Resolution

of the Federal Joint Committee 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

At its session on 17 October 2024, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. The findings on the benefit assessment of the active ingredient melatonin in the therapeutic indication 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, if sleep hygiene measures were inadequate, in Annex XII of the Pharmaceuticals Directive in the version of the resolution of 4 July 2019 (BAnz AT 08.08.2019 B4) are repealed.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 17 October 2024.

The justification to this resolution will be published on the website of the G-BA at www.g-ba.de.

Berlin, 17 October 2024

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

Prof. Hecken