

Guidance on handling of Decentralised and Mutual Recognition Procedures in a no-deal Brexit

This guidance describes the approach the MHRA intends to take for products approved or pending in decentralised procedure (DCP) or mutual recognition procedures (MRP) if there is no-deal Brexit.

Published 18 March 2019

Last updated 8 August 2019 — [see all updates](#)

From:

[Medicines and Healthcare products Regulatory Agency](#)

Contents

1. [Products approved in DCP/MRP on or before exit day with the UK as RMS or CMS](#)
2. [Applications pending in DCP/MRP with the UK as RMS or CMS where the procedure has been positively finalised on or before exit day but the national \(UK\) licence has not yet been granted.](#)
3. [Applications pending in DCP with the UK as RMS or CMS, where the procedure has ended with a negative decision on or before exit day](#)
4. [Applications pending in DCP with the UK as RMS or CMS where the procedure has not been finalised on or before exit day](#)
5. [For a procedure where the UK is the RMS and leading on the assessment of the application](#)
6. [For a procedure where the UK is a CMS and not leading on the assessment of the application](#)
7. [Applications pending in MRP with the UK as CMS where the procedure has not been finalised on exit day](#)
8. [Applications submitted in DCP or MRP with the UK as RMS or CMS where the procedure has not been started on exit day.](#)

At the end of a decentralised procedure with a positive agreement, a national Marketing Authorisation (MA) is issued in all Member States involved. For mutual recognition procedures where the UK is the Reference Member State (RMS), a national (UK) MA has already been granted in the UK before the start of the MRP. For an MRP where the

UK is a concerned Member State (CMS), a national (UK) MA is issued if a positive outcome is reached.

Products approved in DCP/MRP on or before exit day with the UK as RMS or CMS

All medicinal products approved in the UK on or before the day the UK leaves the EU via a DCP or MRP have been issued with a national (UK) MA. These MAs will be unaffected and remain valid in the UK. Any subsequent variation to the MA should be submitted as a national variation using current procedures (see separate guidance on variations).

Applications pending in DCP/MRP with the UK as RMS or CMS where the procedure has been positively finalised on or before exit day but the national (UK) licence has not yet been granted.

All ongoing DCP/MRP procedures that are positively finalised on or before the day the UK leaves the EU, but are in the 30-day national phase of the procedure, will continue to be processed and issued with a national (UK) MA in conformity with the approved assessment report, the summary of product characteristics and the labelling and package leaflet. Any subsequent variation to the MA should be submitted as a national variation.

Applications pending in DCP with the UK as RMS or CMS, where the procedure has ended with a negative decision on or before exit day

All ongoing DCP procedures which are negatively concluded on or before the day the UK leaves the EU will be refused and no national (UK) MA will be issued.

Applications pending in DCP with the UK as RMS or CMS where the procedure has not been finalised on or before exit day

For all ongoing DCPs with the UK as an RMS or CMS in progress on or before the day the UK leaves the EU, and which have not reached the decision phase, the MHRA will complete the assessment as a national procedure. The MHRA will take into account any assessment that has already been reported by the RMS or CMSs including any points raised.

The MHRA will determine the application as soon as reasonably practicable and will take all reasonable steps to ensure that it makes a decision to grant or refuse a UK MA in the time period that would have applied to that application on the date on which the application was submitted in DCP. However, the need for a full assessment may mean that this is not possible.

No additional or different fee will be charged for an application already submitted and ongoing in DCP that is completed as a national procedure.

Action to take if the applicant does not wish to continue with the DCP as a national application

The applicant should notify the licensing authority in writing that they no longer want the application to proceed. A partial fee refund may be applicable in line with the current MHRA fees regulations.

For a procedure where the UK is the RMS and leading on the assessment of the application

The following will apply depending on the stage of the procedure on exit date:

- For procedures which have started, but before Day 70, the MHRA will follow the agreed DCP timetable and the assessment report will be available by Day 70. The assessment of the response to the Day 70 questions will follow the national procedure, and MHRA will make a decision to grant or refuse a UK MA before the end of 210 days
- For procedures after circulation of the Day 70 assessment report but before Day 106 of the procedure, the assessment of the response to the Day 70 questions, and any CMS comments that may have been received, will follow the national procedure and the MHRA will make a decision to grant or refuse a UK MA before the end of 210 days
- For procedures after Day 105, the MHRA will follow the agreed DCP timetable and will make a decision to grant or refuse a UK MA before the end of 210 days

For a procedure where the UK is a CMS and not leading on the assessment of the application

The following will apply depending on the stage of the procedure on exit date.

- For procedures before circulation of the RMS Day 70 assessment report, it will be necessary for the MHRA to do a full assessment of the application. A revised timetable will be issued, and the application will follow the national procedure and timelines. The MHRA will endeavour to complete the procedure within the period of 210 days from the date of submission of the application in the DCP, but the need for the full assessment may mean that this is not possible.
- For procedures after circulation of the RMS Day 70 assessment report but before Day 105 of the procedure, the MHRA will consider the RMS assessment that has already taken place. Any additional questions that MHRA needs to be addressed will be sent to the applicant within the timetable agreed for the DCP. The assessment of the response will follow the national procedure, and the MHRA will make a decision to grant or refuse a UK MA before the end of 210 days.
- For procedures after Day 105 and before circulation of the RMS Day 120 assessment report, it will be necessary for the MHRA to do a full assessment of the response to the RMS Day 70 questions and any additional questions raised by the MHRA (and other CMS). The assessment of the response will follow the national procedure, and the MHRA will make a decision to grant or refuse a UK MA before the end of 210 days.
- For procedures after circulation of the RMS Day 120 assessment report, the MHRA will consider the RMS assessment that has already taken place and any additional questions that MHRA needs to be addressed will be sent to the applicant within the timetable agreed for the DCP. The assessment of the response will follow the national procedure, and the MHRA will make a decision to grant or refuse a UK MA before the end of 210 days.

Applications pending in MRP with the UK as CMS where the procedure has not been finalised on exit day

For all pending MRPs with the UK as CMS in progress immediately before the day the UK leaves the EU, and which have not reached the

decision phase, the MHRA will complete the assessment as a national procedure. The MHRA will take into account any assessment that has already been reported by the RMS or CMS including any points raised. The MHRA will determine the application as soon as reasonably practicable and will take all reasonable steps to ensure that it makes a decision to grant or refuse a UK MA in the time period that would have applied to that application on the date on which the application was submitted.

No additional or different fee will be charged for an application already submitted and ongoing in MRP that is completed as a national procedure.

Action to take if the applicant does not wish to continue with the MRP as a national application

The applicant should notify the licensing authority in writing that they no longer want the application to proceed. A partial fee refund may be applicable in line with the [current MHRA fees regulations](#).

The following will apply depending on the stage of the procedure on exit day.

- For procedures before Day 30, the MHRA will consider the RMS assessment report circulated and any additional questions that MHRA needs to be addressed will be sent to the applicant by Day 30. The assessment of the response will follow the national procedure and the MHRA will make a decision to grant or refuse a UK MA before the end of 90 days.
- For procedures after Day 30, it will be necessary for the MHRA to do a full assessment of the response to any additional questions raised by the MHRA. The assessment of the response will follow the national procedure and the MHRA will make a decision to grant or refuse a UK MA before the end of 90 days.

Applications submitted in DCP or MRP with the UK as RMS or CMS where the procedure has not been started on exit day.

For DCP or MRP procedures that have been submitted to the UK but not started before exit day these will continue as national procedures. Once the application is considered valid, the procedure will start. The MHRA will endeavour to complete the procedure within the period of 210 days from the date of submission of a valid application in the MRP/DCP procedure, but the need for the full assessment may mean that this is not possible.

No additional or different fee will be charged for an application already submitted before exit day and that is to be processed as a national procedure.

Action to take if the applicant does not wish to continue with the procedure as a national application

The applicant should notify the licensing authority in writing that they no longer want the application to proceed. A partial fee refund may be applicable in line with the [current MHRA fees regulations](#).

Contact

For specific queries please contact RIS.NA@mhra.gov.uk.