

## Coughing and sputtering, Hikma's Advair generic comes back to life



[Jacob Plieth](#)

As of yesterday Hikma is back in business with its generic version of Glaxosmithkline's asthma and COPD drug Advair. The group said its version, formerly called VR315 and derived from a deal with Vectura, was being relaunched in the US after a long hiatus; this had involved a complete response letter back in 2017, an unsuccessful appeal, a second CRL last September, approval and launch at last in December 2020, and then a surprising halt to the rollout the following month. The halt had been prompted by Hikma changing its filing to reflect enhanced packaging controls, but apparently that amended ANDA has now been approved. Assuming no further hiccups attention will turn to how big a drug Hikma's generic could become; *Evaluate Pharma* sellside consensus forecasts 2026 revenues of \$164m, but Stifel analysts reckon capturing 20% share of a US market that in 2020 was worth \$3bn is possible within two years. At present the only other generic competitors to Glaxo's Advair, which Stifel says has 49% market share, are Viatris (31%) and Prasco (authorised generic, 20%). Teva's version is not substitutable, while [Cipla's generic was filed last May](#) but is not expected to be approved before 2022.

### Advair and its generics

Company	US status	Note	Global 2021e sales
Glaxosmithkline	Available since 2001	Original brand	\$1,745m
Teva	Airduo Respiclick approved Jan 2017	Not substitutable	\$46m
Viatris	Wixela Inhub approved Jan 2019, after Mar 2017 CRL	Substitutable	\$884m
Prasco Laboratories	Launched Feb 2019	Authorised generic	NA
Hikma/Vectura	CRL May 2017; CRL Sep 2020; approved Dec 2020; halted Jan 2021; approved Apr 2021	Substitutable	\$141m
Cipla	Filed May 2020	US approval not expected before 2022	\$56m
Sandoz (Novartis)	Discontinued after Feb 2018 CRL	Had been aiming to refile in 2019	None

Source: company releases & Evaluate Pharma.

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