Resolution

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

Courtesy translation – only the German version is legally binding.