Survey Results

SUBSEQUENT ENTRY BIOLOGICS

Gastrointestinal Society

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Gastrointestinal Society
Canadian Society of Intestinal Research

2015
The GASTROINTESTINAL SOCIETY represents inflammatory bowel disease (IBD) patients on a variety of health care fronts, including access to medications. During the first part of 2015, we hosted a survey on our English (www.badgut.org) & French (www.mauxdeventre.org) websites to help understand IBD patients’ opinions and outlooks regarding subsequent entry biologics (SEBs). To qualify, survey participants had to confirm that they were either a person with IBD or a caregiver of a person with IBD. We had 423 respondents, 317 in English; 106 in French, but not everyone answered each question, as they were not mandatory.

**BACKGROUND**

Biologics are medicines made from living cell systems, and are intended to act in certain ways in the body to correct malfunctions that might lead to disease. They can also block disease in its early stages from progressing.

Unlike most generic drugs, biosimilars/SEBs are not identical to the original biologic medicine on which they are based; they have slightly different structures, are not therapeutically equivalent, and might not be approved or tested for all the disease areas (indications) for which the reference product was approved, e.g., Crohn’s disease, ulcerative colitis, rheumatoid arthritis, psoriasis.

Health Canada (the government agency responsible for drug safety) might not require a biosimilar to be tested for safety and effectiveness through clinical trials in a specific disease area before approving it for use in that disease area. (The regulations are in flux.) This is in contrast to the approval process for the original biologic, which required extensive studies in all of the disease areas for which Health Canada has approved it. The biosimilar agent has to demonstrate structural and quality aspects for Health Canada to denote it as similar to the original medicine’s clinical experience, not the biosimilar’s own data.

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**DEMOGRAPHICS**

- respondents were from all ten provinces and Yukon, with close proportional representation to the corresponding populations
- the majority (66%) were female
- 91% were between 18-59 years of age, less than 1% were caregivers of children with IBD (n=5), and the remainder were older than 59
- 68% had Crohn’s disease, 30% had ulcerative colitis, and 2% had indeterminate IBD
**UNDERSTANDING BIOLOGIC MEDICATIONS**

- 77% had at least a basic understanding of biologic medications and were currently taking an originator biologic (Remicade®, Humira®, or Simponi®)
- 76% of respondents had heard about SEBs, mostly from a physician or nurse
- 23% had heard about SEBs from the GI Society/seminar

**SUBSEQUENT ENTRY BIOLOGICS**

**HOW** do you think subsequent entry biologics are different from originator biologics?

- cost of medication
- how they are made
- how they work
- how patients react to them
- I have no opinion
- types of side effects

**WHAT** factors are important to you for biosimilar/subsequent entry biologics regulation in Canada?

- safety
- efficacy
- SEBs review & approval identical to originator
- SEB tested for all indications/diseases
- more treatment options
- SEBs clinically tested in Canadians
- other (cost should not be a factor)
WHAT would be the most important consideration in choosing subsequent entry biologic treatment?

- efficacy compared to originator
- safety
- side effects
- doctor recommendation
- cost (co-payment, insurance)
- cost (self-pay)
- manufacturer’s patient support program

CONCLUSION

Canadians with inflammatory bowel disease who responded to our survey were quite familiar with biologics, in fact, 77% are currently taking these medications. However, while many had heard about SEBs, they expressed confusion and concern around the use of subsequent entry biologics. In particular, they were concerned about the safety and efficacy of these products for treatment of inflammatory bowel disease, and how Health Canada will regulate them. They do not want these medications for the wrong reasons, that is, simply because they might be less expensive than the originator medications. These individuals are concerned about the possible switching of drugs between the originators and biosimilars, particularly if the government or private insurance plans switch patients to these drugs without their knowledge or consent.

Not surprisingly, 95% said that it was important for their physician to have the sole authority to decide, together with them, the most suitable biologic medicine to use to treat the disease. This patient directive is very strong.

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