

Table 1 Applications for Community Marketing Authorisations pending on 1 January 2021

CHMP Procedure on exit day	End of Procedure (usually Day 210)	Day 181-209	Day 180	Day 121 – 179	Day 120	Day 80 - 119	Before Day 80
Application status	Application is the subject of a CHMP positive scientific opinion	Assessment of Responses	In Clock Stop List of outstanding issues available	Assessment of Responses	In Clock Stop Review of scientific data available and List of Questions sent to applicant.	Application in the first assessment phase	
Applicant action	Submit application to MHRA for determination in line with CHMP Scientific Opinion ¹ Or (ii) Apply through Reliance Route	(i) Submit EU application and responses to MHRA to complete assessment tailored to outstanding issues or (ii) Await CHMP positive opinion then apply through Reliance Route	(i) When available, submit responses and the EU application to MHRA for In-Flight Assessment or (ii) Await CHMP positive opinion and apply through Reliance Route			(i) Submit EU application to MHRA for independent assessment whilst CHMP assessment continues or (ii) Await CHMP positive opinion then apply through Reliance Route	
Fee payable	No fee	No fee	No fee			In accordance with published fee schedule	
MHRA timeline	(i) Determination as soon as practicable after submission and not later than Commission Decision (ii) On receipt of Commission Decision		(i) 60-day timetable (aligned to published CHM schedule) (ii) On receipt of Commission Decision			In accordance with published guidance	

¹ Except in cases where UK has recorded a divergent decision