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 Vandetanib (Salivary Gland Carcinoma)

of 20 August 2020

Contents

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 5 September 2013, the G-BA passed a resolution on the benefit assessment of vandetanib in accordance with Section 35a SGB V. The period of validity of the resolution is limited to 5 September 2016. On 4 August 2016, it was decided to prolong the limitation of the resolution until 1 October 2020.

In accordance with the justification of this resolution, the limitation was due to the fact that the marketing authorisation of vandetanib was a conditional marketing authorisation in accordance with Article 14, paragraph 7 under Regulation (EC) No 726/2004 in conjunction with Article 4 under Regulation (EC) No. 507/2006. The pharmaceutical company was obliged by the EMA to submit further comprehensive clinical data on the safety and efficacy of the medicinal product Caprelsa®. These comprehensive new clinical data on vandetanib are relevant for the assessment of the benefit of the medicinal product in accordance with Section 35a SGB V. With regard to the evidence to be provided, the EMA requested, inter alia, that a study on the RET mutation status in patients with sporadic medullary salivary gland carcinoma be carried out (study D42000C00104).

Because of the delayed collection of the final study data as a result of COVID-19, the pharmaceutical company cannot meet the deadline for the completion of the study; this has already been extended.

It was decided to prolong the limitation of the resolution until 1 October 2021.

The issues upon which the limitation was based regarding the assessment of the additional benefit are hereby not prejudiced.

In accordance with Section 3, number 5 AM-NutzenV in conjunction with Chapter 5, Section 1, paragraph 2, number 7 VerfO, the procedure for the benefit assessment for the active ingredient vandetanib shall recommence when the limitation has expired. For this purpose, the pharmaceutical company must submit a dossier on the benefit assessment of vandetanib 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).

The possibility that a benefit assessment for vandetanib can be carried out at an earlier point in time because of other reasons (*cf* Chapter 5, Section 1, paragraph 2, no. 2, 3, 5, and 6 VerfO) remains unaffected hereof.

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 August 2020, the plenum decided to amend the limitation of the period of validity of the resolution.

Berlin, 20 August 2020

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

Prof. Hecken