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 Tisagenlecleucel (acute lymphoblastic B-cell leukaemia, quality-assured application)

of 1 August 2019

At its session on 1 August 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), last changed on DD MM YYYY (BAnz AT DD MM YYYY Bx) as follows:

I. In Annex XII, the information concerning the benefit assessment of the active ingredient tisagenlecleucel (acute lymphoblastic B-cell leukaemia) under section "3. Requirements for a quality-assured application" is amended as follows:

1. Section 1.3.3 "Requirements for the qualification of the care service" is amended as follows:

a. In number 1.3.3.1, in the first sentence, after the words "caregiver", the words "or paediatric caregiver" are inserted.

b. In number 1.3.3.2, in the first sentence, after the words "caregiver", the words "or paediatric caregiver" are 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 1 August 2019.

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

Berlin, 1 August 2019

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

Prof Hecken