GBA
Gemeinsamer
Bundesausschuss

Justification

for the Resolution of the Federal Joint Committee on the Discontinuation of the Consultation Procedure under Section 35a paragraph 3b SGB V:
MaaT013 (pooled allogeneic faecal microorganisms) (acute graft-versus-host disease);
requirement of routine practice data collection and evaluations

of 5 November 2026

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1. Legal basis

According to Section 35a, paragraph 3b, sentence 1 SGB V, the Federal Joint Committee (GBA) can demand the pharmaceutical company to submit routine practice data collections and evaluations for the purpose of the benefit assessment within a reasonable period of time for the following medicinal products:

1. in the case of medicinal products authorised to be placed on the market in accordance with the procedure laid down in Article 14, paragraph 8 of Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136 from 30.04.2004, p. 1), as last amended by Regulation 162 Rules of Procedure last revised: 16 December 2020 (EU) 2019/5 (OJ L 4 from 07.01.2019, p. 24), or for which a marketing authorisation has been granted in accordance with Article 14-a of Regulation (EC) No. 726/2004; and
2. for medicinal products approved for the treatment of rare diseases under Regulation No. 141/2000.

2. Key points of the resolution

By the resolution of 5 March 2026, the GBA initiated a procedure for the requirement of a routine practice data collection according to Section 35a, paragraph 3b, sentence 1 SGB V concerning the active ingredient MaaT013 (pooled allogeneic faecal microorganisms) for the treatment of adults with acute graft-versus-host disease (aGVHD) with gastrointestinal involvement following two prior therapies.

The initiation of the procedure was based on the fact that the EMA's central marketing authorisation procedure for the active ingredient MaaT013 (pooled allogeneic faecal microorganisms) was started in June 2025. Given its orphan drug designation, the GBA assumed that the marketing authorisation procedure could result in the European Commission (EC) granting marketing authorisation for MaaT013 (pooled allogeneic faecal microorganisms) for the treatment of rare diseases (orphan drug) under Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999.

For preparation of the resolution, the GBA decide whether to prepare the concept themselves or to commission the Institute for Quality and Efficiency in Health Care (IQWiG) to do so. In the present case, the GBA commissioned IQWiG to prepare the concept for routine practice data collection in order to prepare the resolution on the requirement of routine practice data collection and evaluations.

In preparing the concept, ongoing and planned data collections were taken into account, especially those resulting from conditions or other ancillary provisions imposed by the marketing authorisation or licensing authorities. The expert bodies according to Section 35a, paragraph 3b, sentences 7 and 8 SGB V made a written submission in drawing up the concept. The submission took place in such a way that the expert bodies were given the opportunity in writing to comment on the requirements of routine practice data collection and evaluations in accordance with the concept that had been drawn up.

On 25 June 2026 – during the ongoing submission procedure – a negative opinion was issued in which the European Medicines Agency (EMA) recommended rejecting the marketing authorisation application for MaaT013 (pooled allogeneic faecal microorganisms) (Xervyteg). The pharmaceutical company requested a re-examination of the negative opinion from the EMA. The EMA carried out a re-examination of the negative opinion. On 17 September 2026,

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following the re-examination, the EMA confirmed the recommendation to reject the marketing authorisation application for Xervyteg, as the benefits of Xervyteg did not outweigh its risks according to the EMA's assessment.[1]

The legal requirements for the requirement of a routine practice data collection in accordance with Section 35a, paragraph 3b, sentence 1, number 1 SGB V for the active ingredient MaaT013 (pooled allogeneic faecal microorganisms) could therefore be no longer fulfilled.

The GBA therefore discontinued the consultation on the requirement of routine practice data collection and evaluations of the active ingredient MaaT013 (pooled allogeneic faecal microorganisms) in the treatment of

"Adults with acute graft-versus-host disease (aGVHD) with gastrointestinal involvement following two prior therapies".

3. Bureaucratic costs calculation

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

In order to prepare a recommendation for a resolution on the initiation of a procedure for the requirement of a routine practice data collection (amendment of Annex XII of AM-RL) according to Section 35a, paragraph 3b SGB V, the Subcommittee on Medicinal Products commissioned a working group (WG routine practice data collection (RPDC)) consisting of the members nominated by the leading organisations of the care providers, the members nominated by the SHI umbrella organisation, and representatives of the patient organisations. Representatives of the IQWiG also participate in the sessions. In addition, the competent higher federal authority, the Paul Ehrlich Institute, was involved in the consultation to assess the requirement of a routine practice data collection according to Section 35a, paragraph 3b, sentence 1 SGB V.

The recommendation for a resolution on the initiation of a procedure for the requirement of a routine practice data collection was discussed at the Subcommittee's session on 24 February 2026, and the draft resolution was approved.

At their session on 5 March 2026, the plenum resolved to initiate a procedure for the requirement of a routine practice data collection.

In conjunction with the resolution of 5 March 2026 regarding the initiation of a procedure for the requirement of a routine practice data collection, the GBA commissioned IQWiG to scientifically draw up a concept for routine practice data collection and evaluations for the purpose of drafting a resolution.

The IQWiG's concept was submitted to the GBA on 3 June 2026. On 8 June 2026, the written submission of the expert bodies according to Section 35a, paragraph 3b, sentences 7 and 8 SGB V was initiated. The deadline for making the written submission was 6 July 2026.

1 https://www.ema.europa.eu/en/documents/smop-initial/questions-answers-refusal-marketing-authorisation-xervyteg-allogeneic-faecal-microbiota-pooled-re-examination-confirms-refusal_en.pdf

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The discontinuation of the procedure was discussed at the session of the Subcommittee on Medicinal Products on 27 October 2026, and the draft resolution was approved.

At their session on 5 November 2026, the plenum decided on the discontinuation of consultations on the requirement of routine practice data collection and evaluations.

Chronological course of consultation

Session	Date	Subject of consultation
WG RPDC	4 September 2025 2 October 2025 5 February 2026	Consultation on the initiation of a procedure for the requirement of a routine practice data collection (amendment of Annex XII of the AM-RL), involvement of the higher federal authority
Subcommittee on Medicinal Products	24 February 2026	Concluding discussion of the draft resolution
Plenum	5 March 2026	Resolution on the initiation of a procedure for the requirement of a routine practice data collection (amendment of Annex XII of the AM-RL)
WG RPDC	13 July 2026 3 September 2026	Information on written submissions received
WG RPDC	2 July 2026 1 October 2026	Consultation on IQWiG's concept and on the specifications for the review of the obligation to conduct and submit evaluations, evaluation of the submission procedure
Subcommittee on Medicinal Products	27 October 2026	Concluding discussion of the draft resolution
Plenum	5 November 2026	Resolution on the discontinuation of the consultation procedure on the requirement of a routine practice data collection

Berlin, 5 November 2026

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

Dr Optendrenk

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