

**Initial Submission** Tagrisso (film-coated tablet 80 mg)

**Reg No.** 1C 72/60 (NC)

**Approval date** 25 Sep 2017

Variation submission

<b>Application number</b>	<b>Scope</b>	<b>Approval date</b>	<b>Product Information affected</b>	<b>Summary</b>
15050/61 (N)	<b>Mav 1</b> : Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	14 Nov 2018	PIL	
15030/61 (N)	<b>Mav 15</b> : Extension of shelf-life of the drug product <b>MiV-PA 10</b> : Change of shelf-life or retest period for drug substance	28 Sep 2018		

