## Approval of the first digitally trackable pill likely to drive further innovation

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## GlobalData»

Abilify's groundbreaking trackable drug MyCite is likely to spark a surge in the development of digital pills, reports GlobalData, a leading data and analytics company.

MyCite is the first FDA-approved drug with a digital ingestion tracking system, essentially a drug-device combination of Otsuka's antipsychotic Abilify (aripiprazole) embedded with California-based digital medicine company Proteus's ingestible sensor.

Maura Musciacco, <u>Healthcare Analyst at GlobalData</u>, comments: "The approval of Abilify MyCite represents a new breed of digital innovation."

The sensor is the size of a grain of sand, and is made of silicon, copper and magnesium. When ingested, the stomach acid activates a small electrical signal that is picked up by the wearable MyCite Patch, which is placed on the ribcage. This in turn sends information via Bluetooth to the smartphone MyCite App.

Musciacco notes: "The physician and up to four people chosen by the patient can monitor dosing and adherence to medication. In addition, the patch also monitors activity levels, sleeping patterns, steps taken and heart rate, so this first-of-its-kind approval bodes well for other sensor-embedded products in development. In fact, the FDA is expecting a potential raft of submissions for other digital pills."

However, there are some limitations. MyCite has only been approved to track doses in patients with schizophrenia, manic and mixed episodes of bipolar I, and depression, and has not yet been shown to improve compliance – although this is likely to be demonstrated once it reaches the market. Additionally, the pill may not be adequate for all patients with these conditions, as they often present symptoms of paranoia and delusions, so a digital pill to monitor their compliance and behavior might be met with resistance by some.

Musciacco concludes: "Despite these hurdles, we have clearly entered a new era in healthcare. With the future influx of digital pills and even more healthcare-related technology,

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the proliferation of health analytics and wider access to real-world data will have a major impact on the pharma industry."