Evaluate Vantage

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Novartis gives up trying to copy Advair

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One of the most surprising nuggets of information in Novartis's full-year financials today was the revelation that its Sandoz division had canned development of a generic version of Glaxosmithkline's Advair. The Swiss group had widely been expected to refile imminently, having carried out additional work in response to a US complete response letter. But today is said it could no longer see a pathway to launch in the next 18 months, adding that the decision was "data-driven" rather than regulatory. On the face of it this is good news for Hikma/Vectura, whose rival generic has also been derailed by a CRL, though more realistically it underlines just how tough it will be for anyone to get an approval. Teva's Advair competitor is non-substitutable, and the only true generics to get US FDA approval are from Mylan – also after a lengthy delay – and an authorised product from Prasco Laboratories. Any erosion to branded Advair's US sales looks to be gradual.

Advair and its generics

Company	US status	Note	Global 2019e sales
Glaxosmithkline	Available since 2001	Original brand	$2,232m
Teva	Airduo Respiclick approved Jan 2017	Not substitutable	$12m
Mylan	Wixela Inhub approved Jan 2019, after Mar 2017 CRL	Substitutable	$441m
Prasco Laboratories	Launched Feb 2019	Authorised generic	NA
Hikma/Vectura	CRL May 2017; upheld in Mar 2018	New study requested, Hikma responded Nov 2019	None
Sandoz (Novartis)	Discontinued after Feb 2018 CRL	Had been aiming to refile in 2019	None

Source: company releases & EvaluatePharma.