Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on a Finding in the Procedure of Routine Practice Data Collection and Evaluations according to Section 35a, paragraph 3b SGB V: Talquetamab (multiple myeloma, at least 3 previous therapies) – submission of study protocol and statistical analysis plan

of 17 April 2025

At their session on 17 April 2025, the Federal Joint Committee (G-BA) decided the following in the procedure of routine practice data collection and evaluations according to Section 35a, paragraph 3b SGB V for the active ingredient talquetamab (multiple myeloma, at least 3 previous therapies):

I. The routine practice data collection will not be carried out as it was found that the pharmaceutical company has not fulfilled their obligation - required by resolution of 18 July 2024 - to prepare a statistical analysis plan and study protocol prior to the implementation of the routine practice data collection.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 17 April 2025.

The justification to this resolution will be published on the website of the G-BA at www.g-ba.de.

Berlin, 17 April 2025

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

Prof. Hecken