A quick guide to regulation of medical apps

Produced by

gApps

Developing a regulatory strategy

Failure to obtain the necessary regulatory approvals from the outset can be catastrophic. It is therefore very wise to invest time in developing a regulatory strategy, taking into account the following considerations:

- Take time and (if necessary) obtain advice about which regulatory frameworks will apply to your app - MHRA, FDA, ABPI, MDR
- Failure to have the necessary approval is often an offence and could also lead to app store rejection
- Take care to calculate the timeframe required to complete all of your regulatory approvals, factoring in both the time it takes to complete the required paperwork and the risk of non-approval
- Applications for regulatory approval generally require individuals to be nominated to take on certain statutory functions, making them the first port of call for the relevant regulator
- Review the App Store guidelines for publishing medical apps
- Don’t forget about data protection - HIPAA and GDPR compliance

Medical device regulations

The MHRA is the UK competent authority responsible for ensuring that medicines and medical devices work and are acceptably safe.

In the UK and throughout Europe, mobile apps that meet the definition of a medical device are required to be CE marked in line with the EU medical device directives

This is to ensure they are regulated and safe to use and also perform in the way the manufacturer intends them to. Health related apps that are not medical devices fall outside the scope of the MHRA.

Is my app a medical device?

Key questions to consider:

- Does the app have a 'medical purpose'?
  - prevention/diagnosis of a disease, injury, disability
  - monitoring, treatment or alleviation
  - compensation for an injury or disability
  - investigation, replacement or modification of anatomy or physiological process
  - control of conception
  - prediction, prognosis
- Software intended for lifestyle and well-being purposes is not a medical device

Medical device apps

For apps that meet the definition of a medical device, the following guidance is given to aid some key requirements of CE marking:

- **Classification:** Manufacturers of medical device apps will need to determine the classification of their product to determine the route to compliance.
  - There are four classes as follows: *Class I; Class IIa; IIb; Class III*
- **Essential requirements:** The software must meet all of the general essential requirements and the relevant design and construction essential requirements contained in the medical device directives.
- **Post market surveillance:** Once a medical device has been placed in the UK market, the manufacturer is responsible for monitoring the product and reporting serious adverse incidents.

App labelling

A prospective customer should be able to identify that the app meets the relevant essential requirements prior to download. The manufacturer should display the CE mark on a primary landing page and as a screen shot in any app store.