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The use of mobile apps and software as a form of healthcare within the NHS

Further utilisation by the UK's NHS of mobile apps and software is steadily growing; for instance earlier this year the NHS announced a pilot program involving the prescription of an app created by startup OurPath. Given the increased use of such technologies, the legal landscape for the NHS' use of health and wellbeing apps is increasingly in focus. Hilary Jones and Michaela Herron of Bristows examine this landscape, looking at the regulation of such apps and the liability issues that may arise when they are prescribed on the NHS.

Introduction

The use of apps and software as a form of healthcare is steadily growing, with both new and existing tech-based companies and biopharmaceutical companies entering this space. In May 2017 the NHS launched a pilot across GP surgeries in North West London to prescribe a technology program to patients who are suffering from or at risk of developing type 2 diabetes. The pilot sees the NHS paying £149 to health technology startup OurPath each time the app is prescribed, and could lead to wider rollout of the app throughout the NHS if it is a success. OurPath describes its tool as a six week digital program that allows users to improve their health through behavioural, lifestyle and dietary changes. Their website describes an increase in energy levels, the possibility of a better night's sleep and a "healthier, happier you" as possible outcomes¹.

Diabetes costs the NHS billions every year and it is logical for the NHS to take measures to address the dietary and lifestyle factors that can contribute to the illness. This article takes a look at the current legal landscape for the use of health and wellbeing apps by the NHS and how the regulations may need to develop if the prescription of apps becomes a more mainstream form of healthcare. It also considers potential liability arising from the prescription of behavioural tools, and how the NHS may need to regulate its partnership with the third party app/software providers. Data privacy compliance in relation to the collection and processing of sensitive personal data by such apps is outside the scope of this article.

Regulation of healthcare apps

There is a distinction in the legislation between apps which have a medical purpose and fall within the definition of a standalone software medical device in the legislation², and health and wellness apps which provide advice on a healthy lifestyle which do not fall within the definition of a medical device³. It is important to make this assessment well in advance of the intended launch date for the reasons explained below.

Key to determining whether an app is a medical device will be the intended purpose assigned by the manufacturer in the app's labelling, instructions for use and any associated promotional materials. Claims that the use of an app will prevent, treat or alleviate the symptoms of a disease will indicate a medical purpose within the scope of the legislation, and it will not be possible to use disclaimers to deny that such an app has a medical purpose. Therefore, great care needs to be taken at an early stage in assessing whether an app qualifies as a medical device.

If an app falls within the definition of a medical device, it will be necessary to comply in full with the requirements set out in Directive 93/42/EEC⁴. The Commission has issued extensive guidance on the interpretation of the Directive in the form of the MEDDEV documents, and the MHRA has also issued its own guidance including on standalone software. As from 26 May 2020 Regulation (EU) No 2017/745 will become applicable in place of the Directive (although certain aspects of the Regulation have a different transition

period). Most apps will be classified as class I devices meaning that they can be self-certified (without requiring the involvement of a Notified Body).

Manufacturers of medical devices must comply with the essential requirements set out in the Annexes of the Directive (and in the Regulation, once applicable). In order to demonstrate compliance with the essential requirements it is expected that manufacturers comply with the relevant harmonised standards, and specific harmonised standards exist for software medical devices⁵. The EC Declaration of Conformity must be signed, the CE mark affixed and the appropriate notifications made to the competent authority before an app is placed on the market. Post marketing, manufacturers must operate a device vigilance system and review and act on experience gained from post-market surveillance, which may require the updating of the app, communications to users or a recall⁶. Whilst it is possible for the design, manufacture, packaging and labelling of a device to be outsourced (provided that appropriate contracts are in place which include a clear delineation of tasks) it is not possible for a medical device manufacturer to outsource its responsibility or liability under the legislation, so appropriate contractor oversight is important. Companies that are new to medical devices and which lack a compliance infrastructure, a documented quality management system and an understanding of the regulations will need to invest in developing the required systems, standard operating procedures and expertise. This may include steps such as recruiting new



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colleagues with the relevant experience, training existing colleagues and/ or using third party consultants.

Health and wellness apps that are not medical devices will nonetheless need to be free from defects, fit for purpose and appropriately promoted in order to be compliant with consumer protection and advertising laws. Although such apps are not subject to the medical devices legislation, the General Product Safety Directive ('GPSD') may be applicable⁷. There are also certain published standards that can be applied to health and wellness apps. For example, BSI Publicly Available Standard 277: 2015 on health and wellness apps sets out a code of practice for the development and management of such apps. In addition the NHS Digital Standardisation Committee for Care Information Policy SCCI 0129 sets out detailed requirements for manufacturers of health IT systems used by the NHS. The SCCI requires the nomination of a clinical safety officer; a defined and documented clinical risk management process; the conduct of risk assessments documented in a hazard log and clinical risk management activities during the life of the product/ service. Whether the NHS would require adherence to these standards when an app is prescribed for use by patients at home is not clear, but compliance with the SCCI is good practice in any event.

An app (whether or not a device) will need to be promoted appropriately, in accordance with the principles set out in the ASA Code of Practice and the ABHI Code of Practice (where relevant), ensuring that all claims can be

adequately substantiated. Where the NHS is purchasing the app the Business Protection from Misleading Marketing Regulations 2008 would also apply⁸.

Liability in relation to the prescription of healthcare apps

The prescription of apps for patients raises the issue of potential liability both for the app manufacturer and the NHS. If a patient suffered harm as a result of using a prescribed app, there are a number of potential causes of action available to the patient including negligence, breach of contract and strict liability for a product safety defect. The particular potential claims available would depend on whether the app is considered a medical device or general product (i.e. health and wellness app) and whether the app could be said to include a service element⁹.

The Consumer Protection Act ('CPA')¹⁰ provides for strict liability in relation to defective products. Under the CPA an action can be brought against the producer, the brander or the importer in the EU (and in certain cases the distributor). In the present situation, the most obvious choice of defendant would be the producer (i.e. the app manufacturer) who ought to be identifiable to the patient either from the app itself or from the prescribing doctor/the NHS. Although fault is not a requirement, consumers must still prove defect, injury and a causal link between the two under the CPA. The patient would have to demonstrate that there is a defect in the app and that the safety is 'not such as persons generally are entitled to expect'¹¹. The patient

would need to address how the app is actually defective; e.g. did the app malfunction to produce inaccurate or unreliable data which was then relied upon for treatment of the patient, or was the algorithm used to determine prescribing dosages incorrect, resulting in an overdose of medication. It is harder (although not impossible) to envisage how harm could be caused to the patient for example in the case of an app which only provided diet and lifestyle advice. An injured patient could also potentially bring a claim against the producer in negligence. Negligence claims generally allege fault by reference to design defects, manufacturing defects and failures to warn. Whilst a claim in contract may be attractive (as in addition to damages there may also be a claim for economic loss) it may be hard to show that there is a contract between the seller and the patient where the product has been purchased by the NHS.

An injured patient may also have a claim against the NHS for the prescribing of the app. Such a claim may arise in negligence if the NHS had failed in their duty of care to a patient by recommending prescription of an app that was defective, although if the NHS was neither aware nor reckless to the fact the app was defective and can prove they acted with reasonable care it may be difficult to succeed under this potential cause of action. However, if the app should not have been prescribed in the first place and instead a medical intervention was required which was not prescribed, then the patient may have a claim for clinical negligence. A claim in contract against the NHS by a patient for

continued

the supply/prescription of the defective app may be more difficult. Existing case law in relation to medicinal products establishes that where medicines are supplied on prescription by the NHS, there is no contract between the patient and the prescribing doctor or the pharmacist dispensing the medicines. The same principle may apply in relation to the prescription of apps.

If a health and wellness app has been determined not to meet the requirements of the GPSD¹² then appropriate corrective action must be taken. Under the GPSD producers are required to adopt measures to enable them to take appropriate action in relation to product safety risks, including where necessary, warning and withdrawing or as a last resort, recalling the app. The NHS may also have obligations including having to identify those who have been prescribed the app. Recalling apps can be challenging. For example, if an app has been downloaded from an app store it may not be possible to obtain any information on who has downloaded the app (other than the numbers of downloads in specific countries). App stores may not be willing to publish notices of errors and it may not be possible to ensure that the user removes the app from their device. For this reason, a registration system may be advisable, so that it is possible to communicate directly with everyone using the app.

For apps that are medical devices, if the manufacturer is not compliant with the legislation it could be inspected by the MHRA, ordered to remove the product from the market and in certain cases be liable for a fine and/or imprisonment. When the Medical Devices Regulation becomes applicable, if the NHS falls within the definition of a 'distributor' it too will have certain obligations and potential liability under the Regulation.

Given all of the above the NHS will need to ensure that its contractual arrangements with app providers are sufficiently robust. It would be wise to ensure that contracts include specific reference to the standards and legislation that the app provider must comply with. The NHS should satisfy itself that the app is fully compliant and fit for purpose before prescribing it, which may include an audit of the app producer. The NHS would want to ensure that it has a claim for breach of contract against an app manufacturer if an app was not fit for purpose or otherwise of unsatisfactory quality.

Developments in the regulation of healthcare apps

The regulation of apps that are medical devices is well developed and has been growing increasingly strict over the recent years, albeit that there is some lack of experience in its implementation. Notwithstanding the prospect of Brexit, manufacturers are advised to start

preparing for the applicability of the new Regulation now. The regulation of health and wellness apps that are not medical devices is more complex, arising from several different pieces of legislation and various case law authorities. Nonetheless the scrutiny of such apps, particularly if they are being prescribed by the NHS, is likely to be highly rigorous, and any company supplying a defective app to the NHS may receive a strong public reaction. Therefore whilst clarification as to applicability of the GPSD would be helpful, it would be prudent for manufacturers selling apps to the NHS to comply with these (and the other standards mentioned above) in any event. The ongoing review of the Product Liability Directive, which includes its fitness for purpose in relation to malfunctioning apps, will be of much relevance¹³. Also of interest is the fact that the European Commission's Working Group on mHealth Assessment Guidelines failed in its report last month to reach consensus on the standards for health related apps/ data although the report did highlight some relevant national standards¹⁴.

In conclusion, the regulation of healthcare apps remains an evolving area at the forefront of one of the exciting, but challenging, developing interfaces between technology and the law. It no doubt is, and very much should be, of great interest to all those involved in digital healthcare. This is a space to be watched.

1. <https://www.ourpath.co.uk/>

2. See the Medical Devices Directive 93/42/EEC (as amended). Article 1(2) states that the definition of a device includes software for the prevention, monitoring, treatment or alleviation of disease and the diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap. The software must also have an action on data and for the benefit of individual patients (see MEDDEV 2.1/1 and MEDDEV 2.4/1 rev.9). Regulation (EU) No 2017/745 on Medical Devices which will become applicable in May 2020 changes this definition slightly including adding the prediction or prognosis of a disease.

3. See also the conclusion of the Advocate General in case C-329/16 confirming that software functionality which detects contraindications, drug interactions and excessive doses falls within the definition of a medical device in the Directive.

4. Implemented into UK law by the Medical Devices Regulations 2002 (as amended).

5. EN 62366 (usability engineering), EN 62304 (software life cycle processes), EN ISO 13485 (Quality Management Systems - note not currently mandatory for class I devices but best practice), EN ISO 14971 (risk management).

6. It's worth noting that the Regulation contains increased requirements regarding the ongoing clinical evaluation, risk management and post-marketing surveillance of medical devices.

7. The Commission has previously stated that "due to the fact that both the GPSD and the Product Liability Directive products apply to manufactured products it's not clear if and to what extent they apply to lifestyle and wellbeing apps" (see Staff Working Document dated 10 April 2014 accompanying the Green Paper on mHealth). In its guidance on medical device standalone software the MHRA states that the General Product Safety Regulations may apply (see <https://www.gov.uk/guidance/product-liability-and-safety-law>). Drawing an analogy

with the medical devices legislation and the concept of the legal manufacturer it is certainly arguable that they should apply to apps.

8. If a patient was purchasing the app directly the Consumer Protection from Unfair Trading Regulations 2008 would apply.

9. E.g. if the app combined digital functionality with advice or assistance given by a person.

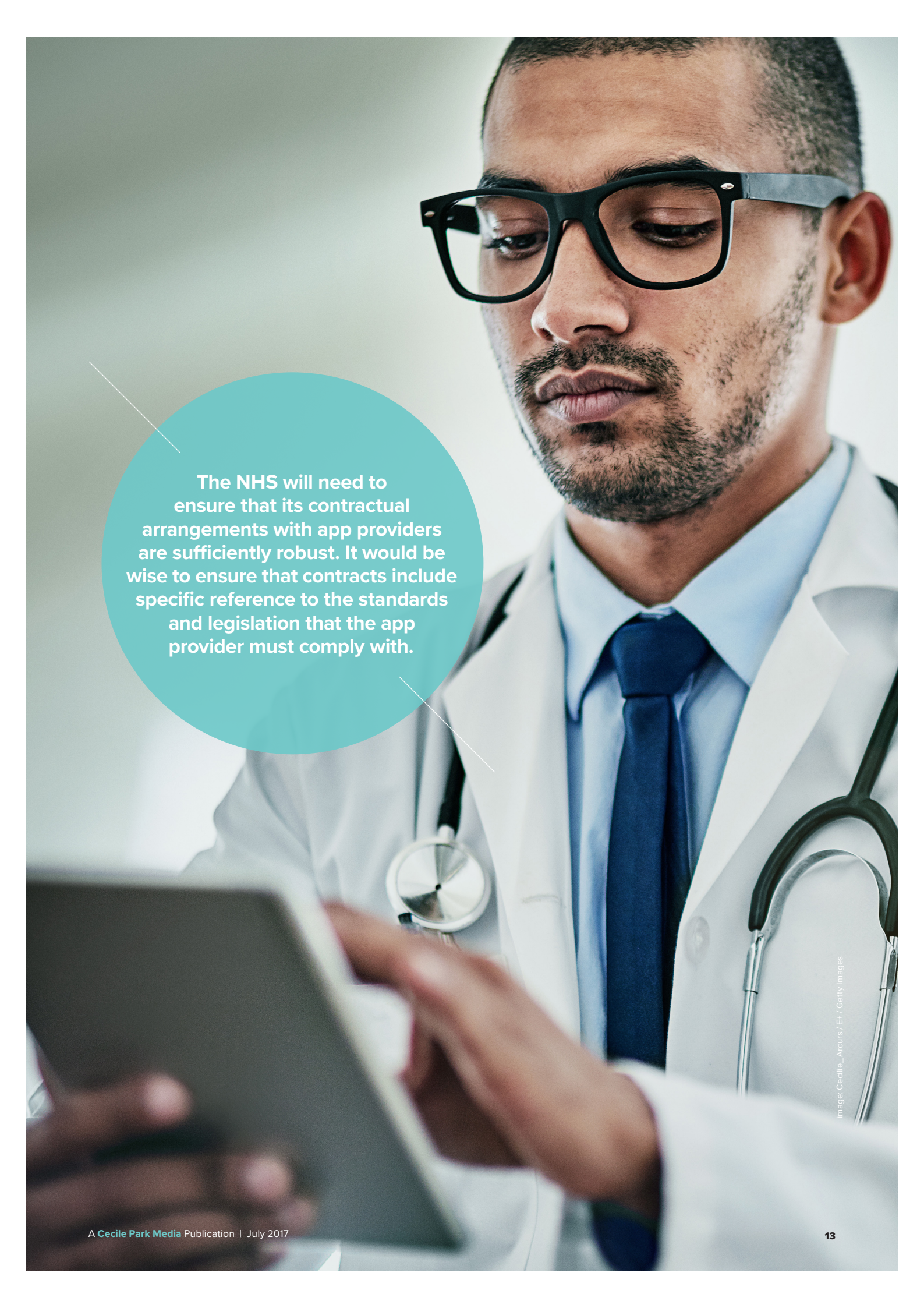
10. The Consumer Protection Act 1987 (CPA) which implements EC Directive 85/374/EEC (the Product Liability Directive).

11. Section 3(1) of the CPA.

12. Implemented into UK law by the General Product Safety Regulations 2005.

13. The deadline for consultation responses was 26 April 2017.

14. Report of the Working group on mHealth Assessment Guidelines February 2016 - March 2017.



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