Resolution

Gemeinsamer Bundesausschuss

by the Federal Joint Committee (G-BA) on the initiation of benefit assessment of pharmaceuticals on the existing market in accordance with the German Social Code, Book Five (SGB V), section 35a, paragraph 6 in connection with the G-BA Rules of Procedure (VerfO), chapter 5, section 16

from 18 April 2013

In its session on 18 April 2013, the Federal Joint Committee resolved to initiate benefit assessments of the pharmaceuticals listed in the chart following. Active ingredients on the existing market whose pharmaceuticals correspond to active ingredients evaluated as significant for healthcare for at least one therapeutic indication have been organized with those active ingredients into existing market groups. The timing for the dossier requirement in accordance with the Rules of Procedure, section 16, chapter 5 for the benefit assessment of active ingredients included in the existing market groups is organized in phases.

Existing market group Number	Weighted overall rank (80% revenue to 20% prescriptions)	Active ingredient	Therapeutic indications	a) Notification date of resolution in accordance with VerfO, section 16, chapter 5 b) Deadline for dossier submission
1	1	Tapentadol	Intense chronic pain	a) 15 July 2013 b) 15 Oct. 2013
2	2	Denosumab	Osteoporosis	a) 15 July 2013 b) 15 Oct. 2013
			Bone metastases	
		Ranelic acid, distrontium salt*	Osteoporosis	
		Recombinant parathyroid hormone*	Osteoporosis	
		Teriparatide*	Osteoporosis	

Existing market group Number	Weighted overall rank (80% revenue to 20% prescriptions)	Active ingredient	Therapeutic indications	a) Notification date of resolution in accordance with VerfO, section 16, chapter 5 b) Deadline for dossier submission
3	3	Rivaroxaban	Atrial fibrillation, stroke prophylaxis, and cardioembolic diseases	a) 1 Sept. 2013 b) 15 Dec. 2013
			Deep venous thrombosis	
		Dabigatran*	Atrial fibrillation, stroke prophylaxis, and cardioembolic diseases	
			Deep venous thrombosis	
4	4	Liraglutide	Diabetes mellitus type 2	a) 1 Oct. 2013 b) 1 Jan. 2014
		Exenatide*	Diabetes mellitus type 2	
5	5	Agomelatine	Depression	a) 1 Nov. 2013 b) 1 Feb. 2014
		Duloxetine*	Depression	
			Pain associated with diabetic polyneuropathy	
			Urge incontinence in women	
6	6	Tocilizumab	Rheumatoid arthritis	a) 1 Dec. 2013 b) 1 March 2014
		Golimumab*	Rheumatoid arthritis	
			Psoriatic arthritis	
			Ankylosing spondylitis	
		Certolizumab pegol*	Rheumatoid arthritis*	

* Active ingredients on the existing market whose pharmaceuticals correspond to active ingredients evaluated as significant for healthcare for least one therapeutic indication

The justification for this resolution will be published on the website of the Federal Joint Committee at www.g-ba.de .

Berlin, 18 April 2013

The Federal Joint Committee
in accordance with SGB V,
section 91

The Chair
Hecken