

09 Sep 2021 | Analysis

Room Available In US Pharma Industry For OTC Switch Leader: Has Perrigo Made A Reservation?

by [Malcolm Spicer](#)

Acquiring HRA Pharma, Perrigo could take OTC switch lead, likely starting with HRA's daily oral contraceptive before moving to numerous other potential candidates. Pharmas previously busy in switch have other priorities for their consumer health businesses.

The US pharma industry has a vacancy for an OTC switch leader as longtime sponsors of applications to make additional ingredients available nonprescription prioritize reorganizing their consumer health businesses over expanding their product portfolios.

By acquiring HRA Pharma, [Perrigo Company PLC](#) could fill the space in the pharma industry. Its switch proposals likely will start with HRA's daily oral contraceptive before moving to numerous other potential candidates.

"There aren't a lot of switch powerhouses out there. I think there's an opportunity for a new player to emerge as a switch powerhouse, given the changing market dynamics," says pharma industry consultant Susan Levy .

"I think this alignment, HRA with Perrigo's scale, is just what the industry needs," said switch consultant Susan Lavine Coleman, president of NCI Consulting in Moorestown, NJ.

Levy and Coleman spoke with HBW Insight following Perrigo's 8 September announcement of an agreement to acquire Paris-based HRA, listed in France as Héra SAS, for €1.8bn (\$2.1bn) in a cash deal.

Perrigo's predominant revenue stream has been private label/store brand OTC drugs, although it

has added brands with its 2014 move into Europe's consumer health market and by acquiring the Prevacid 24 HR (lansoprazole/15 mg) proton pump inhibitor in 2019 and licensing the Burt's Bees brand in May to make and market a line of organic baby formulas and supplements for babies and children.

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But while it consistently is first to launch generic equivalents for brand switches, its name hasn't been linked to submitting proposals for making additional drug ingredients available OTC.

Bringing HRA, including management, under its roof changes the switch outlook for Perrigo.

"These are pros. They know what they're doing," Perrigo president and CEO Murray Kessler said about HRA's management during a briefing about the deal. "They've all agreed to stay on with Perrigo."

Slow Time For Switch NDAs

The HRA acquisition isn't the only reason Perrigo could become a top OTC switch sponsor in the US. Other pharmas are leaving the top spot open.

Looking over the current lineup of major OTC marketers in the US, Levy, founder and principal of Susan B. Levy Consulting LLC in Cranford, NJ, doesn't see any interested in sponsoring new drug applications for OTC switches.

"If you look at who has historically been a driver for OTC switches, you've got GSK, Novartis and Pfizer, but they're all one [consumer health] company now, and it's being spun out. It's kind of unclear to what extent they are positioned right now to invest in expensive growth programs,"

OTC Oral Contraceptive In US Would Bring Market Uncertainties Along With Public Health Benefits

By [Malcolm Spicer](#)

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Perrigo is the top potential marketer of the first OTC oral contraceptive in the US by acquiring HRA Pharma, which is preparing a switch NDA and earlier in 2021 gained UK

she said.

[GlaxoSmithKline plc](#) is the majority owner of a joint venture with [Pfizer Inc.](#) marketing the two firms' consumer health product lines. GSK, with products including brands it acquired after previously operating a consumer health JV with [Novartis AG](#), plans to spin out its current consumer health business. (Also see "[McNamara To Lead GSK's Standalone Consumer Healthcare Business](#)" - HBW Insight, 23 Jul, 2021.)

"Then you've got Sanofi," Levy added.

The French firm is known to be considering proposing switches for flu treatment Tamiflu (oseltamivir) and erectile dysfunction drug Cialis (tdalafil), but it too looks to separate its consumer health business. (Also see "[Sanofi To Divest 60% Of Brands In Consumer Healthcare Overhaul](#)" - HBW Insight, 10 Feb, 2021.)

"It's unclear where they want to put their bets right now as a result of being spun out independently," she said.

[Bayer AG](#) earlier in 2021 received Food and Drug Administration approval for OTC sales of Astepro Allergy (azelastine hydrochloride nasal spray, 205.5 mcg per spray). Bayer plans to launch the first-in-class switch, the first ingredient available OTC that is a first-generation H1 (histamine receptor inhibitor) antihistamine, in 2022. (Also see "[Market Exclusivity Decision Pending For Bayer's First-In-Class OTC Switch Astepro Allergy](#)" - HBW Insight, 24 Jun, 2021.)

Levy pointed out the previous OTC switch for a product the German firm markets in the US was Oxytrol for Women overactive bladder treatment, a first-in-class switch when it was approved in in 2013 when US firm [Merck & Co., Inc.](#) owned the brand. After acquiring Merck & Co.'s consumer business in 2014, Bayer relinquished OTC rights to the 3.9mg oxybutynin transdermal patch to Allergan PLC

regulatory approval for pharmacy sales of a progestin-only contraceptive, desogestrel.

[Read the full article here](#)

Perrigo Continues Overhaul Adding HRA Pharma, Boosts Chances For OTC Oral Contraceptive In US

By [Malcolm Spicer](#)

08 Sep 2021

HRA's approval for pharmacy sales of a daily oral contraceptive the UK and its ongoing work on an NDA to propose making another progestin-only contraceptive ingredient available OTC in the US stand out as additions to Perrigo's business with the most substantial revenue impacts.

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less than a year later.

J&J Large In Consumer, Not In Switch

Johnson & Johnson may be synonymous with OTC drugs due to its market-leading brands, but like Perrigo it hasn't been a switch driver.

"Who could be the powerhouses? ... J&J has not historically been a switch player. They don't have an experienced team of switch professionals," Levy said.

"It speaks to the fact that there is a gap in the marketplace because these switch programs are very expensive for an OTC company. They are somewhat risky, and they're much longer-term than typical OTC innovation. ... If you're heading up a consumer health care company and thinking about where you're going to put your R&D bets, much more incentives are there to do some of the shorter-term, easier innovation."

The FDA is encouraging firms to study making available nonprescription drug ingredients indicated for chronic conditions; in 2012 it opened a docket for recommendations on changing its OTC switch NDA rules to allow for "novel switches" targeting chronic conditions, indications more complicated than most currently available OTC drugs have.

The agency launched the initiative expecting labeling for novel switches to be subject to the same limits as other OTCs, with all necessary information available on a product's Drug Facts label. However, it has since indicated in a 2018 guidance that switch sponsors could tap into digital media and other extra-label tools to help demonstrate that consumers can assess whether an OTC drug is appropriate for them and they can use the product safely. (Also see "[Before Asking FDA For Novel OTC Switch, Be Sure DFL Alone 'Can't Get There'](#)" - HBW Insight, 23 May, 2019.)

In a recent FDA workshop conducted online, industry experts and other stakeholders said some problems with OTC DFLs are worse than others and some likely can be corrected with minor changes to the format, but other changes, notably for supporting OTC labeling for drugs that currently are available Rx-only and are indicated for chronic conditions aren't minor and won't happen within the limits of one-dimensional text media printed on nonprescription drug containers, packages and inserts. (Also see "[Progress On Adding OTC Drugs To US Market? Room To Move But Label Format Limits Options](#)" - HBW Insight, 18 Jun, 2021.)