

**Initial Submission** Alecensa 150 mg hard capsule

**Reg No.** 1C 54/60 (NC)

**Approval date** 3 Aug 2017

Variation submission

<b>Application number</b>	<b>Scope</b>	<b>Approval date</b>	<b>Product Information affected</b>	<b>Summary</b>
15126/61 (N)	<b>MiV-PA3</b> : Addition or replacement of the company or party responsible for batch release	17 Oct 2018		
15042/60 (N)	<b>MiV-PA6</b> : Change of in-process controls applied during the manufacture of the drug substance [including tightening and addition of new inprocess test and where European Pharmacopoeial Certificate of Suitability (CEP) is not available]	20 Feb 2018		
15026/60 (N)	<b>MaV 1</b> : Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	5 Jan 2018	PIL	