Your guide to innovation in the NHS

Regulation stage

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Regulation

There are regulatory requirements that must be met before an innovation can enter the UK market are dependent on the type of innovation. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for ensuring that medicines and medical devices are effective and safe.

Depending on the category of your innovation, there will be different levels of evaluation needed to get the required regulatory approval. For example, there are four different classes of medical devices ranging from low risk (Class I) to high risk (Class III).

If you would like to understand what regulations apply to digital health technologies (DHTs), and how to meet them, visit the AI and Digital Regulations Service. You can learn more about what regulations to follow and how to evaluate effectiveness. The website is aimed at both developers of AI and digital technology, or adopters who will buy or use DHTs in health and social care.

You can access support from the AI and Digital Regulations Service through the NHS Innovation Service.

Visit the AI and Digital Regulations Service

Medical devices

This guidance is specific to the provisions in Great Britain (England, Wales and Scotland). For information on how to comply with the legal requirements in Northern Ireland, please see the MHRA guidance for Northern Ireland.

Medical devices are products or equipment that are used for medical purposes, but work differently to a medicine or a drug.

The clinical data required by regulators to demonstrate that a medical technology product performs as intended and is safe to use is dependent on the class of technology. Higher risk products require more extensive clinical evaluation and evidence standards before they can be launched onto the market.

There are three main types of medical devices:

- general medical devices
- active implantable medical devices
- in vitro diagnostics (IVDs)

Check if your innovation is a medical device, and which of the three main types it is. Further guidance is available:

- medical device stand-alone software including apps
- borderline products- how to tell if your product is a medical device

General medical device and active implantable medical devices

If your product is a general medical device or an active implantable device, you need to determine which 'class' your device is in:

- Class I - generally regarded as low risk
- Class IIa - generally regarded as medium risk
- Class IIb - generally regarded as medium risk
- Class III - generally regarded as high risk

If your product is a general medical device or an active implantable device and it is in class IIa, IIb, III (or is a class I device that is sterile or has a measuring function) then you will need to contact a UK approved body or EU notified body. They can carry out the necessary assessments to ensure your device meets the regulatory requirements.

UK approved bodies can certify devices for the UK market by issuing an UKCA certificate. This is an UK product marking (introduced in January 2021) for goods placed on the market in Great Britain. The UKCA mark covers most goods which previously required the CE marking. The UKCA mark is not recognised by the EU market, to certify a device for both UK and EU markets you will need to use an EU notified body. Find out more about using the UKCA marking.

The UK approved bodies are designated by the MHRA to ensure that manufacturers comply with the regulations set out in UK MDR 2002. If the device meets the regulatory requirements, then the UK approved body has the authority to issue an UKCA certificate. The manufacturer should add the UKCA mark to their device and register the device with the MHRA. The device can then be placed on the Great Britain market.

If you have a class I general medical device that is not sterile and does not have a measuring function, then you can self-certify your device for the UKCA as outlined below:

- confirm that your products are Class I medical devices as described in Part II of the UK MDR 2002, Annex IX (as modified by Part II of Schedule 2A to the UK MDR 2002)
- check that your products meet the relevant essential requirements of Part II of the UK MDR 2002, Annex I (as modified by Part II of Schedule 2A to the UK MDR 2002)

- carry out a clinical evaluation as described in Part II of the UK MDR 2002, Annex X (as modified by Part II of Schedule 2A to the UK MDR 2002)
- notify the MHRA of any proposals to carry out a clinical investigation to demonstrate safety and performance
- prepare technical documentation
- draw up the declaration of conformity
- put the UKCA mark on your device as described in Regulation 10 of the UK MDR 2002
- register the device with the MHRA

In vitro diagnostic

In vitro diagnostic (IVD) is a type of medical device, usually a reagent, calibrator, apparatus, equipment or system used in vitro to examine specimens such as blood, tissue and urine. Examples include:

- pregnancy tests
- blood glucose monitors
- HIV test kits
- certain blood collection tubes
- immunoassays

IVDs are regulated by Part IV of the UK MDR 2002 and all IVDs must be registered with the MHRA. There are four categories of IVDs, listed in order of perceived risk:

- general IVDs
- IVDs for self-testing which are intended to be used by persons in a home environment
- IVDs in the classifications stated in Part IV of the UK MDR 2002, Annex II List B (as modified by Part Ill of Schedule 2A to the UK MDR 2002)
- IVDs in the classifications stated in Part IV of the UK MDR 2002, Annex II List A (as modified by Part Ill of Schedule 2A to the UK MDR 2002)

General IVDs can be self-certified, but all other IVDs need approval from a UK approved body or EU notified body before they can be registered with the MHRA and placed on the UK market. Find out more about the IVD directive and what regulatory approval your IVD needs to go through.

Registering your medical device with MHRA

Medical devices need to be registered with MHRA after they have been certified by an UK approved body, an EU notified body, or where they have been self-certified, and prior to being put onto the UK market. The MHRA performs market surveillance of medical devices in the UK.

There is a fee of £100 for each registration application. You will need to provide detailed information about the manufacturer and device when registering.

Manufacturer details:

- legal entity name and address as it appears on the device labelling or packaging
- company type (for example, limited company or sole trader)
- administrative contact, you can have up to 15 people with access
- a letter of designation for UK Responsible Persons (where applicable)

The letter of designation must be a legal contract, stating that you are the exclusive UK Responsible Person acting for the manufacturer and the mandatory tasks you are contracted to undertake on behalf of the manufacturer. The mandatory tasks that must appear in the designation contract can be found in regulatory guidance for UK Responsible Persons.

Device details:

- which regulations apply
- the class of device you are registering
- Global Medical Devices Nomenclature (GMDN) code and term to describe your device
- basic unique device identification- device identifier (UDI-D1) (if applicable)
- medical device name (brand, trade, or proprietary name)
- model or version detail
- catalogue or reference number
- UK approved body (or EU notified body) where applicable
- attributes such as sterility, contains latex, MRI compatible

Find out more about how to register your device with the MHRA.

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.

Surgical or invasive procedure

This means a new surgical technique or interventional procedure.

A new procedure must be a:

- surgical procedure (making a cut or a hole to gain access to the inside of a patient's body)
- procedure accessing the body cavity without cutting
- procedure using electromagnetic radiation, such as x-rays or lasers

It must also:

- be available within the NHS or independent sector, or be about to be used for the first time outside of formal research
- not yet be considered standard clinical practice

NICE publishes guidance on the use of interventional procedures in the UK. This guidance assesses the safety and efficacy of new techniques and procedures. Notify NICE about a new procedure or find out more about surgical innovations and the advancing surgical care from the Royal College of Surgeons England.

Digital healthcare technologies

Digital healthcare technologies are apps, software, artificial intelligence (AI) and digital platforms or services used for health or social care. Some digital healthcare technologies are considered to be medical devices.

To understand what regulations apply to digital technologies and how to meet them, see the AI and Digital Regulations Service. This explains what regulations you need to follow, how to evaluate effectiveness, and how to generate evidence for the NHS organisations who will buy or use your technology.

You can access support from the AI and Digital Regulations Service through the NHS Innovation Service.

Visit the AI and Digital Regulations Service

If you are unsure about your innovation category

If you are unsure which category your innovation falls under, read the MHRA guidance on:

- how to tell if your product is a medicine
- how to tell if your product is a medical device