

Initial Submission Tagrisso (film-coated tablet 40 mg)

Reg No. 1C 71/60 (NC)

Approval date 25 Sep 2017

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15050/61 (N)	Mav 1 : Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	14 Nov 2018	PIL	
15029/61 (N)	Mav 15 : Extension of shelf-life of the drug product MiV-PA 10 : Change of shelf-life or retest period for drug substance	28 Sep 2018		

