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Regulatory Submissions Lodged as Felix™ Commercial Momentum Builds Across Australia, India and the United Kingdom

Highlights

- **Australian TGA submission lodged for Felix™ System, with approval expected by April, 2026**
- **Indian CDSCO submission lodged, with regulatory outcome anticipated in approximately six months**
- **Submissions delivered as previously guided, following receipt of CE Mark approval**
- **Regulatory approvals represent the final step toward full commercialisation in Australia and India**
- **Company progressing steps required to enable immediate commercial sales of Felix™ in the United Kingdom under CE Mark during the UK transition period**

Memphasys Limited (ASX: MEM) ("Memphasys" or "the Company") is pleased to confirm it has formally lodged regulatory submissions for the Felix™ System with both the Australian Therapeutic Goods Administration (TGA) and India's Central Drugs Standard Control Organisation (CDSCO).

These submissions follow the Company's successful CE Mark approval for Felix™[1] and were undertaken in line with guidance previously provided to the market, which outlined that Australian and Indian regulatory pathways would be progressed immediately upon receipt of CE Mark certification.

Regulatory Pathways and Expected Timeframes

- **Australia (TGA)**

Memphasys has lodged its submission seeking inclusion of the Felix™ System on the Australian Register of Therapeutic Goods (ARTG). Based on regulatory advice and CE Mark conformity, the Company expects the TGA approval by April 2026.

- **India (CDSCO)**

The Company has also lodged its submission with the CDSCO, progressing approval in one of the world's fastest-growing IVF markets. The CDSCO review process is expected to take approximately six months from submission.

Both regulatory pathways leverage the clinical data, manufacturing standards and quality systems underpinning CE Mark approval and represent the final regulatory steps required to unlock commercial execution in these jurisdictions.

[1] Refer ASX announcement dated 29 December 2025

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- **United Kingdom - Immediate Commercial Sales Pathway Under CE Mark**

Memphasys is also progressing the requirements necessary to enable immediate commercial sales of the Felix™ System in the United Kingdom under the current UK transition framework, without the need for a UKCA mark at this time.

To sell medical devices in the UK during the transition period, the following requirements must be met:

- a valid CE Mark under EU MDR or IVDR (as applicable),
- appointment of a UK Responsible Person (UKRP),
- completion of MHRA device registration, and
- UK-compliant labelling, including UKRP details.

No UKCA mark is required during the current transition period.

The Company is actively progressing these steps to allow Felix™ to be marketed and sold immediately into the UK IVF market following completion of the MHRA registration and associated administrative requirements.

Market Opportunity – Australia, India and United Kingdom

Australia

In 2023 there were approximately 103,556 assisted reproductive technology (ART) treatment and lab-only cycles performed (including more than 60,000 fresh cycles where Felix™ has the potential to be used)[2]. Australia represents an attractive near-term market for Felix™, combining advanced clinical standards, high technology adoption and strong reimbursement frameworks. TGA approval is expected to accelerate activation of pending contracts with key Australian stakeholders.

India

India represents one of the largest global ART growth opportunities, with approximately 300,000 IVF cycles performed annually and forecast to grow to 500,000–600,000 cycles in coming years. With male-factor infertility contributing to around half of all cases and ICSI penetration exceeding 70%, Felix™ is well positioned to support increased laboratory efficiency and throughput across India's expanding clinic networks.[3] [4]

United Kingdom

The United Kingdom represents one of Europe's largest and most established assisted reproductive technology (ART) markets, with approximately 75,000–80,000 IVF treatment cycles performed annually, supported by a highly regulated clinical environment and broad adoption of advanced laboratory technologies.[5]

[2] https://www.unsw.edu.au/content/dam/pdfs/medicine-health/npesu/research-reports/2025-09-anzard/2025-09-Assisted-Reproductive-Technology-in-Australia-and-New-Zealand-2023.pdf
[3] https://www.imarcgroup.com/india-in-vitro-fertilization-market?
[4] https://www.fertilitybridge.com/inside-reproductive-health/177-ivf-center-growth-india-vinesh-ghadia?
[5] https://www.hfea.gov.uk/about-us/media-centre/key-facts-and-statistics

Male-factor infertility is a significant contributor to treatment demand, and the UK IVF market has seen increasing utilisation of ICSI procedures, creating a strong addressable use case for the Felix™ System within embryology laboratories.

The UK market is characterised by a combination of National Health Service (NHS) funded treatment and a substantial private clinic network, with private providers accounting for a material proportion of total IVF cycles. This structure supports both initial console placement and recurring consumables revenue models.

With CE Mark approval secured and the Company progressing MHRA registration, appointment of a UK Responsible Person (UKRP) and UK-compliant labelling, Memphasys believes the UK represents an attractive near-term commercial opportunity for Felix™, allowing immediate market entry during the current UK transition period without the requirement for a UKCA mark.

Structured Supply Agreement Positioned for Activation

Memphasys has executed a non-exclusive supply agreement with Andrology Center group company Andro Diagnostics, Coimbatore, under its go-direct commercial strategy[6].

The agreement includes:

- a minimum Year 1 commitment of 1,800 Felix™ cartridges, increasing to at least 2,700 cartridges in Year 2,
- a quarterly delivery cadence post-approval, and
- deployment across a network of more than 200 partner IVF clinics.

Activation of this agreement is contingent on CDSCO approval, which has now been formally progressed.

What This Means for Commercialisation

With CE Mark approval secured and regulatory submissions now lodged, Memphasys is positioned to transition Felix™ into full commercial deployment across multiple large, regulated markets.

Regulatory clearance in Australia and India, together with completion of UK market entry requirements, would enable:

- activation of existing and pending commercial arrangements,
- direct clinic-level sales of Felix™ cartridges,
- expansion of the installed console base, and
- establishment of scalable, recurring cartridge revenue streams.

In India, the Company has a formal commercial supply agreement in place, which is structured for activation upon receipt of CDSCO approval.

In Australia, Memphasys is in advanced commercial negotiations with multiple parties, with discussions focused on distribution structures, console placement and cartridge supply arrangements. These negotiations are intended to enable rapid commercial activation following anticipated TGA approval.

In the United Kingdom, Memphasys is actively engaging with prospective commercial partners and IVF clinics, with discussions progressing regarding distribution, console placement and cartridge supply

[6] Refer ASX announcement dated 28 October 2025

arrangements. While no formal UK commercial agreements have yet been executed, these conversations are intended to ensure the Company is well positioned to commence commercial activity promptly following completion of MHRA registration and related UK entry requirements.

The Company continues to progress its commercial readiness strategy to ensure clinics across each target jurisdiction are operationally prepared upon regulatory clearance and market entry.

Marjan Mikel, Chair of the Commercialisation Committee, commented:

> *"Our go-direct commercial and regulatory strategies are working hand in glove, delivering exactly what we committed to the market. More key regulatory submissions have now been lodged, contracted demand continues to build, and these approvals are expected to further accelerate growth in Felix™ sales as execution progresses.*

Outlook

With regulatory submissions lodged, commercial readiness progressing and market entry pathways advancing across multiple jurisdictions, Memphasys believes Felix™ is entering a new phase of global commercial execution.

In India, the Company is positioned to activate its existing formal supply agreement upon receipt of CDSCO approval, providing a clear pathway to initial cartridge revenues.

In Australia, advanced commercial negotiations are underway with multiple parties, with the Company focused on securing arrangements that enable rapid market entry following anticipated TGA approval.

In the United Kingdom, Memphasys is progressing MHRA registration, appointment of a UK Responsible Person and UK-compliant labelling, while concurrently engaging with prospective commercial partners to support timely commencement of sales under the current CE Mark transition framework.

The Company will continue to update shareholders as regulatory reviews progress and as further commercial agreements and approvals are secured.

Authorised by the Board of Memphasys Limited.

Ends

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About Memphasys

Memphasys Limited (ASX: MEM) is an Australian-based reproductive biotechnology company commercialising the Felix™ System, a patented bio separation technology that isolates the most viable sperm cells for human assisted reproduction.

By combining electrophoresis and size-exclusion membranes, Felix™ delivers a fast, gentle and standardised sperm selection process that enhances sperm quality and reduces laboratory time. The system replaces traditional centrifugation, which can cause cellular stress and DNA damage, offering clinicians a superior, repeatable alternative.

Memphasys' commercial strategy focuses on building contracted sales through direct and distribution-led channels, scaling production to improve margins, and establishing Felix™ as a new global standard in sperm preparation for ART procedures.

Website: www.memphasys.com

Forward Looking Statements

Certain statements made in this announcement are forward-looking statements. These forward-looking statements are not historical facts but rather are based on Memphasys's current expectations, estimates and projections about the industry in which Memphasys operates, and its beliefs and assumptions. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," "guidance" and similar expressions are intended to identify forward looking statements and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the endeavour of building a business around such products and services. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties, and other factors, some of which are beyond the control of Memphasys, are difficult to predict and could cause actual results to differ materially from those expressed or forecasted in the forward-looking statements. Memphasys cautions shareholders and prospective shareholders not to place undue reliance on these forward-looking statements, which reflect the view of Memphasys only as of the date of this release. The forward-looking statements made in this announcement relate only to events as of the date on which the statements are made. Memphasys will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.