

Update on Subsequent Entry Biologics (SEBs)

Health Canada approved two new Subsequent Entry Biologics (SEBs) on January 15th 2014; one is called Inflectra and the other Remsima. The manufacturer (sponsor) of these SEBs requested Health Canada's approval for all of the same indications that the innovator product (REMICADE® (infliximab)) has approval for, which includes diseases like Crohn's Disease (CD), Ulcerative Colitis (UC), Rheumatoid Arthritis (RA), Ankylosing Spondylitis (AS), Psoriasis (PsO), and Psoriatic Arthritis (PsA).

What was Health Canada's decision?

Health Canada only provided approval for the SEBs in RA, AS, PsA and PSO, and did not grant approval for any IBD indications. Of note, Health Canada granted approval for PsA and PSO without clinical trials being done (both RA and AS were approved based on evidence from clinical trials). Health Canada's decision for the approval of PsA and PSO was based on what is called principles of extrapolation i.e., the approvals in these areas were based on the results of the RA and AS trials and deemed appropriate on the basis of similarity and the absence of meaningful differences, between Inflectra/Remsima and the reference product, in product quality, mechanism of action, disease pathophysiology, safety profile, dosage regimen and on clinical experience with the reference product.

Why did Health Canada not approve Inflectra and Remsima for Crohn's disease and Ulcerative colitis?

Health Canada did not approve Inflectra or Remsima for any IBD related indications. Approval "...could not be recommended due to differences between Inflectra/Remsima, and the reference product, that could have an impact on the clinical safety and efficacy of these products in UC & CD indications."¹

Please note that the safety and efficacy of Inflectra and Remsima have not been established in pediatric patients.

It is very important that you continue to have meaningful conversations with your child's physician and be well informed regarding their treatment medications.

¹(http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/drug-med/sbd_smd_2014_inflectra_159493-eng.php)

"This article was made possible by support from Janssen Inc."