Gemeinsamer Bundesausschuss

Justification

for the Resolution of the Federal Joint Committee (G-BA) on the Suspension of the Benefit Assessment under Section 35a SGB V on Melatonin (new therapeutic indication: insomnia in neurogenetic diseases; ≥ 2 to ≤ 18 years)

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

The active ingredient melatonin was approved on 20 September 2018 (Slenyto). The marketing authorisation was granted 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."

After the medicinal product Slenyto with the active ingredient melatonin was placed on the market on 15 January 2019, the G-BA conducted a benefit assessment according to Section 35a SGB V and supplemented Annex XII of the Pharmaceuticals Directive with the active ingredient melatonin by resolution of 4 July 2019.

On 26 August 2024, melatonin 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 from 12.12.2008, sentence 7). The new therapeutic indication is: Treatment of insomnia in children and adolescents aged 2-18 years with [...] neurogenetic disorders with aberrant diurnal

melatonin secretion and/or night-time awakenings, where sleep hygiene measures have been insufficient.

The relevant date for the start of the benefit assessment procedure was on 1 October 2024 in accordance with Chapter 5 Section 8, paragraph 1, number 2 of the Rules of Procedure (VerfO) of the G-BA.

By resolution of 17 October 2024, the G-BA repealed the resolution on the benefit assessment of melatonin of 4 July 2019 because 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, although the active ingredient melatonin was no longer a new active ingredient within the meaning of Section 35a paragraph 1 SGB V in conjunction with Section 2 paragraph 1 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) at the time of marketing authorisation of the medicinal product Slenyto, as the dossier protection for the first approved medicinal product with this active ingredient no longer existed at this time.

The new therapeutic indication of Slenyto cannot be assessed in accordance with Section 35a paragraph 6 SGB V either, because no assessment in accordance with Section 35a paragraph 6 SGB V was carried out when the medicinal product Slenyto was first placed on the market (FSC, judgement of 5 September 2024, B 3 KR 5/23 R, date report number 31/24).

3. Bureaucratic costs calculation

At its session on 8 October 2024, the Subcommittee on Medicinal Products discussed the suspension of the benefit assessment procedure of the active ingredient melatonin in the new therapeutic indication and approved the draft resolution.

At its session on 17 October 2024, the plenum adopted a resolution on the suspension of the benefit assessment procedure of the active ingredient melatonin.

4. Process sequence

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 suspension of the benefit assessment procedure
Plenum	17 September 2024	Resolution on the suspension of the benefit assessment procedure

Berlin, 17 October 2024

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

Prof. Hecken