ASBM/IFA
Canadian Ophthalmologist Biologics / Biosimilars Study

November 2022 – Ophthalmology Specialty Analysis

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Goal:

• Understand prescribers’ attitudes, beliefs, and intentions toward biosimilars medications
# Table of Contents

<table>
<thead>
<tr>
<th>Page</th>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Methodology &amp; Demographics</td>
</tr>
<tr>
<td>6</td>
<td>Screener Questions &amp; Demographics</td>
</tr>
<tr>
<td>11</td>
<td>Primary Findings – Product Identification</td>
</tr>
<tr>
<td>18</td>
<td>Primary Findings – Prescribing Biologics</td>
</tr>
<tr>
<td>29</td>
<td>Primary Findings – Biosimilar Substitution</td>
</tr>
<tr>
<td>32</td>
<td>About ISR</td>
</tr>
</tbody>
</table>
Methodology & Demographics
Data Collection Methodology

On behalf of Alliance for Safe Biologic Medicines (ASBM) and International Federation on Ageing (IFA), Industry Standard Research (ISR) conducted a web-based quantitative survey with 41 participants.

All participants practice ophthalmology in Canada.

A leading 3rd party physician panel was used to recruit research participants.

Research was conducted in October-November 2022.

ASBM was not identified as the sponsor of the research.

Participants were provided an honorarium for their time.
Respondent Profile (n=41)

**Therapeutic Specialty**
- Ophthalmology, 100%

**Practice Type**
- Community setting: 27%
- Academic Medical Center: 22%
- Private, family practice: 20%
- Multi-specialty clinic: 17%
- Hospital: 12%
- Other: 2%

**Country**
- Canada, 100%

**Canadian Territory/Province Representation**
- Ontario: 54%
- Quebec: 24%
- British Columbia: 10%
- Alberta: 7%
- New Brunswick: 2%
- Manitoba: 2%
Respondent Profile (n=41)

Prescribe Biologics In Your Practice?

- Yes, 100%

Familiarity With Biosimilars

- Very familiar, I have a complete understanding of them: 27%
- Familiar, I have a basic understanding of them: 68%
- I've heard of them, but could not define them: 2%
- I have never heard of them: 2%

Tenure In Medical Practice

- 1-5 years: 10%
- 6-10 years: 17%
- 11-20 years: 44%
- 21-30 years: 22%
- ≥ than 30 years: 7%

% of Respondents
Primary Findings –
Product Identification
Explanatory Text

• Given immediately preceding Q7
  • Biologic medicines are therapeutic proteins produced using living cells. The active substances of biological medicines are larger and more complex than those of non-biological medicines. A biosimilar medicine is a biological medicine that is developed to be similar to an existing biological medicine (the ‘reference product’). Biosimilars are not the same as generics, which have simpler chemical structures and are considered to be identical to their reference medicines.
  • In Canada biologics and biosimilars are approved nationally by Health Canada under the New Drug Submission pathway. As a result of patent expiry on the originator products, biosimilars are increasingly becoming available in Canada. Unique to Canada, the patient support program (PSP) for a biologic is paid for by the manufacturer and a change in biologic medications means a change in PSP if the manufacturer is different.
Q7. When you identify the prescription of a biologic drug in your patient record, are you likely to identify the medicine by: (n=41)

- Product / Brand name, 80%
- Non-proprietary / Generic name, 20%

Q8. Physicians play an important role in the identification and reporting of unexpected or serious adverse events to Health Canada and manufacturers.

In the context of identifying a biologic for purposes of reporting an adverse event, how do you identify the medication? (n=41)

- Product Name / Brand Name: 78%
- Non-proprietary name / Generic name: 20%
- DIN number: 2%
Product Identification

Q9. How confident are you in the Canadian pharmacovigilance system’s ability to accurately identify the specific product, at the brand name level, that might be responsible for an adverse drug reaction? (n=41)

- Highly confident: 39%
- Somewhat confident: 56%
- Not confident: 5%
Product Identification

Q10. How often do you include the lot/batch number when reporting adverse events? (n=41)

- Always: 39%
- Usually: 34%
- Sometimes: 5%
- Rarely: 17%
- Never: 5%

Q11. What is the main reason for not reporting the batch number? (n=11, displayed only respondents who sometimes, rarely, or never include the batch number)

- Do not have it available at the time of reporting: 64%
- Form / System does not have dedicated field: 9%
- Forget to include this information: 9%
- Other: 18%

Other Responses:
- Never reported before
- Have not had to report an adverse event
Given immediately preceding Q12

In 2015, the World Health Organization’s International Nonproprietary Names (INN) Programme proposed that a distinguishing suffix be appended to all biologic medicines, including biosimilars, that share an INN to clearly differentiate them from each other and improve global pharmacovigilance. Health Canada was an early supporter of this proposal, and has indicated it would harmonize with the WHO if this system were made available.

Health Canada has also held talks about harmonizing nomenclature with the United States, which uses suffix system similar to that proposed by the WHO. Health Canada currently relies on self-reporting of brand name and Drug Identification Number (DIN) to differentiate similar products from one another.
Product Identification

Q12. Would you support Health Canada harmonizing internationally by adopting a distinct suffix system? (n=41)

- Yes: 88%
- No: 2%
- Unsure: 10%
Primary Findings –
Prescribing Biologics
Prescribing Biologics

Q13. How do costs to the public system impact which biologic drug you prescribe? (n=41)

- I often make an evaluation of biologic drug benefits and cost to the public system to decide which one to prescribe: 37% of Respondents
- I prescribe the biologic drug I believe is most appropriate, regardless of cost to the public system: 63% of Respondents

Q14. If cost to the public system were not a factor, how would that impact your choice of originator biologic vs. biosimilar prescription? (n=15, displayed to respondents who often make an evaluation of drug benefits and cost, or who usually prescribe the lowest cost biologic drug in Q13)

- I would tend to prescribe the biosimilar product: 20% of Respondents
- I would decide between the innovator and biosimilar depending on the individual patient situation: 40% of Respondents
- I would tend to prescribe the innovator product: 40% of Respondents
Prescribing Biologics

Q15. How comfortable are you in prescribing a biosimilar to a “treatment-naïve” patient? (n=41)

- Very comfortable: 29%
- Somewhat comfortable: 54%
- Somewhat uncomfortable: 15%
- Very uncomfortable: 2%

Q16. How comfortable are you with switching a stable patient from one medicine to a biosimilar? (n=41)

- Very comfortable: 20%
- Somewhat comfortable: 42%
- Somewhat uncomfortable: 27%
- Very uncomfortable: 12%
Prescribing Biologics

Q17. Does the quality of a biologic’s patient support program have an influence on which biologic you prescribe? (n=41)

- Significant influence: 24%
- Moderate influence: 29%
- Minimal influence: 34%
- No influence: 12%

Q18. In your opinion, how important is patient education on biosimilars prior to switching a patient to a biosimilar? (n=41)

- Critical: 7%
- Very important: 37%
- Somewhat important: 42%
- Slightly important: 12%
- Not important: 2%
Primary Findings – Biosimilar Substitution
• Given immediately preceding Q19
  • Health Canada has stated, biosimilars are not “generic biologics”... authorization of a biosimilar is not a declaration of pharmaceutical equivalence, bioequivalence or clinical equivalence to the reference biologic drug. – Health Canada Biosimilar Guidance Document, November 2019.

• In Canada, the term "interchangeability" often refers to the ability for a patient to be changed from one drug to another equivalent drug, by a pharmacist, without the intervention of the prescriber who wrote the prescription. The authority to declare two products interchangeable rests with each province/territory according to its own rules and regulations.
Biosimilar Substitution

Q19. In a situation where substitution by a pharmacist is an option in your province, how important would it be for you to have the authority to designate a biologic medicine as “DISPENSE AS WRITTEN” or “DO NOT SUBSTITUTE”? (n=41)

- Critical: 27%
- Very important: 61%
- Somewhat important: 10%
- Slightly important: 2%
- Not important: 0%

Q20. In a situation where a payer (public or private) has the authority to require a patient who is stable on their current biologic to switch to a biosimilar, how important would it be for you to have the authority to designate a biologic medicine as "DISPENSE AS WRITTEN" or "DO NOT SUBSTITUTE"? (n=41)

- Critical: 42%
- Very important: 49%
- Somewhat important: 7%
- Slightly important: 2%
- Not important: 0%
Biosimilar Substitution

Q21. How important would it be for you to be notified by the pharmacist that your patient has received a biologic other than the one you prescribed, if the patient was receiving chronic (repeated) treatment? (n=41)

- Critical: 32%
- Very important: 59%
- Somewhat important: 7%
- Slightly important: 2%
- Not important: 0%

Q22. How acceptable would it be for you if the pharmacist made the determination which biologic (originator or biosimilar) to dispense to your patient on initiation of treatment? (n=41)

- Completely acceptable: 5%
- Acceptable, provided such exchange has been agreed with clinicians for these biologics in advance: 34%
- Not acceptable – only the prescriber should make this determination: 61%
Biosimilar Substitution

Q23. How important is it to you to have the sole authority to decide, together with your patients, the most suitable biologic medicine for their disease? (n=41)

- Critical: 27%
- Very important: 63%
- Somewhat important: 5%
- Slightly important: 5%
- Not important: 5%
Q24. How comfortable are you with personally switching your patient to a biosimilar for non-medical reasons (i.e., coverage)? (n=41)

- Completely comfortable: 15%
- Somewhat comfortable: 51%
- Not comfortable: 29%
- Unsure: 5%

Q25. How comfortable are you with a third party switching your patient to a biosimilar for non-medical reasons (i.e., coverage)? (n=41)

- Completely comfortable: 2%
- Somewhat comfortable: 17%
- Not comfortable: 81%
- Unsure: 0%
Q26. If a patient’s treatment gains were risked by switching to a biosimilar, would you be supportive of a patient’s right to choose the appropriate treatment for their individual circumstance? (n=41)

- Yes: 76%
- No: 10%
- Unsure: 15%

Q27. What is your main concern about non-medical switching to a biosimilar? (n=40, those unsure or uncomfortable in Q24 and Q25)

- Potential of symptom return in patients: 20%
- Legal liability as a physician: 13%
- Unknown immunogenicity reactions: 10%
- Potential adverse effects of biosimilars: 8%
- Change in patient support system: 8%
- Potential psychological impacts: 6%
- Potential impact on adherence: 6%
- None of the above: 50%
- All of the above: 50%
Biosimilar Substitution

Q28. From your perspective, how important is it for government tenders for biosimilars to be awarded to multiple suppliers? (n=41)

- Critical: 5%
- Very important: 44%
- Somewhat important: 42%
- Slightly important: 10%
- Not important: 7%
- Unsure: 10%

Q29. From your perspective, how important is it for factors besides price to be taken into account in national tender offers (e.g. reliability of supply, patient support services, manufacturer reputation)? (n=41)

- Critical: 5%
- Very important: 44%
- Somewhat important: 42%
- Slightly important: 10%
- Not important: 7%
Explanatory Text

• Given immediately preceding Q30
  • In nearly every Western European country, physicians are encouraged to prescribe lower-cost biosimilars to new patients, but ultimately retain the authority to choose between multiple products when prescribing – all of which will to be reimbursed by the payer. Automatic or forced substitution is strongly discouraged and cost savings are achieved through competition between multiple reimbursed products.

• In contrast, some Canadian provinces are adopting the approach used in Eastern Europe: all patients, both treatment-naïve and those who are stable on their current biologic, will be switched to the preferred, government-chosen biosimilar in order to achieve cost savings.
Biosimilar Substitution

Q30. From your perspective, which system would better serve patients in your province? (n=41)

Multiple products including innovator and biosimilars are reimbursed, biosimilars encouraged for new patients, no automatic substitution. 78%

Only the government-chosen biosimilar is reimbursed, new patients must be prescribed this product, and current patients are forced to switch. 15%

Unsure 7%
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