

Physician Views: How will neurologists embrace Teva's new version of Copaxone? What about potential generic versions later this year?

<https://marketpublishers.com/r/P0F6B2F4FBDEN.html>

Date: February 2014

Pages: 0

Price: US\$ 695.00 (Single User License)

ID: P0F6B2F4FBDEN

Abstracts

The US multiple sclerosis market is expected to evolve notably in 2014, with analysts now confident that the FDA will approve at least one generic version of Teva's Copaxone when exclusivity expires in May.

From a commercial perspective, Teva will seek to defend loss of share to generic competition via the launch of a more convenient version of Copaxone, which is dosed three times a week rather than once-daily.

FDA approval for this formulation was secured last week and Teva plans an immediate launch which will be supported by modest list price discounting versus the existing Copaxone brand (reported to be between 2 percent and 8 percent by various sources) - ViewPoints: Do Teva's Copaxone sums add up?

Last month, Teva's chief science officer Michael Hayden said that the company expects to switch around 45 percent of existing Copaxone patients onto the longer-acting formulation (including an aggressive 35 percent switch by June), in order to preserve some patient base prior to the potential launch of generic competition.

The company has become increasingly confident in its ability to convert patients, noted analysts at Bloomberg Industries last week; in late 2012, for example, Teva was suggesting that it could switch around a third of patients to the newer formulation.

Despite newer oral therapies – spearheaded by the launch of Biogen Idec's Tecfidera last year – having made in-roads into the MS market, prescription data illustrates that Copaxone continues to perform robustly. As one US-based key opinion leader told

FirstWord's Therapy Trends team last year, "Copaxone still has a role to play in disease management, particularly when we have been using it for a long time with no real safety issues."

How neurologists utilise any generic version of Copaxone, should one or multiple products gain FDA approval later this year, could emerge as one of the most interesting dynamics in the MS market for some time. Teva continues to argue that the complexity of Copaxone should preclude FDA approval of generic versions not supported by full pivotal-stage clinical data, while KOLs have expressed their own concerns to FirstWord about potential usage of such a product.

This week's Physician Views poll will ask US-based neurologists:

Approximately what percentage of existing Copaxone patients do you expect to switch to the new three-times weekly formulation (approved by the FDA last week) by mid-2014?

Moving away from a once-daily dosing profile, are you concerned about non-compliance issues with the three-times weekly versions?

Assuming the FDA approves a generic version of Copaxone later this year (patent exclusivity expires in May), and based on your knowledge of the product, how comfortable would you be switching an existing Copaxone patient to a generic version?

How comfortable would you be prescribing generic Copaxone as a first-line injectable therapy (i.e. instead of branded Copaxone or the interferon agents)?

Approximately what percentage of newly diagnosed MS patients are you currently treating with Copaxone in a first-line setting?

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