Mental health funding of £1.8m welcomed by MHRA and NICE to explore regulation of digital mental health tools

There has been a large increase in the number of digital mental health tools on the market in recent years. However, these products present regulatory challenges such as clarity around whether they are medical devices and, if so, which risk classification they would fall under.

Wellcome has therefore provided £1.8m of funding to help improve regulatory certainty and safety in this high growth, high impact area, focussing on producing guidance for appropriate, risk-proportionate regulation of digital mental health products.

The project will review key aspects of medical device regulations to produce guidance that will support digital mental health in several significant areas. These include determining what qualifies as a medical device, the risk classification they would fall under, as well as a review of the current evidence base for these devices.

To do this, we will engage with and learn from people with lived experience, subject experts and patients to inform their conclusions, as well as working with international partners to help drive shared learning and consensus in digital mental health regulations globally.

In this way, it is hoped that certain mental health software will be proportionately regulated as a medical device, meaning the public has access to effective and safe products that can significantly help protect or improve their mental health.

Minister for Mental Health, Dr Caroline Johnson, said:

Digital mental health tools can be incredibly useful to help build resilience and prevent problems worsening, but it's crucial these are regulated properly.

This funding will help us to better understand these products and give us the tools to make sure everyone who uses them has access to safe, effective support.

Johan Ordish, Head of Software and AI at the MHRA said:

Digital mental health tools offer millions of people vital support and guidance to explore and help manage their mental health issues every day.

However, there are a number of regulatory complexities in establishing when these products should be regulated and what evidence they must have to demonstrate safety and effectiveness.

We need to make sure that we are able to answer these questions, to ensure that patients can be confident in the choices they make to support their mental health.

Mark Salmon, programme director for Information Services at NICE, said:

This work is one way both organisations can simplify and streamline the process of getting wide-scale adoption of safe, clinical and cost-effective digital mental health products into the hands of the people who need them and help ease the pressure on the NHS.

Dr Miranda Wolpert, Director of Mental Health at Wellcome, said:

As an increasing number of people turn to digital tools for support with mental health problems, we believe that getting the right level of regulation is vital.

At Wellcome, we support the development of new and improved interventions for mental health, which includes digital interventions. One of the ways that we can encourage the development of tools that genuinely help and support as many people as possible will be through risk-appropriate guidance and regulation.

The MHRA will be engaging with and learning from people with lived experience of mental health conditions, helping to ensure that the regulation is at the right level, relevant and robust.

Letter notifying the Treasury Select Committee of the date of OBR's forecast and Chancellor's Medium-Term Fiscal Plan

News story

The Chancellor has commissioned the OBR's forecast for 31 October, and will publish the Medium-Term Fiscal Plan on the same date.



The <u>Chancellor's letter</u> (PDF, 98.9 KB, 2 pages) notifies the Treasury Select Committee that the OBR's forecast has been commissioned for 31 October, and will be accompanied by the Chancellor's Medium-Term Fiscal Plan. The Chancellor confirms that he will attend the Committee soon after 31 October, and that he will respond to the Committee's report on Jobs, growth and productivity after coronavirus following further growth measure announcements throughout October and the announcement of the Government's Medium-Term Fiscal Plan.

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Morrisons' proposals provisionally clear way for McColl's deal

In July 2022, the Competition and Markets Authority (CMA) <u>launched its</u> <u>investigation</u> into Morrisons reported £190 million purchase of stores owned by McColl's Retail Group Plc.

Following its Phase 1 investigation, the CMA found that the deal would not harm the vast majority of shoppers or other businesses, but that it raised competition concerns in 35 areas. The two retailers accepted these concerns and engaged with the CMA in discussing potential remedies.

Morrisons has now offered to divest 28 McColl's stores to a purchaser or purchasers to be approved by CMA. This includes 26 stores in England (in areas such as Swindon, Lincoln and Brentwood), 1 store in Scotland (Perth) and 1 store in Wales (Newport).

The CMA is minded to accept these proposals, which appear to be suitable to restore the loss of competition brought about by the deal across each of the 35 local areas. While the number of McColl's stores that Morrisons is proposing to sell is lower than the number of areas in which concerns were identified, the sale of some stores would address the concerns in multiple areas.

The CMA is now consulting on the proposals — known as undertakings — for the sale of these stores. If the CMA accepts the proposals, the deal would be cleared to proceed.

Sorcha O'Carroll, CMA Senior Director of Mergers, said:

Our preliminary view is that the sale of these stores will preserve competition in these local areas and prevent consumers from losing out due to this deal, at a time when shoppers are already facing rising prices.

If, after reviewing the responses to our consultation, we conclude that the competition issues have been addressed, the deal will be cleared.

McColl's operates convenience newsagent shops, with over 1,100 stores across England, Scotland, and Wales, while Morrisons (owned by parent company Clayton, Dubilier & Rice (CD&R)) has around 500 grocery stores in the UK. CD&R is also the parent company of the Motor Fuel Group (MFG). MFG owns over 800 convenience stores, the vast majority of which are attached to its petrol stations.

For more information, or to respond to our consultation, visit the Morrisons/McColl's merger inquiry page.

- 1. The CMA is publishing a notice of consultation and the text of the Proposed Undertakings, alongside the text of the Phase 1 decision of 8 September 2022 and the decision of 23 September 2022 that the CMA is considering undertakings offered by Morrisons. The CMA's consultation is scheduled to run until 24 October 2022.
- 2. On 8 September 2022, following a Phase 1 review, the CMA has found that Morrisons acquisition of McColl's gives rise to a realistic prospect of substantial lessening of competition (SLC) in relation to retailers in 35 local areas across England, Scotland and Wales.

- 3. The CMA served an initial enforcement order on 25 May 2022, requiring the companies to operate independently, as they did before the purchase, and the order remains in force. Details of the order can be found on the Morrisons/McColl's merger inquiry page.
- 4. The list of the 28 McColl's stores can be found here.
- 5. All media enquiries should be directed to the CMA press office by email on press@cma.gov.uk, or by phone on 020 3738 6460.

<u>Self Assessment customers could be a target for fraudsters, HMRC warns</u>

Self Assessment customers, who are starting to think about their annual tax returns for the 2021 to 2022 tax year, should guard against being targeted by fraudsters, warns HM Revenue and Customs (HMRC).

In the 12 months to August 2022, HMRC responded to more than 180,000 referrals of suspicious contact from the public, of which almost 81,000 were scams offering fake tax rebates.

Criminals claiming to be from HMRC have targeted individuals by email, text and phone with their communications ranging from offering bogus tax rebates to threatening arrest for tax evasion. Contacts like these should sound alarm bells — HMRC would never call threatening arrest.

Anyone contacted by someone claiming to be from HMRC in a way that arouses suspicion is advised to take their time and check the scams advice on GOV.UK.

Customers can report any suspicious activity to HMRC. They can forward suspicious texts claiming to be from HMRC to 60599 and emails to phishing@hmrc.gov.uk. Any tax scam phone calls can be reported to HMRC using the online form on GOV.UK.

Myrtle Lloyd, HMRC's Director General for Customer Services, said:

Never let yourself be rushed. If someone contacts you saying they're from HMRC, wanting you to urgently transfer money or give personal information, be on your guard.

HMRC will never ring up threatening arrest. Only criminals do that.

Tax scams come in many forms. Some threaten immediate arrest for tax evasion, others offer a rebate. Contacts like these should set alarm bells ringing, so take your time and check 'HMRC scams advice' on GOV.UK.

Fraudsters target customers when they know they are more likely to be in contact with HMRC, which is why Self Assessment customers should be extra vigilant to this activity. There is a risk they could be taken in by scam texts, emails or calls either offering a 'refund' or demanding unpaid tax, thinking that they are genuine HMRC communications referring to their Self Assessment return.

Some customers who have not done a Self Assessment return previously might be tricked into clicking on links in these emails or texts and revealing personal or financial information to criminals.

The deadline for filing paper tax returns for the 2021 to 2022 tax year is 31 October 2022, and 31 January 2023 for those filing their tax return online. Customers who file their return online via GOV.UK should not share their HMRC login details. Someone using the details could steal from the customer or make a fraudulent claim in their name.

HMRC is actively tackling the scams and fraudsters who attempt to mimic genuine HMRC activity and messages. The department's dedicated Customer Protection Team works continuously to identify and close down scams.

HMRC also tackles misleading websites designed to make people pay for services that should be free or low cost, charging to connect people to free HMRC phone helplines. To protect the public, HMRC formally disputes and takes ownership of HMRC-branded internet domain or website names. Since 2017, the department has recovered more than 183 websites hosting low-value services such as call-connection sites, saving the public millions of pounds.

More information about Self Assessment

In the 12 months to August 2022, HMRC has:

- responded to 181,296 referrals of suspicious contact from the public. Some 80,662 of these offered bogus tax rebates
- responded to 55,386 reports of phone scams in total, 87% down on the previous year. In April 2020 HMRC received reports of only 425 phone scams. In August 2022 this was 5,913
- reported 10,565 malicious web pages for takedown
- worked with the telecoms industry and Ofcom to remove 48 phone numbers being used to commit HMRC-related phone scams.

UKAEA and Tokamak Energy to collaborate

 Agreement follows news that STEP prototype fusion power plant will be built in North Nottingham UK Atomic Energy Authority (UKAEA) and Tokamak Energy have signed a framework agreement to enable closer collaboration on developing spherical tokamaks as a route to commercial fusion energy.

The five-year agreement will take the form of joint technology development, shared utilisation of equipment and facilities and associated secondment of staff between the two organisations.

The collaboration will focus on areas including materials development and testing, power generation, fuel cycle, diagnostics and remote handling.

Professor Ian Chapman, UKAEA CEO, said:

"Fusion has great potential to deliver almost limitless clean energy for future generations. This new agreement with Tokamak Energy will benefit both organisations and help advance our collective ambitions, because together we are stronger. Fusion presents an exciting opportunity for the UK and we're proud our ground-breaking work here continues to drive innovation and progress as part of a thriving cluster."

Chris Kelsall, CEO Tokamak Energy, said:

"We are in a race against time to phase out the world's reliance on fossil fuels and aim to deliver fusion as a clean, sustainable, low cost and globally available energy source. Tokamak Energy and UKAEA jointly recognise the importance of collaboration to accelerate the delivery of commercial fusion. We welcome the opportunity to progress knowledge, skill sharing and joint development opportunities with UKAEA, further boosting the UK's world leading fusion cluster."

Both organisations have operational spherical tokamak devices, with Tokamak Energy's ST40 recently achieving a plasma temperature of 100 million degrees Celsius, the threshold required for commercial fusion energy.

UKAEA's MAST Upgrade experiment has helped pave the way for the development of its ambitious STEP (Spherical Tokamak for Energy Production) programme, which aims to design and build a prototype fusion powerplant capable of producing net electricity.

It was announced last week that the STEP prototype powerplant will be designed and constructed at West Burton, Nottinghamshire, to demonstrate the ability to put net electricity on the grid, enabling future commercial fusion energy plants to be commissioned and constructed.

Tokamak Energy will soon be unveiling its next device, which will be the world's first high field spherical tokamak to demonstrate the full potential of high temperature superconducting (HTS) magnets, due to be commissioned in the mid-2020s. It will also demonstrate multiple advanced technologies required for fusion energy and inform the design of the company's first commercial fusion power pilot plant, which will demonstrate the capability to deliver net electricity to the grid.