Conditional Marketing Authorisations, exceptional circumstances Marketing Authorisations and national scientific advice if there is a no-deal Brexit

Guidance on Conditional Marketing Authorisations, exceptional circumstances Marketing Authorisations and national scientific advice if there is a no-deal Brexit.

Published 28 March 2019

From:

Medicines and Healthcare products Regulatory Agency

Contents

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

Guidance for UK Conditional Marketing Authorisation Applications

The MHRA will introduce a national Conditional Marketing Authorisation (CMA) scheme for new medicinal products if there is a no-deal Brexit.

The scheme will have the same eligibility criteria as the EU scheme and is intended for medicinal products that fulfill an unmet medical need. Examples would be for serious and life-threatening diseases where no

satisfactory treatment methods are available or where the product offers a major therapeutic advantage.

The MHRA may grant a CMA where comprehensive clinical data is not yet complete, but it is judged that such data will become available soon.

Actions for those submitting an Marketing Authorisation Application (MAA)

The MAA must still contain adequate evidence of safety and efficacy to enable the MHRA to conclude that the risk-benefit balance of the medicinal product is positive.

Applicants wishing to submit an application for a conditional marketing authorisation to the MHRA should state their justification for a CMA and indicate clearly what clinical studies are underway and when comprehensive clinical data will become available.

Eligibility for a CMA will be determined by the MHRA at the time of MAAassessment. There is no specific application route for a CMA; applicants should submit their MAA dossier as for a full Marketing Authorisation.

At the completion of the assessment of a MAA dossier, the MHRA will determine whether to approve the application and grant a conditional MA or whether the risk benefit ratio is negative and reject the application.

The designation of a product as being eligible for a CMA by the EMA or another jurisdiction may be taken into account by the MHRA, but the final decision on eligibility of the product for the UK scheme will rest with MHRA.

CMAs will be valid for one year and will be renewable annually.

Guidance for UK Marketing Authorisations under exceptional circumstances

The MHRA's existing scheme for applications under exceptional circumstances will continue to be available for medicines where a comprehensive data package cannot be provided, because the condition to be treated is rare or because collection of full information is not possible or is unethical.

This is covered under Human Medicines Regulations 2012, Regulation 60, 'Conditions of UK marketing authorisation: exceptional circumstances'.

The scheme has the same eligibility criteria as the EU scheme. Exceptional circumstances approvals will only be granted where the applicant can demonstrate that it is not possible to provide comprehensive data on the efficacy and safety under normal conditions of use.

The designation of a product as being eligible for an exceptional circumstances scheme by the EMA or another jurisdiction may be taken into account by the MHRA, but the final decision on eligibility of the product for the UK scheme will rest with MHRA.

Actions for those applying for UK marketing authorisations under exceptional circumstances

The MHRA is likely to impose specific obligations on the holder of a Marketing Authorisation that is approved under exceptional circumstances. These will be aimed at the provision of information on the safe and effective use of the product.

It is therefore recommended that applicants discuss their submissions with the MHRA prior to submitting their Marketing Authorisation Application.

Guidance for UK scientific advice post exit day

The MHRA will continue to offer its national scientific advice service after the UK leaves the EU if there is a no-deal Brexit. This service is available for developers of medicinal products and can be requested at any stage of the product's development. The procedure for requesting scientific advice is described in further detail.

If there is a no-deal Brexit, there will be one change to the fees payable for scientific advice. Applications for scientific advice submitted by UK-based Small and Medium-sized Enterprises (SME) will be exempt from the fee. Applicants will be required to submit evidence of their SME status together with the scientific advice form.

Requests for advice that is purely regulatory in nature will remain free of charge.

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