Gemeinsamer Bundesausschuss

Justification

of the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive: Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a (SGB V) Melatonin (repeal of the resolution of 4 July 2019)

of 17 October 2024

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 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 trials the pharmaceutical company has conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. approved therapeutic indications,
2. medical 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 decides 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

By implementing decision of the Commission dated 20 September 2018, the active ingredient melatonin was granted a marketing authorisation for paediatric use in accordance with Article 30 of Regulation (EC) No. 1901/2006 for the therapeutic indication "Slenyto is indicated for the treatment of insomnia in children and adolescents aged 2-18 years with Autism Spectrum Disorder (ASD) and / or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient".

The relevant date in accordance with Chapter 5, Section 8, number 1, sentence 2 of the Rules of Procedure of the G-BA (VerfO) for the first placing on the (German) market of the active ingredient melatonin in this therapeutic indication was 15 January 2019. The pharmaceutical company submitted the final dossier to the G-BA in accordance with Section 4, paragraph 3, number 1 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM- NutzenV) in conjunction with Chapter 5, Section 8, number 1 VerfO on 11 January 2019.

On 4 July 2019, the G-BA decided on the benefit assessment of melatonin for the treatment of insomnia in children and adolescents aged 2-18 years with Autism Spectrum Disorder (ASD) and/or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient. Accordingly, the Pharmaceuticals Directive was supplemented by Annex XII for the active ingredient melatonin.

The medicinal product Slenyto was assessed as a medicinal product with a new active ingredient within the meaning of Section 35a paragraph 1 SGB V in conjunction with Chapter 5, Section 2, sentence 3 (old), number 2 VerfO.

Applying the case law of the judgement of the Federal Social Court of 5 September 2024 (B 3 KR 5/23 R, date report number 31/24), Slenyto is a reimbursable medicinal product, but according to the definition of the term in Section 2 paragraph 1 AM-NutzenV, it is not a medicinal product with a new active ingredient. The dossier protection for the first approved medicinal product with the active ingredient melatonin no longer existed at the time of the marketing authorisation of the medicinal product Slenyto.

Accordingly, no mandatory benefit assessment procedure pursuant to Section 35a, paragraph 1, sentence 1 SGB V could be triggered via the provision in Chapter 5, Section 2, paragraph 1, sentence 3 (old), number 2 VerfO.

Consequently, the findings on the benefit assessment of the active ingredient melatonin according to the marketing authorisation of 20 September 2018 for the treatment of insomnia in children and adolescents aged 2-18 years with Autism Spectrum Disorder (ASD) and/or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient, in Annex XII of the Pharmaceuticals Directive in the version of the resolution of 4 July 2019 (BAnz AT 08.08.2019 B4) are to be repealed.

3. Bureaucratic costs calculation

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

4. Process sequence

At its session on 8 October 2024, the Subcommittee on Medicinal Products discussed the repeal of the resolution on the benefit assessment of the active ingredient melatonin in the version of the resolution of 4 July 2019 and approved the draft resolution.

At its session on 17 October 2024, the plenum adopted a resolution to repeal the resolution on the benefit assessment of the active ingredient melatonin in the version of the resolution of 4 July 2019.

Chronological course of consultation

Session	Date	Subject of consultation
Working group Section 35a	1 October 2024	Consultation on the draft resolution
Subcommittee Medicinal products	8 October 2024	Consultation on the draft resolution on the repeal of the resolution
Plenum	17 October 2024	Adoption of the repeal of the resolution

Berlin, 17 October 2024

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

Prof. Hecken