Resolution

Gemeinsamer Bundesausschuss

of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Ropeginterferon Alfa-2b (Number of Patients)

of 16 July 2020

In its session on 16 July 2020, the Federal Joint Committee (G-BA) resolved to amend the Directive on the Prescription of Medicinal Products in SHI-accredited Medical Care (Pharmaceuticals Directive, AM-RL) in the version dated 18 December 2008/22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended on DD MM YYYY (Federal Gazette, BAnz AT DD MM YYYY Bx) as follows:

I. In Annex XII, the information on the benefit assessment of the active ingredient ropeginterferon alfa-2b as amended by the resolution of 5 March 2020 (Federal Gazette, BAnz AT 4 June 2020 B3) under the heading "2. Number of patients or demarcation of patient groups eligible for treatment" is amended as follows:

Under "a) Adult patients with polycythaemia vera without symptomatic splenomegaly not pretreated with hydroxyurea or pretreated with hydroxyurea who are not resistant or intolerant to hydroxyurea", the information on the number of patients

"approx. 1,280–10,530 patients" will be replaced by the following specification:

"approx. 1,560–16,440 patients"

Under "b) Adult patients with polycythaemia vera without symptomatic splenomegaly pre-treated with hydroxyurea who are resistant or intolerant to hydroxyurea", the information on the number of patients

"approx. 240–1,470 patients" will be replaced by the following specification:

"approx. 300–3,360 patients"

II. The resolution will enter into force with effect from the day of its publication on the internet on the website of the G-BA on 16 July 2020.

The justification to this resolution will be published on the website of the G-BA at www.g-ba.de.

Berlin, 16 July 2020

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

Prof. Hecken