Handling of Active Substance Master Files and Certificates of Suitability in the event of no-deal Brexit

The MHRA will continue to accept Active Substance Master Files (ASMFs) and Certificates of Suitability (CEPs) in a no-deal Brexit.

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Following the exit of the UK from the EU, the MHRA will continue to accept an Active Substance Master File and/or a Certificate of Suitability in both new national initial Marketing Authorisation Applications (MAA) and in Marketing Authorisation Variation (MAV) applications.

Active Substance Master File (ASMF)

An ASMF should be prepared in accordance with the Committee for Medicinal Products for Human Use (CHMP) guideline on active substance master file procedure (CHMP/QWP/227/02 Rev 4).

Templates (letter of access; submission letter and administrative details form) included in the annexes to that guideline should continue to be used.

You should submit the Applicant's Part (AP) of the ASMF as part of the MAdossier, together with a letter of access issued by the ASMF holder.

When an ASMF procedure is to be used which relates to an ASMF that has not previously been submitted to the MHRA, the ASMF holder should submit a copy of the AP and Restricted Part (RP) to the MHRA. This should be accompanied by:

- a completed submission letter and administrative details form
- any relevant letter of access
- the Quality Overall Summary for the AP and for the RP
- a curriculum vitae for the Expert

The complete ASMF only needs to be submitted once to register the ASMFwith the MHRA. The relevant documentation should be timed to arrive at approximately the same time as the MAA or MAV, so not more than one month before and not after the intended MAA/MAV submission date.

Changes to an ASMF should be handled in accordance with the CHMP guideline (CHMP/QWP/227/02 Rev 4). The ASMF holder needs to fulfil their responsibilities with respect to notifying each Applicant/MA holder and the MHRA, that changes are being proposed to the ASMF.

Submission of a new ASMF and any update to an ASMF should be made by the ASMF holder using the MHRA

Submissions Portal.

The UK will no longer participate in ASMF worksharing procedures with EU Member States or have access to the EU Communication and Tracking System (CTS) assessment report repository. Any reference in the above guideline to the CTS ASMF assessment repository or to EU/ASMF/XXXXX reference numbers will not be applicable to UK national applications after Brexit.

Where an assessment of a new ASMF or an update to an ASMF has been conducted by an EU Member State before the UK leaves the EU, such an assessment may be taken into consideration in subsequent MAA or MAVapplications that are under assessment after the UK exited the EU.

Certificates of Suitability (CEPs)

CEPs are not affected by the UK leaving the EU as they are issued by the European Directorate for the Quality of Medicines and Healthcare (EDQM). This is a Directorate of the Council of Europe and a body that is independent of the EU. On leaving the EU, the UK will remain a member of the Council of Europe and a signatory to the Convention on the Elaboration of a European Pharmacopoeia.

There will be no change to the procedures relating to the use of a CEP to support an MAA or MAV.

Action for Marketing authorisation applicants

- You should include appropriate information in the MAA or MAV application form.
- You should include a copy of the current version of the relevant CEP in Modules 1 and 3.

The second of these actions relates to applications where there is

- a CEP for a chemical substance that is an active substance or excipient; *a CEP for a herbal drug or herbal drug preparation
- a CEP for materials of animal or human origin that have been subject to an evaluation of the risk related to transmissible spongiform encephalopathies (TSE).

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