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Clinical safety of biosimilar recombinant growth factors: Erythropoietins and granulocyte colony-stimulating factors

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Abstract

Clinicians in Europe continue to be reluctant to use biosimilar recombinant growth factors, specifically erythropoietins (EPO) and granulocyte colony-stimulating factors (GCSF) in the indications approved by the European Medicines Agency (EMA). Despite regulatory criteria that, as biologic agents, biosimilar growth factors be similar in terms of quality, safety, and efficacy to an authorized reference biological medicine, clinicians' core concerns pertain exactly to these three criteria. With biosimilar growth factors in clinical development in the US or under regulatory review by the US Food and Drug Administration (FDA), it is likely that US clinicians will share similar concerns – and this in a more litigious market. We conducted independent, comprehensive reviews of the clinical safety of three biosimilar recombinant human EPOs (Binocrit®, Sandoz; Retacrit®, Hospira; Eporatio®, Teva) and three biosimilar recombinant human GCSFs (Tevagrastim®, Teva; Zarzio®, Sandoz; Nivestim®, Hospira) based on regulatory reports and scientific publications. For the biosimilar EPOs, the safety review focused on immunogenicity, venous thromboembolism, and mortality. There were no differences in the safety profiles of the three products when compared to the reference agent and when compared among themselves. For the biosimilar GCSFs, the safety review focused on immunogenicity, bone pain, splenomegaly, allergic reactions, acute respiratory distress syndrome and mortality. Here too, there were no differences in the safety profiles of the three products when compared to the reference agent and when compared among themselves. As these safety data are mainly from phase I and phase III trials, complemented occasionally with post-approval studies varying in scope and sample size, large-sample post-approval studies are necessary to further evaluate clinical safety – nad gather additional evidence of therapeutic benefit. In the interim, EMA and FDA approved biosimilars should be considered clinically safe.

Biography

Ivo Abraham (BS, 1979, Leuven University College, Belgium; MS, 1982, PhD, 1984, University of Michigan) is an outcomes and effectiveness researcher. Following prior academic appointments in the US, Europe, and Asia and worldwide private sector R&D, he is currently the Director of the Center for Health Outcomes and PharmacoEconomic Research at the University of Arizona; where he also heads up the biosimilar research group. He has over 400 publications and has been the recipient of various professional and scientific honors worldwide.