

Resolution



Gemeinsamer
Bundesausschuss

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

Abemaciclib (Breast Cancer; in Combination with Fulvestrant)

of 5 December 2019

At its session on 5 December 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 D Month YYY (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 of 2 May 2019 on the benefit assessment of abemaciclib in combination with fulvestrant will be amended as follows:

The entry “31 December 2020” will be replaced by “15 March 2020”.

- II. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 5 December 2019.

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

Berlin, 5 December 2019

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

Prof Hecken