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NZX/ASX Announcement

16 November 2026

TruScreen Receives Product Registration in Kenya

Highlights

- TruScreen Ultra® has received product registration in Kenya from the Ministry of Health Pharmacy and Poisons Board, clearing the way for sales into Kenya's public and private health sectors.
- Cervical cancer is the leading cause of cancer death among Kenyan women, with circa 6,000 new cases and 4,000 deaths each year.[1]
- Only 6% of Kenyan women aged 30–49 have been screened with a high-performance test, against the WHO and national target of 70% screening by 2030.[2]
- Kenya is a market of more than 17 million women of screening age[3] and, as an English-speaking former British territory, offers a familiar regulatory, clinical and commercial environment.
- Ansell Pharmaceuticals Limited is TruScreen's distributor for Kenya, Somalia and South Sudan, and supports grant-funded screening programs currently under consideration across eight African nations, including Kenya.

TruScreen Group Limited (NZX/ASX: TRU) ("TruScreen" or "the Company"), a global leader in AI-enabled cervical cancer screening, is pleased to announce that its TruScreen Ultra® device has received product registration in the Republic of Kenya.

Kenya: a priority market for cervical cancer screening

Kenya has a population of 57.5 million,[4] with 17 million women of screening age.[3] It is East Africa's largest economy and a regional hub for quality health care and NGO-funded public health programs.

Cervical cancer is the leading cause of cancer-related death among Kenyan women. The Ministry of Health reports circa 6,000 new cases and 4,000 deaths each year (GLOBOCAN 2022),[1] the equivalent of around 10 women dying every day from a preventable disease.

Screening coverage is very low. Kenya's National Cervical Cancer Elimination Action Plan (NCCEAP) 2025–2030 sets a 2025 baseline of just 6% of women aged 30–49 screened with a high-performance test.[2] The Plan commits Kenya to the WHO 90-70-90 targets by 2030: 90% HPV vaccination, 70% screening coverage and 90% treatment of precancer and invasive cancer.[2]

Increasing screening coverage from 6% to 70% by 2030 will require screening at scale, at the point of care nationally. TruScreen Ultra® provides a real-time instant result at point of care, without the need for

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laboratory or specialist pathology infrastructure, supporting screening in rural and community health clinics.

An English-speaking market with strong links to Australia

As a former British territory, independent since 1963 and a member of the Commonwealth, Kenya has English as an official language alongside Kiswahili. English is the language of government, regulation, medical training and clinical practice.

This heritage shortens TruScreen's path to market. Clinical, training and regulatory materials can be used without translation, and Kenya's health system shares common foundations with TruScreen's established English-speaking markets.

TruScreen's profile in Kenya is building. On 11 September 2026, TruScreen delivered the keynote address at the inaugural Kenya-Australia Trade and Investment Summit in Sydney, attended by His Excellency Ambassador Dr Wilson Kogo, Kenya High Commissioner to Australia, and a Kenyan parliamentary delegation, that included Ministry of Health officials.

Ansell Pharmaceuticals Limited is TruScreen's distributor for Kenya, Somalia and South Sudan. Ansell is an experienced supplier of pharmaceuticals and medical devices for NGO-funded public health programs in East Africa. Ansell also facilitated programs for WHO and the UN.

Next steps

Product training for the Ansell team will commence shortly, with product launch for public and private healthcare providers and engagement with key opinion leaders (KOL's) planned for early 2027.

The Company was assisted by Sydney based Vitti Capital Pty Limited with its market access to Kenya.

African expansion

Kenya is the latest step in TruScreen's African strategy, which targets public screening programs in eight nations – Zimbabwe, South Africa, Eswatini, Rwanda, Nigeria, Ghana, Côte d'Ivoire and Kenya – a screening market of up to 132 million women of screening age.[3]

Current developments include:

- **Kenya:** Product registration received; Ansell Pharmaceuticals appointed distributor, also covering Somalia and South Sudan.
- **Zimbabwe:** A screening program for 10,800 women across 16 public hospitals in Masvingo Province is expected to commence shortly
- **Rwanda:** Product registration in place and a pilot clinical trial was completed at three government hospitals; Biotech Medical Supply, TruScreen's appointed distributor is in discussions with MoH, Rwanda Biomedical Centre (RBC), and CHAI on including TruScreen in their screening programs.
- **Nigeria, Ghana and Côte d'Ivoire:** Zerocancer Professional Consult appointed distributor. Preparations are underway for Nigerian registration and a 300-patient clinical evaluation.
- **Sub-Saharan Africa:** Clinton Health Access Initiative and UNITAID grant applications remain under consideration.

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TruScreen continues to collaborate with global and local partners including PATH, the National AIDS Council (Zimbabwe), Baylor College of Medicine Children's Foundation (Eswatini) and Lagos State University Teaching Hospital (Nigeria).

Commenting on the registration, Executive Chairman Tony Ho said:

"*Kenya is one of Africa's most important markets for cervical cancer prevention. It is the leading cause of cancer related deaths for Kenyan women, yet only around 6% of women aged 30-49 have been screened. Product registration allows TruScreen to work with Ansell and our NGO partners to help the Kenyan Government to reach its 70% screening target by 2030. As an English-speaking country with links to Australia, Kenya is a natural fit for TruScreen and an important market for our expansion in East Africa.*"

This announcement has been approved by the Board.

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[1] Ministry of Health Kenya, citing GLOBOCAN 2022 estimates, cervical cancer awareness media briefing, Nairobi, 24 January 2025.
[2] Ministry of Health Kenya, National Cervical Cancer Elimination Action Plan (NCCEAP) 2025–2030, policy brief, January 2026.
[3] Female population ages 15–64, World Population Prospects, United Nations Population Division, World Bank
[4] UNFPA World Population Dashboard, 2025, based on UN World Population Prospects 2024.

For more information, visit www.truscreen.com or contact:

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About TruScreen

TruScreen Group Limited (NZX/ASX: TRU) is a listed company in New Zealand and Australia with a real-time, AI-enabled cervical cancer screening technology designed to detect pre-cancerous and cancerous changes of the cervix. The TruScreen device is registered for use in multiple markets and has been used to screen more than 1,200,000 women worldwide.

TruScreen's technology is designed to support cervical cancer screening in settings where access to laboratory infrastructure and specialist pathology services may be limited, making it well suited to emerging markets and public screening initiatives.