Justification

Gemeinsamer Bundesausschuss

on the Resolution of the Federal Joint Committee (G-BA) on the Suspension of the Procedure Concerning an Application for Exemption from the Obligation to Submit the Evidence According to Section 35a, Paragraph 1, Sentence 3, Numbers 2 and 3 SGB V because of Reserve Status in Accordance with Section 35a, Paragraph 1c SGB V “Last-resort Antibiotic”

of 20 August 2020

Contents

1. Legal basis

According to Section 35a, paragraph 1c German Social Code, Book Five (SGB V), antibiotics that are effective against infections caused by multi-resistant bacterial pathogens for which only limited alternative treatment options are available and for which the use is subject to a strict indication (last-resort antibiotic) can be exempted from the obligation to present the evidence according to Section 35a, paragraph 1, sentence 3, numbers 2 and 3 SGB V. A prerequisite is that for a last-resort antibiotic, an application for exemption must be submitted before the initial obligation to submit the evidence referred to in paragraph 1, sentence 3 is imposed. The details of the application procedure are regulated by the Rules of Procedure of the Federal Joint Committee until 31 December 2020. In agreement with the Federal Institute for Drugs and Medical Devices, the Robert Koch Institute shall determine criteria for the classification of an antibiotic as a last-resort antibiotic according to the current state of medical science by 31 December 2020 and publish these criteria on its website.

2. Key points of the resolution

Because of the criteria of the Robert Koch Institute (RKI) for the classification of an antibiotic as a last-resort antibiotic, which have not yet been available, and the implementation regulations still to be adopted in the Rules of Procedure of the Federal Joint Committee (VerfO), the Federal Joint Committee (G-BA) has resolved to suspend the following application procedure of a pharmaceutical company for exemption from the obligation to submit the evidence according to Section 35a, paragraph 1, sentence 3, numbers 2 and 3 SGB V:

Therapy class: Antibiotics

Applicant: Pharmaceutical company

Received: 16 July 2020

After publication of the criteria for the classification of an antibiotic as a last-resort antibiotic by the RKI and entry into force of the corresponding regulations in the VerfO of the G-BA, including details of the procedure, the pharmaceutical company is obliged to justify the application on the basis of the criteria of the RKI within three months, taking into account the regulations in the VerfO of the G-BA.

The suspension of the procedure thus ends at the point in time at which the G-BA receives a justification of the application of the pharmaceutical company in accordance with the adapted provisions in the VerfO of the G-BA and the criteria of the RKI for the classification of an antibiotic as a last-resort antibiotic. In this respect, the pharmaceutical company is granted reinstatement to the previous status with effect from the time of first placing on the market. In this case, the G-BA must decide on the application within a period to be determined.

The suspension of the procedure also ends if no justification for the application are received within three months of the entry into force of the relevant procedural rules and the publication of the criteria of the RKI. In this case, a reinstatement to the previous status is granted with effect from the time of first placing on the market. However, because an application for exemption is admissible only before the first obligation to submit evidence according to Section 35a, paragraph 1, sentence 3 SGB V (Section 35a, paragraph 1c, sentence 3 SGB V), if the reasons for the application are not submitted, a comprehensive dossier must be submitted by

this time at the latest; a resolution on exemption as a last-resort antibiotic according to Section 35a, paragraph 1c, sentence 7 in conjunction with sentence 1 is then no longer possible. In this case, the application is deemed to be withdrawn.

The obligation to submit a dossier for the purpose of a benefit assessment at the relevant points in time according to Chapter 5, Section 8, numbers 1, 3, and 7 VerfO is thus not subject to the decision on the application for exemption according to Section 35a, paragraph 1c, sentence 1 SGB V.

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

The application of the pharmaceutical company for exemption from the obligation to submit the evidence according to Section 35a, paragraph 1, sentence 3, numbers 2 and 3 SGB V in accordance with Section 35a, paragraph 1c SGB V was received by the office of the Federal Joint Committee on 16 July 2020. It was discussed in the working group set up by the Subcommittee on Medicinal Products (Section 35a) at its session on 11 August 2020.

At its session on 20 August 2020, the Subcommittee on Medicinal Products finalised the suspension of the procedure and reached consensus on the draft resolution.

Chronological course of consultation

Session	Date	Subject of consultation
Working group Section 35a	5 August 2020	Consultation of the draft resolution
Subcommittee on Medicinal Products	11 August 2020	Concluding discussion of the draft resolution
Plenum	20 August 2020	Resolution to suspend the procedure

Berlin, 20 August 2020

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Prof. Hecken