



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:
Dapagliflozin (new therapeutic indication: type 1 diabetes
mellitus) (repeal of the resolutions of 17 October 2019 and 26
November 2019)

of 18 March 2022

At its session on 18 March 2022, the Federal Joint Committee (G-BA) resolved to amend Annex XII of 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 dapagliflozin (new therapeutic indication: diabetes mellitus type 1) as amended by the resolutions of 17 October 2019 (BAnz AT 20.10.2019 B2) and of 26 November 2019 (BAnz AT 19.12.2019 B3) are repealed.**
- II. **The resolution will enter into force on the day of its publication on the website of the G-BA on 18 March 2022.**

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

Berlin, 18 March 2022

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

Prof. Hecken