Gemeinsamer Bundesausschuss

Justification

to 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
Trastuzumab deruxtecan (new therapeutic indication: breast cancer, HR+, HER2-low or HER2-ultralow, after at least 1 endocrine therapy)

of 16 October 2025

Contents

1. Legal basis

According to Section 35a paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assess the benefit of all 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 studies the pharmaceutical company have 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 decide on the benefit assessment within three months of its publication. The resolution is to be published on the internet and is part of the Pharmaceuticals Directive.

2. Key points of the resolution

The active ingredient trastuzumab deruxtecan (Enhertu) was listed for the first time on 1 February 2022 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

On 31 March 2025, trastuzumab deruxtecan received marketing authorisation for a new therapeutic indication to be classified as a major type 2 variation as defined according to Annex 2, number 2, letter a to Regulation (EC) No. 1234/2008 of the Commission of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, sentence 7).

On 23 April 2025, the pharmaceutical company has submitted a dossier in accordance with Section 4, paragraph 3, No.2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 1, number 2 of the Rules of Procedure (VerfO) of the G-BA on the active ingredient trastuzumab deruxtecan with the new

therapeutic indication in due time (i.e. at the latest within four weeks after informing the pharmaceutical company about the approval for a new therapeutic indication)

"Enhertu as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-low or HER2-ultralow breast cancer who have received at least one endocrine therapy in the metastatic setting and who are not considered suitable for endocrine therapy as the next line of treatment."

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The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 1 August 2025 on the G-BA website (www.g-ba.de), 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 trastuzumab deruxtecan 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, and the addendum to the benefit assessment prepared by IQWiG. In order to determine the extent of the additional benefit, the G-BA have 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 trastuzumab deruxtecan.

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 Trastuzumab deruxtecan (Enhertu) in accordance with the product information

Enhertu as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-low or HER2-ultralow breast cancer who have received at least one endocrine therapy in the metastatic setting and who are not considered suitable for endocrine therapy as the next line of treatment.

Therapeutic indication of the resolution (resolution of 16.10.2025):

See the approved therapeutic indication

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Adults with unresectable or metastatic hormone receptor (HR)-positive, HER2-low or HER2-ultralow breast cancer who have received at least one endocrine therapy in the metastatic setting and who are not considered suitable for endocrine therapy as the next line of treatment

Appropriate comparator therapy for trastuzumab deruxtecan as monotherapy:

[1] General Methods, version 7.0 from 19.09.2023. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

- Doxorubicin

or

- liposomal doxorubicin (only suitable for female patients)

or

- epirubicin

or

- docetaxel (only suitable for female patients)

or

- paclitaxel (only suitable for female patients who are not eligible for anthracycline-containing systemic therapy)

or

- nab-paclitaxel (only suitable for female patients who are not eligible for anthracycline-containing systemic therapy)

or

- capecitabine (only suitable for patients who have failed anthracycline and taxane-containing therapy or who are not eligible for further anthracycline treatment)

or

- Vinorelbine (only suitable for patients who are not eligible for anthracycline or taxane-containing systemic therapy)

<u>Criteria according to Chapter 5 Section 6 of the Rules of Procedure of the G-BA and Section 6 paragraph 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV):</u>

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. The following active ingredients are approved for the present therapeutic indication: 5-fluorouracil, capecitabine, cyclophosphamide, docetaxel, doxorubicin, doxorubicin (liposomal), epirubicin, gemcitabine, ifosfamide, methotrexate, mitomycin, mitoxantrone, paclitaxel, nab-paclitaxel, vinblastine, vincristine and vinorelbine.

Medicinal products with explicit marketing authorisation for HER2-positive breast cancer and for endocrine-based therapy were not included.

On 2. For the present therapeutic indication, it is assumed that there is no indication for (secondary) resection or radiotherapy with a curative objective.

On 3. The following resolutions and guidelines of the G-BA are available for medicinal treatment in the present therapeutic indication:

Annex VI to Section K of the Pharmaceuticals Directive - Active ingredients that cannot be prescribed for off-label use:

- Gemcitabine as monotherapy for breast cancer in women

Guideline on hospital examination and treatment methods (guideline on hospital treatment methods):

- Proton therapy for breast cancer

On 4. The generally recognised state of medical knowledge was illustrated by a systematic search for guidelines as well as systematic 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".

The scientific-medical societies and the Drugs Commission of the German Medical Association (AkdÄ) were also involved in writing on questions relating to the comparator therapy in the present therapeutic indication according to Section 35a, paragraph 7 SGB V.

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.

There are no specific treatment recommendations for patients with HR-positive, HER2-low or HER2-ultralow breast cancer. Therefore, the recommendations for HER2-negative breast cancer are used for determination of the appropriate comparator therapy.

It is assumed that therapy with trastuzumab deruxtecan is not an option for patients with a BRCA1/2-mutation.

According to the present guidelines, HR-positive patients with metastatic breast cancer should only be switched to cytotoxic chemotherapy after all endocrine treatment measures have been exhausted or if there is no response to endocrine therapy. According to the guidelines, monochemotherapies should primarily be used here. A combination therapy can also be considered for patients with a high burden of remission due to severe conditions or rapid tumour growth. However, monochemotherapy is preferable according to the guideline recommendations.

The guidelines mention taxanes and anthracyclines as a therapy option with a high significance if they have not yet been used as part of neoadjuvant or adjuvant therapy. The G-BA therefore determines, among other things, an anthracycline or taxane-containing systemic therapy consisting of doxorubicin, liposomal doxorubicin (only for female patients), epirubicin, docetaxel (only for female patients) or paclitaxel (only for female patients who are not eligible for anthracycline-containing systemic therapy) and nab-paclitaxel (only for female patients who are not eligible for anthracycline-containing systemic therapy) as therapy options as part of the appropriate comparator therapy.

As part of the oral hearing for the present procedure, the clinical experts stated that nab-paclitaxel is used as an alternative to paclitaxel if, for example, allergic reactions to paclitaxel are present. Nab-paclitaxel is therefore seen as an additional option in the context of anthracycline or taxane-containing systemic therapy.

If patients are not (or no longer) eligible for treatment with anthracyclines or taxanes, the active ingredients capecitabine and vinorelbine in particular can be considered.

As part of the present written statement procedure, the scientific-medical societies also list the active ingredients capecitabine, vinorelbine and (liposomal) anthracyclines and taxanes as therapy options for patients with endocrine resistance.

The G-BA therefore determines the appropriate comparator therapy to be an anthracycline or taxane-containing therapy, capecitabine or vinorelbine, taking into account the available evidence and the statements in the present benefit assessment procedure.

<u>Change in the appropriate comparator therapy</u>

In contrast to the originally determined appropriate comparator therapy, the appropriate comparator therapy for the present resolution was expanded to include the active ingredients nab-paclitaxel, capecitabine and vinorelbine.

In the written statements and at the oral hearing for the present procedure, the scientific-medical societies stated that nab-paclitaxel, capecitabine and vinorelbine represent further treatment options in the present therapeutic indication. According to the scientific-medical societies, previous therapies in the (neo-)adjuvant setting and especially cardiac, neurological and metabolic comorbidity are taken into account. Due to the relatively minor side effects and their extent compared to the known side effects (cardiotoxicity and neurotoxicity) of anthracyclines, patients prefer effective therapies with as few side effects as possible, such as capecitabine.

For this reason , the G-BA consider it appropriate to change the appropriate comparator therapy and adapt it to the medical treatment practice described by the scientific-medical societies. Accordingly, nab-paclitaxel, capecitabine and vinorelbine are included as further treatment options in the appropriate comparator therapy.

The change in the appropriate comparator therapy has the consequence for the present assessment of the additional benefit of trastuzumab deruxtecan that the entire study population of the DESTINY-Breast06 study is used as the basis for the assessment of the additional benefit.

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 trastuzumab deruxtecan is assessed as follows:

Adults with unresectable or metastatic hormone receptor (HR)-positive, HER2-low or HER2-ultralow breast cancer who have received at least one endocrine therapy in the metastatic setting and who are not considered suitable for endocrine therapy as the next line of treatment

Hint for a minor additional benefit

Justification:

DESTINY-Breast06 study

The DESTINY-Breast06 study is an ongoing, multicentre, open-label, randomised, controlled phase III study comparing trastuzumab deruxtecan with chemotherapy according to doctor's instructions with selection of capecitabine, paclitaxel or nab-paclitaxel, each as monotherapy.

The study has been conducted in 273 study sites in Europe, North and South America, Asia and Australia since July 2020.

Adults with advanced or metastasised HR-positive, HER2-low or HER2-ultralow breast cancer were enrolled. The disease should have progressed during endocrine therapy in combination with a cyclin-dependent kinase 4/6 inhibitor within 6 months of starting treatment in the metastatic setting or during ≥ 2 endocrine therapies with or without a targeted therapy in the metastatic setting. Patients were not allowed to have received chemotherapy for locally advanced or metastatic breast cancer. Enrolment in the study was permitted if there was a disease-free interval of more than 12 months after neoadjuvant or adjuvant chemotherapy. About one third of the patients had primary endocrine resistance, while the remaining patients had secondary endocrine resistance.

The HER2-low and HER2-ultralow status was determined using an immunohistochemistry test.

A total of 866 patients were randomised in a 1:1 ratio to treatment with trastuzumab deruxtecan (N = 436) or chemotherapy according to doctor's instructions (N = 430). Stratification was based on the characteristics of previous use of CDK-4/6 inhibitors (yes vs no), HER2 IHC expression (IHC 2+/ISH- vs IHC 1+ vs IHC > 0 and < 1+) and previous use of taxanes in the non-metastatic setting (yes vs no).

In addition to the primary endpoint of progression-free survival, endpoints in the categories of mortality, morbidity, health-related quality of life and side effects were collected.

Data on the first data cut-off from 18 March 2024 is available for the DESTINY-Breast06 study. As part of the written statement procedure, the pharmaceutical company presented evaluations for the second data cut-off from 24 March 2025, which were used for the present benefit assessment.

Limitations of the DESTINY-Breast06 study

There are limitations for the study with regard to prior therapies, as different pretreatments (e.g. failure of the previous anthracycline and taxane therapy or another anthracycline-containing therapy is not indicated; see information on the appropriate comparator therapy) are assumed according to the requirements in the respective product information regarding the comparator therapies used in the study. Information on previous antineoplastic systemic therapies is available on the basis of all patients in the comparator arm. A further breakdown of prior therapies is available for the therapy option of paclitaxel. Therefore, it remains unclear for the active ingredients capecitabine and nab-paclitaxel whether the requirements in the product information regarding prior therapies were met for the patients. However, it remains unclear even for paclitaxel-treated patients whether they did not respond to anthracycline-containing therapy or whether they were not eligible for them.

Extent and probability of the additional benefit

Mortality

In the DESTINY-Breast06 study, overall survival is defined as the time between randomisation and death from any cause.

There was a statistically significant difference between the treatment arms with an advantage of trastuzumab deruxtecan, the extent of which was assessed as a relevant improvement, but no more than a minor improvement.

The subgroup analysis showed an effect modification by the "age" characteristic. There was a statistically significant difference to the advantage of trastuzumab deruxtecan in subjects < 65 years, while there was no statistically significant difference between the treatment groups in subjects ≥ 65 years. These subgroup results are considered a relevant outcome of the present benefit assessment. However, they are considered inadequate to derive separate statements on the additional benefit in the overall assessment. Furthermore, the effect modification is not evident for other patient-relevant endpoints.

Morbidity

Progression-free survival

Progression-free survival (PFS) is the primary endpoint of the DESTINY-Breast06 study. It is defined as the time from randomisation to the first RECIST 1.1-defined radiological disease progression or death from any cause without prior progression, regardless of whether the female patient discontinued therapy or received other antineoplastic therapy prior to progression.

For the PFS, there was a statistically significant difference to the advantage of trastuzumab deruxtecan.

The PFS endpoint is a composite endpoint composed of endpoints of the mortality and morbidity categories. The mortality endpoint component is already assessed via the overall

survival endpoint as an independent endpoint. The morbidity component is assessed according to RECIST criteria and thus predominantly by means of imaging procedures.

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

The overall statement on the extent of the additional benefit remains unaffected.

Symptomatology

EORTC QLQ-C30, EORTC QLQ-BR45 and PGIS

Symptomatology was assessed in the DESTINY-Breast06 study using the EORTC QLQ-C30, EORTC QLQ-BR45 and PGIS questionnaires.

The data are unsuitable overall as the return rates to the questionnaires were low in both study arms even at the start of the study and the return rates were further decreasing and varying over the course of the study.

Health status

EQ-5D, visual analogue scale

No suitable data are available for the health status, assessed using the EQ-5D VAS.

The return rate to the questionnaire was low in both study arms even at the start of the study. The data is unsuitable overall due to the decreasing and varying return rate over the course of the study.

PGIC

The health status was assessed using the PGIC questionnaire.

There was a statistically significant difference between the treatment arms to the advantage of trastuzumab deruxtecan.

In the morbidity endpoint category, an overall advantage was found due to the statistically significant difference in the PGIC endpoint, which shows a significant improvement in health status.

Quality of life

EORTC QLQ-C30 and EORTC QLQ-BR45

Health-related quality of life was assessed in the DESTINY-Breast06 study using the EORTC QLQ-C30 and EORTC QLQ-BR45 questionnaires.

The data are unsuitable overall as the return rates to the questionnaires were low in both study arms even at the start of the study and the return rates were further decreasing and varying over the course of the study.

No suitable data are available for assessment of the health-related quality of life.

Side effects

Adverse events (AEs) in total

In the DESTINY-Breast06 study, almost all patients in the trastuzumab deruxtecan arm and 95% of patients in the control arm experienced an AE. The results are only presented additionally.

Serious AEs (SAEs), severe AEs and therapy discontinuation due to AEs

For the endpoints of SAEs, severe AEs and discontinuation due to AEs, there were no statistically significant differences between the treatment groups.

Specific AEs

For the endpoints of musculoskeletal and connective tissue disorders, nervous system disorders, hand-foot syndrome and peripheral oedema, there was a statistically significant difference to the advantage of trastuzumab deruxtecan in each case.

For the endpoints of thrombocytopenia, investigations, anaemia, ILD/pneumonitis, respiratory, thoracic and mediastinal disorders, loss of appetite, constipation, nausea, vomiting and alopecia, a statistically significant disadvantage of trastuzumab deruxtecan was identified.

No advantage or disadvantage was identified in the side effects category.

Overall assessment

Results on mortality, morbidity, health-related quality of life and side effects from the DESTINY-Breast06 study are available for the assessment of the additional benefit of trastuzumab deruxtecan for the treatment of adults with unresectable or metastatic HR-positive, HER2-low or HER2-ultralow breast cancer who have received at least one endocrine therapy in the metastatic setting and who are not considered suitable for endocrine therapy as the next line of treatment. In this RCT, trastuzumab deruxtecan was compared with chemotherapy according to doctor's instructions (capecitabine, paclitaxel or nab-paclitaxel).

For overall survival, there was a statistically significant difference with an advantage of trastuzumab deruxtecan, the extent of which is assessed as a relevant improvement, but no more than a minor improvement. In the subgroup analysis, there was an effect modification by the "age" characteristic. There was a statistically significant difference to the advantage of trastuzumab deruxtecan in subjects < 65 years, while there was no statistically significant difference between the treatment groups in subjects ≥ 65 years. These subgroup results are considered a relevant outcome of the present benefit assessment. However, they are considered inadequate to derive separate statements on the additional benefit in the overall assessment. Furthermore, the effect modification is not evident for other patient-relevant endpoints.

In the morbidity endpoint category, no suitable data are available for symptomatology, assessed using the EORTC QLQ-C30, EORTC QLQ-BR45 and PGIS, and for health status, assessed using the EQ-5D VAS. An advantage was identified for the health status, assessed using the PGIC. An advantage of trastuzumab deruxtecan was derived overall.

No suitable data are available with regard to health-related quality of life (EORTC QLQ-C30 and -BR45).

For the endpoints of SAEs, severe AEs and therapy discontinuation due to AEs, there were no differences between the treatment groups in each case. In detail, there were advantages and disadvantages in the specific AEs. No advantage or disadvantage was identified in the side effects category.

In the overall analysis, the advantages in overall survival and morbidity are not offset by any disadvantages. In the overall assessment, the G-BA concluded the presence of a minor additional benefit of trastuzumab deruxtecan for the treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-low or HER2-ultralow breast cancer who have received at least one endocrine therapy in the metastatic setting and who are not considered suitable for endocrine therapy as the next line of treatment.

Reliability of data (probability of additional benefit)

The randomised, multicentre, controlled DESTINY-Breast06 study forms the basis of the present benefit assessment.

There is a low risk of bias for the endpoint of overall survival and the risk of bias at study level is also classified as low overall.

However, there are relevant overarching uncertainties. There are uncertainties with regard to prior therapies, as different pretreatments are assumed according to the requirements in the respective product information regarding the comparator therapies used in the study. There are also deviations from the marketing authorisation concerning the use of concomitant medication with antiemetics. In addition, a relevant uncertainty in the reliability of data results for the total patient population due to the effect modification by the "age" characteristic in the endpoint of overall survival.

The endpoint-specific risk of bias for the results of the patient-reported endpoints is rated as high due to the lack of blinding.

In summary, the G-BA derive a hint for the identified additional benefit with regard to the reliability of data.

2.1.4 Summary of the assessment

The present assessment is the benefit assessment of a new therapeutic indication for the active ingredient trastuzumab deruxtecan.

The therapeutic indication assessed here is as follows: Enhertu as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-low or HER2-ultralow breast cancer who have received at least one endocrine therapy in the metastatic setting and who are not considered suitable for endocrine therapy as the next line of treatment.

The G-BA determined the appropriate comparator therapy to be an anthracycline or taxane-containing systemic therapy or capecitabine or vinorelbine.

The pharmaceutical company presented the DESTINY-Breast06 RCT comparing trastuzumab deruxtecan with chemotherapy according to doctor’s instructions (capecitabine, paclitaxel or nab-paclitaxel).

The results for overall survival show a statistically significant difference with an advantage of trastuzumab deruxtecan, the extent of which is assessed as a relevant, but no more than a minor improvement. There was an effect modification by the "age" characteristic. There was a statistically significant difference with an advantage for subjects < 65 years, while there was no statistically significant difference for subjects ≥ 65 years. These subgroup results are considered a relevant outcome of the present benefit assessment. However, they are considered inadequate to derive separate statements on the additional benefit in the overall assessment. Furthermore, the effect modification is not evident for other patient-relevant endpoints.

In the morbidity endpoint category, no suitable data are available for symptomatology (EORTC QLQ-C30, EORTC QLQ-BR45 and PGIS) and health status (EQ-5D VAS). An advantage was identified for the health status, assessed using the PGIC. An advantage of trastuzumab deruxtecan was derived overall.

No suitable data are available with regard to health-related quality of life (EORTC QLQ-C30 and -BR45).

For the endpoints of SAEs, severe AEs and therapy discontinuation due to AEs, there were no differences between the treatment groups in each case. In detail, there were advantages and disadvantages for the specific AEs. No advantage or disadvantage was identified in the side effects category.

A hint for the reliability of data can be derived overall due to uncertainties, particularly with regard to prior therapies of the patients enrolled in the study and the effect modification by the age characteristic for the endpoint of overall survival.

In the overall assessment, a hint for a minor additional benefit of trastuzumab deruxtecan compared to the appropriate comparator therapy is identified.

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 base their resolution on the patient numbers from the dossier submitted by the pharmaceutical company. The information provided by the pharmaceutical company tends to be underestimated, as only patients who were diagnosed with metastases for the first time in the year under review were taken into account. Patients who were already in the metastatic stage in previous years and were eligible for treatment with trastuzumab deruxtecan in the year under review were not included in this procedure.

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 Enhertu (active ingredient: trastuzumab deruxtecan) at the following publicly accessible link (last access: 25 June 2025):

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

Treatment with trastuzumab deruxtecan should only be initiated and monitored by specialists in internal medicine, haematology, and oncology who are experienced in the treatment of patients with breast cancer, as well as specialists in obstetrics and gynaecology, and other specialists from other specialist groups participating in the Oncology Agreement.

This medicinal product received a conditional marketing authorisation. This means that further evidence of the benefit of the medicinal product is anticipated. The European Medicines Agency EMA 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 contents of the product information and the information listed in the LAUER-TAXE® (last revised: 15 August 2025). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

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.

The information on dosages refers to applications in women, as breast cancer is relatively rare in men. The average body measurements of adult females were applied for dosages, depending on body weight (BW) or body surface area (BSA) (average body height: 1.66 m; average body weight: 69.2 kg). This results in a body surface area of 1.77 m² (calculated according to Du Bois 1916).[2]

For doxorubicin and epirubicin, the total cumulative dose was considered (450 – 550 mg/m² BSA for doxorubicin or 900 – 1,000 mg/m² BSA for epirubicin). Product information with different dosage recommendations is available for doxorubicin and epirubicin (doxorubicin: 50 – 80 mg/m² BSA and 60 – 75 mg/m² BSA; epirubicin: 75 – 90 mg/m² BSA and 60 – 90 mg/m² BSA). The dosage recommendations with the largest range were used for the cost calculation: Doxorubicin 50 – 80 mg/m² BSA and epirubicin: 60 – 90 mg/m² BSA. In the table "Consumption", only the dosage regimens that result in the range of annual treatment costs when calculated are shown.

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.

Treatment period:

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Trastuzumab deruxtecan	1 x per 21-day cycle	17.4	1	17.4
Appropriate comparator therapy				
Anthracycline or taxane-containing systemic therapy:				
Doxorubicin				
Doxorubicin	1 x per 21-day cycle	5 – 11[3]	1	5 – 11
Liposomal doxorubicin (only suitable for female patients)				
Doxorubicin PEG-liposomal	1 x per 28-day cycle	13.0	1	13.0
Epirubicin				
Epirubicin	1 x per 21-day cycle	10 – 16[4]	1	10 – 16
Docetaxel (only suitable for female patients)				

[2] Federal Health Reporting. Average body measurements of the population (2021, both sexes, 15 years and older), www.gbe-bund.de

[3] The maximum total doxorubicin dose of 450 – 550 mg/m² body surface area should not be exceeded to avoid cardiotoxicity.

[4] The total cumulative epirubicin dose of 900 – 1,000 mg/m² should not be exceeded to avoid cardiotoxicity.

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Docetaxel	1 x per 21-day cycle	17.4	1	17.4
Paclitaxel (only suitable for female patients who are not eligible for anthracycline-containing systemic therapy)				
Paclitaxel	1 x per 21-day cycle	17.4	1	17.4
Nab-paclitaxel (only suitable for patients who are not eligible for anthracycline-containing systemic therapy)				
Nab-paclitaxel	1 x per 21-day cycle	17.4	1	17.4
Capecitabine (only suitable for patients who are not eligible for anthracycline or taxane-containing systemic therapy)				
Capecitabine	2 x on day 1-14 of a 21-day cycle	17.4	14	243.6
Vinorelbine (only suitable for patients who are not eligible for anthracycline or taxane-containing systemic therapy)				
Vinorelbine	1 x every 7 days	52.1	1	52.1

Consumption:

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed					
Trastuzumab deruxtecan	5.4 mg/kg = 373.7 mg	373.7 mg	4 x 100 mg	17.4	69.6 x 100 mg
Appropriate comparator therapy					
Anthracycline or taxane-containing systemic therapy					
Doxorubicin					
Doxorubicin	50 mg/m^2 – 80 mg/m^2 = 88.5 mg – 141.6 mg	88.5 mg – 141.6 mg	2 x 50 mg – 3 x 50 mg	5 – 11[3]	15 x 50 mg – 22 x 50 mg
Liposomal doxorubicin (only suitable for female patients)					
Doxorubicin PEG-liposomal	50 mg/m^2 = 88.5 mg	88.5 mg	1 x 50 mg + 2 x 20 mg	13.0	13 x 50 mg + 26 x 20 mg
Epirubicin					
Epirubicin	90 mg/m^2 = 159.3 mg	159.3 mg	1 x 100 mg + 1 x 50 mg +	10 – 11[4]	10 x 100 mg + 10 x 50 mg +

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
			1 x 10 mg		10 x 10 mg – 11 x 100 mg + 11 x 50 mg + 11 x 10 mg
Docetaxel (only suitable for female patients)					
Docetaxel	100 mg/m^2 = 177 mg	177 mg	1 x 160 mg + 1 x 20 mg	17.4	17.4 x 160 mg + 17.4 x 20 mg
Paclitaxel (only suitable for female patients who are not eligible for anthracycline-containing systemic therapy)					
Paclitaxel	175 mg/m^2 = 309.8 mg	309.8 mg	1 x 300 mg + 1 x 30 mg	17.4	17.4 x 300 mg + 17.4 x 30 mg
Nab-paclitaxel (only suitable for patients who are not eligible for anthracycline-containing systemic therapy)					
Nab-paclitaxel	260 mg/m^2 = 460.2 mg	460.2 mg	5 x 100 mg	17.4	87 x 100 mg

Capecitabine (only suitable for patients who are not eligible for anthracycline or taxane-containing systemic therapy)					
Capecitabine	2,150 mg	2 x 2,150 mg	8 x 500 mg + 2 x 150 mg	243.6	1,948.8 x 500 mg + 487.2 x 150 mg
Vinorelbine (only suitable for patients who are not eligible for anthracycline or taxane-containing systemic therapy)					
Vinorelbine	25 mg/m² – 30 mg/m² = 44.3 mg - 53.1 mg	44.3 mg – 53.1 mg	1 x 50 mg – 1 x 50 mg + 1 x 10 mg	52.1	52.1 x 50 mg – 52.1 x 50 mg + 52.1 x 10 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. Any reference prices shown in the cost representation may not represent the cheapest available alternative.

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					
Trastuzumab deruxtecan 100 mg	1 PCI	€ 1,516.86	€ 1.77	€ 83.36	€ 1,431.73
Appropriate comparator therapy					
Capecitabine 500 mg	120 FCT	€ 151.84	€ 1.77	€ 11.11	€ 138.96
Capecitabine 150 mg	120 FCT	€ 54.15	€ 1.77	€ 3.39	€ 48.99
Docetaxel 160 mg	1 CIS	€ 820.48	€ 1.77	€ 38.40	€ 780.31
Docetaxel 20 mg	1 CIS	€ 112.47	€ 1.77	€ 4.80	€ 105.90
Doxorubicin 50 mg Fehler! Textmarke nicht definiert.	6 SFI	€ 812.52	€ 1.77	€ 63.37	€ 747.38
Doxorubicin, PEG-liposomal 20 mg	1 CIS	€ 721.49	€ 1.77	€ 89.87	€ 629.85
Doxorubicin, PEG-liposomal 50 mg	1 CIS	€ 1,778.90	€ 1.77	€ 224.69	€ 1,552.44
Epirubicin 100 mg	1 CIS	€ 300.84	€ 1.77	€ 13.74	€ 285.33
Epirubicin 50 mg	1 CIS	€ 155.45	€ 1.77	€ 6.84	€ 146.84
Epirubicin 10 mg	1 CIS	€ 39.51	€ 1.77	€ 1.34	€ 36.40
Paclitaxel 300 mg	1 CIS	€ 845.77	€ 1.77	€ 39.60	€ 804.40
Paclitaxel 30 mg	1 CIS	€ 94.76	€ 1.77	€ 3.96	€ 89.03
Nab-paclitaxel 100 mg	1 PIS	€ 429.36	€ 1.77	€ 19.84	€ 407.75

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
Vinorelbine 50 mg	1 CIS	€ 152.64	€ 1.77	€ 6.71	€ 144.16
Vinorelbine 10 mg	1 CIS	€ 38.90	€ 1.77	€ 1.31	€ 35.82
Abbreviations: FCT = film-coated tablets; CIS = concentrate for the preparation of an infusion solution; SFI = solution for injection; PIS = powder for the preparation of an infusion suspension; PCI= powder for a concentrate for the preparation of an infusion solution					

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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.

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	Treatment days/ year	Costs/ patient/ year
Appropriate comparator therapy:							
Paclitaxel							
Dexamethasone**Fehler ! Textmarke nicht definiert.** 2 x 20 mg	50 TAB 20 mg each	€ 118.88	€ 1.77	€ 0.00	€ 117.11	17.4	€ 81.51
Dimetindene IV 1 mg/10 kg = 6.9 mg	5 ILO 4 mg each	€ 26.24	€ 1.77	€ 6.92	€ 17.55	17.4	€ 122.15
Cimetidine IV 300 mg	10 AMP 200 mg each	€ 22.56	€ 1.77	€ 1.42	€ 19.37	17.4	€ 67.41

Other SHI services:

The special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe) (Sections 4 and 5 of the Pharmaceutical Price Ordinance) from 1 October 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 agents a maximum amount of € 100 per ready-to-use preparation, and for the production of parenteral solutions containing monoclonal antibodies a maximum of € 100 per ready-to-use unit are to be payable. These additional other costs are not added to the pharmacy sales 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 purchase 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 special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe).

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 designate 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.

Basic principles of the assessed medicinal product

A designation in accordance with Section 35a, paragraph 3, sentence 4 SGB V requires that it is examined based on the product information for the assessed medicinal product whether it can be used in a combination therapy with other medicinal products in the assessed therapeutic indication. In the first step, the examination is carried out on the basis of all sections of the currently valid product information for the assessed medicinal product.

If the assessed medicinal product contains an active ingredient or a fixed combination of active ingredients in the therapeutic indication of the resolution (assessed therapeutic indication) and is approved exclusively for use in monotherapy, a combination therapy is not considered due to the marketing authorisation under Medicinal Products Act, which is why no designation is made.

A designation is also not considered if the G-BA have decided on an exemption as a reserve antibiotic for the assessed medicinal product in accordance with Section 35a, paragraph 1c, sentence 1 SGB V. The additional benefit is deemed to be proven if the G-BA have decided on an exemption for a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V; the extent of the additional benefit and its therapeutic significance are not to be assessed by the G-BA. Due to the lack of an assessment mandate by the G-BA following the resolution on an exemption according to Section 35a, paragraph 1c, sentence 1 SGB V with regard to the extent of the additional benefit and the therapeutic significance of the reserve antibiotic to be assessed, there is a limitation due to the procedural privileging of the pharmaceutical companies to the effect that neither the proof of an existing nor an expected at least considerable additional benefit is possible for exempted reserve antibiotics in the procedures according to Section 35a paragraph 1 or 6 SGB V and Section 35a paragraph 1d SGB V. The procedural privileging of the reserve antibiotics exempted according to Section 35a, paragraph 1c, sentence 1 SGB V must therefore also be taken into account at the level of designation according to Section 35a, paragraph 3, sentence 4 SGB V in order to avoid valuation contradictions.

With regard to the further examination steps, a differentiation is made between a "determined" or "undetermined" combination, which may also be the basis for a designation.

A "determined combination" exists if one or more individual active ingredients which can be used in combination with the assessed medicinal product in the assessed therapeutic indication are specifically named.

An "undetermined combination" exists if there is information on a combination therapy, but no specific active ingredients are named. An undetermined combination may be present if the information on a combination therapy:

- names a product class or group from which some active ingredients not specified in detail can be used in combination therapy with the assessed medicinal product, or
- does not name any active ingredients, product classes or groups, but the assessed medicinal product is used in addition to a therapeutic indication described in more detail in the relevant product information, which, however, does not include information on active ingredients within the scope of this therapeutic indication.

Concomitant active ingredient

The concomitant active ingredient is a medicinal product with new active ingredients that can be used in combination therapy with the assessed medicinal product for the therapeutic indication to be assessed.

For a medicinal product to be considered as a concomitant active ingredient, it must be classified as a medicinal product with new active ingredients according to Section 2 paragraph 1 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with the corresponding regulations in Chapter 5 of the Rules of Procedure of the G-BA as of the date of the present resolution. In addition, the medicinal product must be approved in the assessed therapeutic indication, whereby a marketing authorisation is sufficient only for a sub-area of the assessed therapeutic indication.

Based on an "undetermined combination", the concomitant active ingredient must be attributable to the information on the product class or group or the therapeutic indication according to the product information of the assessed medicinal product in the assessed therapeutic indication, whereby the definition of a product class or group is based on the corresponding requirements in the product information of the assessed medicinal product.

In addition, there must be no reasons for exclusion of the concomitant active ingredient from a combination therapy with the assessed medicinal product, in particular no exclusive marketing authorisation as monotherapy.

In addition, all sections of the currently valid product information of the eligible concomitant active ingredient are checked to see whether there is any information that excludes its use in combination therapy with the assessed medicinal product in the assessed therapeutic indication under marketing authorisation regulations. Corresponding information can be, for example, dosage information or warnings. In the event that the medicinal product is used as part of a determined or undetermined combination which does not include the assessed medicinal product, a combination with the assessed medicinal product shall be excluded.

Furthermore, the product information of the assessed medicinal product must not contain any specific information that excludes its use in combination therapy with the eligible concomitant active ingredient in the assessed therapeutic indication under marketing authorisation regulations.

Medicinal products with new active ingredients for which the G-BA have decided on an exemption as a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V are ineligible as concomitant active ingredients. The procedural privileging of the reserve antibiotics exempted according to Section 35a, paragraph 1c, sentence 1 SGB V also

applies accordingly to the medicinal product eligible as a concomitant active ingredient.

Designation

The medicinal products which have been determined as concomitant active ingredients in accordance with the above points of examination are named by indicating the relevant active ingredient and the invented name. The designation may include several active ingredients, provided that several medicinal products with new active ingredients may be used in the same combination therapy with the assessed medicinal product or different combinations with different medicinal products with new active ingredients form the basis of the designation.

If the present resolution on the assessed medicinal product in the assessed therapeutic indication contains several patient groups, the designation of concomitant active ingredients shall be made separately for each of the patient groups.

Exception to the designation

The designation excludes combination therapies for which - patient group-related - a considerable or major additional benefit has been determined by resolution according to Section 35a, paragraph 3, sentence 1 SGB V or it has been determined according to Section 35a, paragraph 1d, sentence 1 SGB V that at least considerable additional benefit of the combination can be expected. In this context, the combination therapy that is excluded from the designation must, as a rule, be identical to the combination therapy on which the preceding findings were based.

In the case of designations based on undetermined combinations, only those concomitant active ingredients - based on a resolution according to Section 35a, paragraph 3, sentence 1 SGB V on the assessed medicinal product in which a considerable or major additional benefit had been determined - which were approved at the time of this resolution are excluded from the designation.

Legal effects of the designation

The designation of combinations is carried out in accordance with the legal requirements according to Section 35a, paragraph 3, sentence 4 and is used exclusively to implement the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The designation is not associated with a statement as to the extent to which a therapy with the assessed medicinal products in combination with the designated medicinal products corresponds to the generally recognised state of medical knowledge. The examination was carried out exclusively on the basis of the possibility under Medicinal Products Act to use the medicinal products in combination therapy in the assessed therapeutic indication based on the product information; the generally recognised state of medical knowledge or the use of the medicinal products in the reality of care were not the subject of the examination due to the lack of an assessment mandate of the G-BA within the framework of Section 35a, paragraph 3, sentence 4 SGB V.

The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

Justification for the findings on designation in the present resolution:

Adults with unresectable or metastatic hormone receptor (HR)-positive, HER2-low or HER2-ultralow breast cancer who have received at least one endocrine therapy in the metastatic setting and who are not considered suitable for endocrine therapy as the next line of treatment

No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient authorised in monotherapy.

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 their session on 28 May 2024, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

A review of the appropriate comparator therapy took place once the positive opinion was granted. The Subcommittee on Medicinal Products determined the appropriate comparator therapy at their session on 23 April 2025.

On 23 April 2025, the pharmaceutical company submitted a dossier for the benefit assessment of trastuzumab deruxtecan to the G-BA in due time in accordance with Chapter 5 Section 8, paragraph 1, number 2 VerfO.

By letter dated 28 April 2025 in conjunction with the resolution of the G-BA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefit 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 trastuzumab deruxtecan.

The dossier assessment by the IQWiG was submitted to the G-BA on 30 July 2025, and the written statement procedure was initiated with publication on the G-BA website on 1 August 2025. The deadline for submitting statements was 22 August 2025.

The oral hearing was held on 8 September 2025.

By letter dated 10 September 2025, the IQWiG was commissioned with a supplementary assessment. The addendum prepared by IQWiG was submitted to the G-BA on 26 September 2025.

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 7 October 2025, and the proposed draft resolution was approved.

At their session on 16 October 2025, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	28 May 2024	Determination of the appropriate comparator therapy
Subcommittee on Medicinal Products	23 April 2025	New determination of the appropriate comparator therapy
Working group Section 35a	3 September 2025	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	8 September 2025	Conduct of the oral hearing, commissioning of the IQWiG with the supplementary assessment of documents
Working group Section 35a	17 September 2025 01 October 2025	Consultation on the dossier evaluation by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	7 October 2025	Concluding discussion of the draft resolution
Plenum	16 October 2025	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 16 October 2025

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

Prof. Hecken