Groups Push Plasma Protein Therapy Exclusion From Biosimilars Pathway

Patient and industry groups are pushing FDA to exclude plasma protein therapies — including immunoglobulin therapies — from the health reform-created biosimilars pathway, arguing that current science does not support clinical interchangeability for these products and noting that European regulators have decided to exclude these products from their follow-on biologics pathway.

The Immune Deficiency Foundation at a recent FDA public meeting on biosimilars urged the agency to exempt immunoglobulin therapies from the pathway until the science advances significantly. The group said these therapies — derived from plasma — can differ in terms of processing and end composition. Further, current science cannot demonstrate that two of these products will provide the exact same clinical results for a large number of patients or that switching patients from one product to another will pose no additional risks, the group said.

Marcia Boyle, president and founder of IDF, told FDA Week that the group will continue to work with FDA, rather than through Congress, on granting an exemption for immunoglobulin products. But she said the group has not received any indication from the agency of whether it wants to exclude certain classes of drugs from the biosimilars pathway.

The Plasma Protein Therapeutics Association also has said the current science and experience does not support the safety and efficacy of a biosimilar pathway for plasma protein therapies.

Both groups are urging FDA to take a global approach to its evaluation of plasma protein therapies for the biosimilars process. The European Medicines Agency exempts certain plasma protein therapies, including recombinant blood clotting factors, from the biosimilar process in the European Union.

FDA has the authority in the Affordable Care Act to exclude a product or product class — not including any recombinant protein — from the biosimilars pathway based on science and experience.

PPTA specifically wants FDA to issue a product-class specific guidance document indicating that the current state of science and experience do not allow approval of an application under the biosimilars pathway for plasma-derived products. The group has said it also supports a specific guidance document with strict criteria for approval of an application under the biosimilars pathway for recombinant analogs.

FDA, however, has yet to issue any product-specific guidance documents. The agency is focusing on general, overarching guidances as suggested by stakeholders at a November 2010 public hearing.

“In reviewing the comments received from the November 2010 Part 15 public hearing, we noted that many comments suggested the Agency begin with general, overarching guidances describing the general requirements and principles for biosimilar product development,” an FDA spokeswoman said in an e-mail. “We agreed with this approach and began with the three draft guidance documents issued earlier this year. FDA will carefully review and consider all comments, including those from the public hearing docket and those from the draft guidance dockets, as we move forward in finalizing the guidances and determine plans for development of future policies regarding biosimilars.” — Nanci Bompey