USE OF APPS IN MEDICINES INFORMATION

# Background

It is the role of the Quality and Risk Management Group (QRMG) to advise on suitable resources for provision of an MI service. In recent years, due to widespread availability of smart phones, there has been an explosion in availability of health apps; in 2017 there were 325,000 available health apps, 78,000 of which were added in the previous 12 months [1].

Health app developers often, and legally, share consumer data with third parties in exchange for services that enhance the user’s experience (e.g. connecting to social media) or to monetise the app (e.g. hosted advertisements) [2]. Little transparency exists around third party data sharing, and health apps often fail to provide privacy assurances, despite collecting and transmitting multiple forms of personal and identifying information [2]. Reviews have concluded that the quality, scientific basis and safety of the available medical apps is variable, with some excellent, but also some providing cause for concern [3].

Apps that provide medicines-related information and services may be particularly likely to share or sell data, given that these apps collect sensitive, specific medical information of high value to third parties [2]. For example, drug information and clinical decision support apps that target health professionals are of particular interest to pharmaceutical companies, which can offer tailored advertising and glean insights into prescribing habits [2].

Some apps are classified as medical devices. These are apps which gather data from the person or a diagnostic device, such as diet, heartbeat, or blood glucose levels and then analyse and interpret the data to make a diagnosis, prescribe a medicine, or recommend treatment [4]. Throughout the EU, including the UK, all apps that meet the definition of a medical device are required to be CE marked in line with EU medical devices directives and regulations. Those apps governed by medical device legislation in the UK have to register with the MHRA, provide clinical data, and are obliged to conduct post-marketing surveillance. If there is an adverse reaction, it has to be reported. The obligation to decide whether or not it is a medical device falls on the manufacturers, following guidance from the MHRA [5]. Some companies may put a disclaimer that the product is not a medical device, but this does not exempt them from the legislation.Different guidance issued by the FDA applies in the US.

As the final form of the UK’s relationship with the EU post-Brexit has not been clarified, it is not possible to state what form the regulation of medical devices will take after the transition period (ending 31st December 2020). However, it is likely that, from the point of view of the end-user/healthcare professional, little will change.

* It is likely that those elements of EU law already incorporated into UK law will ‘freeze’ unless they are deliberately changed.
* If the EU CE mark is no longer valid in the UK, it is likely that a similar UK-specific mark will emerge to mark approved medical devices.

Healthcare professionals should therefore assume that, unless deliberately changed, the definition of a medical device will be the same after the end of the transition period, although it may be that over time UK rules diverge from EU rules.

Health-related apps and software that are not medical devices fall outside the scope of the MHRA. NHS Digital has developed a range of Digital Assessment Questions (DAQ) and an assessment review process to assess health-related apps and software that are not medical devices. This process is designed to ensure only safe and secure apps and digital tools are made available via the [NHS Apps Library](https://www.nhs.uk/apps-library/) [6].

In April 2015, the Royal College of Physicians (RCP) produced a factsheet providing guidance on use of medical apps, in conjunction with the MHRA and the General Medical Council. The factsheet explains what is and what is not a medical app, what to do if you are using or developing a medical app, and how to report issues or problems with apps. The guidance underlines two key pieces of advice:

* You should not use medical apps, including web apps, that do not have a CE mark.
* Always exercise professional judgement before relying on information from an app.

The [factsheet](https://www.rcplondon.ac.uk/news/rcp-issues-new-guidance-using-medical-apps) [7] states *“The RCP has no plans to endorse particular medical apps (in the same*

*way that it would not endorse a particular drug), although it is centrally involved with other organisations in establishing quality criteria for apps.”*

Public Health England (PHE) guidance also requires health app developers to show how they meet the technical criteria set out in the DAQ before PHE will endorse a public health digital product. The guidance states this will eventually be required by any national health body commissioning a health app developer’s product or service [8].

In addition, an app developer must register with the CQC if their app provides a health or social care service that fits in one of 14 regulated activities [9].

# Relevance to Medicines Information Professionals

Although MI professionals may be asked about the suitability of apps for use in clinical settings, apps used in the MI centre itself are less likely to be categorised as a medical device and more likely to be a different presentation of a currently available resource. However, even if the app is based on a well-recognised and widely used resource, the way the data are presented is likely to look different and as such could present risks. An app can also reduce risk, for example, with the use of colour coding (BNF - compare interactions information via Medicines Complete with that via the BNF app).

So how would an MI professional know whether an app they use in their day to day work can be trusted? The answer is much the same as when assessing a new resource including websites. The following checklist is suggested (adapted from articles published in BMJ and Journal of Medical Internet Research) [10,11]:

*Questions to ask before downloading an app:*

* Is it a medical device? Does it have a CE mark?
* Has it been assessed by PHE or NHS Digital?
* Is it produced by a trusted publisher?
* Is it regularly updated?
* Is it properly referenced?
* Are the authors listed?
* Is it possible to give feedback?
* Is the content peer reviewed?
* Is its primary purpose to inform health professionals?
* Do you know what the funding source is? (may be conflict of interest)
* Does the app require input of confidential or sensitive data?
* Which data leave the device?
* How are these data stored? (e.g. de-identified, encrypted)
* Who will have access to these data?

# Conclusion

UKMi are aware that various ‘apps’ are available for health information resources. UKMi will not review the content or functionality of such apps. However, if an ‘app’ is available as another platform for an already endorsed UKMi resource, this may be highlighted as being available.

MI professionals are advised to use the checklist above to assess the suitability of an app before using it.

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# Contact

Author Nicola Bradley

QRMG.ukmi@nhs.net