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News We're Watching: UK Plans Digital Health Guidance, FDA Warns Against Getinge/Marquet Cardiac Devices

by Natasha Barrow

This week, MHRA and NICE released results from their first survey of potential digital health tool users; the FDA warned against using Getinge/Marquet cardiac devices; and Illumina announced plans to hand its Grail spin-off to existing shareholders.

UK To Establish Regulatory Guidance On Digital Mental Health Technologies

British health care regulators MHRA and NICE have initiated a three-year project to develop guidance for developers, healthcare professionals, and patients to clarify regulatory and evaluation requirements for Digital Mental Health Technology (DMHTs) in 2023.The project is being funded by the Wellcome Trust.

On 7 May, the project's first work package concluded, in which potential users of DMHTs were surveyed. Woodnewton, the UK-based research firm contracted to produce the report, queried users on their attitudes and perceptions of DMHT and their views on how these services should be regulated.

Following this, the project's future work packages will explore the classification of DHMTs, whether DHMTs will be considered Software as a Medical Device, and the clinical evidence and post-market surveillance requirements necessary.

From the first work package, individuals agreed on the potential benefits of DMHT but thought apps should be used as additional support, not to replace professional help, and included in a wider treatment package of therapy sessions and medication.

Participants said that DMHTs should have a clear pathway for individuals who need immediate

health care. They also suggested apps could be used as a temporary substitute while waiting for diagnosis or treatment.

In general, participants were in favor of DHMT regulation; however, they did not want it to restrict access. Participants agreed data security and interactions with mental health professionals should be fully regulated.

Concerns were raised over DMHTs providing misleading information or diagnosis, particularly to children or vulnerable people. Some participants supported the idea that DHMTs should be required to show effectiveness in a similar model to clinical trials for medicines.

Participants commented that the main barrier to DMHT use was the app cost and that the apps should be free if prescribed by the NHS.

Find Alternatives To Getinge Heart Devices, FDA Says

The US Food and Drug Administration is advising health care providers to stop using various cardiovascular devices from Getinge/Maquet and start seeking alternatives.

In a recent *letter* to providers, the agency says it has continued concerns over the company's failure to "sufficiently address" the problems and risks linked to certain heart devices that have been recalled going back to January 2023.

Specifically, the letters references issues with the Getinge/Maquet/Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pump (IABP) devices — a cardiac assist device placed in the artery that is in the chest and abdomen; and the Getinge/Maquet Cardiohelp system and HLS Sets — a cardiopulmonary bypass device that pumps blood out of the patient to oxygenate the blood during cardiopulmonary bypass surgeries.

As the agency notes, the company initiated 12 recalls of the Cardiosave IABP between January 2023 and 11 April. Of these recalls, the FDA classified eight as class I, the most serious type.

Some of these include a recall of the IABPs in March 2023 for a potentially faulty cable connection. (Also see "*Another Class I Recall For Datascope's Aortic Balloon Pumps*" - Medtech Insight, 20 Mar, 2023.)

Another IABP recall, in April 2023, was due to a communication loss between the circuit board and video generator. (Also see "*Total Recall: Datascope/Getinge Gets Another Class I Recall For Its Aortic Balloon Pumps*" - Medtech Insight, 5 Apr, 2023.)

And in August 2023, the company recalled more IABPS after reports they might shut down unexpectedly due to failures in the printed circuit board assembly in the charging path. (Also see "*Recalls For Datascope And Abiomed Designated Class I*" - Medtech Insight, 18 Aug, 2023.)

Further, in the last 12 months, the FDA says it has received 2,964 medical device reports (MDR) related to these devices, — of which 15 resulted in serious injury or death.

In addition, the says it has been evaluating and monitoring MDRs that describe Cardiosave IABP devices shutting down as far back as 2017; and references other concerns associated with the device, such as blood entering the device, which can cause rupture as well as expose the patient or health care provider being exposed to patient blood.

Regarding the Cardiohelp system and HLS Sets, the letter references eight recalls during the same timeframe, of which the FDA designated one as a class I recall.

The FDA also issued a safety alert in March 2023 over sterility concerns concerning a disposable component of the Cardiohelp system. (Also see "*News We're Watching: Renal Denervation Trial Highlights, TAP Pilot Update, Cardiohelp Safety Alert*" - Medtech Insight, 3 Mar, 2023.)

In the last 12 months, the FDA received 246 MDRs related to the Cardiohelp system, including the HLS Set. Of those, 33 were reported as resulting in serious injury or death.

The FDA notes, however, that as with the Cardiosave IABP, “it may be difficult to confirm a direct cause and effect between an adverse event report and a specific medical device based on the limited information provided in the reports.”

Nevertheless, the FDA recommends transitioning from these devices to alternatives, although the agency recognizes other treatment options are limited.

For that reason, the letter provides several recommendations for providers still using the Getinge devices in question.

Illumina Gifts Grail To Shareholders

Genetic testing firm Illumina will hand control of its Grail spin-off to Illumina’s shareholders after failing to find a buyer, the company said in a *6 May filing* with the US Securities and Exchange Commission.

Illumina paid $8bn for the liquid biopsy firm in 2020, but was swiftly instructed to divest Grail by US and European antitrust regulators. After a legal battle, Illumina announced plans to sell Grail

in December 2023. The EU also mandated that Illumina provide $1bn in funding to Grail as part of any divestment deal. (Also see "*News We're Watching: Apple/Masimo Patent Fight Update; Acutus Winds Down; Illumina Bails On Grail*" - Medtech Insight, 18 Dec, 2023.)

The company has eliminated about 340 jobs in the last two years as part of cost-cutting efforts spurred by the divestment. (Also see "*News We're Watching: Layoffs At Illumina, Canary's Heart Sensor; SCS To Help Amputees; Samsung's Apnea Monitor*" - Medtech Insight, 12 Feb, 2024.)

Under the terms of the new SEC filing, Illumina will distribute 84.5% of Grail stock to Illumina shareholders, with larger investors receiving more shares. (Illumina will retain the remaining 14.5%) The distribution is intended to be tax-free for investors. Once it is complete, Grail shares will trade on the Nasdaq stock market under the symbol GRAL.

Alex Dickinson, a life sciences company board member and former Illumina senior vice president, noted on *LinkedIn* that this is almost the same model investor Carl Icahn suggested a year ago to prior management. However, Dickinson writes, Icahn wanted Illumina shareholders to agree to buy Grail stock, rather than being forced to give it away.

FDA Lists Seven Tips For Safety Recharging Medical Device Batteries

The US FDA is offering consumers *seven safety tips* for charging batteries the power an array of medical devices. While devices with rechargeable batteries meet important medical needs, if not charged properly they can overheat, resulting in fires, minor injuries, as well as serious burns.

The agency's tips are for devices that use USB ports for battery recharging, such as hearing aids, glucose monitors, insulin pumps, and a variety of other devices, including those used in the home.

When recharging batteries, the agency says consumers should, among other safety measures, follow the manufacturer's instructions, only use accessories provided by the manufacturer, inspect the device and accessories for damage, and always recharge batteries in view and away from potential fire hazards, such as curtains and pillows.

Battery issues with devices are not uncommon, and often lead to recalls, such as Abbott recalling millions of its glucose monitoring devices last year due to overheating when not properly used with the appropriate USB cable and power adapter. (Also see "*News We're Watching: Abbott FreeStyle Libre Recall, Medtronic Partners With DaVita, Free SBOM Software*" - Medtech Insight, 7 Apr, 2023.)

And in 2022, Insulet recalled its Omnipod DASH personal diabetes manager over potential fire

hazards related to battery issues. (Also see "*Battery Issues Result In Recall Of Insulet's Omnipod DASH Diabetes Manager*" - Medtech Insight, 18 Oct, 2022.)