

Regulation stage

Medicinal product guide

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Medicinal product

Get in touch [with the MHRA](#) as soon as possible if your innovation is a medicinal product. You can access support from MHRA through the [NHS Innovation Service](#). You should also register new medicines with [UK Pharmascan](#). This supports the uptake of new medicines into the NHS. They will help you understand what is required from the marketing authorisation process and how to comply with the [Human Medicines Regulations 2012](#).

Marketing authorisation is the process of reviewing and assessing the supporting evidence for a medicinal product in relation to its marketing. The process is finalised by the granting of a licence to be sold. The marketing authorisation process has a number of routes to follow and takes 6 to 12 months. The MHRA provides [guidance on your application for a licence](#), which includes:

- [MHRA fee](#) and proof of payment
- [Summary of Product Characteristics \(SmPC\) and label and leaflet](#)
- [Reference Medicinal Product](#)
- [Pharmacovigilance System Summary](#)
- [Risk Management Plan](#)
- [Active Substance Master File \(ASMF\)](#)

If your application is for a new active substance, a pre-submission meeting with the MHRA 90 days before your intended submission is recommended. You can arrange this by emailing presubmission@mhra.gov.uk.

The [Innovative Licensing and Access Pathway \(ILAP\)](#) aims to accelerate the time to market, facilitating patient access to medicines. These medicines include new chemical entities, biological medicines, new indications and repurposed medicines. The ILAP works with UK-based and global developers of medicines (both commercial and non-commercial). The entry point into ILAP is the [innovation passport application](#). This is open to medicines at the pre-clinical trial stage through to the mid-development programme point.