Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive: Bedaquiline (reassessment after the deadline: pulmonary multidrug-resistant tuberculosis) (naming of concomitant active ingredients)

Please note: The benefit assessment procedure comprises several resolutions. Current version of the Pharmaceuticals Directive/Annex XII.

of 7 August 2025

At their session on 7 August 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 dd.mm.yyyy (Federal Gazette, BAnz AT dd.mm.yyyy BX), as follows:

I. The information in Annex XII on the benefit assessment of the active ingredient Bedaquiline (reassessment after the deadline: pulmonary multidrug-resistant tuberculosis) in the version of the resolution of 1 February 2024 (BAnz AT 25.04.2024 B2) is amended as follows:

In Section "5. Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product", following the information

"Adult patients with pulmonary multidrug-resistant tuberculosis for whom an effective treatment regimen cannot be composed other than with bedaquiline (as part of an appropriate combination therapy) for reasons of resistance or intolerance",

the information

"The following medicinal products with new active ingredients that can be used in a combination therapy with bedaquiline in the therapeutic indication of the resolution on the basis of the marketing authorisation under Medicinal Products Act are named (active ingredients and invented names) in accordance with Section 35a, paragraph 3, sentence 4 SGB V:"

is replaced by the information

"The following medicinal products with new active ingredients that can be used in a combination therapy with the assessed medicinal product in the therapeutic indication of the present resolution on the basis of the marketing authorisation under Medicinal Products Act are excluded from the designation, as the G-BA has identified at least

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considerable additional benefit for the combination with the assessed medicinal product in the present resolution:"

with effect from 1 February 2024.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 7 August 2025.

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

Berlin, 7 August 2025

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

Prof. Hecken

Benefit assessment procedure comprises several resolutions.
Please note the current version of the Pharmaceuticals Directive/Annex XII.

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