Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee(G-BA) on an Amendment of the Pharmaceuticals Directive: Annex XII - Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V: Onasemnogene abeparvovec (spinal muscular atrophy); restrictions regarding supply

of 6 May 2021

At its meeting on 6 May 2021, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceutical Directive in the version dated 18 December 2008/22 January 2009 (BAnz. No. 49a of 31 March 2009), last amended on D. month YYYY (BAnz AT DD.MM.YYYY V), as follows:

I. In Annex XII, in the provision under II. regarding the effective date of the resolution to limit authority to provide, of 4 February 2021, after the statement

"The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 4 February 2021."

attached:

"The restriction of the authority to supply regulated in the resolution to such care providers who participate in the required application-supporting data collection only takes effect from the confirmation of the study protocol and the statistical analysis plan submitted by the pharmaceutical company and publication of the confirmation on the websites of the G-BA."

II. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 6 May 2021.

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

Berlin, 6 May 2021

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

Prof. Hecken