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Guidance

Apply for a licence to market a medicine in the UK

An overview of the process including submitting or fast tracking an application, naming your medicine and paying fees.

From:
Medicines and Healthcare products Regulatory Agency (/government/organisations/medicines-and-healthcare-products-regulatory-agency)

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This information is common to all procedures. You should read the guidance for your specific pathway for any extra information or steps that might be required. The pathway that you follow will depend on your intended market and the type of application you are making.

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Application process

All UK and Great Britain (England, Scotland and Wales) national applications should be submitted through the MHRA Submissions Portal.

If you have any questions about the Submissions Portal, you should email submissions@mhra.gov.uk.

You should submit your application using the electronic Common Technical Document (eCTD) (http://esubmission.ema.europa.eu/ectd/).

Use the pre-submission checklist (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/368314/Pre-submission_checklist.pdf) (PDF, 129 KB, 7 pages) to help you with your application. You should also use our eAF and cover letter tool (https://www.gov.uk/government/publications/electronic-application-form-and-cover-letter-tool) to determine what information you need to include in your application. If you do not include the correct information your application will not be validated.

We recommend that you use a validation tool to check your submission as we will check that NeeS and eCTD submissions are technically valid using the Extedo Eurs is Yours (EiY) validation tool.

If you have any questions about submitting your application you should email ris.na@mhra.gov.uk.

PL number

If you are applying for a UK, Great Britain or Northern Ireland licence, you must get a PL number from the MHRA Portal (https://pclportal.mhra.gov.uk/) or by emailing PLNumberAllocation@mhra.gov.uk before you submit your application.

Active substance master files (ASMFs)

ASMFs holders must submit their dossier to the MHRA. It is the MA applicant's responsibility to make sure that the ASMF is submitted either before you submit your application or at the same time, as your application will not be valid without it.

Submission of a new ASMF and any update to an ASMF should be made by the ASMF holder using MHRA Submissions . If you have any questions about MHRA Submissions , you should email submissions@mhra.gov.uk.

You can read our guidance about the submission of ASMFs (https://www.gov.uk/guidance/handling-of-active-substance-master-files-and-certificates-of-suitability--2).

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Certificates of Suitability (CEPs) continue to be acceptable in support of UK and GB national authorisations..

Summary of product characteristics (SmPC)

The summary of product characteristics (SmPC) should be submitted to the MHRA in the correct format using the SPC template (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/368316/SPC_template.doc) (MS Word Document, 36 KB). If you do not use this template your submission will be rejected. These templates should not be altered in any way, other than inserting the relevant information.

Providing a name for your medicine

MHRA considers each application for a product name to ensure that the proposed name will allow the medicine to be taken safely and correctly.

You can find out more in our naming of medicines guidance (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/366645/naming_of_medicines_guidance.pdf) (PDF, 235 KB, 20 pages).

Fast track your marketing authorisation

Applications can be fast tracked if there is compelling evidence of benefit in a public health emergency or if there is a shortage of supply of an essential medicine that has been verified by the Department of Health and Social Care (DHSC).

To make a request for fast tracking your marketing authorisation you should email a letter of no more than 3 pages to RIS.NA@mhra.gov.uk.

The letter should include:

- the justification for fast tracking
- a brief description of the major clinical properties of the product
- evidence supporting the claimed benefits of the product for the proposed indication(s)

If you want to fast track your application because of a shortage of supply we recommend you discuss this with DHSC by emailing DHSCmedicinesupplyteam@dhsc.gov.uk.

There is no additional fee for fast-tracking applications.

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Fees vary depending on the type and route of application. You can find out more about the fees we charge in the guidance MHRA fees (https://www.gov.uk/government/publications/mhra-fees).

You can find out more about how to pay your fees in our guidance on making a payment to MHRA (https://www.gov.uk/guidance/make-a-payment-to-mhra).

Purchase Orders (POs)

It is your responsibility to make sure the invoices for your submissions are paid on time. If your organisation operates a PO system, please make sure that the relevant PO is provided to the MHRA before the invoice is issued.

Refusal to pay outstanding fees on the grounds that the PO is not provided on the invoice will not be accepted. The use of POs is an internal control process and cannot be used as a reason to withhold payment of legitimate invoices.

Payments

Once your application has been validated you will receive an invoice so that you can make a payment for the outstanding amount. All invoices must be settled upon receipt.

Penalty fees may be incurred for non-payment. Details of the penalties are explained in our Fees Regulations.

Non-payment may also result in suspension of any licence or authorisation, followed by legal proceedings for any unpaid amounts, as a debt due to the Crown.

Rejection

Any submission that does not meet the requirements will be rejected.

If a submission is rejected, we will email you the reasons for the rejection. You must then resend the entire submission with the errors corrected. Do not send the corrected deficiencies by email.

You will not be charged if your submission is rejected for technical reasons.

If you think your submission has been wrongly rejected, you should email ris.na@mhra.gov.uk.

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Decentralised and mutual recognition reliance procedure for marketing authorisations (/guidance/decentralised-and-mutual-recognition-reliance-procedure-for-marketing-authorisations)

Medicines: apply for a variation to your marketing authorisation (/guidance/medicines-apply-for-a-variation-to-your-marketing-authorisation)

Licensing: how to apply (/government/collections/licencing-how-to-apply)

Electronic Application Form and Cover Letter Tool (/government/publications/electronic-application-form-and-cover-letter-tool)

Naming human medicines (/government/publications/naming-human-medicines)

Collection

Licensing: how to apply (/government/collections/licencing-how-to-apply)

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Explore the topic

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