**Crohn's and Colitis Canada position statement:**

# Biosimilars or Subsequent Entry Biologics (SEBs)

October 2016

## Background

Biologics are drugs produced from living organisms. In the context of inflammatory bowel disease (IBD), biologics are drugs designed to target and block the cells responsible for inflammation. As patents expire on existing innovator biologics, drug manufacturers are developing new options based on existing biologics. These new drugs are called subsequent entry biologics (SEBs), though they are also commonly referred to as biosimilars. Unlike traditional generic drugs, biosimilars are not identical to their innovator biologic. This is due to complex manufacturing processes. Even the smallest variations in the manufacturing process between an innovator biologic and a biosimilar may have unforeseen and unanticipated impacts. Biosimilars represent a potentially effective and cost saving option for the management of IBD that may enhance access to biologic therapy.

Health Canada currently does not recognize biosimilars as interchangeable or substitutable for their innovator biologic. In June 2016, Health Canada approved Inflectra™ (a biosimilar of Remicade®) for the treatment of Crohn's disease, fistulising Crohn's disease and ulcerative colitis in adults but did not grant approval for pediatric indications for treatment of IBD even though those indications have been granted to the innovator biologic, Remicade®.

## Key Recommendations

Crohn's and Colitis Canada has been closely monitoring developments at the federal and provincial levels relating to biosimilars and we continue to proactively advocate on behalf of Canadians living with Crohn's disease or ulcerative colitis. Our position on biosimilars for IBD is:

- **We support the introduction of safe and effective treatments for IBD.** This includes lower-cost treatment options like biosimilars. Doctors and patients in all provinces should have access to biosimilars alongside existing treatment options, including non-biologic medications and innovator biologics.
- **Doctors and their patients must be able to select the treatment option best suited to each patient's individual circumstances**, without undue interference from government or private payers. Treatment decisions must never be made on the basis of cost alone. This will help ensure the best interest of the patient remains at the forefront of every treatment decision.
- **Patients in remission being treated with an innovator biologic should not be forced to switch to a biosimilar** by any government or private payer without the informed consent of the prescribing doctor and the patient. For Crohn's and colitis patients, the ultimate goal of treatment is stability, achieved through disease remission. The uncertainty associated with a forced switch, may put this stability in jeopardy.