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Advair lives another day

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Glaxosmithkline dodged a bullet yesterday, with the US FDA's rejection of Mylan's generic version of Advair delaying the decline of the UK company's top-selling drug.

First-cycle rejections of generic applications are not uncommon – nevertheless, news of the complete response letter disappointed Mylan investors, who drove the shares down 3% yesterday. It is only a matter of time before generics arrive, but the extra months of delay will give Glaxo and its incoming chief executive, Emma Walmsley, time to strengthen their defence.

Hikma up next

Mylan did not provide any detail on the FDA's letter or on a timeline for a resubmission. Leerink analyst Jason Gerberry said a Mylan generic launch was more likely in 2018, while Bryan Garnier's Eric Le Berrigaud said competition for Advair could emerge in mid-2017; Hikma has an FDA decision deadline on May 10, while Teva has already achieved approval for AirDuo, which contains the same active ingredients with a different inhaler.

Mr Le Berrigaud wrote that the current scenario, which has the potential for Hikma entry in mid-year, would see Advair's US sales decline to £1.4bn ($1.7bn) in 2017. He said this number could increase if Hikma also got a complete response letter – Mr Gerberry wrote that this was a likely outcome.

Even with Teva now representing immediate competition, AirDuo comes with a disadvantage – unlike generics, it is not directly substitutable, so it will be up to payer formulary positioning and physician prescribing to drive utilisation. Glaxo has been active in combatting this by cutting prices and striking multi-year deals to preserve favourable formulary positions (*Event – Glaxo mounts final push as US Advair generics loom, March 7, 2017*).

EvaluatePharma's consensus of sellside forecasts indicates that global Advair sales will shrink from $4.7bn in 2016 to $1.3bn in 2022.

Not a pardon

Advair lost US patent protection more than a year ago, but its Diskus device has protected it from competition – substitutable generics makers have needed to show that their devices are similar. Thus Teva's use of its Respiclick inhaler made use of the 505(b)(2) pathway, which while less onerous than a new drug application for a novel agent does not allow for direct substitution.

There can be no doubt that for Advair this is a stay, not a pardon – generics are coming. But for a company facing shrinking prescription sales this lifeline of at least a couple of months will make the profit and loss statement look a little bit better until growth drivers like its newer HIV and respiratory agents can take off.

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