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 Fluticasone furoate/Umeclidinium/Vilanterol (patient numbers) (new therapeutic indication: COPD that is not adequately treated by a combination of LAMA and LABA)

of 19 September 2019

At its session on 19 September 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 DD MM YYYY (Federal Gazette, BAnz AT DD MM YYYY Bx) as follows:

I. In Annex XII, the information on the benefit assessment of the active ingredient combination fluticasone furoate/umeclidinium/vilanterol under the heading "2. Number of patients or demarcation of patient groups eligible for treatment" is amended as follows:

Under the heading "Number of patients or demarcation of patient groups eligible for treatment", the information is replaced by the following:

Under "Adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of a long-acting β2-agonist (LABA) and a long-acting muscarinic antagonist (LAMA)", the specification of the number of patients

"approx. 571,000–1,501,000" will be replaced by the following specification:

"approx. 524,000–1,217,000 patients"

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 19 September 2019.

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

Berlin, 19 September 2019

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

Prof Hecken