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:
Vigabatrin (repeal of the resolutions of 19 December 2019 and repeal of the naming)

of 6 February 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 all 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

By the Commission’s implementing decision of 20 September 2018 in accordance with Article 38 paragraph 1 of the Regulation (EC) No. 1901/2006, the active ingredient vigabatrin was granted a marketing authorisation for paediatric use according to the Articles 5 to 15 of the Regulation (EC) No. 726/2004 for the therapeutic indications "Kigabeq is indicated in infants and children from 1 month to less than 7 years of age for:

- Treatment in monotherapy of infantile spasms (West's syndrome).
- Treatment in combination with other antiepileptic medicinal products for patients with resistant partial epilepsy (focal onset seizures) with or without secondary generalisation, that is where all other appropriate medicinal product combinations have proved inadequate or have not been tolerated.".

After the medicinal product Kigabeq with the active ingredient vigabatrin was placed on the market on 1 July 2019, the G-BA conducted a benefit assessment for each of the two approved therapeutic indications according to Section 35a SGB V and supplemented Annex XII of the Pharmaceuticals Directive with the active ingredient vigabatrin by resolutions of 19 December 2019.

The medicinal product Kigabeq was assessed as a medicinal product with a new active ingredient within the meaning of Section 35a paragraph 1 SGB V in conjunction with Chapter 5 Section 2, sentence 3 (old), number 2 VerfO.

Applying the case law of the judgement of the Federal Social Court of 5 September 2024 (B 3 KR 5/23 R, session report number 31/24), Kigabeq is a reimbursable medicinal product, but according to the definition of the term in Section 2 paragraph 1 AM-NutzenV, it is not a medicinal product with a new active ingredient. The dossier protection for the first approved medicinal product with the active ingredient vigabatrin no longer existed at the time of the marketing authorisation of the medicinal product Kigabeq.

Accordingly, no mandatory benefit assessment procedure pursuant to Section 35a, paragraph 1, sentence 1 SGB V could be triggered via the provision in Chapter 5 Section 2, paragraph 1, sentence 3 (old), number 2 VerfO.

Consequently, the findings on the benefit assessments of the active ingredient vigabatrin in the therapeutic indications according to the marketing authorisation of 20 September 2018, for treatment in monotherapy of infantile spasms (West's syndrome), in Annex XII of the Pharmaceuticals Directive in the version of the resolution of 19 December 2019 (BAnz AT 20.01.2020 B3), as well as for treatment in combination with other antiepileptic medicinal products for patients with resistant partial epilepsy (focal onset seizures) with or without secondary generalisation, that is where all other appropriate medicinal product combinations have proved inadequate or have not been tolerated, in Annex XII of the Pharmaceuticals Directive in the version of the resolution of 19 December 2019 (BAnz AT 17.01.2020 B2), last amended on 5 October 2023 (BAnz AT 22.01.2024 B2), should be deleted.

Applying the case law of the FSC, the active ingredient vigabatrin can no longer be named as a concomitant active ingredient in the resolutions that have already been adopted, since the proprietary medicinal product Kigabeq with the active ingredient vigabatrin 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. 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 28 January 2025, the Subcommittee on Medicinal Products consulted on the revocation of the findings on the benefit assessments of the active ingredient vigabatrin in Annex XII of the Pharmaceuticals Directive in the version of the resolutions of 19 December

2019 (BAnz AT 20.01.2020 B3) and of 19 December 2019 (BAnz AT 17.01.2020 B2), last amended on 5 October 2023 (BAnz AT 22.01.2024 B2), and on the revocation of the naming of the active ingredient vigabatrin in Annex XIIa, and approved the draft resolution.

At its session on 6 February 2025, the plenum consulted and decided on the revocation of the findings on the benefit assessments of the active ingredient vigabatrin in Annex XII of the Pharmaceuticals Directive in the version of the resolutions of 19 December 2019 (BAnz AT 20.01.2020 B3) and of 19 December 2019 (BAnz AT 17.01.2020 B2), last amended on 5 October 2023 (BAnz AT 22.01.2024 B2), and on the revocation of the naming of the active ingredient vigabatrin in Annex XIIa.

Chronological course of consultation

Session	**Date**	**Subject of consultation**
Working group Section 35a	15 January 2025	Consultation of the draft resolution
Subcommittee on Medicinal Products	28 January 2025	Consultation on the draft resolution on the repeal of the resolution in Annex XII and repeal of the naming in Annex XIIa
Plenum	6 February 2025	Adoption of resolution on the repeal of the resolution in Annex XII and repeal of the naming in Annex XIIa

Berlin, 6 February 2025

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

Prof. Hecken