Justification

Gemeinsamer Bundesausschuss

to 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 Bedaquiline (New Therapeutic Indication: Multi-drug-resistant Pulmonary Tuberculosis, 12 to < 18 years)

of 6 August 2020

Contents

1. Legal basis

According to Section 35a, paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assesses the benefit of reimbursable medicinal products with new active ingredients.

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 of 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 SGB V. Evidence of the medical benefit and the additional medical benefit in relation to the appropriate comparator therapy need not 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, Nos. 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 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 during the last twelve 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, paragraphs 1–6 VerfO, in particular regarding the additional medicinal 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). On the basis of the statutory requirement in Section 35a, paragraph 1, sentence 11 SGB V that the additional benefit of an orphan drug is deemed to have been proven through the grant of 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, in the case of 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 provided is assessed exclusively on the basis of the approval 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 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 of 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

On 27 January 2020, bedaquiline received the marketing authorisation for a new therapeutic indication classified as a major type 2 variation according to Annex 2, number 2a to Regulation (EC) No. 1234/2008 of the Commission from 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 December 2008, p. 7).

Bedaquiline for the treatment of adolescent patients (12 years to less than 18 years of age and weighing at least 30 kg) as part of an appropriate combination regimen for multi-drug-resistant pulmonary tuberculosis was 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 sentence SGB V, the additional benefit is considered to be proven through the grant of the marketing authorisation. The probability and extent of the additional benefit are assessed on the basis of the pivotal studies by the G-BA.

On 13 February 2020, the pharmaceutical company submitted a dossier in accordance with Section 4, paragraph 3, number 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 bedaquiline with the new therapeutic indication (SITURO is indicated for use as part of an appropriate combination regimen for pulmonary multi-drug-resistant tuberculosis [multi-drug-resistant *Mycobacterium tuberculosis* (MDR-TB)] in adults and adolescent patients (12 years to less than 18 years of age and weighing at least 30 kg) when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability).

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 May 2020 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 has adopted its resolution on the basis of the dossier of the pharmaceutical company, the dossier assessment carried out by the G-BA, the assessment of treatment costs and patient numbers (IQWiG G20-01) 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 studies relevant for marketing authorisation with regard to their therapeutic relevance (qualitative) in accordance with the criteria laid down in Chapter 5, Section 5, paragraph 7, sentence 1, numbers 1 through 4 VerfO. The methodology proposed by the IQWiG in accordance with the General Methods 1 was not used in the benefit assessment of bedaquiline.

1 General Methods, Version 5.0 dated 10 July 2017. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen [Institute for Quality and Efficiency in Health Care], Cologne.

In the light of the above and taking into account the statements received and the oral hearing, the G-BA has arrived at the following assessment:

2.1 Additional benefit of the medicinal product

2.1.1 Approved therapeutic indication of bedaquiline (Sirturo®) in accordance with the product information

Situro is indicated for use as part of an appropriate combination regimen for pulmonary multi-drug-resistant tuberculosis [multi-drug-resistant *Mycobacterium tuberculosis* (MDR-TB)] in adults and adolescent patients (12 years to less than 18 years of age and weighing at least 30 kg) when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

This resolution relates exclusively to the newly approved therapeutic indication of adolescent patients (12 years to less than 18 years of age and weighing at least 30 kg) with multi-drug-resistant pulmonary tuberculosis (MDR-TB), when an effective treatment regimen other than bedaquiline (as part of an appropriate combination regimen) cannot be composed for reasons of resistance or tolerability.

2.1.2 Extent of the additional benefit and the significance of the proof

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

Adolescent patients (12 years to less than 18 years of age and weighing at least 30 kg) with MDR-TB when an effective treatment regimen cannot be established because of resistance or intolerance.

For bedaquiline as part of an appropriate combination regimen for adolescent patients (12 years to less than 18 years of age and weighing at least 30 kg) with MDR-TB when an effective treatment regimen cannot be composed for reasons of resistance or tolerability, there is a hint for a non-quantifiable additional benefit because the scientific data base does not allow quantification.

Justification:

For adolescent patients with MDR-TB, results of the C211 study (interim report) are available. This is a single arm, open-label, multi-centre Phase II study to investigate the pharmacokinetics, safety, tolerability, and anti-mycobacterial efficacy of bedaquiline as part of a combination therapy (base therapy or background regime, BR) in adolescent patients with confirmed or possible MDR-TB. Data are available for age cohort 1 (≥ 12 to < 18 years; the youngest patient included was 14 years old). Patients in this sub-population (n = 15) were treated with bedaquiline for 24 weeks.

The primary endpoint of study C211 was to collect data on pharmacokinetics, safety, and tolerability during 24 weeks of treatment with bedaquiline. In addition, the morbidity endpoints “absence of pathogens in sputum”, “remission of TB symptomatology – assessed by medical examiners”, and “relapses” were recorded.

Because the C211 study is an open and non-randomised study without a control arm, a high risk of bias at the study and endpoint level is generally assumed.

The pharmaceutical company also incorporates the evidence from the C208 study, a completed double-blind, randomised, placebo-controlled, multi-centre Phase IIb study evaluating the efficacy, safety, and tolerability of bedaquiline as part of a combination therapy

in adult patients with pulmonary MDR-TB with positive sputum smear. The C208 study was used for the early benefit assessment of bedaquiline for the treatment of adult patients with pulmonary MDR-TB (resolution of 4 July 2019).

The EMA (European Medicines Agency) agreed to a marketing authorisation extension in the form of an evidence transfer based on comparable biology between adolescents and adults as well as similar pharmacokinetic data.

For the G-BA, the findings of the EMA form the minimum prerequisite for a transfer of evidence, whereby the comparability of the clinical picture is taken into account by the underlying *Mycobacterium tuberculosis* infection.

However, for the early benefit assessment, the evidence transfer is not followed in this case because of the following points: There is no patient-relevant endpoint that would allow transferability of the data from adults to adolescents. The evidence transfer established by the EMA is based not only on comparable biology between adolescents and adults but also on comparable systemic exposure measured by pharmacokinetic parameters. These are not patient-relevant surrogates or surrogates validated for patient-relevant endpoints to derive the additional benefit. Furthermore, the comparability of patient populations and disease symptoms between study C211 and C208 cannot be assessed. There are differences or ambiguities in patient characteristics between the studies, including differences in symptomatology, disease severity, and resistance between the two study populations. The shorter observation period and small size of the C211 study (interim data until week 24; base therapy not completed) compared with the C208 study (study duration 120 weeks) also makes it difficult to transfer adult data to adolescents. Because of the large uncertainties mentioned above, an evidence transfer of patient-relevant endpoints from the direct comparative C208 study on adults to adolescents is not possible.

The results of Study C211 at week 24 are presented below as the basis of the present benefit assessment.

Mortality

No deaths occurred in the C211 study.

Morbidity

Remission of clinical TB symptomatology

The remission of the TB symptomatology should be assessed by the medical examination staff based on a consensus statement. Although an external assessment of the symptomatology is not relevant to the patient per se, the remission of the TB symptoms is a relevant aspect of a cure.

At week 24, it was summarised as “completely resolved”, “partially resolved”, or “not resolved”, although it remains unclear how the categorisation came about in practice. A standardised procedure with a priori defined criteria for classification was not planned for the multi-centre study. However, individual symptoms were not presented in the study documents.

Because of the unclear operationalisation, the endpoint cannot be assessed.

Absence of pathogens in sputum

In the C211 study, only people with confirmed MDR-TB and *Mycobacteria Growth Indicator Tube* (MGIT)-evaluable samples during the course of the study were evaluated for the endpoint “absence of pathogens in sputum”.

The operationalisation of the endpoint in the study required two consecutive microbiological sputum cultures free of pathogens at a minimum interval of 25 days. The German S2k guidelines for the treatment of tuberculosis recommend three microscopically negative sputum samples before repeal of the isolation.

Absence of pathogens eliminates the risk of contagion and is therefore a prerequisite for the repeal of isolation. Isolation duration has an influence on quality of life and is relevant for patients. However, the pharmaceutical company neither collected quality of life nor hospitalisation data. The duration of isolation depends not only on the absence of pathogens but also on other factors. It is therefore debatable to what extent the endpoint "time to pathogen-free sputum" alone is able to yield information on the actual duration of patient isolation in the current operationalisation.

A total of 11 people (73.3% of the ITT population) with confirmed MDR-TB have evidence of the pathogen during screening or up to six months before screening. The endpoint "absence of pathogens in sputum" was evaluated in only eight persons (53.3%) of the ITT population. A confirmed MDR-TB was detected in these persons, and MGIT-evaluable samples were available in the further course of the study. It remains unclear whether the partial lack of evidence of MDR-TB is due to the unclear resistance situation in conjunction with a response to the base therapy started before the baseline as well as to what extent the results on the endpoint pathogen-free status in study C211 are influenced by the base therapy. Six persons (40%) were found to be pathogen-free.

In view of the limitations mentioned above, the endpoint absence of pathogens in sputum is not assessable.

Relapse

Like the "Absence of pathogens in sputum" endpoint, the "relapse" endpoint is based on an objective standardised laboratory diagnostic procedure that can be carried out only on persons with confirmed TB and MGIT-compatible samples (n = 8). The relapses (i.e. confirmed positive sputum samples with pathogens of *Mycobacterium tuberculosis*) after successful culture conversion are examined. The reference to cure is missing. It also remains unclear whether relapses are counted if a new pathogen-free status is subsequently proven. Because the endpoint "Absence of pathogens in sputum" overwrites persons who suffer a relapse, relapses are indirectly included in the evaluation. This is why the endpoint relapse is also covered by the endpoint "Absence of pathogens in sputum". For this reason, the resolution neither describes the endpoint nor uses it to derive the additional benefit.

In summary, no statements on the extent of the additional benefit can be derived from the data on morbidity.

Quality of life

Data on patients' quality of life were not collected in the C211 study.

Side effects

Adverse events (AE) were recorded both for the 24-week treatment phase with bedaquiline + BR and for the entire duration of the study (24-week treatment phase (bedaquiline + BR) + follow-up phase (BR only)) up to the data cut-off of 14 November 2017 (median observation period approx. 40 weeks).

The number of persons with AE was highly similar in both observation periods, although the total study duration was about 16 weeks longer than the 24-week treatment phase with bedaquiline + BR. 93.3% of the persons experienced an AE; of these approx. 26.7%

experienced an AE with severity ≥ 3, 13.3% experienced a serious AE, and 33.3% an AE of special interest. No AE led to the discontinuation of the bedaquiline therapy; however, 33.3% of the patients had to discontinue base therapy medications.

Results for a longer observation period have not been provided. A comprehensive assessment of the long-term effects of treatment is therefore not yet possible.

In conclusion, no statements on the extent of the additional benefit can be derived from the data on side effects.

Overall assessment/conclusion

For bedaquiline as part of an appropriate combination regimen for the treatment of adolescent patients (12 years to less than 18 years of age and weighing at least 30 kg) with pulmonary multi-drug-resistant tuberculosis [*multi-drug-resistant Mycobacterium tuberculosis* (MDR-TB)], when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability, results on mortality, morbidity, and side effects from the C211 study are available.

No deaths occurred in the C211 study.

In the endpoint category morbidity, the endpoints “absence of pathogens in sputum”, “remission of TB symptomatology – assessed by medical examiners”, and “relapses” were recorded.

Because of limitations with regard to operationalisation, the single-arm study design, the small number of cases, and the short observation period of 24 weeks for this therapeutic indication, the endpoints are not assessable. In summary, no statements on the extent of the additional benefit can be derived from the data on morbidity.

Still no data on quality of life were surveyed.

In conclusion, no statements on the extent of the additional benefit can be derived from the data on side effects.

The evidence transfer aimed for by the pharmaceutical company is not followed, among other things because of the unclear comparability of the patient populations and disease symptoms between the C208 and C211 studies and the significantly shorter observation period of 24 weeks for the C211 study compared with the C208 study (120 weeks) for the early benefit assessment.

Because of the lack of comparative data, the short study duration, and the high bias risk of bias of the single-arm C211 study, the G-BA classifies the extent of the additional benefit of bedaquiline as non-quantifiable on the basis of the criteria in Section 5, paragraph 7 AM-NutzenV, taking into account the severity of the disease, the written statements, and the oral hearing. Thus, on the basis of the submitted data, it is not possible to quantitatively assess the extent of the effect or the additional benefit into one of the three categories ‘low’, ‘considerable’ or ‘substantial’.

Significance of the evidence

For Study C211, there is risk of bias at the study level because of the single-arm, open study design. Furthermore, the significance of the results is limited because of the small number of cases, the small number of cases that can be evaluated, and the short observation period for this therapeutic indication. Because of the limitations of the evidence available, there is a hint for a non-quantifiable additional benefit in terms of the significance of the evidence.

2.1.3 Summary of the assessment

The present assessment refers to the benefit assessment of the medicinal product Sirturo® with the active ingredient bedaquiline. Bedaquiline has been granted marketing authorisation as an orphan drug.

This assessment relates exclusively to the therapeutic indication “adolescent patients (12 years to less than 18 years of age and weighing at least 30 kg) with multi-drug-resistant pulmonary tuberculosis (MDR-TB), when an effective treatment regimen other than bedaquiline (as part of an appropriate combination regimen) cannot be composed for reasons of resistance or tolerability”.

The basis of the benefit assessment is the single-arm, open-label, multi-centre Phase II C211 study in which adolescent patients with confirmed or probable MDR-TB were treated with bedaquiline as part of a combination therapy over a period of 24 weeks.

Data on mortality, morbidity, and adverse events are available; data on quality of life were not collected. No deaths occurred in the C211 study. In summary, the data on morbidity and side effects do not allow any statements to be made about the extent of the additional benefit.

The evidence transfer (from the C208 study on adults to the adolescent study population to be assessed) aimed for by the pharmaceutical company is not followed, among other things because of the overall unclear comparability of the patient populations and the different disease symptomology between the patients of the C208 and C211 studies and the significantly shorter observation period of 24 weeks for the C211 study compared with the C208 study (120 weeks) for the early benefit assessment.

In summary, for bedaquiline as part of a combination regimen for multi-drug-resistant pulmonary tuberculosis in adolescents, a hint for a non-quantifiable additional benefit can be derived.

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 information provided follows the descriptions of the pharmaceutical company and the assessment of IQWiG.

The pharmaceutical company calculates the number of patients with MDR-TB based on a report by the Robert Koch Institute (RKI) on the epidemiology of tuberculosis in Germany for 2018. Assuming a constant growth rate, patient numbers are extrapolated for the year 2020. With reference to a special evaluation of the RKI, the proportion of patients from 12 to under 18 years of age with pulmonary tuberculosis is determined.

The calculation of the target population of bedaquiline is transparent and mostly comprehensible. There are uncertainties with regard to limitations in the data basis and the transferability of multi-resistant cases in the reported cases to the age group of adolescents. Taking into account the aforementioned uncertainties, the range of case numbers in the SHI target population stated by the pharmaceutical company can nevertheless be considered plausible.

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 Sirturo® (active ingredient: bedaquiline) at the following publicly accessible link (last access: 28 July 2020): https://www.ema.europa.eu/documents/product-information/sirturo-epar-product-information_en.pdf

Treatment with bedaquiline should be initiated and monitored only by specialists who are experienced in the treatment of patients with MDR-TB.

It is recommended that directly observed therapy (DOT) be used as a strategy when administering bedaquiline (Sirturo).

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.

Adolescents with a body weight between 30 and 40 kg are expected to have a higher average exposure than adult patients. This could be associated with an increased risk of QT prolongation or hepatotoxicity.

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 July 2020).

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 Sections 130 and 130 a 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.

Treatment with Sirturo® may not exceed 24 weeks.

Treatment duration:

Designation of the therapy	Treatment mode	Number of treatments/patient/year	Treatment duration/treatment (days)	Treatment days/patient/ year
Medicinal product to be assessed				
Bedaquiline	Weeks 1–2: 1 × daily Weeks 3–24: 3 × per week	80	1	80

Usage and consumption:

Designation of the therapy	Dosage/application	Dose/patient/treatment days	Consumption by potency/treatment day	Treatment days/patient/year	Annual average consumption according to potency
Medicinal product to be assessed					
Bedaquiline	Weeks 1–2: 400 mg Weeks 3–24: 200 mg	200 – 400 mg	2–4 × 100 mg	80	188 × 100 mg

Costs:

Costs of the medicinal product:

Designation of the therapy	Package 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					
Bedaquiline	24 Tablets	€ 3,625.39	€ 1.77	€ 0.00	€ 3,623.62

Pharmaceutical retail price (LAUER-TAXE®) as last revised: 15 July 2020

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 assessed 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.

No additionally required SHI services are taken into account for the cost representation.

3. Bureaucratic costs

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 13 February 2020, the pharmaceutical company submitted a dossier for the benefit assessment of bedaquiline 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 May 2020 together with the IQWiG assessment of treatment costs and patient numbers on the G-BA website (www.g-ba.de), thus initiating the written statement procedure. The deadline for submitting written statements was 5 June 2020.

The oral hearing was held on 22 June 2020.

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 were discussed at the session of the subcommittee on 28 July 2020, and the proposed resolution was approved.

At its session on 20 August 2020, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	5 May 2020	Information of the benefit assessment of the G-BA
Working group Section 35a	16 June 2020	Information on written statements received; preparation of the oral hearing

Subcommittee on Medicinal Products	22 June 2020	Conduct of the oral hearing
Working group Section 35a	30 June 2020 14 July 2020 21 July 2020	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 on Medicinal Products	28 July 2020	Concluding discussion of the draft resolution
Plenum	20 August 2020	Adoption of the resolution on the amendment of Annex XII of the AM-RL

Berlin, 20 August 2020

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Prof. Hecken