment of adult patients with platinum-sensitive, relapsed, high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in response (complete or partial) to platinum-based chemotherapy, is

- olaparib

or

- monitoring wait-and-see approach.

Taking into account the significance of PARP inhibitors in the present therapeutic indication and in the pretreatment of patients as outlined in current guidelines and by the scientific-medical societies in the context of the written statement procedure, this was taken into account accordingly when determining the appropriate comparator therapy for the present resolution. In addition, the PARP inhibitor niraparib was included in the appropriate comparator therapy.

This change to the appropriate comparator therapy has no effects on the present assessment of the additional benefit, nor does it require the benefit assessment to be carried out again.

2.1.3 Extent and probability of the additional benefit

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

The additional benefit is deemed not to have been proven.

Justification:

The pharmaceutical company did not submit any dossier at the relevant time. According to Section 35a, paragraph 1, sentence 5 SGB V, this means that no assessment is carried out on

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the question of whether the active ingredient rucaparib in the therapeutic indication as maintenance treatment of adult patients with platinum-sensitive, relapsed, high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy has an additional benefit, no additional benefit or a reduced benefit compared to the appropriate comparator therapy and that the additional benefit of rucaparib in relation to the appropriate comparator therapy is deemed not to have been proven.

As part of the written statement procedure, the pharmaceutical company submitted results of the ARIEL3 study. These data were not used as they should have been submitted with a dossier at the relevant time.

2.1.4 Summary of the assessment

The present assessment is a new benefit assessment of the active ingredient rucaparib due to the expiry of the limitation of the resolution of 15 August 2019.

The therapeutic indication assessed here is as follows:

Rubraca is indicated as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.

The G-BA determined a patient-individual therapy as the appropriate comparator therapy, selecting olaparib, niraparib and monitoring wait-and-see approach (only for patients who have already received a PARP inhibitor); taking into account previous therapy with a PARP inhibitor as the appropriate comparator therapy.

The pharmaceutical company did not submit any dossier at the relevant time. According to Section 35a, paragraph 1, sentence 5 SGB V, this means that there is no assessment of whether or to what extent there is an additional benefit of the active ingredient rucaparib in the therapeutic indication "maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy" compared with the appropriate comparator therapy. The additional benefit of rucaparib in relation to the appropriate comparator therapy is deemed not to have been proven.

2.2 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 calculation of patient numbers is based on IQWiG's calculation in the benefit assessment of niraparib in a similar therapeutic indication[2].

Based on the incidence for 2017 of the Robert Koch Institute (RKI)[3] with 7,300 patients with the ICD-10 diagnosis C56 (ovarian cancer), the following percentage values were calculated[2]:

- 78.7% for the percentage of epithelial tumours in all malignant ovarian tumours without borderline tumours,
- 22.4% for patients with platinum-sensitive relapse of high-grade serous ovarian cancer,

2 Institute for Quality and Efficiency in Health Care, Niraparib (Ovarian Cancer), report no. 604, 2018
3 Robert Koch Institute, Cancer in Germany for 2017/2018, 2021

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- 81.2% for patients with a first platinum-sensitive relapse who receive chemotherapy again,
- of which 78.5% with platinum-containing chemotherapy and
- approx. 30% for patients who subsequently receive further platinum-containing relapse therapy.

Subsequently, the patients with platinum-containing second-line therapy were used to determine a lower limit (820 patients) and the number of patients with further follow-up therapies was additionally added to determine an upper limit (1,066 patients). There are uncertainties because there is no information on whether the patients received bevacizumab in addition to chemotherapy.

The distribution of diagnoses of ovarian, peritoneal and fallopian tube cancer was taken from the NOVA study[2]:

- 83.73% for patients with ovarian cancer,
- 8.14% for patients with peritoneal cancer and
- 7.96% for patients with fallopian tube cancer.

Consequently, 80 to 104 patients with peritoneal cancer and 78 to 101 patients with fallopian tube cancer were calculated.

In total, there are 978 to 1271 patients with ovarian, peritoneal and fallopian tube cancer. However, it must be taken into account that these figures refer exclusively to incidence and would therefore have to be multiplied by the mean survival time of the target population to determine prevalence. For this purpose, an average survival time of 2 to 3 years is assumed.

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 Rubraca (active ingredient: rucaparib) at the following publicly accessible link (last access: 9 August 2023):

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

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

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.

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Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Rucaparib	Continuously, 2 x daily	365.0	1	365.0
Appropriate comparator therapy				
Patient-individual therapy selecting olaparib, niraparib and monitoring wait-and-see approach (only for patients who have already received a PARP inhibitor); taking into account previous therapy with a PARP inhibitor				
Olaparib	Continuously, 2 x daily	365.0	1	365.0
Niraparib	Continuously, 1 x daily	365.0	1	365.0
Monitoring wait-and-see approach	incalculable			

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					
Rucaparib	600 mg	1,200 mg	4 x 300 mg	365.0	1,460 x 300 mg
Appropriate comparator therapy					
Patient-individual therapy selecting olaparib, niraparib and monitoring wait-and-see approach (only for patients who have already received a PARP inhibitor); taking into account previous therapy with a PARP inhibitor					
Olaparib	300 mg	600 mg	4 x 150 mg	365.0	1,460 x 150 mg
Niraparib	300 mg	300 mg	3 x 100 mg	365.0	1,095 x 100 mg
Monitoring wait-and-see approach	incalculable				

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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					
Rucaparib 300 mg	60 FCT	€ 2,592.43	€ 2.00	€ 248.16	€ 2,342.27
Appropriate comparator therapy					
Olaparib 150 mg	112 FCT	€ 4,945.71	€ 2.00	€ 478.56	€ 4,465.15
Niraparib	84 FCT	€ 5,955.07	€ 2.00	€ 577.38	€ 5,375.69
Monitoring wait-and-see approach	incalculable				
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 need 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

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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 3 January 2019, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

The pharmaceutical company did not submit a dossier for the benefit assessment of rucaparib to the G-BA in accordance with Chapter 5, Section 8, paragraph 1, number 5 VerfO.

The G-BA prepared the benefit assessment.

The written statement procedure was initiated with the publication of the benefit assessment prepared by the G-BA on 3 July 2023 on the G-BA's website. 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.

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Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee Medicinal products	3 January 2019	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	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

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