

Draft Resolution

of the Federal Joint Committee (G-BA) on a Non-amendment of the Pharmaceuticals Directive (AM-RL):

Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a (SGB V) Marstacimab (haemophilia A and B); restriction of the authority to supply care

of 5 December 2024

At its session on 5 December 2024, the Federal Joint Committee (G-BA) resolved not to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009) with regard to a restriction of the authority to supply care, as the consultation procedure for the requirement of routine practice data collection and evaluations of the active ingredient marstacimab in the treatment of

"Adults and adolescents aged 12 years and older with severe haemophilia A without factor VIII inhibitors or with moderate-to-severe haemophilia B without factor IX inhibitors"

was suspended by resolution of the G-BA on 5 December 2024.

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

Berlin, 5 December 2024

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

Prof. Hecken