Gemeinsamer Bundesausschuss

Justification

on the Resolution of the Federal Joint Committee (G-BA) on the Suspension of a Consultation Procedure under Section 35a paragraph 3b SGB V
Glofitamab (relapsed or refractory diffuse large B-cell lymphoma); requirement of routine practice data collection and evaluations

of 5 June 2025

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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 16 January 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 for the active ingredient glofitamab in the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), after two or more lines of systemic therapy, who are ineligible for CAR-T cell therapy and stem cell transplantation.

The initiation of the procedure was based on the EMA's orphan designation of 15 October 2021 - available at the time of the resolution - for the active ingredient glofitamab for the treatment of DLBCL as well as on a conditional marketing authorisation of 7 July 2023 (Article 14-a of Regulation (EC) No 726/2004, as last amended by Regulation (EU) 2019/5) for the treatment of DLBCL.

A concept was drawn up in preparation for the resolution on the requirement of routine practice data collection and evaluations. The concept contains in particular requirements for:

1. the type, duration and scope of data collection,
2. the research question (PICO framework: patient/population, intervention, comparison, outcomes) that is to be the subject of the data collection and evaluations, including the patient-relevant endpoints to be collected,
3. the data collection methods,
4. the evaluations by the pharmaceutical company according to Section 50, paragraph 2 of the VerfO.

The G-BA decides whether to prepare the concept itself 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. 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.

The requirement of routine practice data collection and evaluations is essentially determined by the prerequisites according to Section 35a, paragraph 3b, sentence 1, numbers 1 and 2 SGB V that the medicinal product in question is a medicinal product, whose placing on the market has been authorised in accordance with the procedure set out 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136 of 30.04.2004, p. 1), as last amended by Regulation (EU) 5/2019 (OJ L 4, 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, or it is a medicinal product approved for the treatment of rare diseases under Regulation (EC) No 141/2000.

On 8 May 2025, the European Commission converted the conditional marketing authorisation for the active ingredient glofitamab into a marketing authorisation without specific conditions.

The medicinal product Columvi with the active ingredient glofitamab for the treatment of DLBCL (EU/3/21/2497) was deleted from the Community Register of Orphan Drugs on 21 March 2025.

The legal requirements for the requirement of a routine practice data collection in accordance with Section 35a, paragraph 3b, sentence 1, numbers 1 and 2 SGB V for the active ingredient glofitamab are therefore not fulfilled at the time of this resolution.

Therefore, the G-BA suspends the consultation on the requirement of routine practice data collection and evaluations for the active ingredient glofitamab in the treatment of adults with relapsed or refractory DLBCL, after two or more lines of systemic therapy, who are ineligible for CAR T-cell therapy and stem cell transplantation.

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 7 January 2025 at the subcommittee session and the draft resolution was approved.

At their session on 16 January 2025, the plenum resolved to initiate a procedure for the requirement of a routine practice data collection.

In conjunction with the resolution of 16 January 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.

IQWiG's concept was submitted to the G-BA on 16 April 2025. On 17 April 2025, 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 15 May 2025.

The evaluation of the written submissions received was discussed at the session of the Subcommittee on 27 May 2025.

The suspension of the procedure was discussed at the session of the Subcommittee on Medicinal Products on 27 May 2025, and the draft resolution was approved.

At their session on 5 June 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	14 November 2022 16 January 2023	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	7 January 2025	Concluding discussion of the draft resolution
Plenum	16 January 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	27 May 2025	Consultation on the draft resolution on suspension of the procedure
Plenum	5 June 2025	Resolution on the suspension of the consultation procedure on the requirement of a routine practice data collection

Berlin, 5 June 2025

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

Prof. Hecken