Guidance on Marketing Authorisation Applications (MAA) submitted to the UK that have been referred under Article 29 in a no-deal Brexit

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Article 29 referrals are triggered when a consensus cannot be reached between Member States on the outcome for a Marketing Authorisation Application (MAA) which has been evaluated in a mutual-recognition procedure (MRP) or decentralised procedure (DCP), on the grounds of a potential serious risk(s) to public health (PSRPH).

How we will treat MAAs at different stages of the process on exit day

For MAAs that have been referred under Article 29, where either a positive or negative opinion has been taken at the Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) or the Committee for Medicinal Products for Human Use (CHMP) but no decision issued by the time the UK leaves the EU, the MHRA will either grant or refuse the application with regard to the relevant committee decision.

For all pending MAAs submitted in the UK, either as Reference Member State (RMS) or Concerned Member State (CMS), that have been referred under Article 29 before the UK leaves the EU but no opinion has been reached by CMDh or CHMP, the MHRA will complete the assessment as a national procedure.

The MHRA assessment will take into account the existing RMS and CMSassessments with particular focus on the identified PSRPH. If the MHRA are minded to refuse an application based on a PSRPH, consultation with the Commission on Human Medicines (CHM) and other relevant expert advisory committees will take place.

On completion of the MHRA assessment, and consultation with expert advisory committees as required, the MHRA will issue its decision on approval or refusal of the Marketing Authorisation.

For applications where the MHRA had a positive opinion at Day 210 of a DCPor Day 90 of an MRP, and considered that the risk/benefit of the product is positive in the subsequent referral procedure, a Marketing Authorisation will be granted following receipt of UK product information.

No additional or different fee will be charged for applications that are completed as a national procedure having previously been referred under Article 29. If a Marketing Authorisation applicant does not wish the MHRA to continue with the DCP/MRP as a national application, the applicant should submit a withdrawal letter to the UK.

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