Published on *The National Law Review* https://natlawreview.com

Approval of First Biosimilar Monoclonal Antibody in Brazil

Article By:

Lisa L. Mueller

Today, the ***National Sanitary Vigilance Agency (ANVISA)*** granted marketing authorization to Celltrion Healthcare Distribuidora de Produtos Farmaceuticos do Brasil Ltda's (the Brazilian subsidiary of Celltrion, Inc. (a Korean company)) for the monoclonal antibody *Remsina*, a copy of Janssen's Remicade (infliximab). The approved indications include rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis, adult and pediatric Crohn's Disease, fistulizing Crohn's disease and adult and pediatric ulcerative colitis or retocolitis.

Today's approval is the first granted by ANVISA for a biosimilar monoclonal antibody. Celltrion's approval followed the abbreviated pathway as set forth in ANVISA's Rule #55/2010, which does not use the terms "biosimilar" or "biogeneric", but instead refers to a "new biologic product" for an innovator product and a "biologic product" for a biosimilar.

Anvisa's Rule #55/2010, establishes two pathways for the abbreviated approval of copies of biological products: (1) development by comparability (Article 22, XXV); and (2) individual development (Article 22, XXVI). The individual development pathway requires the submission of a full dossier of data relating to the development, manufacturing and quality of the biosimilar version of the biological product as well as the results of non-clinical and clinical studies performed with the product. In contrast, the comparative pathway requires the submission of a comparative dossier containing data from non-clinical and clinical studies used to demonstrate the comparability between the biological comparator product (a reference product) and the follow-on the biological product for which approval is sought. Remsina was approved under the comparability pathway.

National Law Review, Volumess V, Number 118