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:
Ivermectin (repeal of the resolutions)

of 16 January 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.

2. Key points of the resolution

The active ingredient ivermectin was approved on 2 May 2015 in the decentralised procedure in accordance with Section 25b paragraph 3 and paragraph 4 Medicinal Products Act (AMG) in conjunction with Article 28 et seqq. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the creation of a Community code for medicinal products for human use (OJ L 311 of 28.11.2001, pp. 67-128) in Germany for the treatment of inflammatory lesions of (papulopustular) rosacea in adult patients. The medicinal product Soolantra with the active ingredient ivermectin was granted data exclusivity with the marketing authorisation. Soolantra was listed for the first time on 1 June 2015 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices and the active ingredient ivermectin was thus placed on the German market for the first time.

The relevant date in accordance with Chapter 5 Section 8, number 1, sentence 2 of the Rules of Procedure of the G-BA (VerfO) for the first placing on the (German) market of the active ingredient ivermectin in this therapeutic indication was 1 June 2015. The pharmaceutical company did not submit any dossier at the relevant time.

On 27 November 2015, the G-BA decided on the benefit assessment of ivermectin for the treatment of inflammatory lesions of (papulopustular) rosacea in adult patients. Accordingly, Annex XII of the Pharmaceuticals Directive was amended to include the findings on the active ingredient ivermectin in this therapeutic indication.

The information on the benefit assessment of the active ingredient ivermectin was amended by resolution of 21 January 2016 under section "4. Treatment costs".

Subsequently, the pharmaceutical company and the National Association of Statutory Health Insurance Funds agreed on a reimbursement agreement for Soolantra in accordance with Section 130b SGB V (agreement dated 10.05.2016).

The pharmaceutical company filed an isolated declaratory action against the benefit assessment resolution of 27 November 2015 with the Regional Social Court (RSC) Berlin-Brandenburg (file ref.: L 1 KR 558/15 KL). The RSC Berlin-Brandenburg dismissed the claim as inadmissible by judgement of 19 October 2018. Following an authorised appeal by the pharmaceutical company, the Federal Social Court (FSC) repealed this judgement and referred the case back for a new hearing and decision (file ref.: B 3 KR 11/19 R). The RSC Berlin-Brandenburg dismissed the claim as unjustified by judgement of 9 November 2022. Also against this judgement passed by the RSC Berlin-Brandenburg, the pharmaceutical company

lodged an appeal with the Federal Social Court (FSC). In its judgement of 5 September 2024, the FSC ruled that the amendment to Annex XII of the Pharmaceuticals Directive on the benefit assessment of the active ingredient ivermectin made by resolution of the G-BA on 27 November 2015 was invalid because, in the opinion of the FSC, no decision was to be made on a benefit assessment of the medicinal product Soolantra due to the lack of novelty of the active ingredient ivermectin.

Consequently, the findings on the benefit assessment of the active ingredient ivermectin in the therapeutic indication according to the marketing authorisation of 2 May 2015 for the treatment of inflammatory lesions of (papulopustular) rosacea in adult patients, in Annex XII of the Pharmaceuticals Directive in the version of the resolutions of 27 November 2015 (BAnz AT 22.12.2015 B2) and of 21 January 2016 (BAnz AT 19.04.2016 B3) must be deleted.

3. 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.

4. Process sequence

At its session on 7 January 2025, the Subcommittee on Medicinal Products consulted on the deletion of the findings on the benefit assessment of the active ingredient ivermectin in Annex XII of the AM-RL (Pharmaceuticals Directive) in the version of the resolutions of 27 November 2015 (BAnz AT 22.12.2015 B2) and of 21 January 2016 (BAnz AT 19.04.2016 B3), and approved the draft resolution.

At its session on 16 January 2025, the plenum consulted and decided on the deletion of the findings on the benefit assessment of the active ingredient ivermectin in Annex XII of the Pharmaceuticals Directive in the version of the resolutions of 27 November 2015 (BAnz AT 22.12.2015 B2) and of 21 January 2016 (BAnz AT 19.04.2016 B3).

Chronological course of consultation

Session	Date	Subject of consultation
Working group Section 35a	18 December 2024	Consultation of the draft resolution
Subcommittee on Medicinal Products	7 January 2025	Consultation on the draft resolution on the repeal of the resolutions in Annex XII
Plenum	16 January 2025	Adoption of the resolution on the repeal of the resolutions in Annex XII

Berlin, 16 January 2025

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

Prof. Hecken