

Process and timetable for national major or standard reclassification applications, including combinations with simple abridged procedures

The following timetable with notes and flowchart cover the procedure for national major or standard reclassification procedure, including those in combination with simple abridged procedures.

It includes the following possible work flows, none, some or all of which may apply:

- Presentation to an Ad Hoc Stakeholder Group,
- Seeking advice from CHM and, if needed a CHM EAG,
- Public Consultation

For optimal functioning of the process the following points must be noted:

- a) The applicant must submit their application on the date provided in advance to the MHRA and confirm by email to the Self Medication Unit when the application had been submitted
- b) The MHRA would make contact with the applicant at the agreed milestones even if there was nothing specific to report
- c) The MHRA would appoint a named “lead assessor” to be the contact point for the applicant during the assessment process
- d) The MHRA could not guarantee to adhere to the timetable if the applicant did not respond within the stated deadline.
- e) The timetable does not apply to European procedures.
- f) The timetable does not preclude the possibility for the applicant to shorten their clock stop periods by responding more quickly to RFIs and for MHRA to shorten their assessment periods where possible
- g) The timetable would vary if any of these steps are not needed or if CHM slots are not available.

Timetable 1: for Major Applications

Day	Clock status	MHRA Actions	Notes for MAH
Pre-validation	OFF	Application received by MHRA and awaits validation	Applicant must be in contact with the MHRA Self-medication Unit about plans/timings for submission. MAH to email reclassification@mhra.gsi.gov.uk entitled “Submission notification: [product name, PL number]” the day the application is submitted providing details of the application and a link to the portal or the CESP details.
		Initial planning meeting to take place before validation. Assessors to be allocated.	

0	ON	Validation	
		Assessment starts – high level assessment review takes place	
20 MHRA/MAH Contact Step		Assessors review meeting. Provisional timetable (estimated stakeholder meeting, Expert Advisory Group(s), Commission on Human Medicines dates) provided to MAH.	
	OFF	If any data or documents are missing an Ad hoc letter will be sent to MAH (clock OFF) or an email will be sent to MAH to confirm no ad hoc letter required (clock remains ON)	MAH has 30 days to respond to ad hoc letter. NB: There will be no extension to the permitted time of response. If the applicant cannot respond in this timeframe the MHRA will assess the submission provided. Alternatively, the applicant has the opportunity to withdraw.
21	ON	MAH response received	
		Assessment period of reclassification dossier (and simple abridged dossier, if applicable)	
70 MHRA/MAH Contact Step	OFF	1st RFI sent consolidating all the points raised by all assessors allocated to the case includes a consolidated response for pharmaceutical and medical points	MAH has 60 days to respond in full. No partial or incomplete response will be accepted. Extensions to the response time will be considered on a case by case basis. Extensions will not be granted for extensive periods. If it is likely to take a considerable time to respond to the RFI, the likelihood is that the application is inadequate and consideration should be given to withdrawing.
71	ON	MAH response received	
		Assessment period (30 days)	
100 MHRA/MAH Contact Step	OFF	2nd RFI sent. This should not contain any new issues, except in exceptional circumstances. It should only address issues that have not been successfully dealt with in the response to the first RFI or that are consequential to the first RFI. No more than 2 RFIs will be sent.	MAH has 60 days to respond. No partial or incomplete response will be accepted. Extensions to the response time will be considered on a case by case basis. Extensions will not be granted for extensive periods. If it is likely to take a considerable time to respond to the RFI, the likelihood is that the application is inadequate and consideration should be given to withdrawing. This will be the final opportunity to complete the dossier. If on receipt of the RFI the applicant feels that it will not be possible to resolve the issues raised in the second RFI, consideration could be given to withdrawing at this stage.
101	ON	MAH response received	
MHRA/MAH		Assessment period (30 days)	

Contact Step		If issues have not all been addressed adequately in the second RFI response the assessor(s) will make contact with the applicant and explain this. The unresolved issues will be highlighted in the assessment report that will be presented to CHM and or/its EAGs. At this stage the applicant will have the option to withdraw and start a new procedure or ask for the application to be considered by the CHM as it is.	
130 MHRA/MAH Contact Step	OFF (If next step is a stakeholder meeting)	Assessment completed. Major or Standard application confirmed. . At this point in the procedure, MHRA will advise whether the application is major, or standard and, if standard, whether there will be a public consultation period, and confirm timings. The timetable will be updated and provided to MAH (See separate table for procedure for standard applications)	
		Stakeholder meeting takes place Clock off period for the stakeholder meeting will usually be for a maximum of 60 days but may be extended if necessary.	
131	ON	EAG and/or CHM meeting	
140 MHRA/MAH Contact Step	OFF	CHM final advice sent to MAH if approvable. (If CHM advice is that the application is not approvable a separate procedure will be triggered)	CHM advice may include conditions under which the application is approvable, requiring change to be made to the SPC or patient information. This will be outlined in the final advice letter. MAH has 60 days to respond No partial or incomplete response will be accepted. Extensions to the response time will be considered on a case by case basis. Extensions will not be granted for extensive periods. If it is likely to take a considerable time to respond to the RFI, the likelihood is that the application is inadequate and consideration should be given to withdrawing. If the applicant feels that it will not be possible to resolve the issues raised in the CHM final advice, consideration could be given to withdrawing at this stage
141	ON	MAH response received	
		Assessment period (30 days)	

		If the response is incomplete or inadequate a decision on whether to refuse or withdraw will be made on a case by case basis in discussion with the MAH.	
170	OFF	Public consultation period (21 days)	
171	ON	Assess responses to public consultation (30 days)	
200 MHRA/MAH Contact Step	OFF	Public consultation assessment completed. Further RFI sent to MAH if issues are raised in the consultation that require changes to be made or issues to be addressed by the MAH.	MAH has 60 days to respond No partial or incomplete response will be accepted. Extensions to the response time will be considered on a case by case basis. Extensions will not be granted for extensive periods. If it is likely to take a considerable time to respond to the RFI, the likelihood is that the application is inadequate and consideration should be given to withdrawing. If on receipt of the RFI the applicant feels that it will not be possible to resolve the issues raised consideration could be given to withdrawing at this stage
201	ON	Response received Assessment period (10 days)	
210 MHRA/MAH Contact Step		Approval/refusal	
Within 60 days of approval/refusal		Public assessment report and response to public consultation will be published The PAR will be sent to the MAH for comment.	The MAH will have 1 week to respond to the request for comment.

Timetable 2: for Major Applications that have been reclassified as Standard

See table 1 for day 0 – day 129			
Day	Clock status	MHRA Actions	Notes for MAH
130 MHRA/MAH Contact Step	OFF (If next step is public consultation)	Assessment completed. Standard application confirmed. Confirmation of standard, and procedure and timetable update provided to MAH.	The MAH will be advised if the applicaiton will go to public consultation or straight to approval/refusal
131	ON	Prepare for public consultation	
160	OFF	Public consultation period (21 days)	
161	ON	Assess responses to public consultation (30 days)	
190 MHRA/MAH Contact Step	OFF	Public consultation assessment completed. Further RFI sent to MAH if issues are raised in the consultation that require changes to be made or issues to be addressed by the MAH.	MAH has 60 days to respond No partial or incomplete response will be accepted. Extensions to the response time will be considered on a case by case basis. Extensions will not be granted for extensive periods. If it is likely to take a considerable time to respond to the RFI, the likelihood is that the application is inadequate and consideration should be given to withdrawing. If on receipt of the RFI the applicant feels that it will not be possible to resolve the issues raised consideration could be given to withdrawing at this stage
191	ON	Response received	
		Assessment period (10 days)	
200 MHRA/MAH Contact Step		Approval/refusal	
Within 60 days of approval/refusal		Public assessment report and response to public consultation will be published	The MAH will have 1 week to respond to the request for comment.

Flowchart for national major or standard reclassification applications

