HBW INSIGHT
CITELINE COMMERCIAL

12 Mar 2024 | **Analysis**

ASA Files: How Not To Advertise A Digital Health App In The UK

by David Ridley

ADHD-management software Happyo falls foul of UK advertising rules in a recent ASA case. The lesson: if in the UK the intended use of a digital health app is the diagnosis of a serious medical condition, supervision by a healthcare professional such as a doctor is likely to be necessary, in which case advertising to the public would also be prohibited.

Digital consumer health is an exciting area of innovation, and many OTC companies may be thinking about stepping into this space with a digital health app, for example.

However, a recent UK Advertising Standards Authority ruling shows that companies must be very careful not to overstep regulatory boundaries that distinguish medical devices from other consumer products.

The *ruling in question* concerns a September 2023 paid-for UK Facebook advertisement for Happyo – a behaviour programme aimed at those with attention deficit hyperactivity disorder (ADHD) – which the ASA said made medical claims breaching the UK advertising code and "discouraged essential treatment for a condition for which medical supervision should be sought."

The ASA noted that Happyo – which describes itself on its *website* as providing a "quiz-answer-based personalized plan" that helps users "learn to handle ADHD" – is not registered with the UK Medicines and Healthcare products Regulatory Agency (MHRA) as a medical device.

The UK Code of Non-broadcast Advertising and Direct & Promotional Marketing (CAP Code) states that medicinal or medical claims and indications can only be made for a medicinal product licensed by the MHRA, or under the auspices of the European Medicines Agency (EMA), or for a medical device with the applicable conformity marking, the ASA pointed out.

The ASA thus found Happyo's claims – including "Manage your ADHD with Happyo" – in violation of the code and determined that they should be discontinued. Happyo provided evidence that it had removed the ad in response to the complaint.

Unsupervised? Unlikely

However, it's not at all clear that Happyo would be able to obtain a UKCA mark or CE mark for the app to be used as a home diagnostic for ADHD, regulatory expert Jamie Hatzel told HBW Insight, which seems to be the current intended purpose of the web-based quiz.

"It looks like Happyo is primarily an app offering cognitive behavioural therapy (CBT) exercises to users to help with ADHD," commented Hatzel, an associate at law firm Bristows LLP. "We see these kinds of apps quite a lot."

In Hatzel's view, "if Happyo could gather clinical data to validate the exercises provided in its app, and it operated an appropriate ISO 13485 quality management system, it might be able to obtain a UKCA or EU CE mark."

While Happyo would perhaps be classed as a low- to medium-risk medical device in either jurisdiction, its intended use as a diagnostic would likely require the supervision of a doctor, in the sense that a doctor would review the results and take them into account in their assessment of whether the patient had ADHD.

"If that were the case," Hatzel explained, "Happyo would not be able to market the app as being suitable for home diagnosis, because the app would not be approved for this intended use."

Must Not Discourage Treatment

In its decision, the ASA stated, "advertisers must not offer specific advice on diagnosis of or treatment for such conditions, unless that advice, diagnosis or treatment was conducted under the supervision of a suitably qualified medical professional.

"However, we did not receive evidence to show that treatment for those with ADHD using the Happyo program was carried out under the supervision of a suitably qualified medical professional," the ASA continued.

"We considered that, in the absence of such a professional, the ad discouraged consumers from seeking essential treatment for conditions for which medical supervision should be sought, and therefore breached the Code."

James Walmsley from advertising review specialist Advercheck added that there were two key takeouts from the ASA ruling: "If an advertiser wants to make medicinal claims for an app, it needs to be registered as a medical device. But even if appropriately CE marked, the CAP Codes

essentially prohibit advertising to the public of self-care apps for serious conditions."

US Model

There is however an "OTC" medical device for ADHD in the US. Adults with the condition can download Akili Inc.'s EndeavorOTC digital treatment directly from the US Apple Store and Google Play, for example. (Also see "*Akili Awaits FDA Feedback On Data Needs For OTC Marketing Of ADHD Digital Therapeutic*" - HBW Insight, 23 Nov, 2023.)

The US Food and Drug Administration in June 2020 granted Akili de novo marketing authorization for its EndeavorRx game-based digital therapeutic to improve attention function in children ages eight to 12 with ADHD.

However, Akili has struggled to secure reimbursement for its innovative non-drug cognitive treatment and in June 2023 changed course, repackaging EndeavorRx and launching it directly to adults with ADHD.

The move was enabled by an FDA Enforcement Policy for Digital Health Devices For Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, which fell out of effect on 7 November.

Akili has since submitted a 510(k) notification for EndeavorOTC to the FDA on 30 October and it is currently undergoing technical review by the agency. The firm can continue to offer EndeavorOTC without a prescription while the application is under review.

Akili is able to leverage search marketing and social media platforms, in addition to its own organic content such as blog posts, to drive traffic to its website and app.