Gemeinsamer Bundesausschuss

Justification

of the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V Pertuzumab/trastuzumab (breast cancer, HER2-positive, metastatic or locally recurrent (unresectable), first-line, combination with docetaxel)

of 15 July 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. 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 benefits,
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. Costs of therapy for the statutory health insurance,
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 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 pertuzumab/trastuzumab in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 of the Rules of Procedure of the G-BA (VerfO) is 1 February 2021. The pharmaceutical company has 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 14 January 2021.

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on the website of the G-BA (www.g-ba.de), on 3 May 2021, thus initiating the written statement procedure. In addition, an oral hearing was held.

The G-BA came to a resolution on whether an additional benefit of pertuzumab/trastuzumab 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 pertuzumab/trastuzumab.

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 pertuzumab/trastuzumab (Phesgo) according to product information

Phesgo is indicated for use in combination with docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.

Therapeutic indication of the resolution (resolution of 15.07.2021):

see approved therapeutic indication

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Adult patients with HER2-positive metastatic or locally recurrent, unresectable breast cancer who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease

Appropriate comparator therapy for pertuzumab/trastuzumab in combination with docetaxel:

- Pertuzumab in combination with trastuzumab and docetaxel

Criteria according to Chapter 5, Section 6 of the Rules of Procedure of the G-BA:

The appropriate comparator therapy must be an appropriate therapy in the therapeutic indication in accordance with the generally recognised state of medical knowledge (Section 12 SGB V), preferably a therapy for which endpoint studies are available and which has proven its worth in practical application unless contradicted by the guidelines under Section 92, paragraph 1 SGB V or the principle of economic efficiency.

In determining the appropriate comparator therapy, the following criteria, in particular, must be taken into account as specified in Chapter 5, Section 6, paragraph 3 VerfO:

1. To be considered as a comparator therapy, the medicinal product must, principally, have a marketing authorisation for the therapeutic indication.
2. If a non-medicinal treatment is considered a comparator therapy, this must be available within the framework of the SHI system.

1 General Methods, version 6.0 from 5.11.2020. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

3. As comparator therapy, medicinal products or non-medicinal treatments for which the patient-relevant benefit has already been determined by the Federal Joint Committee shall be preferred.
4. According to the generally recognised state of medical knowledge, the comparator therapy should be part of the appropriate therapy in the therapeutic indication.

Justification based on the criteria set out in Chapter 5, Section 6, paragraph 3 VerfO:

on 1. In terms of authorisation status, the cytostatic drugs capecitabine, cyclophosphamide, docetaxel, doxorubicin, epirubicin, eribulin, 5-fluorouracil, gemcitabine and ifosfamide, methotrexate, mitomycin, mitoxantrone, nab-paclitaxel, vinblastine, vincristine, and vinorelbine, and the HER2-targeting agents lapatinib, pertuzumab, trastuzumab, and trastuzumab emtansine are available for the treatment of HER2-positive metastatic or locally recurrent unresectable breast cancer.

Medicinal products with explicit marketing authorisation for the treatment of hormone-receptor positive breast cancer or in the context of endocrine therapy were not included.

on 2. A non-medicinal treatment cannot be considered as a comparator therapy in this therapeutic indication.

on 3. The following resolutions or guidelines of the G-BA for medical products and non-medicinal treatments are available:

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

- Pertuzumab: Resolution of 1 October 2013
- Eribulin: Resolution of 22 January 2015

Methods Hospital Treatment Policy - Section 4 Excluded Methods, effective 19 December 2019:

- Proton therapy for breast cancer

on 4. The general state of medical knowledge, on which the finding of the G-BA is based, was illustrated by systematic research for guidelines as well as reviews of clinical studies in the present therapeutic indication.

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.

National and international guidelines for the treatment of HER2-positive metastatic breast cancer are unanimously in favour of anti-HER2 therapy, provided there are no cardiac contraindications. In the guidelines as well as in the conclusions of systematic reviews, dual blockade of the HER2 receptor with pertuzumab in combination with trastuzumab and a taxane is recommended over singular inhibition of the HER2 receptor with trastuzumab in combination with a taxane.

The active ingredient pertuzumab was evaluated within the benefit assessment framework according to Section 35a SGB V. By resolution of 1 October 2013, a hint on substantial additional benefit was identified for pertuzumab in combination with trastuzumab and docetaxel in patients with HER2-positive metastatic breast cancer with visceral metastasis compared with the appropriate comparator therapy trastuzumab in combination with a taxane. An additional benefit was not proven for patients without visceral metastasis compared to the same appropriate comparator therapy. For the third patient group - patients with HER2-positive locally recurrent, unresectable breast cancer - an additional benefit compared to radiotherapy was not proven because no data were available.

In view of the entire body of evidence and unanimous recommendations in the guidelines, pertuzumab in combination with trastuzumab and docetaxel is determined to be the appropriate comparator therapy for the entire patient population according to the present therapeutic indication.

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

2.1.3 Extent and probability of the additional benefit

In summary, the additional benefit of pertuzumab/trastuzumab in combination with docetaxel is assessed as follows:

<u>Adult patients with HER2-positive metastatic or locally recurrent, unresectable breast cancer who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease</u>

An additional benefit is not proven

Justification:

For the benefit assessment of the subcutaneous fixed combination of pertuzumab/trastuzumab, the pharmaceutical company uses the CLEOPATRA[2] study to compare the free intravenous combination of pertuzumab + trastuzumab vs placebo + trastuzumab, each in combination with docetaxel, in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer who have not previously received anti-HER2 therapy or chemotherapy for the treatment of metastatic disease.

The pharmaceutical company thereby chose trastuzumab in combination with a taxane (docetaxel or paclitaxel) as comparative therapy, in deviation from the G-BA's stipulation. In addition, for the intervention, he does not choose pertuzumab/trastuzumab as a fixed combination administered subcutaneously, but the free combination of pertuzumab + trastuzumab with intravenous administration in each case in combination with docetaxel.

2 Swain SM, Miles D, Kim SB et al. Pertuzumab, trastuzumab, and docetaxel for HER2-positive metastatic breast cancer (CLEOPATRA): end-of-study results from a double-blind, randomised, placebo-controlled, phase 3 study. Lancet Oncol 2020; 21(4): 519-530.

on the deviation of the pU from the appropriate comparator therapy

The pharmaceutical company justifies its choice of comparative therapy by stating that the combination of trastuzumab and taxane, in addition to the combination of pertuzumab with trastuzumab and chemotherapy, continues to be a therapeutic option recommended by guidelines.

As already stated in the justification for the appropriate comparator therapy under point 4), it is clear from the guidelines and the evidence as a whole that dual HER2 blockade with pertuzumab and trastuzumab in combination with chemotherapy is clearly preferred over HER2 blockade alone with trastuzumab in combination with chemotherapy for patients with HER2-positive metastatic breast cancer in first-line therapy.

on the deviation of the pU from the intervention

The pharmaceutical company justifies the use of the intravenously administered free combination of pertuzumab + trastuzumab (additionally in combination with docetaxel) as an intervention for the benefit assessment by stating that the free intravenous combination is bioeffectively equivalent to the subcutaneous fixed combination.

For the assessment of the additional benefit of the subcutaneously administered fixed medicinal product combination of pertuzumab/trastuzumab, a study comparing the subcutaneously administered fixed medicinal product combination pertuzumab/trastuzumab with the drug pertuzumab i.v. formulation in free combination with trastuzumab would be suitable, provided that patient-relevant endpoints are collected.

Taken together, the comparison of the CLEOPATRA study conducted by the pharmaceutical company for its benefit assessment does not correspond to the research question of the benefit assessment and is therefore not suitable for the assessment.

In addition, the pharmaceutical company presents in the dossier supplementary results from the ongoing FeDeriCa[3] study, in which, in addition to non-inferiority with regard to pharmacokinetics and total pathological complete remission, patient-relevant endpoints (e.g. overall survival and adverse events) are also being investigated. In this study, the comparison of the subcutaneously administered fixed combination pertuzumab/trastuzumab with the free intravenous combination (in each case in combination with chemotherapy) is investigated, however, in a patient population that differs from the present therapeutic indication (patients with operable or locally advanced, inflammatory early stage HER2-positive breast cancer). The study is therefore not relevant for the assessment of the additional benefit in the present therapeutic indication.

2.1.4 Summary of the assessment

The present assessment concerns the benefit assessment of the new medicinal product Phesgo with the s.c. fixed combination pertuzumab/trastuzumab in combination with docetaxel.

3 Tan AR, Im S-A, Mattar A et al. Fixed-dose combination of pertuzumab and trastuzumab for subcutaneous injection plus chemotherapy in HER2-positive early breast cancer (FeDeriCa): a randomised, open-label, multicentre, non-inferiority, phase 3 study. Lancet Oncol 2021; 22(1):85-97.

The fixed combination pertuzumab/trastuzumab is approved for adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.

The G-BA determined pertuzumab in combination with trastuzumab and docetaxel as an appropriate comparator therapy.

For the benefit assessment of the subcutaneous fixed combination of pertuzumab/trastuzumab, the pharmaceutical company draws on the CLEOPATRA study to compare the free intravenous combination of pertuzumab + trastuzumab vs placebo + trastuzumab, each in combination with docetaxel, in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer who have not previously received anti-HER2 therapy or chemotherapy for the treatment of metastatic disease.

The pharmaceutical company thereby chose trastuzumab in combination with a taxane (docetaxel or paclitaxel) as comparative therapy, in deviation from the G-BA's stipulation. In addition, for the intervention, he does not choose pertuzumab/trastuzumab as a fixed combination administered subcutaneously, but the free combination of pertuzumab + trastuzumab with intravenous administration in each case in combination with docetaxel.

Taken together, the comparison of the CLEOPATRA study conducted by the pharmaceutical company for its benefit assessment does not correspond to the research question of the benefit assessment and is therefore not suitable for the assessment.

In addition, the pharmaceutical company presents results from the ongoing FeDeriCa study in the dossier. In this study, the comparison of the subcutaneously administered fixed combination pertuzumab/trastuzumab with the free intravenous combination (in each case in combination with chemotherapy) is investigated, however, in a patient population that differs from the present therapeutic indication. The study is therefore not relevant for the assessment of the additional benefit in the present therapeutic indication.

Based on the data described above, it is not possible to assess the overall additional benefit. Therefore, an additional benefit is not 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 number of patients in the SHI target population derived by the company in the present procedure is based on more up-to-date data than the previous procedure (particularly regarding HER2 positivity). Accordingly, the number estimated in the present procedure is to be considered more recent, taking into account the uncertainties.

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 Phesgo (active ingredient: pertuzumab/trastuzumab) at the following publicly accessible link (last access: 07 April 2021):

https://www.ema.europa.eu/en/documents/product-information/phesgo-epar-product-information_de.pdf

Treatment with pertuzumab/trastuzumab should only be initiated and monitored by specialists in internal medicine, haematology, and oncology, specialists in obstetrics and gynaecology, and specialists participating in the Oncology Agreement who are experienced in the treatment of adults with breast cancer.

Pertuzumab/trastuzumab should be used by medical professionals trained in the treatment of anaphylaxis and in an environment where full resuscitation equipment is immediately available.

2.4 Treatment costs

The treatment costs are based on the contents of the product information and the information listed in the LAUER-TAXE® (last revised: 15 June 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 co-morbidities) are not taken into account when calculating the annual treatment costs.

The information on dosages refers to applications in women, as breast cancer is relatively rare in men. Body surface area is calculated using the Du Bois formula using average body weight for women of 68.7 kg and an average height of 1.66 m according to the 2017 microcensus = 1.76 m².[4]

The annual treatment costs shown refer to the first year of treatment.

Treatment duration:

Designation of the therapy	Treatment mode	Number of treatments/ patient/year	Treatment duration/ treatment (days)	Days of treatment/ patient/ year
Medicinal product to be assessed				
Pertuzumab /trastuzumab	Once every 21 days	17.4	1	17.4
In combination with the chemotherapeutic agent				

[4] Federal Statistical Office, Wiesbaden 2018: http://www.gbe-bund.de/

Designation of the therapy	Treatment mode	Number of treatments/ patient/year	Treatment duration/ treatment (days)	Days of treatment/ patient/ year
Docetaxel	Once every 21 days	17.4	1	17.4
Appropriate comparator therapy				
Pertuzumab	Once every 21 days	17.4	1	17.4
Trastuzumab	Once every 21 days	17.4	1	17.4
In combination with the chemotherapeutic agent				
Docetaxel	Once every 21 days	17.4	1	17.4

Consumption:

Designation of the therapy	Dosage/ Application	Dosage/patient/days of treatment	Usage by potency/ day of treatment	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed					
Pertuzumab/ trastuzumab	Cycle 1: 1,200 mg/600 mg From cycle 2 onwards: 600 mg/600 mg	1200 mg/600 mg 600 mg/600 mg	1 x 1,200 mg/600 mg 1 x 600 mg/600 mg	17.4	1 x 1,200 mg/600 mg + 16.4 x 600 mg/600 mg
In combination with the chemotherapeutic agent					
Docetaxel	75 - 100 mg/m²	132 - 176 mg	1 x 140 mg to 1 x 160 mg 1 x 20 mg	17.4	17.4 x 140 mg to 17.4 x 160 mg 17.4 x 20 mg
Appropriate comparator therapy					
Pertuzumab	Cycle 1: 840 mg	840 mg 420 mg	2 × 420 mg 1 × 420 mg	17.4	2 × 420 mg 16.4 × 420 mg

Designation of the therapy	Dosage/ Application	Dosage/patient/days of treatment	Usage by potency/ day of treatment	Treatment days/ patient/ year	Average annual consumption by potency
	From cycle 2 onwards: 420 mg				
Trastuzumab	Cycle 1: 8mg/kg KG From cycle 2 onwards: 6mg/kg KG	549.6 mg 412.2 mg	1 x 420 mg + 1 x 150 mg 1 × 420 mg	17.4	1 x 420 mg + 1 x 150 mg 16.4 × 420 mg
Docetaxel	75 - 100 mg/m²	132 - 176 mg	1 x 140 mg to 1 x 160 mg 1 x 20 mg	17.4	17.4 x 140 mg to 17.4 x 160 mg 17.4 x 20 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. I 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.

Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate § 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates
Medicinal product to be assessed					
Pertuzumab 600 mg Trastuzumab 600 mg	1 SFI	€ 5,385.83	€ 1.77	€ 304.31	€ 5,079.75
Pertuzumab 1200 mg Trastuzumab 600 mg	1 SFI	€ 8,107.65	€ 1.77	€ 459.75	€ 7,646.13
Docetaxel 140 mg	1 CIS	€ 1,145.74	€ 1.77	€ 53.85	€ 1,090.12
Docetaxel 160 mg	1 CIS	€ 1,397.36	€ 1.77	€ 175.44	€ 1,220.15
Docetaxel 20 mg	1 CIS	€ 172.41	€ 1.77	€ 7.66	€ 162.98
Appropriate comparator therapy					

Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate § 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates
Pertuzumab 420 mg	1 CIS	€ 2,779.19	€ 1.77	€ 155.44	€ 2,621,98
Trastuzumab 150 mg	1 PIC	€ 786.79	€ 1.77	€ 42.95	€ 742.07
Trastuzumab 420 mg	1 PIC	€ 2,163.13	€ 1.77	€ 120.26	€ 2,041.10
Docetaxel 140 mg	1 CIS	€ 1,145.74	€ 1.77	€ 53.85	€ 1,090.12
Docetaxel 160 mg	1 CIS	€ 1,397.36	€ 1.77	€ 175.44	€ 1,220.15
Docetaxel 20 mg	1 CIS	€ 172.41	€ 1.77	€ 7.66	€ 162.98

LAUER-TAXE® last revised: 15 June 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 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 standard expenditure in the course of the treatment are not shown.

Because there are no regular differences in the necessary medical treatment or the prescription of other services when using the medicinal product to be assessed and the appropriate comparator therapy according to the product information, no costs for additionally required SHI services had to be taken into account.

Other SHI services:

The special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe) (contract on price formation for substances and preparation of substances) from 1.10.2009 is not fully used to calculate costs. Alternatively, the pharmacy sales price publicly accessible in the directory services according to Section 131 paragraph 4 SGB V is a suitable basis for a standardised calculation.

According to the currently valid version of the special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe), surcharges for the production of parenteral preparations containing cytostatic drugs a maximum amount of € 81 per ready-to-use preparation, and for the production of parenteral solutions containing monoclonal antibodies a maximum of € 71 per ready-to-use unit are to be payable. These additional other costs are not added to the pharmacy retail price but rather follow the rules for calculating in the Hilfstaxe. The cost representation is based on the pharmacy retail price and the maximum surcharge for the preparation and is only an approximation of the treatment costs. This presentation does not take into account, for example, the rebates on the pharmacy sales price of the active ingredient, the invoicing of discards, the calculation of application containers, and carrier solutions in accordance with the regulations in Annex 3 of the Hilfstaxe.

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 21 April 2020, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 14 January 2021, the pharmaceutical company submitted a dossier for the benefit assessment of pertuzumab/trastuzumab to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 VerfO.

By letter dated 18 January 2021 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 pertuzumab/trastuzumab.

The dossier assessment by the IQWiG was submitted to the G-BA on 29 April 2021, and the written statement procedure was initiated with publication on the website of the G-BA on 3 May 2021. The deadline for submitting written statements was 25 May 2021.

The oral hearing was held on 7 June 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 were discussed at the session of the subcommittee on 6 July 2021, and the proposed resolution was approved.

At its session on 15 July 2021, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee Medicinal products	21 April 2020	Determination of the appropriate comparator therapy
Working group Section 35a	1 June 2021	Information on written statement procedures received; preparation of the oral hearing
Subcommittee Medicinal products	7 June 2021	Conduct of the oral hearing

Working group Section 35a	15 June 2021 29 June 2021	Consultation on the dossier assessment by the IQWiG, evaluation of the written statement procedure
Subcommittee Medicinal products	6 July 2021	Concluding discussion of the draft resolution
Plenum	15 July 2021	Adoption of the resolution on the amendment of Annex XII AM-RL

Berlin, 15 July 2021

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

Prof. Hecken