Gemeinsamer Bundesausschuss

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 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

At its session on 6 February 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 D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. Annex XII is amended as follows:

1. The findings on the benefit assessment of the active ingredient vigabatrin in the therapeutic indication according to the marketing authorisation of 20 September 2018 for treatment in combination with other anti-epileptic medicines 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), are deleted.

2. The findings on the benefit assessment of the active ingredient vigabatrin in the therapeutic indication according to the marketing authorisation of 20 September 2018 for treatment in monotherapy of infantile spasms (West's syndrome) in children from 1 month to less than 7 years of age, in Annex XII of the Pharmaceuticals Directive in the version of the resolution of 19 December 2019 (BAnz AT 20.01.2020 B3), are deleted.

Courtesy translation – only the German version is legally binding.

II. Annex XIIa is amended as follows:

1. The information on the active ingredient vigabatrin of the assessed medicinal product (resolution according to Section 35a paragraph 3 SGB V of 19 December 2019) in the version of the resolution of 5 October 2023 (BAnz AT 22.01.2024 B2) is deleted.

2. The information on the active ingredient brivaracetam of the assessed medicinal product (resolution according to Section 35a paragraph 3 SGB V of 17 January 2019) in the version of the resolution of 5 October 2023 (BAnz AT 22.01.2024 B4) is amended as follows:

   The information "Vigabatrin (Kigabeq)" is deleted after the heading "Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names[2])".

3. The information on the active ingredient brivaracetam of the assessed medicinal product (resolution according to Section 35a paragraph 3 SGB V of 1 September 2022) in the version of the resolution of 5 October 2023 (BAnz AT 22.01.2024 B2) is amended as follows:

   The information "Vigabatrin (Kigabeq)" is deleted after the heading "Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names[2])".

4. The information on the active ingredient cannabidiol of the assessed medicinal product (resolution according to Section 35a paragraph 3 SGB V of 15 April 2021 and resolution according to Section 35a paragraph 3 SGB V of 16 May 2024) in the version of the resolution of 16 May 2024 (BAnz AT 02.07.2024 B3) is amended as follows:

   The information "Vigabatrin (Kigabeq)" is deleted after the heading "Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names[2])".

5. The information on the active ingredient cannabidiol of the assessed medicinal product (resolution according to Section 35a paragraph 3 SGB V of 15 April 2021 and resolution according to Section 35a paragraph 3 SGB V of 16 May 2024) in the version of the resolution of 16 May 2024 (BAnz AT 02.07.2024 B5) is amended as follows:

   The information "Vigabatrin (Kigabeq)" is deleted below the heading "Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names[2])".

6. The information on the active ingredient cannabidiol of the assessed medicinal product (resolution according to Section 35a paragraph 3 SGB V of 4 November 2021 and resolution according to Section 35a paragraph 3 SGB V of 16 May 2024) in the version of the resolution of 16 May 2024 (BAnz AT 02.07.2024 B4) is amended as follows:

   The information "Vigabatrin (Kigabeq)" is deleted below the heading "Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names[2])".

Courtesy translation – only the German version is legally binding.

III. The resolution will enter into force on the day of its publication on the website of the G-BA on 6 February 2025.

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

Berlin, 6 February 2025

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

Prof. Hecken

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