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
Pemigatinib (cholangiocarcinoma with FGFR2 fusion or FGFR2 rearrangement, after at least one prior therapy)

of 7 October 2021

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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.

For medicinal products for the treatment of a rare disease (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), the additional medical benefit is considered to be proven through the grant of the marketing authorisation. 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, Ordinance on the Benefit Assessment of Pharmaceuticals (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 €50 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, subsection 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 marketing authorisation 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 legal limit of €50 million and is therefore subject to an unrestricted benefit assessment (cf. Section 35a paragraph 1, sentence 12 SGB V). 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 forms part of the Pharmaceuticals Directive.

2. Key points of the resolution

The relevant date for the first placing on the (German) market of the combination of active ingredient pemigatinib in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 of the Rules of Procedure of the G-BA (VerfO) is 15 April 2021. 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 30 March 2021.

Pemigatinib for the treatment of cholangiocarcinoma (with FGFR2 fusion or FGFR2 rearrangement, after at least one prior therapy) is approved as a medicinal product for the treatment of a rare disease under Regulation (EC) No 141/2000 of the European Parliament and 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 marketing authorisation 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 15 July 2021 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 G12-12) and the statements made in the written statements and oral hearing process, 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 marketing authorisation considering 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 pemigatinib.

[1] General Methods, version 6.0 from 05.11.2020. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

2.1 Additional benefit of the medicinal product

2.1.1 Approved therapeutic indication of pemigatinib (Pemazyre) in accordance with the product information

Pemazyre monotherapy is indicated for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.

Therapeutic indication of the resolution (resolution from the 7 October 2021):

see the approved therapeutic indication

2.1.2 Extent of the additional benefit and significance of the evidence

Adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy

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

In conclusion, there is a hint for a non-quantifiable additional benefit since the scientific data does not allow quantification.

Justification:

For the benefit assessment, the pharmaceutical company submitted the results of the pivotal FIGHT-202 study. In addition, a non-adjusted indirect comparison for overall survival from the FIGHT-202 study compared to the population in the Jain et al., 2018[2] publication was provided by the pharmaceutical company.

FIGHT-202 study

FIGHT-202 study is an open-label, uncontrolled, multicentre Phase II study evaluating the efficacy and safety of pemigatinib in patients with advanced/metastatic or surgically unresectable cholangiocarcinoma who have received prior therapy.

The study was conducted in 67 study centres, mainly in Europe and the USA. The study was launched in January 2017 and is currently ongoing.

Patients with histologically or cytologically confirmed advanced/metastatic or unresectable cholangiocarcinoma based on genetic testing for FGF/FGFR status were included. Patients were divided into cohorts according to test results.

In the present therapeutic indication, cohort A of the FIGHT-202 study is the relevant sub-population for the benefit assessment of pemigatinib. Cohort A includes patients with FGFR2 fusion or FGFR2 rearrangement, according to central laboratory report. Patients with

[2] Jain A, Borad MJ, Kelley RK, Wang Y, Abdel-Wahab R, Meric-Bernstam F, et al. Cholangiocarcinoma with FGFR genetic aberrations: a unique clinical phenotype. JCO Precision Oncology 2018(2):1-12.

FGF/FGFR alterations that do not show any fusions or rearrangements in FGFR2 will be assigned to cohort B. Cohort C included patients with no detectable changes in FGF/FGFR. Cohorts B and C do not correspond to the approved therapeutic indication and are therefore not included in the benefit assessment.

As of the 22 March 2019 data cut-off, the relevant study population consists of 107 patients. One subject was recruited additionally up to the 7 April 2020 data cut-off, bringing the sample size to 108 subjects at the later data cut-off.

The mean age of the patients is 55 years. The percentage of women included is greater than the proportion of men (38.9% vs 61.1%). Except for one test subject, all study participants had an intrahepatic tumour location and were treated with at least one prior systemic cancer therapy. The majority of the study population shows an ECOG status of 0 or 1 at baseline.

Study participants received pemigatinib in consecutive 21-day cycles of therapy. Therapy with pemigatinib was continued until disease progression, unacceptable toxicity, initiation of other antineoplastic therapy, or withdrawal of consent. The end of therapy was followed by a 30-day safety follow-up. Disease and/or vital status were recorded at long-term follow-up after the end of therapy.

Up to the data cut-off on 7 April 2020,, patients received the study medication for a mean of approximately 300 days, with a median of 220 days. The average number of therapy cycles was 14.3 and the median 10.5. Up to the data cut-off on 7 April 2020, pemigatinib use had been discontinued by 48.1% of participants or dose reduced by 22.1% of participants.

Up to the data cut-off on 7 April 2020, 90.7% of patients had discontinued therapy predominantly due to disease progression (67.6%). Discontinuation or withdrawal from the study for 67.6% of patients was largely due to the death of the patients concerned (55.6%).

Results on 4 data cut-offs (22 March 2019, 20 August 2019, 15 October 2019, 7 April 2020) were submitted with the dossier. None of the data cut-offs was prespecified in the study records. The data cut-offs on 22 March 2019 and 7 April 2020 were interim data cut-offs for the Medicines Agency. The pharmaceutical company did not provide any further information on the justification of the selected data cut-offs. For the purposes of this assessment, the data cut-off from 7 April 2020, will be used for the endpoints mortality and safety, and the data cut-off from 22 March 2019 will be used for the endpoints of the PRO instruments used, as these have the longest follow-up time.

Indirect comparison to the population of the publication Jain et al., 2018

The pharmaceutical company presents an indirect comparison on overall survival data on the population of the publication Jain et al, 2018.

This indirect comparison is not used for the benefit assessment of pemigatinib due to the following uncertainties:

In order to establish putative comparability in the operationalisation for follow-up on overall survival for the indirect comparison, the start time for a follow-up on overall survival for the patients in the FIGHT-202 study was backdated from the start of therapy with pemigatinib to the time of diagnosis. This means that patients must have survived to the start of therapy with pemigatinib in order to be included in the FIGHT-202 study at all, which results in a selection

bias. This selection likely leads to the inclusion of patients with lower disease severity. Thus, backdating for the period from the date of diagnosis to the start of treatment with pemigatinib results in an immortal time bias, which likely results in an overestimation of survival compared to the external control group.

In addition, there are further limitations to the indirect comparison that lead to a high degree of uncertainty regarding the comparability of the two study populations. The external control population is a study of the natural history of cholangiocarcinoma in patients with FGFR genomic aberration. This genomic aberration was not limited to the fusions or rearrangements in the FGFR2 gene. Of the 95 patients included in the external control population, 63 had a change in FGFR2. It remains unclear whether these were always fusions or rearrangements. In addition, patients with non-metastatic or unresectable stage disease were also included in Jain et al. Furthermore, some of the 63 patients had been treated with FGFR-targeted therapy, which is why the pharmaceutical company limited the comparison to patients who did not receive FGFR-targeted therapy (n = 50). It is not clear from the publication which therapies were administered in detail. Descriptions regarding the patient characteristics of the relevant sub-population of the external control group (n = 50) are also not available in the publication.

Overall, this is a naive (without bridge comparator) indirect comparison with serious methodological weaknesses due to the backdating of the start of the observation period. The similarity of the patient populations used for the indirect comparison cannot be assessed due to the lack of information or missing representations in the publication by Jain et al. Thus, the results of the indirect comparison on overall survival do not allow reliable conclusions for the assessment of the extent of additional benefit of pemigatinib.

Mortality

The endpoint overall survival in the FIGHT-202 study is operationalised as the time from the first day of treatment with pemigatinib until death from any cause.

Since no comparative data are available, no overall conclusions on the extent of additional benefit in the mortality category can be derived from the results of the FIGHT-202 study.

Morbidity

Progression-free survival

Progression-free survival is operationalised in the FIGHT-202 study as the time from the start of treatment to the time of disease progression or death from any cause, whichever occurs first. Disease progression was assessed by a central review committee and based on the Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1.

The PFS endpoint is a combined endpoint composed of endpoints of the categories "mortality" and "morbidity". The endpoint component "mortality" is already assessed via the endpoint "overall survival" as an independent endpoint. The "disease progression" component is based on the assessment of radiological findings. Thus, morbidity is not primarily assessed based on disease symptoms but solely based on asymptomatic findings that are not directly relevant to the patient.

Taking into account the aspects mentioned above, there are different opinions within the G-BA regarding the patient relevance of the endpoint PFS.

The overall statement on the additional benefit remains unaffected.

Symptomatology

The symptomatology of the FIGHT-202 study patients is assessed using the symptom scales of the EORTC QLQ-C30 questionnaire.

Due to a lack of return rate information and descriptive analyses in the data cut-off of the 7 April 2020, results from the 22 March 2019 data cut-off are used. At this time, patients underwent a mean of 11.8 (SD: 7.9) and a median of 10 (min: 1; max: 34) therapy cycles. Return rates decreased over the course of the study and were only sufficiently high (> 70%) at the cycle 3 and cycle 6 survey time points on the data cut-off of the 22 March 2019.

In the dossier, the pharmaceutical company presents absolute scores and their mean and median changes from baseline. Higher values indicate more pronounced symptomatology.

In the absence of comparative data, a conclusive assessment of the effect of pemigatinib on morbidity is not possible.

Health-related quality of life

EORTC QLQ-C30

Health-related quality of life is assessed in the FIGHT-202 study using the EORTC QLQ-C30 functional scales.

Due to a lack of return rate information and descriptive analyses in the data cut-off of the 7 April 2020, results from the 22 March 2019 data cut-off are used. At this time, patients underwent a mean of 11.8 (SD: 7.9) and a median of 10 (min: 1; max: 34) therapy cycles. Return rates decreased over the course of the study and were only sufficiently high (> 70%) at the cycle 3 and cycle 6 survey time points on the data cut-off of the 22 March 2019.

In the dossier, the pharmaceutical company presents absolute scores and their mean and median changes from baseline. Higher values mean better functioning or health/quality of life.

EORTC QLQ-BIL21

Disease-specific quality of life will be assessed in the FIGHT-202 study using EORTC QLQ-BIL21 in the USA, UK, Italy, Germany and Korea only.

Due to a lack of return rate information and descriptive analyses in the data cut-off of the 7 April 2020, results from the 22 March 2019 data cut-off are used. At this time, patients underwent a mean of 11.8 (SD: 7.9) and a median of 10 (min: 1; max: 34) therapy cycles. Return rates decreased over the course of the study and were only sufficiently high (> 70%) at the cycle 6 survey time point on the data cut-off of 22 March 2019.

In the dossier, the pharmaceutical company presents absolute scores and their mean and median changes from baseline. The range of the score is between 0 and 100 points; the higher the score, the worse the disease-specific quality of life.

Overall, a conclusive assessment of the effect of pemigatinib on quality of life is not possible due to the lack of comparative data.

Side effects

Adverse events were collected continuously from signing the consent form until 30 (+ 5) days after discontinuation or termination of pemigatinib therapy. The results of the final data cut-off of 7 April 2020 are used.

Adverse events (AEs) in total

AE occurred in all patients relevant for the benefit assessment. The results were only presented additionally.

Serious adverse events (SAE)

Serious AEs have been reported. The most frequent SAEs include SAEs in the system organ classes "Infections and infestations" and "Gastrointestinal disorders".

Severe AEs (CTCAE grade ≥ 3)

Severe AEs occurred in 66.7% of participants. Most frequently, severe AEs of the system organ classes "Gastrointestinal disorders" and "Metabolism and nutrition disorders" were reported.

Therapy discontinuations due to AE

Pemigatinib therapy was discontinued by 7 of the 108 patients (6.5%) due to AEs.

AE of special interest

The majority of patients relevant for the benefit assessment reported the occurrence of AEs of special clinical interest (84.3%). AEs were most frequently reported in the groups "hyperphosphataemia" and "nail toxicity". Only a small percentage of the AEs of special clinical interest had NCI-CTCAE severity grades 3 and 4. Severe AEs of special clinical interest occurred mainly in the "hyperphosphatemia" group.

The specified PTs of the groups "nail toxicity" and "severe retinal detachments" presented in the dossier show inconsistencies with regard to the selection and presentation of the PTs. This results in uncertainties regarding the validity of the selected AEs of particular clinical interest.

In summary, due to the lack of a control population, no comparative evaluation is possible regarding the occurrence of safety events.

Overall assessment / conclusion

For the assessment of the additional benefit of pemigatinib for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy, results for the endpoint categories mortality, morbidity, quality of life, and side effects are available from the uncontrolled FIGHT study.

A comparative assessment of the study results is not possible due to the uncontrolled design of the FIGHT-202 study.

The indirect comparison on overall survival presented by the pharmaceutical company in the dossier against data from the publication Jain et al., 2018 is not used. Limitations here are methodological weaknesses due to the backdating of the start of the observation period as well as the missing data or missing representations in the publication by Jain et al., so that the comparability of the two study populations cannot be assessed.

Thus, quantification of the additional benefit is not possible on the basis of the data presented.

The overall conclusion is that pemigatinib for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy is of non-quantifiable additional benefit since the scientific data does not allow quantification.

Significance of the evidence

The FIGHT-202 study is an uncontrolled study, so that a comparative assessment is not possible.

In the overall review, the result is a hint for a non-quantifiable additional benefit concerning significance of the evidence.

2.1.3 Summary of the assessment

The present assessment concerns the benefit assessment of the new medicinal product Pemazyre with the active ingredient pemigatinib.

Pemigatinib was approved under "exceptional circumstances" as an orphan drug.

Pemigatinib is indicated for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.

The uncontrolled FIGHT-202 study presents results on the endpoint categories mortality, morbidity, quality of life, and side effects for the benefit assessment.

A comparative assessment of the study results is not possible due to the uncontrolled design of the FIGHT-202 study.

In addition, the pharmaceutical company provided an indirect comparison on the overall survival of the FIGHT-202 study compared to the population of the Jain et al, 2018 publication.

The indirect comparison set out above is not used. This is justified with methodological weaknesses as well as missing data or missing representations in the publication of Jain et al., since comparability of the two study populations cannot be assessed.

Thus, quantification of the additional benefit is not possible on the basis of the data presented.

In the overall review, the result is a hint for a non-quantifiable additional benefit concerning the significance of the evidence.

Overall, a hint for a non-quantifiable additional benefit is identified for pemigatinib because the scientific data basis does not allow quantification.

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 G-BA bases its resolution on the information from the dossier of the pharmaceutical company.

Uncertainties exist regarding the size of the target population.

In particular, there is uncertainty regarding the proportion of intrahepatic cholangiocarcinoma with an FGFR2 fusion or an FGFR2 rearrangement. This uncertainty should be taken into account by means of a wider range. In addition, the inclusion of carcinomas of the gall bladder may result in additional patients in the target population.

In addition, various derivation steps contain over-or underestimations, the respective extent of which cannot be quantified.

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 Pemazyre (active ingredient: pemigatinib) at the following publicly accessible link (last access: 20 July 2021):
https://www.ema.europa.eu/en/documents/product-information/pemazyre-epar-product-information_de.pdf

Treatment with pemigatinib should only be initiated and monitored by specialists in internal medicine, haematology, and oncology, internal medicine and gastroenterology, and specialists participating in the Oncology Agreement experienced in the treatment of adults with cholangiocarcinoma.

This medicinal product was approved under "special conditions". This means that further evidence of the benefit of the medicinal product is anticipated. The European Medicines Agency will evaluate new information on this medicinal product at a minimum once per year and update the product information where necessary.

2.4 Treatment costs

The treatment costs are based on the product information as well as the information in the LAUER-TAXE® (last revised: 15 September 2021).

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

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

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Treatment period:

Designation of the therapy	Treatment mode	Number of treatments/ patient or patient//year	Treatment duration/ treatment (days)	Days of treatment/ patient/ year
Medicinal product to be assessed				
Pemigatinib	daily on days 1 - 14 of a 21-day cycle	17.4 cycles	14	243.6

Consumption:

Designation of the therapy	Dosage/ application	Dose/ patient/ or patient/ treatment days	Usage by potency/ day of treatment	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed					
Pemigatinib	13.5 mg	13.5 mg	1 x 13.5 mg	243.6	243.6 x 13.5 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					
Pemigatinib	14	€ 9,534.49	€ 1.77	€ 541.24	€ 8,991.48

LAUER-TAXE® last revised: 15 September 2021

Costs for additionally required SHI services:

Only costs directly related to the use of the medicinal product are taken into account. If there are regular differences in the necessary use of medical treatment or in the prescription of other services in the use of the medicinal product to be evaluated and the appropriate comparator therapy in accordance with the product information, the costs incurred for this must be considered 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 standard expenditure in the course of the treatment are not shown.

Designation of the therapy	Type of service	Costs/ pack or service	Days of treatment/year	Annual costs/ patient
Pemigatinib	Determination of the FGFR2 status Mutation search for the detection or exclusion of a disease-relevant or disease-causing somatic genomic mutation with clinically relevant properties (GOP number 19453)	€ 75.42	1	€ 75.42
	Ophthalmological examination (GOP numbers 06211, 06212 and 06220)	€ 15.36 - € 17.47	4	€ 61.44 - € 69.88
	Optical coherence tomography for the diagnosis of the right and left eye (GOP numbers 06336 and 06337)	€ 89.88	5	€ 449.4
	Monitoring of the blood phosphate level (GOP number 32197)	patient-individual		

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 30 March 2021, the pharmaceutical company submitted a dossier for the benefit assessment of pemigatinib to the G-BA in due time in accordance with Chapter 5, Section 8, number 1, sentence 2 VerfO.

The benefit assessment of the G-BA was published on 15 July 2021 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 written statements was 5 August 2021.

The oral hearing was held on 24 August 2021.

In order to prepare a recommendation for a resolution, the Subcommittee on Medicinal Products commissioned a working group (Section 35a) consisting of the members nominated by the leading organisations of the care providers, the members nominated by the SHI umbrella organisation, and the 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 subcommittee session on 28 September 2021, and the draft resolution was approved.

At its session on 7 October 2021, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee Medicinal product	6 July 2021	Information of the benefit assessment of the G-BA
Working group Section 35a	18 August 2021	Information on written statements received; preparation of the oral hearing
Subcommittee Medicinal product	24 August 2021	Conduct of the oral hearing
Working group Section 35a	1 September 2021 22 September 2021	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 product	28 September 2021	Final discussion of the draft resolution
Plenum	7 October 2021	Adoption of the resolution on the amendment of Annex XII AM-RL

Berlin, 7 October 2021

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

Prof. Hecken