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:
Semaglutide (type 2 diabetes mellitus) (amendments to Annexes XII and XIIa)

of 20 March 2025

At its session on 20 March 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. In Annex XII, the information on the active ingredient Semaglutide, as last amended by the publication of the resolution of 5 August 2021 (BAnz AT 22.10.2021 B3), is amended as follows:

1. The information added to Annex XII by Section I. 2 of the resolution of 15 April 2021 (BAnz AT 02.06.2021 B5) in the version of the resolution of 5 August 2021 (BAnz AT 22.10.2021 B3) on the active ingredient semaglutide in the therapeutic indication for the treatment of insufficiently controlled type 2 diabetes mellitus in adults is deleted.

2. The repeal - ordered by Section I. 1. resolution of 15 April 2021 (BAnz AT 02.06.2021 B5) - of the information added to Annex XII by resolution of 2 May 2019 (BAnz AT 04.06.2019 B3) in the version of the resolution of 4 July 2019 (BAnz AT 12.09.2019 B3) on the active ingredient semaglutide is cancelled.

3. It is determined that the information on the active ingredient semaglutide that entered into force by resolution of 2 May 2019 (BAnz AT 04.06.2019 B3) in the version of the resolution of 4 July 2019 (BAnZ AT 12.09.2019 B3) with effect from 2 May 2019 and 4 July 2019 continues to apply unchanged.

II. In Annex XIIa, the information on the active ingredient Semaglutide of the assessed medicinal product (resolution pursuant to Section 35a paragraph 3 SGB V of 15 April 2021), as last amended by the publication of the resolution of 8 October 2024 (BAnz AT 22.11.2024 B1), is amended as follows:

1. After the heading "Resolution pursuant to Section 35a paragraph 3 SGB V of", the date specification "15.04.2021" is deleted and replaced by "02.05.2019".

2. After the heading "Therapeutic indication of the resolution", the information "Rybelsus is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise
   - as monotherapy when metformin is considered inappropriate due to intolerance or contraindications
   - in combination with other medicinal products for treatment of diabetes."

   is deleted.

III. The resolution will enter into force on the day of its publication on the website of the G-BA on 20 March 2025.

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

Berlin, 20 March 2025

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

Prof. Hecken