Justification

Gemeinsamer Bundesausschuss

to the Resolution of the Federal Joint Committee (G-BA) on the Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Onasemnogene Abeparvovec (Spinal Muscular Atrophy); Requirement of Routine Data Collection and Evaluations

of 4 February 2021

Contents

1. Legal basis

According to Section 35a, paragraph 3b, sentence 1 German Social Code Book V (SGB V), the Federal Joint Committee (G-BA) can demand that the pharmaceutical company submit routine data collection and evaluations of the following medicinal products for the purpose of the benefit assessment within a reasonable period of time:

1. for medicinal products, the marketing of which has been authorised according to the procedure laid down in Article 14, paragraph 8 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30 April 2004, p. 1), as last amended by Regulation 162 Rules of Procedure, last revised: 16 December 2020 (EU) 2019/5 (OJ L 4, 7 January 2019, p. 24) or for which a marketing authorisation has been granted according to Article 14-a of Regulation (EC) No 726/2004 as well as
2. for medicinal products approved for the treatment of a rare disease under Regulation No 141/2000.

2. Key points of the resolution

The active ingredient onasemnogene abeparvovec (Zolgensma®) received a conditional marketing authorisation (Article 14-a of Regulation (EC) No 726/2004) for the treatment of spinal muscular atrophy from the European Commission (EC) on 18 May 2020. The first listing in the directory services according to Section 131, paragraph 4 SGB V took place on 1 July 2020.

On the basis of the ongoing or completed studies on onasemnogene abeparvovec considered for the marketing authorisation, the G-BA identified evidence gaps, in particular for the following aspects relevant to the early benefit assessment; these justify the necessity of a routine data collection and evaluations according to Section 35a, paragraph 3b, sentence 1 SGBV for the active ingredient onasemnogene abeparvovec:

- Data to assess the long-term (incremental) benefits and harms of treatment with onasemnogene abeparvovec for the approved patient population;
- Comparative data of treatment with onasemnogene abeparvovec compared with existing treatment alternatives for the approved patient population;
- Data from patients with 5q spinal muscular atrophy older than 6 months or 6 weeks at the time of gene therapy with onasemnogene abeparvovec.

At present, for the active ingredient onasemnogene abeparvovec, only data without comparison with existing therapy alternatives for a period up to about 2 years after treatment in patients in whom the medicinal product was used at an age of less than 6 weeks or less than 6 months are available. Taking into consideration the aforementioned evidence gaps, the question of the present routine data collection involves the assessment of the benefit and harm profile of onasemnogene abeparvovec compared with existing therapy alternatives and the assessment of the sustainability of a therapy success for patients with 5q spinal muscular atrophy for whom treatment with onasemnogene abeparvovec is indicated.

With its resolution of 16 July 2020, the G-BA initiated a procedure to require a routine data collection according to Section 35a, paragraph 3b, sentence 1 SGB V for the active ingredient onasemnogene abeparvovec.

A concept was drawn up in preparation for the resolution on the requirement of routine data collection and evaluations. The concept contains in particular requirements for

1. the type, duration, and scope of the data collection
2. the research question (PICO scheme) that is to be the subject of data collection and evaluations, including the patient-relevant endpoints to be recorded
3. the methodology of data collection
4. the evaluations according to Section 50, paragraph 2 and 3 VerfO by the pharmaceutical company.

The G-BA decides whether to prepare the concept itself or to commission the IQWiG to do so. In the present case, the G-BA commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to prepare the concept. The expert bodies according to Section 35a, paragraph 3b, sentences 7 and 8 SGB V were involved in writing in the preparation of the concept. The participation was such that the expert bodies were given the opportunity to submit written statements on the requirements for routine data collection and evaluations in accordance with the concept that had been drawn up. In addition, a professional exchange was held.

In preparing the concept, current and planned data collections were considered, in particular those resulting from conditions or other ancillary provisions imposed by the marketing authorisation or licensing authorities. A review of the ongoing or planned interventional studies of onasemnogene abeparvovec commissioned by the regulatory authority showed that these studies cover only part of the population relevant for the routine data collection and that the number of patients included is low. In addition, no comparison is made in the commissioned interventional studies. The associated extension studies aim primarily to examine data on long-term side effects and do not include any patients beyond those considered for the marketing authorisation and relevant to the present research question.

In the written involvement procedure, the Drug Commission of the German Medical Association (AkdÄ) and the professional societies also assess the commissioned intervention studies for onasemnogene abeparvovec as unsuitable for answering the question of the present routine data collection because of the limitations identified. On the other hand, the pharmaceutical company concerned is in favour of taking into consideration the planned and ongoing interventional studies on onasemnogene abeparvovec in terms of the use of long-term evidence.

Because of the aforementioned limitations, the G-BA classifies the studies commissioned by the regulatory authority as not suitable for improving the existing evidence base sufficiently and for the purpose of the benefit assessment.

Based on the aforementioned question, with the present resolution, the G-BA, on the basis of the concept of the IQWiG and the participation of the expert bodies in the concept, passed a resolution on the requirements for the routine data collection and evaluations as well as on the specifications to review the obligation to perform and on the deadline for the submission of evaluations.

2.1 Requirement of routine data collection and evaluations

2.1.1 Question in accordance with PICO scheme

Patient population

According to the marketing authorisation, the target population for the active ingredient onasemnogene abeparvovec includes patients with 5q spinal muscular atrophy (SMA) with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA Type 1 or patients with

5q SMA with a bi-allelic mutation in the SMN1 gene and up to 3 copies of the SMN2 gene. For the present requirement of a routine data collection and evaluations according to Section 35a, paragraph 3b, sentence 1 SGB V, the pharmaceutical company shall collect and evaluate comparative data for the following patient population in the therapeutic indication: Pre-symptomatic patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to 3 copies of the SMN2 gene, symptomatic patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA Type 1, and symptomatic patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA Type 2 and up to 3 copies of the SMN2 gene. The survey should also include patients in the above patient population who are older than 6 months or 6 weeks at the time of gene therapy with onasemnogene abeparvovec.

Symptomatic patients with 5q SMA Type 3 with a bi-allelic mutation in the SMN1 gene and up to 3 copies of the SMN 2 gene are also included in the approved therapeutic indication for onasemnogene abeparvovec. However, according to the literature, the proportion of patients with SMA Type 3 in the total number of patients with SMA is small (approx. 12%)[1], and an overwhelming majority of patients have SMA Type 1 and Type 2 (approx. 60% and 27%, respectively). In addition, approx. 95% patients with type 3 SMA are thought to have 3 or 4 copies of the SMN 2 gene. However, because the active ingredient onasemnogene abeparvovec is not approved for patients with Type 3 SMA and 4 copies of the SMN 2 gene, the eligible number of patients with symptomatic Type 3 SMA for the present routine data collection is further reduced.

Because, based on the above point, it cannot be assumed that sufficiently significant data for symptomatic Type 3 SMA patients can be obtained for a comparative benefit assessment, the G-BA considers the requirement of a routine data collection for symptomatic type 3 SMA patients to be disproportionate.

Symptomatic patients with 5q SMA Type 3 with a bi-allelic mutation in the SMN1 gene and up to 3 copies of the SMN 2 gene are accordingly not part of the requirement of a routine data collection and evaluations according to Section 35a, paragraph 3b, sentence 1 SGB V for the active ingredient onasemnogene abeparvovec.

Intervention

According to the present requirement of a routine data collection and evaluations according to Section 35a, paragraph 3,b sentence 1 SGB V, the intervention includes the active ingredient onasemnogene abeparvovec.

Comparator/comparator therapy

The following criteria were used:

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 applications or non-medicinal treatments for which the patient-relevant benefit has already been determined by the Federal Joint Committee shall be preferred.

[1] e.g. Chen, 2020: New and Developing Therapies in Spinal Muscular Atrophy: From Genotype to Phenotype to Treatment and Where Do We Stand? Int J Mol Sci. 2020 May 7;21(9):3297

4. According to the generally recognised state of medical knowledge, the comparator therapy should be part of the appropriate therapy in the therapeutic indication.

On 1. The active ingredient nusinersen is approved for the treatment of 5q spinal muscular atrophy.

On 2. Supportive measures and symptom treatment include physiotherapy and occupational therapy as well as voice, speech, and language therapy in accordance with the catalogue of remedies, surgical measures (e.g. tracheostomy), ventilation, respiratory hygiene, nutrition management, and aids.

On 3. In the aforementioned therapeutic indication, there is a resolution of the G-BA on the benefit assessment of nusinersen according to Section 35a SGB V.

On 4. The generally accepted state of medical knowledge was illustrated by systematic research for guidelines and reviews of clinical studies in this indication.

Overall, the evidence in the therapeutic indication of SMA is limited.

In its resolution of 21 December 2017, the G-BA declared a major additional benefit for the active ingredient nusinersen for patients with 5q spinal muscular atrophy (5q-SMA) Type 1, a considerable additional benefit for patients with 5q-SMA Type 2, and a non-quantifiable additional benefit for patients with 5q-SMA Type 3 and Type 4. In addition, Cochrane reviews on medicinal treatment for patients with spinal muscular atrophy Type 1 and for Types 2 and 3 and a systematic review on the treatment of SMA with nusinersen were included in the evidence synopsis. Accordingly, treatment with nusinersen to improve motor functioning is recommended for patients with early and late-onset SMA based on a high level of evidence. It should be noted that there is currently insufficient evidence to support efficacy in SMA Types 3 and 4 or to start treatment in adults.

Based on the evidence available, the G-BA determined nusinersen as the comparator therapy for pre-symptomatic patients with 5q SMA and up to 3 copies of the SMN2 gene as well as for symptomatic patients with 5q SMA and clinically diagnosed type 1 SMA and symptomatic patients with 5q SMA and a clinical diagnosis of SMA Type 2 and up to 3 copies of the SMN2 gene.

In the written participation procedure, the pharmaceutical company concerned points out that there are evidence gaps for nusinersen and no long-term data are available and that the suitability of nusinersen as a comparator in a long-term study is therefore questionable. On the other hand, no objections to the comparator nusinersen for the aforementioned patient population were raised by the AkdÄ and the professional societies.

For the presently required patient population in the therapeutic indication, data are to be surveyed according to the aforementioned explanations compared with the comparator therapy nusinersen for the routine data collection according to Section 35a, paragraph 3b, sentence 1 SGB V.

Outcome

For the patient population required here, comparative data on the following endpoint categories are to be surveyed for the routine data collection according to Section 35a, paragraph 3b, sentence 1 SGB V: mortality, morbidity, and side effects.
In particular, deaths (mortality category) and at least one endpoint from each of the following patient-relevant morbidity categories should be surveyed: Motor functioning (surveyed with age-appropriate instruments), achievement of motor development milestones of the WHO, respiratory function (need for [continuous] ventilation), bulbar function (e.g. ability to swallow

and speak, need for oral nutritional support), and further complications of the disease (e.g. pain, orthopaedic complications). The endpoint need for [continuous] ventilation is not limited to the need for continuous ventilation but rather includes a survey and evaluation of the need for ventilation.

With regard to side effects, serious adverse events and the following serious specific unwanted side effects identified on the basis of the information provided in the Risk Management Plan and the EPAR of the intervention onasemnogene abeparvovec and the comparator nusinersen should be surveyed: Hepatotoxicity, thrombocytopenia, cardiac events, inflammation of spinal ganglion cells, renal toxicity, hydrocephalus. Adverse events that lead to hospitalisation and which are therefore included in the endpoint "serious adverse events" should additionally be surveyed and presented as a separate endpoint.

Because of the lack of sufficiently suitable and valid measurement instruments for the required patient population, data on health-related quality of life are not part of the requirement of a routine data collection and evaluations according to Section 35a, paragraph 3b sentence 1 SGB V for the active ingredient onasemnogene abeparvovec.

In the written participation procedure, the operators of the SMArtCARE register also point out that no data on quality of life are currently surveyed because of the lack of a suitable and valid measurement instrument.

When using the SMArtCARE register as a primary register, the waiver of a requirement for data on health-related quality of life consequently also allows the use of already collected (not collected parallel) data on nusinersen if these are suitable.

2.1.2 Type and methodology of data collection

In accordance with Section 35a, paragraph 3b SGB V, the Federal Joint Committee can demand routine data collection without randomisation for the data collection accompanying the application. For the present requirement, non-randomised comparisons within a study (parallel control) or the comparison of individual arms of different (single- or multi-arm) studies (parallel or historical control) can be considered accordingly.
The comparison of individual arms from different studies is fundamentally associated with a potential bias because of the use of different data sources (among other things because of different survey times or different definitions of data points or possible changes in the examination and treatment methods).
In order to avoid these additional potentially biasing factors in an already potentially highly biased non-randomised comparison of two medicinal products, a non-randomised comparison of onasemnogene abeparvovec and nusinersen using parallel controls within one data source is required for the routine data collection on onasemnogene abeparvovec.
Taking into consideration an uncertain future distribution of patients with spinal muscular atrophy in Germany who are treated with the intervention therapy onasemnogene abeparvovec or with the comparator therapy nusinersen, the G-BA considers it necessary to additionally perform a comparison of onasemnogene abeparvovec and data not collected in parallel to nusinersen within one data source provided that the data not collected in parallel also meet the stated requirements for data quality under Point 1.2.2 in the resolution.

For the present requirement of a routine data collection, indication registers that meet the requirements for routine data collection and fulfil at least the quality criteria specified in the resolution are to be used as the data source. The minimum data quality requirements mentioned are based on the national and international quality criteria for registries mentioned in the IQWiG concept. The focus was placed on the quality criteria for standardisation and

validity of data collection as well as for sample collection because these were considered particularly relevant for the present requirement.
In order to ensure the suitability of the data collected, the use of an indication register in which spinal muscular atrophy is treated in accordance with everyday care in Germany or is sufficiently similar to care in Germany is required.

In accordance with an international analysis, there are relevant differences in the standard of care between different countries[2]; this concerns, for example, standards for and availability of non-medicinal measures, including the provision of remedies and aids, different standards for ventilation (invasive vs non-invasive), and the availability of nusinersen and onasemnogene abeparvovec as well as their quality-assured application. In the written statements, the AkdÄ points out that the inclusion of registers from other countries would lead to strong bias because of nationally different regulations of prescribability and the possibility of using high-priced medicinal products and speaks out against the inclusion of registers from other countries. Nevertheless, most pharmaceutical companies participating in the written statement procedure are in favour of the possibility of integrating several, and even non-national, registers. The guarantee of sufficiently similar care in Germany, which is required when using indication registers, is intended to enable the integration of other, also non-national registers, without compromising data quality. When examining the suitability of the register with regard to transferability to the German health care context, the aforementioned aspects in particular should be taken into consideration. If there are relevant differences in the standard of care in another country, register data from this country should not be used for the present routine data collection and evaluations.

Based on the information available, the SMArtCARE register appears to be the most suitable primary data source at present. Provided that the quality criteria specified in this resolution are met, the SMArtCARE register is to be used accordingly as the primary register.

2.1.3 Duration and scope of data collection

The duration and scope of the routine data collection result from the estimated suitable patient-related observation period and the estimated number of patients required (number of cases).

In the present clinical presentation, the assessment of motor development is of particular importance. In the CL-303 study on onasemnogene abeparvovec, which was pivotal for marketing authorisation, 85% of patients achieved control of the head, 59% achieved turning from the supine position, and 64% achieved sitting without support at the end of study at 18 months of age. However, it remains unclear whether and how many of the patients can achieve further motor milestones and how long the achieved milestones are maintained. The WHO describes the motor development of infants with 6 milestones, which are achieved by healthy children in about 18 months (sitting without support to walking without support[3]). To assess the sustainability of the motor development achieved, observation until the end of the 5th year of life (month 60) is considered sufficient. Taking into consideration the child's developmental process on the basis of the motor milestones in accordance with WHO, the therapy results of onasemnogene abeparvovec and nusinersen as well as the assessment of the sustainability of the motor development achieved, the following patient-related observation period is therefore to be taken into consideration when collecting the routine data: Observation of the

[2] Bladen CL, Thompson R, Jackson JM, Garland C, Wegel C, Ambrosini A et al. Mapping the differences in care for 5,000 spinal muscular atrophy patients, a survey of 24 national registries in North America, Australasia and Europe. J Neurol 2014; 261(1): 152–163.
[3] WHO Multi-centre Growth Reference Study Group. WHO Motor Development Study: windows of achievement for six gross motor development milestones. Acta Paediatr Suppl 2006; 95(S450): 86–95.

achievable motor development until month 36 and observation of the sustainability of the achieved development until month 60.

As an approximation of the appropriate number of cases for the routine data collection, a case number of approx. 500 patients is assumed as a result of an orienting case number estimate based on the combined endpoint of mortality or continuous ventilation.

2.1.4 Evaluations of the data collection

The general requirements for the evaluation of comparative studies without randomisation must correspond to the evaluation of comparative studies with randomisation. The pharmaceutical company must therefore prepare a study protocol and a statistical analysis plan in which the information specified in the resolution in particular must be taken into consideration before carrying out the routine data collection and evaluations.

The G-BA assumes that under the aforementioned conditions, in addition to data on nusinersen collected at the same time, data on nusinersen not collected at the same time (i.e. register data that have already been surveyed since the marketing authorisation of the active ingredient nusinersen) can be used for the present requirement of a routine data collection. The evaluation of data collected in parallel and data not collected in parallel should be done separately. The same applies to the use of data from different data sources (i.e. different registers). Here, too, an evaluation should be carried out separately for each register.

After checking the suitability, an additional pooled analysis is possible both for data collected in parallel and not in parallel as well as for data from different data sources. Information on the verification of eligibility for pooled analysis should be set out accordingly in advance in the SAP.

The pharmaceutical company must perform the evaluations mentioned in the resolution (interim analyses and final evaluation) according to the specifications in the study protocol and statistical analysis plan. The interim analyses are to be prepared on the basis of Module 4 of the dossier template with provision of the full texts and study documents. The final evaluations are to be prepared in a dossier in accordance with the provisions of Section 9, paragraphs 1 to 7 VerfO of the G-BA. The relevant times for conducting the interim analyses and for submitting the final evaluations to the G-BA are the times specified in the resolution under Sections 2.3 and 3, respectively.

The orienting case number estimate is subject to uncertainties because of the small information base available and therefore represents a first hint of the required size of the study population. Against this background, the G-BA considers it expedient for the pharmaceutical company to conduct a review during the course of the study; this may lead to an adjustment of the number of cases. If necessary, this can also be carried out at this time on the basis of other benefit endpoints (such as motor development or a different operationalisation of the need for ventilation) and taking into consideration a shifted hypothesis boundary following the procedure in the concept of the IQWiG[4]. Alternatively, if the pharmaceutical company does not seek superiority in benefit endpoints (such as the aforementioned achievement of motor milestones), a case number can be estimated based on another endpoint. The G-BA points out that when deriving the additional benefit on the basis of harm endpoints, the non-inferiority on the benefit side is also considered in the new benefit assessment.

[4] IQWiG Rapid Report A20-61: Concept for a routine data collection – onasemnogene abeparvovec.

2.2 Requirements for checking whether the pharmaceutical company has fulfilled its obligation to carry out routine data collection and evaluations

The pharmaceutical company shall prepare a study protocol and a statistical analysis plan before carrying out the routine data collection and evaluations for coordination with the Federal Joint Committee. Taking into consideration the time frame required for preparing the draft, the pharmaceutical company shall submit the final drafts for a study protocol and for a statistical analysis plan to the G-BA for approval by **15 August 2021** at the latest.
The G-BA, with the involvement of the IQWiG, will review the study protocol and the statistical analysis plan and send the pharmaceutical company the result in writing within 4 to 6 weeks.

If, after review by the Subcommittee on Medicinal Products of the G-BA, there is no need to adapt the study protocol and the statistical analysis plan submitted by the pharmaceutical company, the pharmaceutical company shall be informed of the result in writing. If, after examination by the Subcommittee on Medicinal Products of the G-BA, there is a need for adjustments, the G-BA will pass a resolution regarding the adjustments deemed necessary.

In order to be able to clarify queries during the preparation of the final drafts for a study protocol as well as for a statistical analysis plan, before submitting the documents to the G-BA, the pharmaceutical company can request consultation from the G-BA in accordance with Section 35a, paragraph 7 SGB V in conjunction with Section 8 AM-NutzenV.

According to Section 35a, paragraph 3b p. 10 SGB V, the data obtained and the obligation for data collection must be reviewed by the G-BA at regular intervals but at least every 18 months. With regard to the information on the course of data collection (in particular information on the status of recruitment), information on the number and the respective medicinal treatment of the patients included so far, on patient-related observation times, and on possible deviations regarding the expected number of recruits at intervals of 18 months must be submitted to the G-BA by the pharmaceutical company.
The subject of the continuous review of the data obtained is, in particular, whether the data collection is carried out´ or can no longer be carried out.

In order to review the orienting case number estimate and to review the suitability of the data obtained for the purpose of the new benefit assessment, in particular with regard to the question of whether the data collection will provide sufficient evidence for a new benefit assessment or whether there is a need for an adjustment of the specifications in the resolution according to Chapter 5 Section 58 VerfO, interim analyses are to be submitted to the G-BA 18 months after the date of resolution (interim analysis for the case number estimate) as well as 36 and 60 months after the date of resolution.

2.3 Deadline for the submission of evaluations of the data collected with the routine data collection

For the implementation of a new benefit assessment, the evaluations must be submitted by **1 July 2027** at the latest.

These evaluations must be submitted in the form of a dossier according to the provisions in Chapter 5, Section 9, paragraphs 1 to 7 VerfO of the G-BA, taking into consideration the requirements of this resolution according to Chapter 5 Section 58 VerfO.

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

In order to prepare a recommendation for a resolution on the initiation of a procedure to require a routine data collection (amendment of Annex XII of the AM-RL) in accordance with Section 35a, paragraph 3b SGB V, the Subcommittee on Medicinal Products commissioned a working group (AG 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. In addition, the competent higher federal authority, the Paul Ehrlich Institute, was involved in the consultation to assess the necessity of a routine data collection according to Section 35a, paragraph 3b, sentence 1 SGB V.

The recommendation for a resolution on the initiation of a procedure to require a routine data collection (amendment of Annex XII of the AM-RL) was discussed at the session of the subcommittee on 7 July 2020, and the proposed resolution was approved.

At its session on 16 July 2020, the plenum passed a resolution to initiate a procedure to require a routine data collection.

In connection with the resolution of 16 July 2020 regarding the initiation of a procedure to require a routine data collection, the G-BA commissioned the IQWiG to develop a concept for a routine data collection and evaluation for the purpose of preparing a resolution.

The concept of the IQWiG was submitted to the G-BA on 1 October 2020. On 2 October 2020, the written participation of the expert bodies according to Section 35a, paragraph 3b, sentences 7 and 8 SGB V was initiated. The deadline for submitting the written participation was 30 October 2020.

The technical exchange within the framework of the participation of the expert bodies took place on 23 November 2020.

The evaluation of the written participation and the exchange of expertise were discussed at the session of the subcommittee on 26 January 2021, and the proposed resolution was approved.

At its session on 4 February 2021, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation

Working group Section 35a	15 April 2020 16 June 2020	Consultation on the initiation of a procedure to require a routine data collection (amendment of Annex XII of the AM-RL), involvement of the higher federal authority
Subcommittee on Medicinal Products	7 July 2020	Concluding discussion of the draft resolution
Plenum	16 July 2020	Adoption of the resolution on the initiation of a procedure to require a routine data collection (amendment of Annex XII of the AM-RL)
Working group Section 35a	18 November 2020	Information on written participation received, preparation of the exchange of expertise
Subcommittee on Medicinal Products	23 November 2020	Implementation of the exchange of expertise
Working group Section 35a	2 December 2020 16 December 2020 6 January 2021 20 January 2021	Consultation on the concept of the IQWiG as well as on the specifications for the review of the obligation to conduct and submit evaluations, evaluation of the participation procedure
Subcommittee on Medicinal Products	26 January 2021	Concluding discussion of the draft resolution
Plenum	4 February 2021	Adoption of the resolution on the requirement of a routine data collection (amendment of Annex XII of the AM-RL)

Berlin, 4 February 2021

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

Prof. Hecken