Guidance on the handling of applications for Centrally Authorised Products (CAPs) pending on exit day

This guidance sets out how the MHRA will handle centralised applications that are still pending on exit day, in the event of a no deal Brexit.

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Leaving the EU with a deal remains the Government's top priority. This has not changed. However, a responsible government must plan for every eventuality, including a no deal Brexit.

This guidance will apply from exit day in line with the Human Medicines Regulations (Amendment etc.) (EU Exit) Regulations 2019.
The Medicines and Healthcare products Regulatory Agency (MHRA) has issued guidance on grandfathering of CAPs, which covers the issuing of UK marketing authorisations for products subject to Community Marketing Authorisations already issued by the European Commission following an application through the European Medicines Authority's (EMA) centralised procedure.

This guidance sets out how the MHRA will handle centralised applications that are still pending on exit day, in the event of a no deal Brexit.

The approach of the MHRA is to take into account any assessment that has already been reported on before exit day. The handling will be determined by the stage of the procedure on the application was at on that day, as detailed in the table below.

As the MHRA does not hold supporting data for applications made to the EMA. Applicants will need to submit an application and supporting dossier to the MHRA.

Procedures that have been completed with a positive opinion from the Commission for Medicinal Products for Human Use (CHMP) and are waiting to receive a Commission Decision will be determined as soon as practicable by MHRA. This will be done in line with the CHMP opinion, unless the UK recorded a divergent decision.

In other cases, MHRA will need to undertake an assessment.

If the procedure has reached day 181 of the assessment timetable

In this circumstance, the MHRA will complete the assessment tailored to the outstanding issues to reach an assessment decision and determine the application as soon as practicable.

If the procedure has reached day 120 of the assessment timetable

If the procedure has reached day 120 day (the first clock stop) but has not reached day 181 MHRA is introducing two routes to completion.

Route 1 (In flight assessment)

The applicant submits the same application to MHRA as has been submitted to the EMA. They also include responses to the list of

questions raised by CHMP to enable the MHRA independently to complete its assessment of the application while the EMA centralised procedure is on-going.

In this case the application will follow a schedule (including a set start date) that will enable MHRA to seek advice from the Commission on Human Medicines (CHM) with a view to reaching an assessment decision no later than 60 days following the start date. Start dates will be aligned with published CHM dates to facilitate the 60-day process.

Route 2 Targeted assessment

If the product is eligible, the applicant makes a separate application using the published Targeted Assessment process for the MHRA to reach its assessment decision after the CHMP has issued its opinion, usually on day 210. Applications for new active substances and biosimilars are eligible to use the Targeted Assessment route.

Procedures still in the first phase of assessment

If a procedure is in the first phase of assessment (before Day 120) it will need an independent assessment by the MHRA after a submission has been made through one of the published routes for assessment.

Procedures with a positive CHMP opinion where UK has recorded a divergent opinion

In these cases, if the applicant intends to pursue the application in the UK a separate application will need to be submitted for independent assessment according to published assessment routes.

After independent assessment, if the decision is not to grant, the usual national appeal processes are available to the applicant and will be explained in the MHRA decision letter.

In all cases, the MHRA will contact applicants individually to address any questions, establish how they wish to proceed and confirm which documentation to submit and when to submit it.

The handling of applications at all stages of the EU procedure is summarised in this table. (PDF, 72.1KB, 1 page)

To avoid delay to the completion of these applications and to take account of timetable changes for any applications following an accelerated timetable, an application manager will be assigned to each one.