HERA MED

ASX ANNOUNCEMENT

27 September 2024

HeraBEAT TGA REGULATORY CLASSIFICATION TO BE UPGRADED

HeraMED Limited (ASX: HMD) ("HeraMED" or the "Company"), a medical data and technology company leading the digital transformation of maternity care, wishes to provide an update with respect to the Therapeutic Goods Administration's ("TGA") position, following their two-year post market review[1], on home-use foetal dopplers which included the Company's HeraBEAT device.

Foetal dopplers are handheld devices used to detect or monitor the heartbeat of a baby during pregnancy. Traditionally these devices are used by health professionals in clinical settings, however more recently home use consumer foetal dopplers have become more widely available which don't provide any clinical supervision or training on use for the pregnant mother.

In July 2022, the TGA began a review of the benefits and risks associated with home-use consumer foetal heart monitors in the market. The purpose of this review was to determine whether the potential risk of using these devices outside of a clinical environment outweighed the potential consumer benefit.

The TGA review confirmed that the lack of specialised training to use these devices could result in false reassurance of the health of a baby[2]. As a result, the TGA made the decision to cancel all home-use foetal dopplers supplied in Australia.

As part of this decision to cancel all consumer at home foetal dopplers by the TGA, HeraBEAT is now required to reclassify to a higher class of regulatory classification with its existing Class IIa approval now also cancelled. The decision to reclassify the HeraBEAT is wholeheartedly supported by HeraMED and HeraMED is now actively working on this reclassification in consultation with the TGA. Since this review began, HeraMED has been in constant engagement with the TGA and will meet again in October to finalise the reclassification pathway for reapproval.

HeraMED CEO Anoushka Gungadin said, "We continue to maintain really strong engagement with the TGA and support their view of removing the use of consumer foetal dopplers without clinical oversight. The removal of all consumer dopplers from the market provides an exciting commercial opportunity for our proprietary HeraBEAT device and the market position that is now open to it. We will continue to work closely with the TGA to complete our regulatory process as quickly as possible. Our FDA and CE regulatory approvals for the HeraBEAT in the US and European markets remain as is."

The HeraBEAT has the ability to meet the criteria of higher classification as the device is intended to be used by trained pregnant women in a home environment as part of their clinically supervised care plan. The HeraBEAT is supplied via a relevant trained healthcare professional (HCP) who can access and interpret the results from the device's dashboard. The TGA's review of HeraBEAT's training of pregnant women and HCP was not a concern.

On completion of the reclassification, HeraBEAT will be uniquely positioned in the market and will likely be the only foetal heart rate monitor for home use available in Australia. This position in the market would provide significant commercial opportunity for HeraMED. This position would also allow further significant strategic value for HeraMED's data base as it would be the only maternity database capable of continuing to build its foetal heart rate measurements as part of its vital measurements for maternity.

[1] https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/medical-device-post-market-reviews/post-market-review-home-use-foetal-dopplers

The HeraBEAT device is proven to have the same quality, safety and accuracy as expensive hospital-based monitors with the ability to distinguish maternal from foetal heartbeat. All the data from the HeraBEAT, as part of the proprietary HeraCARE platform, is seamlessly shared, in real-time, via a medically approved, encrypted channel with the doctor or midwife for professional analysis and consultation. In any case of concern or potential risk, the professional care manager will take immediate action, and the expecting mother will receive full professional support.

The HeraBEAT is the only device globally that includes a unique combination of an Ultrasound Doppler sensor to monitor Foetal HR and an optical sensor to monitor Maternal HR - preventing any possible confusion or cross-talk.

Where a foetal doppler device is cancelled by the TGA a product recall has not been instigated. The cancellation in this context simply means home-use devices can no longer be imported or locally manufactured. This position does also include HeraBEAT until its new registration has been received. However, with the amount of HeraBEATs already within Australia, which can continue to be used and resold, is expected to meet market needs until reapproval is achieved.

HeraMED will continue to provide updates as the regulatory pathway for HeraBEAT progresses.

END

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

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About HeraBEAT

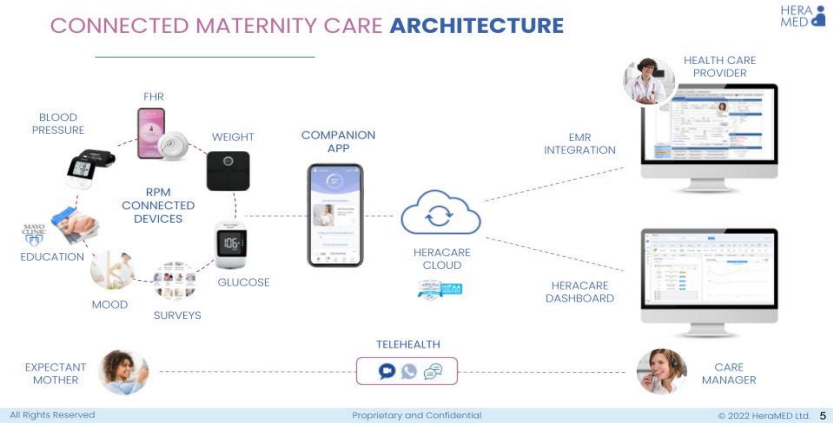
This unique device has 3 independent sensors that, together with its own proprietary algorithm, enable;

- Smart detection that automatically differentiates between fetal HR to the maternal HR
- Optical sensors capture and monitor the Maternal HR
- wide-beam Ultrasound sensor captures the Fetal HR; and
- smart algorithms prevent any option for a “cross-talk” or confusion between the two.

All data is medical-grade (CE and FDA certified) and shared with the doctor via HeraCARE.

About HeraCARE

A comprehensive Connected Maternity Care platform which is cloud-based and supported by a mobile APP enabling the pregnant mother to perform scheduled vitals measurements and the care provider to monitor synchronous or asynchronous the mother's vitals. HeraCARE is a clinical grade remote monitoring solution for healthcare providers that offer maternity services (hospitals or OB clinics). The measurements are managed by the doctor via a personalised care plan which is specific and optimised according to the needs of the individual expecting mother and her medical situation - so that the frequency and timing of each measurement are set by the professional healthcare provider.



About HeraMED Limited (ASX: HMD)

HeraMED is an innovative medical data and technology company leading the digital transformation of maternity care by revolutionising the prenatal and postpartum 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, and big data. 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.