FDA Releases Important Information Focused on Digital Health

Brisbane, Australia and Carlsbad, Calif., August 9, 2016 - ImpediMed Limited (ASX: IPD), a global provider of medical technology to measure, monitor and manage fluid status and body composition, today announced that the U.S. Food and Drug Administration (FDA) has issued new guidance surrounding digital health.

“These guidance documents could significantly impact those companies already in, or about to enter, the digital health space,” said Richard Carreon, Managing Director and CEO of ImpediMed.

The new FDA draft guidance, “Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices,” allows manufacturers of medical devices to use Real-World Evidence (RWE) to support their application for submission to the FDA for clearance and/or approval. RWE refers to evidence of a product’s performance and outcomes in settings outside of clinical trials, such as in hospitals, doctors’ offices and patients’ homes.

The new draft guidance can be accessed on the FDA website:
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM513027.pdf

In addition, the FDA released their guidance document, “General Wellness: Policy for Low Risk Devices.” The policy states that the agency does not intend to examine low risk, general wellness products. General wellness products include devices and software which monitor health information. Devices and apps marketed to promote healthy behaviors have also been exempted by the FDA. The FDA will continue to regulate devices and apps that make disease-specific claims.

The policy can be accessed on the FDA website:
http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429674.pdf

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About ImpediMed
Founded and headquartered in Brisbane, Australia with U.S. offices in Carlsbad, Calif. and Bloomington, Minn., ImpediMed is the world leader in the development and distribution of medical devices employing bioimpedance spectroscopy (BIS) technologies for use in the non-invasive clinical assessment and monitoring of fluid status in patients. ImpediMed has the first medical device with FDA clearance in the U.S. to aid healthcare professionals to clinically assess secondary unilateral lymphoedema of the arm and leg in women and the leg in men. For additional information, visit www.impedimed.com.

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