Justification

Gemeinsamer Bundesausschuss

to the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Amendment of Information on the Period of Validity of a Resolution on the Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Apalutamide

of 20 February 2020

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1. Legal basis

According to Section 35a, paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assesses the benefit of reimbursable medicinal products with new active ingredients. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the G-BA electronically, including all clinical trials the pharmaceutical company has conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. Approved therapeutic indications,
2. Medical benefit,
3. Additional medical benefit in relation to the appropriate comparator therapy,
4. Number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. Treatment costs for statutory health insurance funds,
6. Requirements for a quality-assured application.

The G-BA may commission the Institute for Quality and Efficiency in Health Care (IQWiG) to carry out the benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment must be completed within three months of the relevant date for submission of the evidence and published on the internet.

According to Section 35a, paragraph 3 SGB V, the G-BA decides on the benefit assessment within three months of its publication. The resolution is to be published on the internet and forms part of the Pharmaceuticals Directive.

2. Key points of the resolution

At its session on 1 August 2019, the G-BA passed a resolution on the benefit assessment of apalutamide in accordance with Section 35a SGB V. The period of validity of the resolution was limited to 15 May 2020.

In accordance with the justification for this resolution, the reason for the limitation was that the overall survival data available for assessment from the SPARTAN study were inconclusive because of the small number of events at the time of the data cut-off used. With regard to the second data cut-off submitted with the statement of the pharmaceutical company, there were significant uncertainties. This was therefore not used for the benefit assessment. In order to promptly include a more significance data basis on overall survival as well as other patient-relevant outcomes in the benefit assessment, the resolution was limited in time. For the renewed benefit assessment, a data cut-off of the SPARTAN study was to be carried out on 1 December 2019.

The pharmaceutical company informed the G-BA that the required data cut-off of the SPARTAN study was made on 1 December 2019 and that a complete presentation of all endpoints relevant for a renewed benefit assessment is possible before the deadline set by the G-BA.

In order to ensure that the new results of the SPARTAN study are included in the new benefit assessment of the medicinal product in accordance with Section 35a SGB V in a timely manner, the period of validity of the resolution, originally limited until 15 May 2020, will be shortened. A shortening of the time limit until 1 April 2020 is considered appropriate for this purpose.

The questions underlying the limitation with regard to the assessment of the additional benefit remain unaffected by this.

In accordance with Section 3, No. 5 AM-NutzenV in conjunction with Chapter 5 Section 1, paragraph 2, No. 7 VerfO, the procedure for the benefit assessment for the active ingredient apalutamide shall recommence when the deadline has expired. For this purpose, the pharmaceutical company must submit a dossier on the benefit assessment of apalutamide to the G-BA at the latest on the day of expiry of the deadline (Section 4, paragraph 3, No. 5 AM-NutzenV in conjunction with Chapter 5, Section 8, No. 5 VerfO).

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 matter was discussed in the Subcommittee on Medicinal Products, and an amendment resolution was passed.

At its session on 20 February 2020, the plenum decided to amend the limitation of the period of validity of the resolution.

Berlin, 20 February 2020

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

Prof. Hecken