Gemeinsamer Bundesausschuss

Justification

to the Resolution of the Federal Joint Committee (G-BA) on the Suspension of a Consultation Procedure under Section 35a paragraph 3b SGB V
Lifileucel (melanoma); requirement of routine practice data collection and evaluations

of 16 October 2025

Contents

1. Legal basis

According to Section 35a, paragraph 3b, sentence 1 SGB V, the Federal Joint Committee (G-BA) 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, 30.4.2004, p. 1), as last amended by Regulation 162 Rules of Procedure last revised: 16 December 2020 (EU) 2019/5 (OJ L 4, 7.1.2019, 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 resolution of 5 June 2025, the G-BA initiated a procedure for the requirement of a routine practice data collection - in accordance with Section 35a, paragraph 3b, sentence 1 SGB V - of the active ingredient lifileucel for the treatment of adults with unresectable or metastatic melanoma who have been previously treated with a PD-1 blocking antibody and, if a BRAF V600 mutation is present, with a BRAF inhibitor with or without an MEK inhibitor.

The initiation of the procedure was based on the fact that the EMA's central marketing authorisation procedure for the active ingredient lifileucel was started in August 2024. Based on the classification of the medicinal product as an Advanced Therapy Medicinal Product (ATMP) and against the background of the study available at the time of the resolution (pivotal single-arm phase II C-144-01 study), the G-BA assumed that a conditional marketing authorisation for placing on the market (Article 14-a of Regulation (EC) No. 726/2004) by the European Commission (EC) could be a possible outcome of the marketing authorisation procedure for lifileucel.

For preparation of the resolution, the G-BA 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 G-BA 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.

The marketing authorisation application for the medicinal product Amtagvi with the active ingredient lifileucel was withdrawn on 22 July 2025 – before IQWIG had finalised the concept.[1] At the time of the withdrawal of the marketing authorisation application, the EMA considered that the advantages of Amtagvi did not outweigh the risks.

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 lifileucel could therefore be no longer fulfilled.

1 https://www.ema.europa.eu/en/medicines/human/EPAR/amtagvi

The G-BA therefore suspended the consultation on the requirement of routine practice data collection and evaluations of the active ingredient lifileucel in the treatment of

"Adults with unresectable or metastatic melanoma who have been previously treated with a PD-1 blocking antibody and, if a BRAF V600 mutation is present, with a BRAF inhibitor with or without an MEK inhibitor."

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 the 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 recommended resolution on the initiation of a procedure for the requirement of a routine practice data collection was discussed on 27 May 2025 at the subcommittee session and the draft resolution was approved.

At their session on 5 June 2025, the plenum resolved to initiate a procedure for the requirement of a routine practice data collection.

In conjunction with the resolution of 5 June 2025 regarding the initiation of a procedure for the requirement of a routine practice data collection, the G-BA commissioned IQWiG to scientifically develop a concept for routine practice data collection and evaluations for the purpose of preparing a resolution.

The suspension of the procedure was discussed at the session of the Subcommittee on Medicinal Products on 7 October 2025, and the draft resolution was approved.

At their session on 16 October 2025, the plenary decided on the suspension of consultations on the requirement of routine practice data collection and evaluations.

Chronological course of consultation

Session	Date	Subject of consultation
WG RPDC	3 April 2025 2 May 2025	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	27 May 2025	Concluding discussion of the draft resolution
Plenum	5 June 2025	Resolution on the initiation of a procedure for the requirement of a routine practice data collection (amendment of Annex XII of the AM-RL)
Subcommittee on Medicinal Products	7 October 2025	Consultation on the draft resolution on suspension of the procedure
Plenum	16 October 2025	Resolution on the suspension of the consultation procedure on the requirement of a routine practice data collection

Berlin, 16 October 2025

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

Prof. Hecken