Gemeinsamer Bundesausschuss

Justification

to the Resolution of the Federal Joint Committee on an amendment to the Pharmaceuticals Directive
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Bedaquiline (reassessment after the deadline: pulmonary multidrug-resistant tuberculosis)
(naming of concomitant active ingredients)

of 7 August 2025

Contents

1. Legal basis

According to Section 35a paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assesses the benefit of reimbursable medicinal products with new active ingredients.

According to Section 35a paragraph 6 SGB V, the G-BA can also initiate a benefit assessment according to Section 35a paragraph 1 SGB V for reimbursable medicinal products with an active ingredient that is not a new active ingredient according to Section 35a paragraph 1 SGB V, if a new marketing authorisation with new dossier protection is granted for the medicinal product. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the G-BA electronically, including all clinical trials the pharmaceutical company has conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. approved therapeutic indications,
2. medical benefit,
3. additional medical benefit in relation to the appropriate comparator therapy,
4. number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. treatment costs for the statutory health insurance funds,
6. requirements for a quality-assured application.

The G-BA may commission the Institute for Quality and Efficiency in Health Care (IQWiG) to carry out the benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment must be completed within three months of the relevant date for submission of the evidence and published on the internet.

According to Section 35a paragraph 3 SGB V, the G-BA decides on the benefit assessment within three months of its publication. The resolution is to be published on the internet and is part of the Pharmaceuticals Directive.

2. Key points of the resolution

At their session on 1 February 2024, the G-BA decided on the benefit assessment of bedaquiline in accordance with Section 35a SGB V. The therapeutic indication of the resolution was limited to the following patient population: "Adult patients with pulmonary multidrug-resistant tuberculosis if an effective treatment regimen cannot be composed otherwise due to resistance or intolerance".

Following the publication of this resolution on the G-BA website, the G-BA came to the conclusion that there is a need to adapt the information on the medicinal products with new active substances, which were named in the resolution in accordance with Section 35a,

paragraph 3, sentence 4 SGB V and can be used in a combination therapy with the assessed medicinal product.

In accordance with Section 35a, paragraph 3, sentence 4 SGB V, the Federal Joint Committee names - in the resolution according to Section 35a, paragraph 3, sentence 1 SGB V - all medicinal products with new active ingredients that can be used in a combination therapy with the assessed medicinal product for the therapeutic indication to be assessed on the basis of the marketing authorisation under Medicinal Products Act, unless the Federal Joint Committee has identified at least a considerable additional benefit of the combination pursuant to sentence 1 or has determined pursuant to paragraph 1d sentence 1 that the combination is expected to have at least a considerable additional benefit.

In the resolution of 1 February 2024, "Delamanid (Deltyba)" was designated as a medicinal product with a new active ingredient in accordance with Section 35a, paragraph 3, sentence 4 SGB V, which can be used in a combination therapy with bedaquiline in the above-mentioned therapeutic indication of the resolution on the basis of the marketing authorisation under Medicinal Products Act. The designation was made regardless of the fact that a hint for a considerable additional benefit of bedaquiline as part of a suitable combination therapy was identified in the therapeutic indication of the resolution of 1 February 2024 as a result of the additional benefit assessment. The considerable additional benefit in the therapeutic indication investigated can also be assumed for the possible combination of bedaquiline and delamanid as no restriction of the identified additional benefit to specifically named combination medicinal products was made in the additional benefit assessment.

Since an exception to the combination designation must be made according to Section 35a, paragraph 3, sentence 4 SGB V if at least a considerable additional benefit of the combination has been identified according to Section 35a, paragraph 3, sentence 1 SGB V, delamanid (Deltyba) should not be designated as a concomitant active ingredient of bedaquiline in the therapeutic indication of the resolution of 1 February 2024.

Since the resolution of 1 February 2024 only led to an addition to the designation in Annex XII of the Pharmaceuticals Directive, but not in Annex XIIa of the Pharmaceuticals Directive, the findings on the designation of the concomitant active ingredient delamanid (Deltyba) as a concomitant active ingredient of bedaquiline exclusively in Annex XII are to be replaced by the finding of the exception to the designation due to at least a considerable additional benefit for the combination of delamanid (Deltyba) and bedaquiline in the therapeutic indication of the resolution of 1 February 2024. An amendment to Annex XIIa is not necessary in this context.

3. Written statement procedure according to Section 92, paragraph 3a SGB V

A written statement procedure in accordance with Section 92 paragraph 3a SGB V need not be carried out for the amendment of the Pharmaceuticals Directive.

Pharmaceutical companies will not be adversely affected by the correction of the designation of the concomitant active ingredients; the amendment excludes delamanid (Deltyba) from the designation of the concomitant active ingredients in the therapeutic indication of the resolution on the benefit assessment of bedaquiline of 1 February 2024. The amendment is legally required for the reasons stated under 2. due to the provision in Section 35a, paragraph 3, sentence 4 SGB V.

4. Bureaucratic costs calculation

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

5. Process sequence

Following the adoption of the resolution, the need for adaptation with regard to the designation of concomitant active ingredients in the resolution of 1 February 2024 on an amendment to the Pharmaceuticals Directive in Annex XII on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V concerning bedaquiline became apparent.

The issue was discussed in the working group Section 35a and in the Subcommittee on Medicinal Products.

At their session on 7 August 2025, the plenum resolved by consensus to amend the Pharmaceuticals Directive with regard to proper correction of the designation of the concomitant active ingredients in the resolution of 1 February 2024.

Chronological course of consultation

Session	Date	Subject of consultation
Working group Section 35a	15 July 2025	Consultation on the issue
Subcommittee on Medicinal Products	29 July 2025	Consultation on an amending resolution regarding the designation of concomitant active ingredients of the resolution of 1 February 2024
Plenum	7 August 2025	Drafting of resolution on an amending resolution with regard to the the designation of concomitant active ingredients of the resolution of 1 February 2024

Berlin, 7 August 2025

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

Prof. Hecken