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# Haleon Enters US OTC Erectile Dysfunction Race With Futura Deal

by [David Ridley](#)

Haleon steps into the US OTC erectile dysfunction market with a commercialization deal for Futura's drug-free MED3000 gel, recently approved by the FDA as a de novo medical device.

[Haleon plc](#) has made the first move into the US's new OTC erectile dysfunction (ED) category with a multimillion-dollar deal for [Futura Medical plc](#)'s non-prescription MED3000 gel.

Paying initially \$4m to commercialize Futura's topical treatment – which was recently approved by the US Food and Drug Administration as an OTC medical device – Haleon will be responsible for all investment and activities related to the launch and marketing of the product in the country, according to the terms of the deal. (Also see "[ED Indication Reaches US OTC Market With FDA Approval Of UK Firm Futura's Eroxon Gel](#)" - HBW Insight, 20 Jun, 2023.)

Futura in return will provide ongoing technical support for development and commercialization opportunities for MED3000, it says, which was recently launched in the UK and Belgium by Cooper Consumer Health under the brand name Eroxon. (Also see "[Futura's Eroxon OTC Erectile Dysfunction Gel Gets UK Launch](#)" - HBW Insight, 20 Apr, 2023.)

“As a company focused on consumer health, we are always looking for opportunities to provide self-care solutions that increase access to better everyday health,” a Haleon representative told HBW Insight. “It is early in the life cycle of this opportunity, and we will share more in the future.”

## Pipped To The Post?

With the deal, which will also see Haleon pay Futura royalty payments on all sales of MED3000, as well as potential commercial and performance-driven sales milestone payments totaling between \$5m and \$45m over the course of several years, Haleon has jumped ahead of competitor

[Sanofi US](#) in the race to offer the country's first OTC ED treatment.

Sanofi is currently working to switch from Rx-to-OTC status its Cialis-branded tadalafil ED treatment, most recently having an actual use trial for its application "placed on clinical hold due to matters surrounding the protocol design" by the FDA. (Also see "[Sanofi Feeling Positive On Cialis Switch Progression As Q2 Sales Rise](#)" - HBW Insight, 29 Jul, 2022.)

While numerous non-prescription topical formulations and dietary supplements are marketed online in the US as ED treatments, Cialis – which was recently switched and launched in the UK as Cialis Together – would, if switched, be the country's first non-prescription drug for the condition. (Also see "[UK Cialis Rx-To-OTC Switch World-First For Sanofi, H2 2023 Launch Planned](#)" - HBW Insight, 14 Mar, 2023.)

However, Futura's "drug-free" alternative is not only already approved as a non-prescription medical device, via the FDA's De Novo pathway, but also claims to deliver a more rapid onset of action than tadalafil, according to a confirmatory Phase III clinical study.

Investigating the efficacy and safety of MED3000 gel in 96 male patients clinically diagnosed with a mix of mild, moderate, and severe ED, the trial found that users achieved an erection within 10 minutes, Futura claims. MED3000 also showed a more favorable side effect profile compared to tadalafil.

## Major Milestone

For Futura CEO James Barder, the deal represents a "major milestone" for his company.

"The US is the largest ED market in the world and we believe Haleon, with its strong capabilities in brand-building and marketing through an unrivalled breadth of channels, as well as its connections and market reach, makes it the ideal partner to introduce MED3000 to the millions of ED sufferers in the US who will soon be able to buy MED3000 in US pharmacies, without the need for a doctor's prescription," Barder commented.

Since its UK launch, Eroxon has got off to a flying start, according to Cooper Consumer Health's UK partner Ceuta Healthcare. In the first five weeks, Eroxon sold at a rate of one every 30 seconds on boots.com, said Ceuta's marketing director Jon Connolly, a level of success he said was "just unheard of." (Also see "['A Phenomenon' – Futura's Eroxon ED Gel Gets Off To Flying Start In The UK](#)" - HBW Insight, 5 Jul, 2023.)

Describing Eroxon's recent launch as a "phenomenon," Connolly said that sales have now reached around the £2m (\$2.5m) mark.