**ASX ANNOUNCEMENT** **27 February 2020**

# New FDA recommendations for Fetal and Maternal monitors during Covid-19

- **The US Food and Drug Administration (FDA) released updated guidance for the use of Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring during COVID-19 which encompasses HMD's fetal heart rate monitor, HeraBEAT.**
- **According to the FDA enforcement policy, lay users (e.g., patient, or caregiver) could now be instructed to use Fetal dopplers in a home setting under the direction of a health care provider via prescription.**
- **Only devices under specific codes which previously received FDA clearance for professional use are included under the new guidelines.**
- **The HeraBEAT device received FDA 510(k) clearance for prescription use by medical professionals on the 18th November 2019 (K191110), and can now expand its cleared indications for use to allow the device to be used by a lay user in a home setting under the direction of a health care provider, without a prior 510k submission.**
- **'FDA believes the policy set forth in this guidance will help address these urgent public health concerns by helping to expand the availability and capability of non-invasive fetal and maternal monitoring devices. Modified use of these devices may increase access to important prenatal data without the need for in-clinic visits and facilitate patient management by health care providers while reducing the need for in-office or in-hospital services during the COVID-19 public health emergency. Increased utilization of non-invasive fetal and maternal monitoring devices may ease burdens on hospitals and other healthcare facilities and reduce the risk of exposure for patients and health care providers to SARS-CoV-2. '**
- **Release of FDA new guidance expands HMD capabilities and allows the sales of the HeraBEAT device in the US for home use by the pregnant woman, following the launch of its US market entry strategy.**
- **HMD is poised to deliver material operational progress and expedite commercial deployment during the COVID-19 period and beyond.**

**HeraMED Limited (ASX:HMD)** ("HeraMED" or the "Company"), a medical technology company leading the digital transformation of maternity care with its proprietary in-home maternity care platform, is pleased to announce that the US Food and Drug Administration ("**FDA**") has issued guidance notes and correct usage recommendations for **Non-Invasive Fetal and Maternal Monitoring Devices** during COVID-19 which encompasses HMD's fetal heart rate monitor, **HeraBEAT US**.

The FDA guidance notes have been released to assist and improve the care of expectant mothers during COVID-19 where only remote and telehealth appointments are available, unless an emergency.

The FDA recommendations titled ***'Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency'*** further elaborates that 'In the context of the COVID-19 public health emergency, expanding the capability of currently marketed non-invasive fetal and maternal monitoring devices may help facilitate patient care while reducing patient and healthcare provider contact and risk of exposure to SARS-CoV-2 by helping expand the availability of these devices to patients who require fetal and/or maternal monitoring for conditions unrelated to COVID-19 so they can be monitored outside of health care facilities'.

This represents a significant step forward for the pregnancy telehealth solutions and enables HMD to expedite the discussions and negotiation with potential distribution and clinical partners while creating a unique opportunity which strengthens the company's technological and commercial positioning.

Release of the new guidelines highlights the growing need of remote monitoring devices, even more specifically during the COVID-19 pandemic and potential benefits and efficiency of HMD's pioneering technology, innovative telehealth

solution and results achieved to date, and use of such technology is expected to drive macro changes within the global healthcare and telehealth sectors for the long-term benefit of patients.

HMD is in a strong position to deliver commercial progress during the COVID-19 period and beyond, and the Company will leverage all commercial progress upon the full launch of its proprietary fully integrated hybrid maternity care platform, HeraCARE later this year.

More information on the FDA recommendations and the full report can be found here:

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-fetal-and-maternal-monitoring-devices-used-support-patient

**CEO and Cofounder Mr David Groberman said:** "We are extremely excited and draw encouragement and motivation from the new approach announced by the FDA. The Coronavirus outbreak has already caused a paradigm shift in the mindset of healthcare systems worldwide causing them to adopt innovative methods to monitor patients and, in our case, pregnant women from a safe distance. The FDA's new guidance is a groundbreaking landmark in our industry, in which, the FDA, acknowledged and recognized the potential benefits of digital health and remote monitoring solutions in fetal and maternal medicine".

Pregnancy is not an illness, it is the ultimate expression of health, and unless there is a genuine medical necessity, there is no need for pregnant woman to arrive at a hospital or a clinical setting for simple, regular measurements and surveillance which might put them in danger. As long as the solutions are carefully validated and optimized for home use, are proven to be reliable, safe and accurate, and as long as it is carefully integrated into the medical continuum of care and being supervised by the healthcare provider, the benefits are clear and significant.

We see a quantum leap in digital health and remote monitoring solutions, that are materializing in front of our eyes, and HMD is one of the leaders and uniquely positioned in the forefront of this revolution.

We believe that HeraMED has a significant opportunity to further roll-out our remote monitoring and comprehensive digital health solution and satisfy the rapidly increasing US and global demand.

This announcement has been approved by the Board of HeraMED Limited.

**-ENDS-**

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**About HeraMED Limited (ASX:HMD):**

HeraMED is an innovative medical technology company leading the digital transformation of maternity care by revolutionising the pre and postnatal experience with its hybrid maternity care platform. HeraMED offers a proprietary platform that utilises hardware and software to reshape the Doctor/Patient relationship using its clinically validated in-home foetal and maternal heart rate monitor, HeraBEAT, cloud computing, artificial intelligence, big data and a digital social networking dashboard.

**About HeraCARE**

The Company's proprietary offering, HeraCARE, has been engineered to offer a fully integrated maternal health ecosystem designed to deliver better care at a lower cost, ensure expectant mothers are engaged, informed and well-supported, allow healthcare professionals to provide the highest quality care and enable early detection and prevention of potential risks.