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 Enalapril (heart failure, from birth to ≤ 17 years) (repeal of the resolution of 15 August 2024)

of 7 November 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 all reimbursable medicinal products with new active ingredients. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the G-BA electronically, including all clinical trials the pharmaceutical company has conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. approved therapeutic indications,
2. medical benefit,
3. additional medical benefit in relation to the appropriate comparator therapy,
4. number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. treatment costs for the statutory health insurance funds,
6. requirements for a quality-assured application.

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

By the Commission's implementing decision of 15 November 2023 in accordance with Article 38 paragraph 1 of the Regulation (EC) No. 1901/2006, the active ingredient enalapril 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 indication "AQUMELDI is indicated for the treatment of heart failure in children from birth to less than 18 years".

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 enalapril in this therapeutic indication was 1 March 2024. The pharmaceutical company submitted the final dossier to the G-BA in accordance with Section 4, paragraph 3, number 1 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5 Section 8, number 1 VerfO on 29 February 2024.

On 15 August 2024, the G-BA adopted a resolution on the benefit assessment of enalapril for the treatment of heart failure in children from birth to less than 18 years. Accordingly, the Pharmaceuticals Directive was supplemented with Annex XII with regard to the findings on the benefit assessment of the active ingredient enalapril according to Section 35a SGB V.

The medicinal product AQUMELDI 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), AQUMELDI 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 enalapril no longer existed at the time of the marketing authorisation of the medicinal product AQUMELDI.

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 assessment of the active ingredient enalapril according to the marketing authorisation of 15 November 2023, for the treatment of heart failure in children from birth to less than 18 years, in Annex XII to the Pharmaceuticals Directive in the version of the resolution of 15 August 2024 (BAnz AT 17.09.2024 B2) are to be repealed.

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 29 October 2024, the Subcommittee on Medicinal Products discussed the repeal of the resolution on the benefit assessment of the active ingredient enalapril in the version of the resolution of 15 August 2024 and approved the draft resolution.

At its session on 7 November 2024, the plenum adopted a resolution to repeal the resolution on the benefit assessment of the active ingredient enalapril in the version of the resolution of 15 August 2024.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee Medicinal products	29 October 2024	Consultation on the draft resolution on the repeal of the resolution
Plenum	7 November 2024	Adoption of the repeal of the resolution

Berlin, 7 November 2024

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

Prof. Hecken