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Physician Views: Will generic Copaxone have traction in the MS market given emergence of oral therapies?

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Abstracts

A recent ruling by the US Court of Appeals for the Federal Circuit has increased the likelihood of generic competition to Teva's multiple sclerosis treatment Copaxone entering the market in May 2014, note analysts, a year earlier than some had anticipated.

Sales of Copaxone are already under threat from oral therapies, most notably Biogen Idec's Tecfidera, so how will a generic version of the drug fare commercially?

Furthermore, Teva hopes to switch up to a third of existing Copaxone patients onto a less frequently dosed version of the drug – three-times weekly versus once daily – but is now potentially faced with a reduced window of opportunity to achieve this before generic versions of the product reach the market.

Current market leader

Copaxone is the current market-leading MS therapy and generated global sales of $4 billion in 2012 – equal to 27 percent of the market in value terms. Copaxone commanded a 32 percent share of the US market in 2012, based on country-specific sales of $2.9 billion.

Second-quarter global and US sales of Copaxone crept up sequentially, driven in part by price increases and the impact of patient warehousing for Tecfidera (a recent presentation by Symphony Health Solutions suggested that by its third week of availability, Tecfidera accounted for around 30 percent of all new patient starts in the MS market) - see ViewPoints: Tecfidera streaks towards blockbuster run rate, questions remain over European launch.

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The competitive threat from orals

However, of those patients prescribed Tecfidera since launch who have switched from another therapy, around 30 percent have reportedly been migrated from Copaxone. This suggests that over the next year we can expect to see continued uptake of Biogen Idec's drug have a more pronounced negative impact on the performance of Copaxone – a trend that may be enhanced by Tecfidera's favourable comparison to Copaxone in the CONFIRM study.

Teva's efforts to retain market share for the Copaxone franchise are centred on the development of a three-times weekly dosed version of the drug, which would provide added convenience versus the current once-daily version. A supplemental new drug application was accepted by the FDA in April and the company expects a regulatory decision to be made in Q1 2014.

Speaking recently with analysts from Deutsche Bank, Teva management also reiterated its view that erosion to Copaxone should occur at a slower than typical generic rate due in part to the company's patient access programme. Generic challenges do not have the necessary infrastructure to compete in this sense, they argue. Management has previously suggested that they expect to switch around 30 percent of existing Copaxone patients to the new dose.

What about generic Copaxone?

The potential launch of both a new three-times weekly branded Copaxone and cheaper generic Copaxone in 2014 could further shift the dynamics of the MS market, which is currently undergoing notable evolution via the launch or oral products, most notably Tecfidera. Bloomberg Industries analyst Asthika Goonewardene notes suggests that availability of cheaper generic Copaxone may cause some healthcare providers in the US to promote injectable therapies over more expensive oral alternatives.

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

> What percentage of Copaxone patients they anticipate switching to a three-times weekly formulation
>
> Whether a three-times weekly formulation will have much impact on oral switching trends

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What percentage of Copaxone patients they expect to switch to an oral therapy over the next 12 months

What type of pricing discount they anticipate necessary to drive uptake of a generic Copaxone product

Whether they believe it ethical to require generic Copaxone to be used as a first-line therapy in relapsing, remitting MS patients?

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