Regulation stage

Medicinal product guide

Medicinal product

If your innovation is a medicinal product, then get in touch with the MHRA as soon as possible. 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 Regulation 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 license 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, then a pre-submission meeting with the MHRA 90 days before your intended submission is recommended. You can arrange this by emailing AcceleratedandRollingReview@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.