

Physician Views: The great generic Advair opportunity – a physician perspective

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Abstracts

As illustrated here – see FirstWord Lists: Leading respiratory drugs 2012 and 2018 – the respiratory market is poised to evolve considerably over the next five to 10 years.

There remains, however, some ambiguity around one of the key dynamics in the asthma/chronic obstructive pulmonary disease (COPD) market, which concerns the commercial profile of GlaxoSmithKline's \$8 billion a year Advair franchise.

The FDA recently published draft guidance that appears to have lowered regulatory barriers for substitutable generic versions of the drug (see Spotlight On: FDA shifts landscape for generic respiratory products – is GlaxoSmithKline's \$8 billion Seretide/Advair franchise in the firing line?).

This in turn has prompted some speculation that the first AB-rated generic version of GlaxoSmithKline's product could reach the market by 2016. Confirming its own development efforts last week, Teva suggested that such a timeline is overly optimistic; the Israeli company expects to be the first player to file a substitutable generic in 2017, which could facilitate a 2018 approval and launch - see ViewPoints: Teva makes u-turn in generic Advair chase, but can it catch rivals?

As and when a generic version of Advair is launched in the US will prove integral to how the broader asthma/COPD market develops. The longer that it takes to approve such a product, for example, provides GlaxoSmithKline a greater window of opportunity to switch patients to its new once-daily ICS/LABA combination Breo Ellipta or potentially its LAMA/LABA combination Anoro Ellipta, which could secure FDA approval by the end of 2013.

A previous Physician Views poll run by FirstWord suggests that enthusiasm for a once-daily ICS/LABA combination is relatively high among pulmonologists. Respondents (n=43) indicated that they would use Breo in around 40 percent of patients whom they would typically treat with Advair.

However, they also believe that payers will be restrictive in their use of Breo, given that once-daily dosing is perceived to be its primary advantage versus Advair. This assessment appears to have gained some currency with the recent confirmation that Express Scripts will exclude Breo from its formulary listing in 2014, and becomes the second pharmacy benefits manager to do so (after CVS Caremark) - see Physician Views Poll Results – US Pulmonologists keen for Breo Ellipta – can payers be convinced?

This suggests that from a payer perspective, there will potentially be momentum to support use of generic Advair. Furthermore, this may actually intensify (among patients retained on Advair) if physicians are keen to switch some patients to Breo; pulmonologists polled by FirstWord suggested that around a third of patients treated with twice-daily ICS/LABA therapies fail to comply with the dosing schedule.

Therefore key questions focus on how pulmonologists would expect to use a substitutable generic version of Advair if such a drug was available, and how patients would react to using an alternative product to GlaxoSmithKlines established and familiar brand and inhaler device.

This week's Physician Views poll asks pulmonologists and general practitioners based in the US and 5EU markets (where a substitutable generic version of Advair is also yet to launch):

If a substitutable generic version of Advair was available today – in a 'similar' device to the Diskus inhaler – to what percentage of patients being treated with an ICS/LABA therapy would they expect to prescribe the generic product?

How they expect patient loyalty and familiarity towards GlaxoSmithKline's Diskus inhaler to shape the uptake of generic Advair (assuming any generic is sold in a device that has the same 'look and feel')?

How significant – based on their experience – they would anticipate payer pressure to be in driving use of generic Advair?

How they rate their enthusiasm for a branded equivalent to Advair that provided comparable efficacy but with a notably reduced dose of salmeterol (due to improved delivery via device)?

What their main reason would be for not prescribing a generic version of Advair if available?

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