



of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL):

Annex XII – Amendment of Information on the Period of Validity of a Resolution on the Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V

Pembrolizumab (Urothelial Carcinoma)

of 5 March 2020

At its session on 5 March 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), last amended on D Month YYYY (Federal Gazette, BAnz AT DD MM YYYY BX), as follows:

I. In Annex XII, the provision under II. 2. concerning the period of validity of the resolution on the benefit assessment of pembrolizumab of 20 June 2019 will be amended as follows:

The entry "1 July 2020", which entered into force with the resolution of 20 June 2019, will be replaced by "1 April 2021".

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 5 March 2020.

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

Berlin, 5 March 2020

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

Prof. Hecken