IN THE NEWS

**DOUBT OVER AZILECT®
RELABELING**

Advisors to the Food and Drug Administration (FDA) have expressed skepticism over the relabeling of Azilect® (Teva Pharmaceutical Industries Ltd [TEVA], Petah Tikva, Israel)—a formulation of rasagiline, which is already approved for the treatment of the symptoms of Parkinson disease (PD)—as a drug that can alter the progression of disease.

In the first case of its kind, TEVA applied for the reclassification of Azilect®, claiming that it could slow the progression of PD. TEVA presented data showing that treatment of patients with 1 mg doses of Azilect® improved the symptoms of PD and slowed disease progression compared with placebo. However, no effect on disease progression was seen in patients who received 2 mg doses of Azilect®.

“If you tell people in labeling that a drug has an effect on disease progression, you want to be sure that it does indeed have an effect on disease progression,” Russell Katz, Head of the FDA’s Division of Neurology Products, was quoted to have told the advisors before their decision. “This is really going to be the flagship [case],” said Robert Clancy from the Children’s Hospital of Philadelphia, “and we have to be very solid in this and set a very high standard” (*Baltimore Sun*, 17 October 2011).

The panel voted unanimously against the relabeling of Azilect®. “I believe the drug shows signs of effectiveness for symptomatic use,” said panel member Justin Zivin from the University of California, San Diego, “...the higher bar is whether [Azilect®] does anything for disease modification, and it did not meet that standard” (*Huffington Post*, 17 October 2011). Other panel members were reported to have reached similar conclusions: “I think the data is consistent with a disease-modifying effect,” said Ralph D’Agostino from Boston University, “but it is just not compelling enough” (*Fox Business*, 17 October 2011).

Representative groups for patients with PD accepted that TEVA’s findings were not yet definitive, but were encouraged by the data, as they indicated that drugs might soon be found to slow the progression of PD. “Azilect® is clearly the furthest ahead, but this is an area of incredible research and need,” said Todd Sherer, Chief Executive of the Michael J. Fox Foundation (*Reuters*, 17 October 2011).

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