



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
Obeticholic acid (repeal of the resolutions of 6 July 2017 and
16 February 2023)

of 3 April 2025

At their session on 3 April 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. The findings on the benefit assessment of the active ingredient obeticholic acid in
Annex XII of the Pharmaceuticals Directive in the version of the resolutions of 6 July
2017 (BAnz AT 01.08.2017 B4) and of 16 February 2023 (BAnz AT 09.03.2023 B5) are
deleted.
- II. The resolution will enter into force on the day of its publication on the website of the
G-BA on 3 April 2025.

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

Berlin, 3 April 2025

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

Prof. Hecken