

Arepanrix

Procedural steps taken and scientific information after the authorisation

No	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
IB/0007	Administrative: correction	22/11/2010	n/a		
IA/0001	Administrative: correction	19/11/2010	n/a	Annex II	
IB/0005	B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.f.1.a.1 - Stability of FP – Reduction of the shelf life of the finished product - As packaged for sale	13/08/2010	n/a	SPC	

¹ Notifications are issued for type I variations (unless part of a group or a worksharing application). Opinions are issued for all other procedures.

² No Commission Decision is issued for type IA and type IB variations or for type II variations and annual re-assessments that do not affect the annexes.

³ SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).