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Futura's Drug-Free Erectile Dysfunction Gel On Track For US And EU Launch

by David Ridley

Futura Medical's latest meeting with the FDA puts the UK start-up one step closer to launching its drug-free erectile dysfunction gel MED3000 in the US in 2023, while the firm gets ready to launch in the EU next year following its recent CE-mark approval.

UK-based Futura Medical is moving ever closer to OTC approval in the US for its drug-free erectile dysfunction (ED) treatment MED3000.

Futura recently met with the US Food and Drug Administration for a pre-submission meeting to define and confirm the detail of the work required for OTC classification for MED3000 – a gel that works via a mixture of volatile and non-volatile ingredients applied directly to the tip of the penis.

At the meeting, the FDA agreed – subject to the issue of the final meeting minutes – to the design of a non-clinical "Human Factors Study," which will "test the ability of subjects to self-diagnose their ED, correctly select the product based on label information and test their ability to correctly use the product without supervision of a doctor."

Meanwhile, the company has begun the "comprehensive planning and preparation activities, including active site selection" for the commencement of a clinical study – "FM71" – that was deemed necessary by the FDA at a previous meeting. (Also see "*Futura's Revolutionary ED Treatment One Step Closer To US And EU OTC Approval*" - HBW Insight, 27 Jul, 2020.)

The first patient dosing is expected during the third quarter, Futura said, with the completion of both FM71 and the Human Factors study for Q2 2022.

This put the firm "on track" for US OTC marketing authorisation in Q1 2023, the firm revealed.

“We are pleased that the requirements to enable an OTC application for MED3000 have been clarified with the FDA,” commented Futura CEO James Barder. “The US remains the largest market opportunity globally for ED treatments and we are making steady progress on attaining approval for MED3000 in the region.”

EU Launch In 2022

In Europe, where MED3000 earlier this year gained a CE Mark under the EU Medical Devices Regulation (2017/745) as a Class II(b) medical device, Futura is now getting reading for launch. (Also see "*Futura Gains EU CE Mark For Drug-Free OTC Erectile Dysfunction Treatment*" - HBW Insight, 6 May, 2021.)

“Manufacturing scale up and capacity to meet projected demand is progressing well in conjunction with commercial out-licensing agreements covering the remaining major regions and countries of the world with a number of interested parties,” the company noted.

Futura said it expects to be able to update shareholders further during the remainder of 2021 as it looks to target the launch of MED3000 during 2022.

European approval also paves the way for approval in many countries around the world, including in the Middle East, Africa, the Far East and Latin America, which allow fast-track review based on recognition of an EU CE mark, the firm pointed out.

“MED3000 is a highly differentiated product, with a rapid speed of onset addressing significant unmet needs, across all patient severities in the $5.6bn global ED market,” Barder said. “We look forward to further MED3000 marketing approvals in the coming years in multiple regions across the world, including Asia.”