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 Emicizumab (haemophilia A with inhibitors, quality-assured application)

of 17 October 2019

At its session on 10 September 2019, 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 concerning the benefit assessment of the active ingredient emicizumab (haemophilia A with inhibitors) under section "3. Requirements for a quality-assured application" is amended as follows:

In Sentence 4, after the words "on the influence of emicizumab on coagulation tests", the parenthetical statement "(risk of misinterpretation)" shall be inserted.

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 17 October 2019.

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

Berlin, 17 October 2019

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

Prof Hecken