How renewals of Marketing Authorisations will be handled in a no-deal Brexit

This guidance describes the approach the MHRA will take to the processing of applications to renew a Marketing Authorisation (MA).

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General principles

All Marketing Authorisations (MAs) in the UK will become purely national. Any pending and new applications to renew a MA will therefore only be processed to conclusion after exit as national renewals and the relevant national procedures will be followed.

For the purpose of renewals, MAs for centrally authorised products (CAPs) converted into national MAs are treated as if they were granted on the date on which the corresponding EU MA was granted. The converted EU MA will therefore have the same renewal date in the UK as in the EU. Transitional provisions make special arrangements to handle these renewals and these are explained in separate guidance on CAPs conversion in the event of a no-deal scenario.

In all cases where an application for renewal is made, the MA will remain in force until the Medicines and Healthcare products Regulatory Agency

(MHRA) notifies the marketing authorisation holder (MAH) of its decision on the renewal application.

Renewal applications submitted before exit day in relation to UK MAs granted through the mutual recognition (MRP) or decentralised (DCP) procedures.

For renewal applications submitted before exit day which relate to MAsgranted under the MRP or DCP procedures but where no decision was made before exit day, the MHRA will conduct the assessment of the application making every effort to ensure that relevant procedural time periods are observed. The assessment will take into account the point in the overall procedure that the application has reached on exit day.

Consequently, any information previously obtained, and any assessment undertaken before exit date will be taken into consideration as part of the UK assessment process.

Where a final decision has already been taken by the lead authority but has not been processed in the UK before exit day, the MHRA will take the necessary steps to implement the agreed outcome of the procedure.

Renewal applications submitted following exit day

Renewal applications should be submitted to the MHRA, as usual, 9 months prior to expiry. The application should consist of the same documents currently required in the EU for both CAPs ([EU guidance on renewal and annual re-assessment) and products authorised via the MRP or DCPprocedures (Best practice guide on MRP/DCP renewals).

The UK will continue to follow the reduced submission requirements for renewal applications of MAs for products authorised under Article 10.1 as outlined in the current CMDh best practice guidance for processing renewals in MR/DCP (Best practice guide on MRP/DCP renewals).

Renewals for conditional Marketing Authorisations

Applications to renew conditional MAs should be submitted to the MHRA, as usual, 6 months before the expiry date of the conditional MA. The MHRA will consider the application in accordance with new regulation 66B of the Human Medicines Regulations 2012.

The same applies to converted EU MAs which were granted as conditional MAs. Transitional arrangements for these are set out in separate guidance on CAPS conversion in the event of a no-deal Brexit.

Fees

A fee of £9,682 will apply to the first renewal of a MA for a product which contained a new active ingredient at the time of authorisation, with a reduced fee of £747 for related applications made at the same time. There will be no fee for subsequent MA renewal applications.

There is no fee for a renewal of a conditional MA.

This guidance will apply from exit day in line with the Human Medicines Regulations (Amendment etc.) (EU Exit) Regulations 2019.