Canadian Physician Perspectives on Subsequent Entry Biologics (SEBs)

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About ASBM
The Alliance for Safe Biologic Medicines

• 2010 ASBM formed to provide STAKEHOLDER GUIDANCE on SEBs/biosimilars to regulators worldwide

• MEMBERS: consist primarily of physician and patient groups, EuropaBio, and BIOTECCanada.

• ADVISORY BOARD: Composed of Physicians, Researchers, Pharmacists, and Patients from around the world. Serves as resource on the science and clinical use of SEBs/biosimilars, guides our policy recommendations

• Learn more at www.safebiologics.org
ASBM International Advisory Board

- Composed of Physicians, Researchers, Pharmacists, and Patients from around the world.
- Serves as an authoritative resource on the science and clinical use of biosimilars, which guides and validates ASBM policy recommendations.

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“The Four Pillars”

ASBM’S GUIDING PRINCIPLES

1. Prioritizing Patient Safety
2. Leveraging What We Have Learned
3. Promoting Pharmacovigilance
4. Keeping Doctors Relevant
ASBM Physician Surveys

U.S. Prescriber Survey (September 2012)
- 376 physicians

E.U. Prescriber Survey (November 2013)
- 470 physicians
- Subject of June 2014 research paper in the Journal of the Generics and Biosimilars Initiative (GaBi Journal)

Canadian Prescriber Survey (November 2014)
- 427 physicians
Recent ASBM Activity

August 14: Chairman-elect Dr. Gewanter presented at the 4th Latin America Forum on Biosimilars in Brasília on physician perspectives on biosimilars

August 24: Co-founder and Steering Committee member Andrew Spiegel of the Global Colon Cancer Association presented at 16th PRE-ICDRA conference in Rio de Janeiro

October 14: Chairman presents at 59th WHO Consultation on International Nonproprietary Names

October 20: Presented to Italian Ministry of Health

November 25: Presented to Spanish Ministry of Health

December 2: Presented to DIA Biosimilars Conference in Berlin
Canadian Physician Survey
About the Respondents

• 427 Prescribers were recruited from 4 provinces in Canada
  – Alberta
  – British Columbia
  – Ontario
  – Quebec
Survey Objectives

Provide empirical data to Health Canada and other regulators on the perspective of Canadian physicians regarding subsequent entry biologics (SEBs), particularly in regard to SEB naming:

• Measure physician familiarity and understanding of SEBs
• Assess the implications of an SEB sharing a nonproprietary name with its reference innovator product
• Determine how physicians identify biologics in patient records and in adverse event reporting
• Gather physician perspective on the importance of distinguishable naming
• Gauge physician attitudes on pharmacy substitution
Respondents: Primary Therapeutic Area

“Please indicate your primary practice area or therapeutic area in which you practice?” (N=427)

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Dermatology</td>
<td>14%</td>
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<tr>
<td>Internal Medicine</td>
<td>13%</td>
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<td>Gastrointestinal</td>
<td>12%</td>
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<td>Oncology</td>
<td>10%</td>
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<td>Respiratory / Pulmonology</td>
<td>9%</td>
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<td>Rheumatology</td>
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<td>Neurology</td>
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<td>Urology</td>
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<td>Nephrology</td>
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<tr>
<td>Endocrinology</td>
<td>5%</td>
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<tr>
<td>Infectious Diseases</td>
<td>4%</td>
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<tr>
<td>Allergy / Immunology</td>
<td>4%</td>
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Respondents: Practice Setting

“Which of the following best describes the type of practice in which you work?” (N=427)

- Community setting: 35%
- Academic medical center: 33%
- Hospital: 17%
- Private, family practice: 7%
- Multi-specialty clinic: 7%
- Other: 1%
Length of Time in Healthcare Sector

“How long have you been in medical practice?” (N=427)

- 1-5 years: 8%
- 6-10 years: 16%
- 11-20 years: 35%
- 21-30 years: 29%
- More than 30 years: 11%
Physician Knowledge of SEBs
Familiarity with SEBs

“How familiar are you with subsequent entry biologic (biosimilars) medicines?” (N=427)

- Very familiar, I have a complete understanding of them: 10%
- Familiar, have a basic understanding of them: 48%
- I've heard of them but could not define them: 31%
- Have never heard of them: 10%
“Are you aware that a subsequent entry biologic may be approved for several or all indications of the reference product on the basis of clinical trials in only one of those indications?” (N=427)
Naming of SEBs
Nonproprietary Name Implications – Structurally Identical?

“If two medicines have the same non-proprietary scientific name, does this suggest to you or imply that the medicines are structurally identical?” (N=427)
Nonproprietary Name Implications: Same Results?

“If two medicines have the same non-proprietary scientific name, does this suggest to you or imply that a patient could receive either biologic product and expect the same result?” (N=427)
Nonproprietary Name Implications: Substitution During Course of Treatment

“If two medicines have the same non-proprietary scientific name, does this suggest to you or imply that a patient could be safely switched from a reference biological medicine to its SEB during a course of treatment and expect the same result with either of the products?” (N=427)
Nonproprietary Name Implications: Approved for Same Indications?

“If two biologic medicines have the same non-proprietary / generic name, does this suggest to you the medicines are approved for the same indications?” (N=427)
Identification of Biologic Medicines
**Biologic Recording – Patient Record**

“When you identify the prescription of a biologics drug in your patient record, are you likely to identify the medicine by:” (N=427)

- **Product name / Brand name**: 82%
- **Non-proprietary / Generic name**: 17%
- **DIN number**: 0%
- **Other**: 1%
“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 medicine?” (N=427)

- Product name / Brand name: 70%
- Non-proprietary name / Generic name: 26%
- DIN number: 3%
- Other: 1%
Batch Number Inclusion

“How often do you include the batch number when reporting adverse events?” (N=427)

- **Always**: 45%
- **Sometimes**: 29%
- **Never**: 26%
Reason for Not Including Batch Number

“What are the main reasons for not reporting the batch number?” (N=317)

- Do not have it available at the time of reporting: 50%
- Not sure where to find this information: 29%
- Forget to include this information: 15%
- Form / System does not have dedicated field: 3%
- Other: 4%
Distinguishable Naming
Distinct Nonproprietary Names

“In your opinion, should Health Canada insist on a distinct non-proprietary / generic name for every biologic or SEB product approved by them?” (N=427)

- Yes: 79%
- No: 13%
- No Opinion: 8%
Differentiating SEBs from Innovator Products

“What is the best way for Health Canada to differentiate a SEB from the innovator biologic?” (N=427)

- A completely different INN for SEB/biosimilar and reference product: 54%
- The same INN as the innovator product with a differentiating prefix: 26%
- The same INN as the innovator product with a differentiating suffix: 11%
- The same INN as the innovator product with a code identifying the manufacturer: 9%
- Other (Please specify): 0%
Pharmacy Substitution
Acceptability of Pharmacist Determination

“How acceptable would it be for you if the pharmacist made the determination which biologic (innovator or SEB/biosimilar) to dispense to your patient on initiation of treatment?” (N=427)

- Not acceptable - only the prescriber should make this determination: 71%
- Acceptable, provided such an exchange has been agreed with clinicians for these biologics in advance: 27%
- Totally acceptable: 2%
Importance of DAW

“In a situation where substitution by a pharmacist was an option in your province, how important would it be to you to have the authority to designate a biologic medicine as ‘DISPENSE AS WRITTEN’ or ‘DO NOT SUBSTITUTE’?” (N=427)

- Very important or Critical: 80%
- Somewhat important: 15%
- Not or Slightly important: 5%
Importance of Prescribing Authority

“How important is it to you as a prescribing physician to decide the most suitable therapeutic biologic for your patients?” (N=427)

- Very important or Critical: 87%
- Somewhat important: 9%
- Not or slightly Important: 4%
“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=427)

- Very Important or Critical: 85%
- Somewhat important: 11%
- Not or Slightly Important: 4%
What We Learned

The survey identifies a need for additional education and information on SEBs among Canadian physicians.

Misconceptions about SEBs, along with physician prescribing and recording practices, highlight the need for a distinguishable naming scheme for all biologics, including SEBs.

Physicians overwhelmingly (79%) supported Health Canada implementing distinguishable names, with the majority (54%) identifying unique nonproprietary names as their preferred method.

Canadian physicians feel strongly about the need to retain sole prescription authority, the need to have DAW authority, and the need to notify them in the event of a substitution. It is not acceptable to them for a pharmacist to make this determination.
Thank You For Your Attention