

Mental Health Goes Digital

A Blueprint For Digital
Health Medical
Technologies
(DHMTs)





MANAGEMENT SUMMARY

Mental health conditions such as depression, anxiety, and insomnia are becoming increasingly prevalent worldwide, with both diagnosed and undiagnosed cases exerting a growing social and economic toll. Limited access to care—driven by stigma, eligibility thresholds, long waiting times, and cultural barriers—has left large swaths of the population without adequate treatment. In regions like the UK, US, and Europe, mental health disorders are now major contributors to healthcare costs and workforce inactivity. As traditional mental health services struggle to meet demand, digital mental



health technologies (DMHTs) have emerged as promising tools to bridge the treatment gap.

To provide greater clarity in this rapidly evolving field, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) has released new

guidance on how to classify and regulate DMHTs, including those powered by AI and large language models. This guidance helps determine whether a tool should be regulated as a medical device, based on its functionality and intended use. It marks a critical step toward standardizing how digital mental health tools are brought to market, improving safety, transparency, and compliance. As global markets grapple with similar challenges, the MHRA is providing support for innovation in the digital mental health space in the form of greater clarity. Companies developing DMHTs are encouraged to assess their regulatory status early in the product lifecycle to streamline market entry and ensure long-term competitiveness.



INTRODUCTION

Mental health is reaching a crisis point in much of the modern world. The World Health Organization (WHO) estimates that around 3.8% of the global population will suffer from depression at some point and reports that more than 700,000 people die due to suicide every year, making it also the fourth leading cause of death in 15–29-year-olds.¹ The WHO has also stated that depression will be the leading cause of the disease burden globally by 2030.²

Whether diagnosed or undiagnosed, mental health disorders such as depression, anxiety and insomnia, have a profound economic and societal impact as well as significantly affecting the lives of those that suffer from them. In addition to stigma associated with these conditions leading to fewer people actively seeking support, lack of access to diagnosis and availability of treatment still provide significant obstacles to helping people.



Specifically, undiagnosed mental health conditions have a wider-reaching economic impact and include reduced productivity, increased absenteeism, and higher healthcare use.

Across Europe statistics suggest that one-third of the adult population in Europe experiences a mental disorder each year.³ A statistical breakdown in the US shows that 19.1% of US adults had an anxiety disorder and 14.5 million adults experienced a major depressive episode in the past year.⁴ Globally, sleep disorders, including insomnia, affect approximately 30% of adults.⁵ In the UK alone, 12 million prescriptions for sleeping pills are written each year.⁶

Also in the UK, approximately 10.3 million instances of mental ill-health were recorded over a one-year period, with depression ranking as the third most common cause of disability.⁷ Similarly, records show 8.2 million cases of anxiety disorders and over 5.2



million cases of sleep disorders in the UK in 2013.⁸ The cost to the economy is of at least £117.9 billion annually, equivalent to around 5% of the country's GDP. This figure includes costs related to healthcare, social services, and lost productivity due to



mental health conditions.⁹ At an individual level, mental health issues are a leading cause of worklessness, with two-thirds of new incapacity benefit claims attributed to mental health conditions, primarily depression and anxiety.¹⁰

According to Statista, in 2022 32% of EU adults aged 30–44 reported unmet mental healthcare needs,¹¹ while in the US, around two thirds of adults with mental health issues were unable to access treatment.¹² There are a number of reasons that drive this scarcity in mental health care and while country or healthcare system specific issues exist, some common denominators can also be found. These are: high eligibility thresholds, so patients often face stringent criteria to qualify for mental health services, excessively long waiting times due to lack of medical personnel to carry out treatment as well as remoteness, and cultural challenges that range from stigma to cultural discrimination or language barriers.

As the burden of mental health care increases, the gap between treatment availability and need is widening but digital mental health care devices are increasingly stepping in to fill it. It's not surprising therefore that the global market for emerging mental health devices and platforms was valued at \$3.22 billion in 2023 and is projected to reach \$17.70 billion by 2031, growing at a compound annual growth rate (CAGR) of 23.81%.¹³ The novelty of these devices however, as well as their integration of Artificial Intelligence (AI) and Large Language Models (LLMs) for diagnostic and treatment purposes, poses a series of regulatory concerns that need to be addressed to ensure safety, positive patient outcomes as well as the continuing competitiveness and compliance of these devices.



Despite challenges, Digital Mental Health Technologies (DMHTs) are emerging as innovative tools to support individuals, enhance self-management, and empower clinicians. These technologies have the potential to transform the landscape of mental health care by making support more accessible, personalised, and data-driven. In this whitepaper we tackle the initial critical step to achieving these objectives: defining whether an application or software is a medical device or a Digital Mental Health Technology (DMHT) and therefore needs to go through regulatory processes and verifications before it is safely placed on the UK market.

DMHTs cover such a wide range of digital services (websites, internet-based platforms or apps, fitness wearables, virtual reality (VR) headsets as well as transcranial direct current stimulation (tDCS) headsets) that



regulating them is highly complex task. In addition to the forms they are delivered in they can also be available as direct-to-consumer products or used with a referral or supervision from healthcare or educational professionals.



GUIDANCE ON DMHTS BY THE MHRA SETS NEW STANDARD

Despite their rapid adoption and promise, there has been a persistent challenge around the lack of regulatory clarity around which of these tools qualify as medical devices. In this context, the UK Medicines and Healthcare products Regulatory Agency (MHRA) which regulates medicines, medical devices and blood components for transfusion in the UK, has provided a new critical piece of guidance that will help inform DMHT manufacturers that want to put their devices on the UK market.



This recent guidance from the MHRA¹⁴ is a key output from the Wellcome Trust project, part of an £1.8 million investment by the UK government to explore the regulation of digital mental health tools¹⁵. The initiative reflects the increasing

need for a structured regulatory framework that balances innovation, safety, and efficacy while ensuring that clinically impactful tools fall within the scope of medical device regulations.

UNDERSTANDING THE QUALIFICATION PROCESS FOR DMHTS

The MHRA's new framework for determining whether a DMHT qualifies as a medical device follows a structured analysis, considering various aspects of the tool's design, functionality, and intended use (see figure 1):

- **Intended purpose:** The first step in qualification is assessing what the manufacturer claims the tool is designed to do. If the software explicitly states that it diagnoses, treats, prevents, or monitors a medical condition, it is more likely to fall under medical device regulations.



- **Level of functionality:** A key additional factor in the new guidance is that a tool's functionality now plays a decisive role. A DMHT may have a medical purpose but could be excluded from regulation if its functional impact is low. This ensures that only those tools providing a clinical effect or influencing patient care decisions are classified as medical devices.

If the function **only** performs one or more of the following computational tasks it is considered **low functionality**:

- A. Stores data/ information without change**
- B. Communicates data/ information without change or prioritisation**
- C. Processes user instructions to show fixed content** in a similar manner to a user choosing a chapter in a digital book, audio book or video
- D. Processes data/ information with an easily verifiable calculation/ algorithm**

If the function performs computational tasks (other than A-D on the left), such as the following, it is considered **high functionality**:

- E. Processes user instructions with an interactive and/or personalised output**
- F. Processes data/ information with a calculation/ algorithm that is not easily verifiable**
- G. Processes data/ information using AI**

Medical purpose + low functionality = not SaMD

Medical purpose + high functionality = **SaMD**

Figure 1. Summary of qualification criteria of DMHTS (source: MHRA DMHT Guidance p19).

DMHT manufacturers may proactively complete a "Device Characterization Form", or be asked to complete one if their product has been flagged as a potential medical device. In this case the MHRA will analyse websites or screenshots and may request additional information and ask the provider to define intended purpose and functionality. Specifically, device characterisation, informs whether the product is a medical device.

To determine whether a DMHT qualifies as SaMD it is necessary to consider intended purpose and functionality of the device in the labelling, IFU and promotional materials as well as technical documentation.





EXAMPLES OF LOW VS. HIGH FUNCTIONALITY DMHTS

Classification of a DMHT depends on whether it is regarded to have high or low functionality and fulfil a clinical role. Simple tools that add up a series of numbers as scores to provide a diagnosis typically classified as low for example. The same applies of



transcription tools used by GPs during appointments, so-called ambient scribes. The table below provides a sample from the guidance to explain how different DMHTs may be classified based on their level of functionality and intended purpose:

Type of Tool	Description	Functionality?	Likely Medical Device?
User sign-in	User sign-in via a fixed digital form prompting the user to input their personal data / information	Low	No
User sign-in	User sign-in via a generative-AI chatbot that responds adaptively based on the user input	High	Yes
PHQ-9 Calculator	User responds to PHQ-9 questions on a fixed form and outputs easily verifiable total score.	Low	No
Adaptive Questionnaire	Patient answers large number of personalised questions, AI ensures questions are relevant to users and shows the likelihood of mental health conditions	High	Yes
AI transcriber	Patient consultation is recorded and converts speech to text within the Electronic Health Record. Healthcare Professional may not have time to verify summaries.	High	Yes



THE EMERGING ROLE OF GENERATIVE AI

One of the most forward-looking aspects of the MHRA's guidance is its recognition of generative AI tools such as mental health chatbots. Many generative AI tools currently in use, such as ambient scribes, have recently been registered as Class I medical devices. The DMHT Guidance further highlights how generative AI tools like mental health chatbots for 'user sign in' may also qualify as medical device. and require higher regulatory oversight.



The MHRA has also provided a *Software and AI Change Programme Roadmap*¹⁶ which builds upon wider reforms for medical devices and provides programme of work to ensure regulatory requirements for software and AI are clear and patients are protected. Similarly, the EU has developed a legislation that covers AI-based medical devices: the EU's AI Act, effective August 1, 2024, which introduces a comprehensive regulatory framework for AI.

AI systems used as safety components or directly as products, if they fall under certain EU harmonization legislations, are classified as high-risk and require third-party compliance assessments before being placed on the market or put into service. This applies to AI-based software intended for medical purposes, requiring risk mitigation, high-quality data, user information, and human oversight. The EU AI Act categorizes AI systems based on risk levels (minimal, limited, high, unacceptable). In the EU medical device sector, most SaMDs are typically at least Class IIa or greater. The exception are very basic tools such as fertility trackers and prognostic tools which typically will remain Class I.

The FDA has similarly provided guidance such as *its Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan*¹⁷ but clearly states that: "The FDA's traditional paradigm of medical device regulation was not designed for adaptive artificial intelligence and machine learning technologies. Many changes to artificial intelligence and machine learning-driven devices may need a premarket review."¹⁸ Suggesting that devices will need to be evaluated on a case-by-case basis.



In addition to this, Generative AI poses additional challenges to regulators. As GenAI models can autonomously generate new information they are particularly prone to hallucinations, some recent research even suggests it is able to hide the fact that information it has created is made-up by masking its thinking processes. This introduces uncertainty in the device's behaviour, which can lead to difficulty in



defining the device's intended use. The FDA offers this example in a recent paper: when a summarization GenAI recollects a conversation between a patient and their doctor, it may infer or fill in additional information that

suggests or even creates a new diagnosis that was never discussed.¹⁹ In addition to this, the foundation models that GenAI is built on may not be fully accessible and have usually not been developed for medical use and may have been built based on large amounts of data that was not well-controlled.

For manufacturers developing AI-powered DMHTs, the new MHRA guidelines present both a challenge and an opportunity to design their products with clear regulatory pathways in mind while ensuring they provide meaningful, evidence-based clinical benefits. These pathways may provide a blueprint for dealing with the regulatory requirements of other jurisdictions such as the US and EU.

A POSITIVE STEP TOWARD REGULATORY CLARITY

The MHRA's new guidance is a significant step toward greater transparency and regulatory certainty in the DMHT space. By refining the criteria for qualification, it ensures regulation remains proportionate, focusing on higher-risk technologies while allowing lower-risk tools to remain accessible without unnecessary compliance burdens. Manufacturers will benefit from this reduced uncertainty, enabling them to successfully navigate medical device compliance more effectively and may apply these guidelines to provide greater transparency in areas where other jurisdictions have provided cloudier directions.



Understanding the regulatory impact of this guidance is crucial to ensuring compliance and avoiding unnecessary regulatory hurdles. Reaching out for expert consultancy support in defining a medical product



at the earliest stages of development can help digital health companies assess whether their product qualifies as a medical device, navigate regulatory pathways, and implement robust compliance strategies. Assessing your DMHT under the new MHRA framework to determine if it falls under UK medical device regulations and support in preparing technical documentation and regulatory submissions to ensure a smooth market entry. Similarly, expert international support can future-proof regulatory strategy in light of evolving regulations on AI and digital health technologies.

WITH THE REGULATORY LANDSCAPE FOR DMHTS BECOMING CLEARER, NOW IS THE TIME TO ACT.

ABOUT THE AUTHOR

Benjamin Austin - *Senior QA/RA Consultant (SaMD/AI)*

Benjamin Austin is IMed Consultancy's newest Senior QA/RA Consultant, bringing 8 years of specialised experience in Software as a Medical Device (SaMD) and AI-driven healthcare solutions. He has worked extensively with startups on innovative projects, including AI tools for Alzheimer's detection and drug dose optimisation. With a strong background in quality assurance, regulatory affairs, clinical investigations, and data protection, Benjamin plays a key role in guiding digital health innovators through the complex regulatory landscape.





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