Gemeinsamer Bundesausschuss

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:
Ivermectin (repeal of the resolutions)

of 16 January 2025

At its session on 16 January 2025, 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. Annex XII is amended as follows:

The findings on the benefit assessment of the active ingredient ivermectin in the therapeutic indication according to the marketing authorisation of 2 May 2015 for the treatment of inflammatory lesions of (papulopustular) rosacea in adult patients, in Annex XII of the Pharmaceuticals Directive in the version of the resolutions of 27 November 2015 (BAnz AT 22.12.2015 B2) and of 21 January 2016 (BAnz AT 19.04.2016 B3), are deleted.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 16 January 2025.

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

Berlin, 16 January 2025

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

Prof. Hecken