Omnitrope Application Faces Potential European Roadblock

Sandoz' application to market its generic human growth hormone Omnitrope may not meet the European Commission's (EC) current regulatory pathway for follow-on biologics but is still likely to be approved, according to an expert.

EC guidelines for biosimilar products have been updated several times since Sandoz submitted applications for Omnitrope in 2001 and 2004.

Sandoz appears to have done the "comparability exercises" for its July 2004 application based in part on the European Medicines Agency's (EMEA) adoption in 2001 of the International Conference on Harmonisation's (ICH) guidance on comparability, which only gives guidelines for biosimilars being developed by the same manufacturer, said Linda Horton, a partner in the Brussels office of law firm Hogan & Hartson. She based her conclusion on the EC's notice of a Sandoz lawsuit involving Omnitrope.

"The only [European] guidance document that could have been in effect when Omnitrope was being developed was written for a very different and much more limited situation," Horton said during a recent FDAnews audioconference. Omnitrope is a version of Pfizer's Genotropin (somatropin recombinant).

First Application Rejected

The EC rejected Sandoz' first application on legal grounds related to the selected approval pathway — a move that came despite a 2003 recommendation for approval by the EMEA's Committee for Medicinal Products for Human Use (CHMP). Sandoz submitted a second application based on EMEA and EC recommendations. The 2004 application followed an amended EC regulatory directive in 2003 that provided a pathway for these products, Sandoz said.

But Horton noted that if both the 2001 and 2004 applications are essentially the same and the EC approves the second application, this raises questions as to why it did not approve Sandoz' first application. It also means that, as other manufacturers submit their applications, the EC will have to contend with the same kind of situation in the coming months, Horton said.

CHMP can recommend approval, but its opinions are not legally binding. Only the EC can approve a drug or biological product.

Even if Sandoz' second application does not meet current guidelines, the EC will most likely approve the application for two reasons, Horton said. First, if the EC goes against CHMP's opinion, it will have to provide a detailed explanation as to why it made that decision. Secondly, Sandoz has sued the EC because of its published comment that CHMP improperly approved the first application.

EC Faces Decision

If the first and second applications are essentially the same and CHMP has recommended approval for both applications, the EC will be in an uncomfortable position, Horton explained. Because the EC wants the lawsuit to "go away," the commission will most likely approve Omnitrope so that Sandoz will drop its suit, Horton said.

In its 2001 application, Sandoz seems to have demonstrated compatibility between Omnitrope and the innovator product based on the ICH guidance, which the EC adopted in 2001, Horton said. This may not be appropriate for Sandoz' product, she added.

The ICH guidance only applies to biosimilars that are a "linear descendant of the reference product," Horton noted. A linear descendant would be a biosimilar developed by the same manufacturer, such as when a manufacturer's own product evolves. On the other hand, an amendment in March 2004 to EC regulations defines the term "similar biological medicinal product" in a way that the product could be produced by another firm using different materials and a different manufacturing process.

To order the CD/transcript package of the March 14 audioconference, "Biogenerics in Europe and the U.S.," go to http://www.fdanews.com/wbi/cds/2220-1.html. — Dar Haddix

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