Gemeinsamer Bundesausschuss

Justification

of the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a (SGB V) and Annex XIIa – Naming of Medicinal Products with New Active Ingredients according to Section 35a, paragraph 3, sentence 4 SGB V:
Beclometasone/ formoterol/ glycopyrronium (repeal of the resolution and repeal of the naming)

of 19 December 2024

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. This includes in particular the assessment of the additional benefit and its therapeutic significance.

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.

In accordance with Section 35a, paragraph 3, sentence 4 SGB V added to the Act on the Financial Stabilisation of Statutory Health Insurance (GKV-FinStG), which came into force on 8 November 2022, the G-BA names - in the resolution according to Section 35a paragraph 3 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.

2. Key points of the resolution

The combination of active ingredients beclometasone/ formoterol/ glycopyrronium (Trimbow) was approved for the indication COPD on 15 August 2017. The combination of active ingredients was granted new dossier protection with the first marketing authorisation. Trimbow was listed for the first time on 18 August 2017 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices. On 14 January 2021, Trimbow was granted marketing authorisation for a new therapeutic indication under Chapter 5, Section 2, paragraph 2 of the Rules of Procedure (VerfO). The new therapeutic indication bronchial asthma was classified as a major type 2 variation according to Regulation (EC) No. 1234/2008 of the Commission of 24 November 2008 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, p. 7). The scope of the benefit assessment resolution according to Section 35a SGB V was opened for Trimbow with the new therapeutic indication bronchial asthma according to Chapter 5 Section 1, Paragraph 2, No. 4a of the Rules of Procedure (VerfO), since the reimbursable medicinal product Trimbow with a new combination of active ingredients , which was first placed on the market on or after 1 January 2011, justified a marketing authorization for a new therapeutic indication according to Chapter 5, Section 2, Paragraph 2 VerfO and for the first time created an obligation to submit a complete dossier according to Chapter 5 Section 2, paragraph 1, Sentence 3, Number 1, Indent 2 VerfO. In due time on 8 February 2021, i.e. at the latest within four weeks after the disclosure, the pharmaceutical company, on the approval of a new therapeutic indication as

amendment of type 2 variation according to Regulation (EC) No. 1234/2008 , submitted a dossier in accordance with Section 4, paragraph 3, number 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5 Section 8, paragraph 1, number 3a of the Rules of Procedure (VerfO) of the G-BA on the combination of active ingredients beclometasone/ formoterol/ glycopyrronium (Trimbow) with the new therapeutic indication bronchial asthma.

On 5 August 2021, the G-BA decided on the benefit assessment of beclometasone/ formoterol/ glycopyrronium for the treatment of asthma in adult patients not adequately controlled with a combination of a long-acting beta2-agonist and medium dose or high dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year. Accordingly, Annex XII of the Pharmaceuticals Directive was amended to include the combination of active ingredients beclometasone/ formoterol/ glycopyrronium.

Subsequently, the pharmaceutical company and the National Association of Statutory Health Insurance Funds agreed on a reimbursement agreement for Trimbow® in accordance with Section 130b SGB V (agreement dated 10 March/ 21 March 2022).

The pharmaceutical company filed an isolated declaratory action against the benefit assessment resolution of 5 August 2021 with the Regional Social Court (RSC) Berlin-Brandenburg (L 9 KR 26/21 KL). The RSC Berlin-Brandenburg dismissed the claim in its judgement of 26 April 2023.

The pharmaceutical company has lodged an appeal against the judgement of the RSC Berlin-Brandenburg with the Federal Social Court (FSC) (file ref.: B 3 KR 5/23 R). In its judgement of 5 September 2024, the FSC determined that the amendment to Annex XII of the Pharmaceuticals Directive by the G-BA's resolution of 5 August 2021 on the benefit assessment of the combination of active ingredients beclometasone/ formoterol/ glycopyrronium (first dossier requirement: asthma) is ineffective because, in the opinion of the FSC, a resolution on a benefit assessment of the medicinal product Trimbow in the new therapeutic indication of bronchial asthma was not to be adopted due to a lack of a viable legal basis.

Consequently, the findings on the benefit assessment of the combination of active ingredients beclometasone/ formoterol/ glycopyrronium according to the extension of the marketing authorisation of 14 January 2021 for the treatment of asthma in adult patients not adequately controlled with a combination of a long-acting beta2-agonist and medium dose or high dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year should be deleted from Annex XII of the Pharmaceuticals Directive in the version of the resolutions of 5 August 2021 (BAnZ AT 11.10.2021 B1) and 12 October 2021 (BAnz AT 17.12.2021 B4).

Since, in the opinion of the FSC, the proprietary medicinal product Trimbow with the combination of active ingredients beclometasone/ formoterol/ glycopyrronium should not have been assessed as a medicinal product with new active ingredients within the meaning of Section 35a, paragraph 1, sentence 1 SGB V, the fixed combination can no longer be named as a concomitant active ingredient in the resolutions that have already been adopted. In this respect, the naming in the affected sections of Annex XIIa should also be deleted.

3. Bureaucratic costs

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.

4. Process sequence

At its session on 10 December 2024, the Subcommittee on Medicinal Products consulted on the revocation of the findings on the benefit assessment of the combination of active ingredients beclometasone/ formoterol/ glycopyrronium in Annex XII of the Pharmaceuticals Directive in the version of the resolutions of 5 August 2021 (BAnz AT 11.10.2021 B1) and 12 October 2021 (BAnz AT 17.12.2021 B4), and on the revocation of the naming of the combination of active ingredients beclometasone/ formoterol/ glycopyrronium in Annex XIIa, and approved the draft resolution.

At its session on 19 December 2024, the plenum consulted and decided on the revocation of the findings on the benefit assessment of the combination of active ingredients beclometasone/ formoterol/ glycopyrronium in Annex XII of the Pharmaceuticals Directive in the version of the resolutions of 5 August 2021 (BAnz AT 11.10.2021 B1) and 12 October 2021 (BAnz AT 17.12.2021 B4), and on the revocation of the naming of the combination of active ingredients beclometasone/ formoterol/ glycopyrronium in Annex XIIa.

Chronological course of consultation

Session	Date	Subject of consultation
Working group Section 35a	4 December 2024	Consultation of the draft resolution
Subcommittee on Medicinal Products	10 December 2024	Consultation on the draft resolution on the repeal of the resolution in Annex XII and repeal of the naming in Annex XIIa
Plenum	19 December 2024	Adoption of resolution on the repeal of the resolution in Annex XII and repeal of the naming in Annex XIIa

Berlin, 19 December 2024

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

Prof. Hecken