Ugandan firm advances to US market with bone drug

By Vision Reporter

Local pharmaceutical company DEI Biopharma has secured a patent to manufacture a drug for osteoporosis treatment.

Osteoporosis is a disease that weakens bones, making them porous and prone to fractures, often without symptoms, until a break occurs. The condition commonly affects the hip, spine or wrist due to bone mass loss beyond normal ageing.

The US Food and Drug Administration (FDA) has accepted DEI Biopharma's Abbreviated New Drug Application (ANDA) for teriparatide injection within three days of submission. In a statement, the company said the swift response signals confidence in its regulatory preparedness and the quality of its filing.

Dr Magola of DEI Biopharma

ACCESS OF GLOBAL MARKETS

The application positions DEI Biopharma to enter the US market for teriparatide, a treatment widely used for osteoporosis. The company says it is now accelerating plans for commercial rollout, supply chain readiness and market access strategies to ensure affordability and broad patient availability.

"This level of FDA responsiveness is exceptional and reflects the scientific rigour, completeness and clarity of our submission," Dr Matthias Magoola, the chief executive officer of DEI Biopharma, said.

"It validates our platform approach to complex injectable generics and positions DEI to move decisively toward US market entry for teriparatide."

Access to teriparatide in Africa remains limited due to high costs and regulatory hurdles. DEI Biopharma says FDA acceptance of its application will help dismantle the barriers and improve availability across the continent.

WHAT OTHERS SAY

Science minister Monica Musenero, said the Government has positioned the pharmaceutical industry as one of the new strategic economies.

"We are, therefore, very excited by this development. Government is supporting the industry from end to end and right from ideas, through research up to manufacturing and marketing. Our weakest point was the manufacturing capacity which meets the strict global standards," she told *New Vision when* contacted.

The science minister, Dr Monica Musenero, said steoporosis affects over 200 million people worldwide.

The minister said the Government's partnership with Dei Biopharma has, therefore, been to intentionally build manufacturing and position it not only to meet local and regional drug needs, but also the global market.

"Therefore, the company strategically works at global levels of accreditation. FDA approval is extremely important because it enables Ugandan manufactured drugs to access global markets. This is Uganda's strategic positioning – to contribute to the global health agenda," she said.

"For example, osteoporosis affects over 200 million people globally. Many of them cannot currently access these effective drugs either because they are too expensive or not available in our countries. Uganda's entry will mean that many can access this life-saving drug affordably," she added.

Dr Sarah Nambasa, a Kampala-based clinical pharmacologist, described the development as "a game-changer for osteoporosis management in Africa". She said teriparatide is often inaccessible in Uganda due to high prices.

"If DEI can leverage FDA approval to streamline supply chains and reduce prices, it will significantly improve treatment outcomes for thousands of patients," Nambasa said.

Health economist James Okello highlighted the wider implications for the region's health systems.

"This move signals that African pharmaceutical companies can compete globally in complex generics," he said.