

# Resolution



## **of the Federal Joint Committee (G-BA) on 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 “Antibiotics”**

of 17 September 2020

At its session on 17 September 2020, the Federal Joint Committee passed the following resolution:

Regarding the informal application of a pharmaceutical company received on 17 April 2020 and 31 July 2020 for exemption from the obligation to submit evidence according to Section 35a, paragraph 1, sentence, 3 numbers 2 and 3 SGB V in accordance with Section 35a, paragraph 1c SGBV:

I. The application procedure is suspended. The suspension ends three months after the entry into force of the Rules of Procedure of the G-BA (VerfO) adapted on the basis of Section 35a, paragraph 1c, sentence 4 SGB V and after publication of the criteria determined by the Robert Koch Institute (RKI) in agreement with the Federal Institute for Drugs and Medical Devices (BfArM) for classification as a last-resort antibiotic according to Section 35a, paragraph 1c, sentence 5 SGB V. The pharmaceutical company must, at the latest at the end of the day on which the suspension ends, submit a justification of the application in accordance with the adapted regulations in the VerfO on the basis of the criteria of the RKI according to Section 35a, paragraph 1c, sentence 5 SGB V. Otherwise, the application is deemed to be withdrawn.

II. Upon submission of the justification for the application, reinstatement into the previous status is granted with effect from the time of the first obligation to submit the evidence according to Section 35a, paragraph 1, sentence 3 SGB V. The same shall apply at the end of the day on which the suspension ends without any justification being received.

Berlin, 17 September 2020

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

Prof. Hecken