Part of
UK and EU transition: new rules for 2021 (https://www.gov.uk/transition)

Guidance

Guidance note on new assessment routes from 1 January 2021

New routes for assessment including an accelerated procedure and rolling review.

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Medicines and Healthcare products Regulatory Agency (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency)

New rules for January 2021

The UK has left the EU, and the transition period after Brexit comes to an end this year.

This page tells you what you'll need to do from 1 January 2021. It will be updated if anything changes.

For current information, read: Apply for a licence to market a medicine in the UK (https://www.gov.uk/guidance/apply-for-a-licence-to-market-a-medicine-in-the-uk)

You can also read about the transition period (https://www.gov.uk/transition).

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From 1 January 2021 the MHRA is introducing changes to national licensing procedures, including procedures to prioritise access to new medicines that will benefit patients, an accelerated assessment procedure and new routes of evaluation for novel products and biotechnological products.

Pre-submission scientific advice meetings with the MHRA assessment teams (https://www.gov.uk/guidance/medicines-get-scientific-advice-from-mhra) at suitable times during the development cycle are encouraged. At the meeting the company may present their intentions, a short summary of the dossier and raise any special issues such as requests for consideration for conditional marketing authorisation (CMA) or marketing authorisation (MA) under exceptional circumstances. Pre-submission meetings offer opportunity to enhance joined up work with the HTA evaluation process.

The services of the MHRA Innovation Office are also available to provide access to world-class expertise within the MHRA regulatory centre, as well as from the Clinical Practice Research Datalink (CPRD) and the National Institute of Biological Standards and Control (NIBSC).

The MHRA Innovation Office (https://www.gov.uk/government/groups/mhra-innovation-office) is open to all innovation queries - particularly those that challenge the current regulatory framework.

Prioritising Access to New Medicines

The MHRA is working with partner organisations in the UK to develop approaches to reduce the time to patient access for new medicines and technologies that will benefit patients. The key features of the approach will include a new medicine designation that links to the development of a roadmap to patient access in the UK healthcare system.

The roadmap will provide a clear pathway for product development, offering a toolkit of support options and providing a platform for sustained multi-stakeholder interactions. The toolkit is intended to drive efficiencies in the development programme by supporting data generation and advising on evidence requirements.

An integrated pathway will pull together expertise from across the MHRA and partners in the wider healthcare system such as NICE, with multiple entry points available to developers. Further detailed information will be published by December.

Accelerated Assessment Procedure

From 1 January 2021, MHRA will introduce an accelerated procedure and will reach its opinion on approvability of marketing authorisation applications within 150 days of submission of a valid application.

This section provides guidance on the procedural aspects for the accelerated assessment process. National application fees apply.

Eligibility for Accelerated Assessment

The Accelerated Assessment option is available for good quality new marketing authorisation applications for both new and existing active substances and submitted directly to UK.

Eligibility will also include those applications seeking an orphan MA approval in GB and those submitted for conditional and full marketing authorisations as well as those submitted for approval under exceptional circumstances.

Conditional marketing authorisation applications and applications submitted under exceptional circumstances will be evaluated in accordance with UK legislation and MHRA will initially adopt the relevant technical guidance published by EMA.

How to apply for Accelerated Assessment

Applicants interested in seeking Accelerated Assessment should contact the MHRA in advance of the intended date of submission. The letter requesting Accelerated Assessment should include the intended date of submission of the dossier. Insert contact point

The accompanying cover letter should detail the intention to seek orphan status or an MA under exceptional circumstances, as applicable.

The MHRA will operate a ‘fixed submission date’ system to facilitate consultation with the Commission on Human Medicines (CHM) at its scheduled meetings. MHRA will publish a programme of dates to facilitate planning for and agreeing the submission date and coordinating with appropriate meeting dates of CHM.

Validation of applications for Accelerated Assessment

Applications should be submitted through the MHRA portal. See guidance on how to make submissions to MHRA through the portal (https://www.gov.uk/guidance/registering-to-make-submissions-to-the-mhra-from-1-january-2021).

A valid application/dossier for Accelerated Assessment should include common technical modules (CTD modules 2-5), a UK specific CTD module 1, and an appropriate Risk Management Plan. Appropriate justification and compliance with GB paediatric requirements and investigation plans should be included.

Compliance with the Paediatric Investigation Plans (PIPs) will be performed as part of the validation. To prevent delays at the time of validation, the applicants are encouraged when possible to request a compliance check by the MHRA at least one month prior to the planned submission of a regulatory application.

Applications that refer to an Active Substance Master File (ASMF) should ensure that the file has already been submitted to MHRA or included in the submission. See guidance on how to handle ASMFs (https://www.gov.uk/guidance/handling-of-active-substance-master-files-and-certificates-of-suitability-from-1-january-2021).

Accelerated assessment process and expert advice

The multidisciplinary assessment teams in the Licensing Division of MHRA will carry out the assessment of the application collaborating with Vigilance and Risk Management of Medicines assessors for evaluation of the Risk Management Plan. Consultation with the Devices Division will be necessary if a companion diagnostic device is required for safe and effective use of the medicinal product.

When necessary, the assessment process includes consultation with the CHM. The MHRA may additionally wish to seek advice/input from therapy area expert groups during the assessment process.

The assessment process will run in two phases totalling 150 days with an intervening clock-off period between phase I and phase II. Assessment phase I including CHM consultation will be completed 80 days after clock start. Any questions arising from initial assessment will be raised with the applicant and should be addressed in the clock off period of up to 90 days. Phase II assessment will begin on receipt of the applicant's responses. Assessment in phase I will also address eligibility for grant of orphan status or a conditional MA.

Based on the assessment, the MHRA will provide an opinion on approvability of the product by day 150, and if positive, will grant the MA.

Publication

Conclusion of the accelerated assessment will lead to publication of a Public Assessment Report for the product.

Guidance on the Rolling Review route

The Rolling Review is a new route for marketing authorisation applications, intended to enhance development of novel medicines. It does this by offering on-going regulatory input and feedback enabling the applicants to 'get it right first time' and ensuring that applications can be approved as efficiently as possible. Fees applicable will be published in due course.

Eligibility

Applications for any new active substances including biological products that wish to obtain a marketing authorisation in GB based on submission of a 'full dossier' to MHRA are eligible for a rolling review. Similar biological applications (biosimilar products) are also eligible for rolling review.

Process and sequence

The process is a phased, modular, iterative approach to evaluation of marketing authorisation applications. The quality, non-clinical and clinical modules may be submitted separately or in combination depending on the individual circumstances as data becomes available. It is expected that each module will be near completion to avoid multiple iterations of assessment of the same module.

Each assessment phase will progress independently, and any questions raised will offer the applicant the opportunity and time for a comprehensive update of the modules prior to final submission.

The final phase will involve submission of a complete application including updated versions of the modules evaluated previously.

Compliance with GB paediatric requirements are expected to be addressed prior to the final phase. The final assessment is expected to be a single phase with the decision on approval of the marketing authorisation. The Risk Management Plans (RMP) will also be part of the final evaluation.

Enhanced regulatory interaction and advice will be available during the rolling review process supporting the development process and reducing the risk of delay at the final stage.

Expert input

Consultation with expert advisory groups is anticipated at each stage and with CHM and therapy areas experts prior to grant of the MA. MHRA will publish further information on the details of the scheme in due course.

Recognition of a European Commission licensing decision for products approved in the community marketing authorisation procedure and recognition of marketing authorisation approval decisions taken by European Union Member States in decentralised and mutual recognition procedures.

For two years from 1 January 2021, Great Britain will adopt decisions taken by the European Commission on the approval of new marketing authorisations in the community marketing authorisation procedure .

Applications should include all information provided to EMA during the licensing procedure and should be accompanied by all iterations of the CHMP assessment report including the final CHMP opinion. A declaration of conformity of the Great Britain application with the dossier approved by the European Commission.

Marketing authorisation applications should be submitted to MHRA following receipt of the CHMP opinion and will be determined following confirmation of notification of the EC decision.

All UK national requirements apply.

The UK will also have the power to take into account marketing authorisation decisions of EU Member States when considering applications for marketing authorisations for products that have been approved in decentralised or mutual recognition procedures.

Applications should include all information submitted to the reference Member State and accompanied by all iterations of the RMS assessment report, including the RMS end of procedure notification. A declaration of conformity of the UK application with the dossier approved in the RMS should be provided.

The application should be submitted to MHRA following receipt of the RMS end of procedure notification.

All UK national requirements apply.

Applications will be reviewed for compliance with UK specific requirements.

Guidance on supply of medicines from Northern Ireland to Great Britain under Unfettered Access will be provided in due course

Fees applicable to GB marketing authorisations taking account of an EU decision will be published in due course.

Applications should be submitted through the MHRA portal. See guidance on how to make submissions to MHRA through the portal (https://www.gov.uk/guidance/registering-to-make-submissions-to-the-mhra-from-1-january-2021).

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Transition period

Find out what it means for you (https://www.gov.uk/transition)

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Collection

- MHRA post-transition period information (https://www.gov.uk/government/collections/mhra-post-transition-period-information)

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