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Sanofi Hopes UK Cialis Launch Will Illustrate US Switch Potential

by Tom Gallen

Sanofi's upcoming launch of OTC Cialis in the UK "is quite important for getting a sense of what the over-the-counter opportunity could be and the appetite [in the US]," according to company CEO Paul Hudson.

Sanofi is hoping its delayed program to switch Cialis in the US can learn lessons from the upcoming OTC launch of the erectile dysfunction treatment in the UK.

The Paris, France-based firm plans to launch Cialis Together (tadalafil 10 mg) in the second half of 2023 following a successful reclassification from prescription-only to pharmacy status. (Also see "[UK Cialis Rx-To-OTC Switch World-First For Sanofi, H2 2023 Launch Planned](#)" - HBW Insight, 14 Mar, 2023.)

Sanofi's Consumer Healthcare head Julie Van Ongevalle said with the launch of Cialis Together the firm will enter the UK's intimate wellness category for the first time, offering a "new self-care solution for an estimated eight million men in the UK suffering from erection difficulties."

According to CEO Paul Hudson, "The UK launch is quite important for getting a sense of what the over-the-counter opportunity could be and the appetite [in the US]."

"I think the UK experience will be a good bellwether to what the market opportunity could be of scale to the size of the US," Hudson told Sanofi's Q1 earnings call. "So, that's good. That's exciting."

US Delay

While Sanofi has secured the UK switch, its attempt to reclassify Cialis in the US has hit a stumbling block.

Sanofi's planned actual use trial to support OTC use of Cialis was placed on clinical hold by the US Food and Drug Administration in May 2022 "due to matters surrounding the protocol design." (Also see "[Delay For Sanofi's OTC Cialis Study In US Could Be Sign of Hurdles Holding Back Other Switches](#)" - HBW Insight, 31 May, 2022.)

One year on, the company continues to work with FDA to progress its application. Van Ongevalle said on the earnings call that Sanofi is "advancing on the execution of our strategy to lift the clinical hold and including the generation of the necessary data that was requested."

"So, we're still moving," she insisted.

Sanofi's Hudson is also upbeat about the US switch despite the setbacks. "We continue to have very active and encouraging dialogue with the FDA. I mean it's been quite a journey, but we still maintain a lot of confidence in getting there."

Sanofi's struggles with Cialis is an example of the high bar for approval in the US to make available OTC drug ingredients indicated for chronic conditions. Applicants must convince FDA a consumer can safely and appropriately self-select a product without the intervention of a healthcare professional.

By contrast, the UK's pharmacy category provides an extra level of assurance to the Medicines and Healthcare products Regulatory Agency as consumers can only access newly-switched drugs following a discussion with a pharmacist.

In the case of Cialis, pharmacists will decide if the drug is appropriate for the consumer or if further consultation with a general practitioner is required.

Growing ED Market

Products for the treatment of erectile dysfunction have been available to purchase in UK pharmacies since 2018 when Pfizer's Viagra Connect (sildenafil 50mg tablets) was first reclassified as a pharmacy medicine.

Since then, generic and lower cost versions of sildenafil have entered the market from companies such as Teva and Perrigo.

A drug-free erectile dysfunction treatment was recently launched under the Eroxon brand name by Futura Medical in partnership with Cooper Consumer Health. (Also see "[Futura's Eroxon OTC Erectile Dysfunction Gel Gets UK Launch](#)" - HBW Insight, 20 Apr, 2023.)

