# Justification

Gemeinsamer Bundesausschuss

## to the Resolution of the Federal Joint Committee (G-BA) on an Application for Exemption from the Benefit Assessment Because of Insignificance According to Section 35a, Paragraph 1a SGB V “Other Diagnostic Agents”

of 18 June 2020

**Contents**

## 1. Legal basis

According to Section 35a, paragraph 1a SGB V, proprietary medicinal products can be exempted from the benefit assessment according to Section 35a, paragraph 3 SGB V, although they fulfil the factual requirements for a benefit assessment according to Section 35a, paragraph 1 SGB V. The prerequisite is that the expected expenditure of the proprietary medicinal product for the statutory health insurance funds is negligible. Details of the procedure for exempting a medicinal product from the benefit assessment according to Section 35a, paragraph 1a SGB V are governed by Chapter 5, Section 15 VerfO.

## 2. Key points of the resolution

Based on the standards for assessing the insignificance of the expenditure for the medicinal product specified in Chapter 5, Section 15 VerfO and taking into account the documents submitted by the applicant, the Federal Joint Committee has decided to uphold the following objection of a pharmaceutical company against the resolution of the Federal Joint Committee of 17 October 2019 on the application for exemption of a proprietary medicinal product from the benefit assessment according to Section 35a, paragraph 1a SGB V:

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| Therapy class: | “Other diagnostic agents” |
| Applicant: | Pharmaceutical company |
| Received: | 25 October 2019 (opposition; 22 November 2019, reasons for opposition). |

The objection of the pharmaceutical company against the resolution of the Federal Joint Committee of 17 October 2019 regarding the application for exemption from the benefit assessment because of insignificance according to Section 35a, paragraph 1a SGB V is upheld because the information provided by the pharmaceutical company is sufficient to substantiate the insignificance of the expected sales based on Section 84, paragraph 5, sentence 4 SGB V.

Further details can be found in the reasons for the resolution.

## 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 objection of a pharmaceutical company against the resolution of the Federal Joint Committee of 17 October 2019 regarding the application for exemption from the benefit assessment according to Section 35a SGB V was received by the office of the Federal Joint

Committee on 25 October 2019. The corresponding grounds for appeal were received by the office of the Federal Joint Committee on 22 November 2019. The objection was discussed in the working group “Section 35a SGB V” established by the Subcommittee on Medicinal Products at the session on 21 January 2020 and the session on 4 February 2020. By letter dated 4 February 2020, the Federal Joint Committee requested further data on the substantiation of the objection by the pharmaceutical company. The pharmaceutical company complied with this request by letter dated 15 April 2020. The objection, including the subsequent submissions was discussed in the working group “Section 35a SGB V” established by the Subcommittee on Medicinal Products at the session on 19 May 2020 and the session on 3 June 2020.

At its session on 9 June 2020, the Subcommittee on Medicinal Products discussed the application and consented to the draft resolution.

Berlin, 18 June 2020

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

Prof. Hecken