



Smarter questions • Smarter answers

ASBM Biosimilars

Canada Prescribers and Biosimilars

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METHODOLOGY

Study methodology

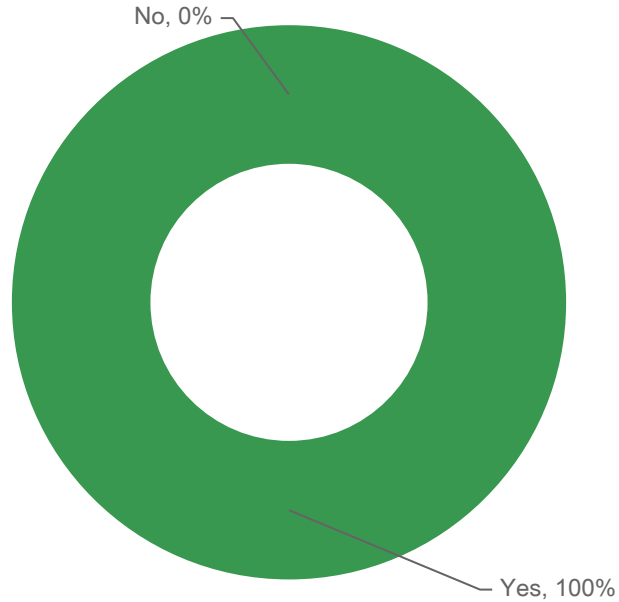
- 403 prescribers
- 15-minute web-based survey
- All participants practice in Canada, in the following provinces
 - Ontario (n=214)
 - Alberta (n=55)
 - British Columbia (n=57)
 - Quebec (n=77)
- Participants recruited from large, global panel of healthcare professionals
- Participants screened as follows:
 - Specialize in one of 13 therapeutic specialties, including: Allergy / Immunology, Dermatology, Endocrinology, Gastrointestinal, Hematology oncology, Infectious Diseases, Internal Medicine, Nephrology, Neurology, Oncology, Respiratory / Pulmonology, Rheumatology, Urology
 - Must have been in practice for 1 year or longer
 - Must prescribe biologic medicines in their practice
- Participants received a \$40.00 cash stipend for their time
- Data collected in September-October, 2017
- Study was sponsored by ASBM and administered by Industry Standard Research, LLC



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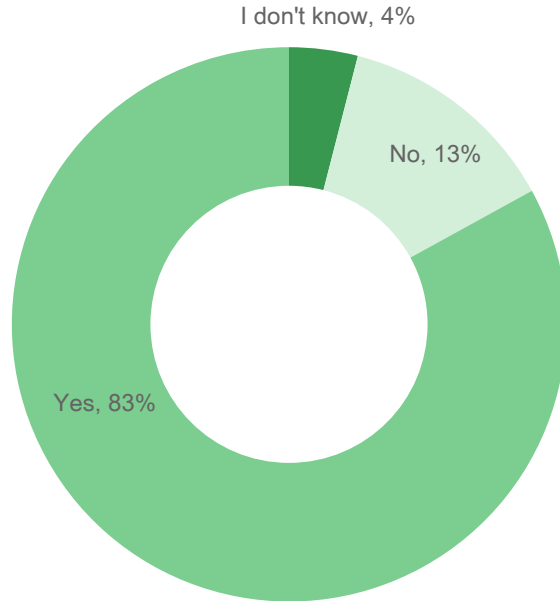
SAMPLE CHARACTERISTICS

Prescribe biologics?



- Question
 - “Do you prescribe biologic medicines in your practice?” (n=403)

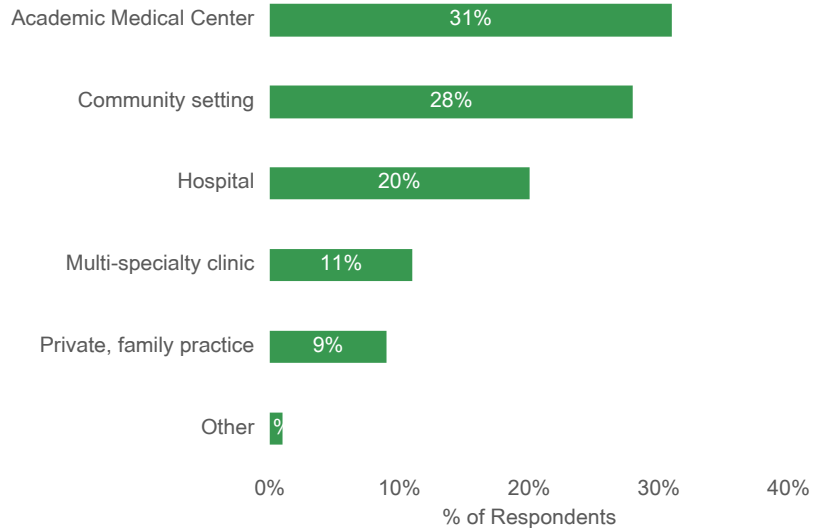
Biologics prescribed by others



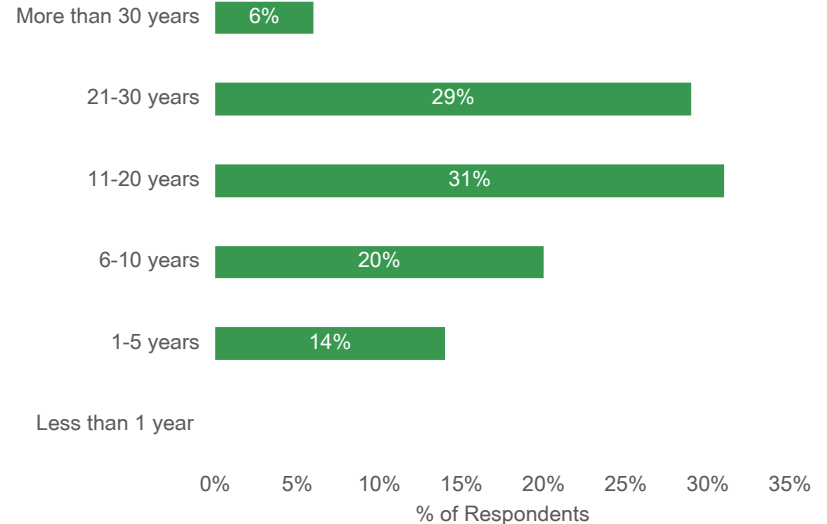
- Question
 - “Do you commonly treat patients who you are aware are being prescribed biologic medicines by another health care provider?” (n=403)

Setting and experience

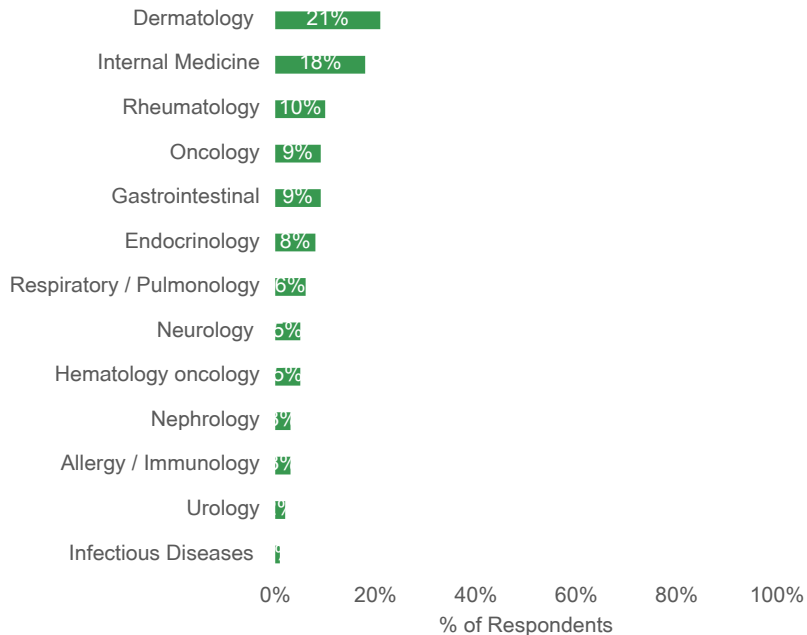
Practice Setting



Years in Practice

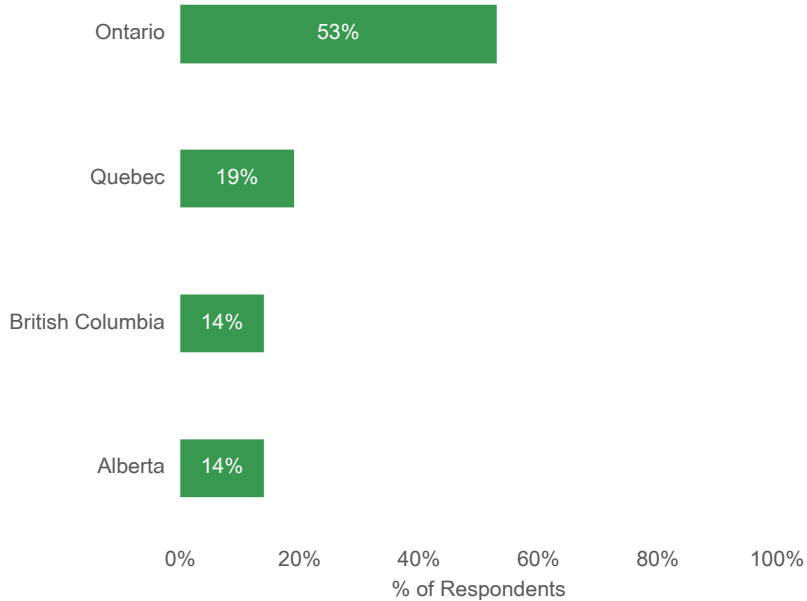


Therapeutic specialty



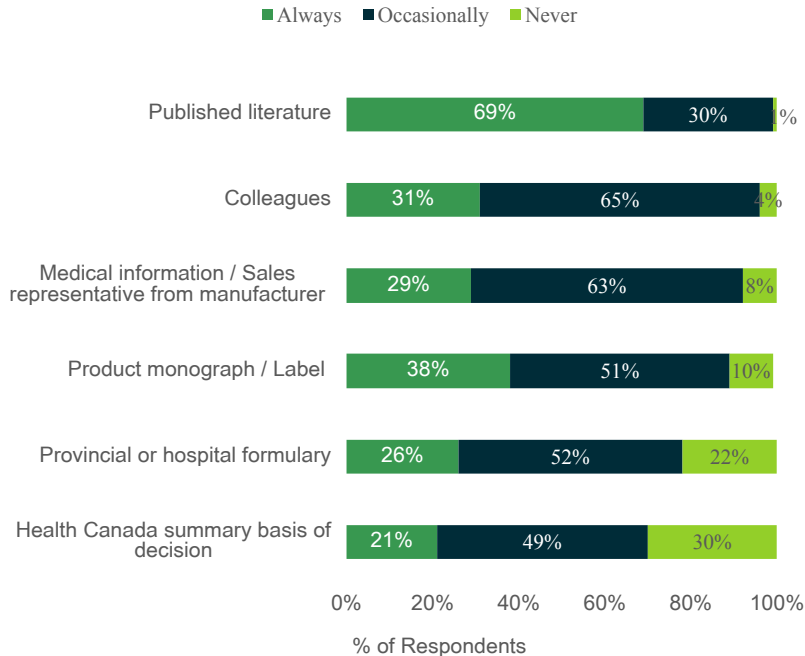
- “Please indicate your primary practice area or therapeutic area in which you practice.” (n=403)

Province



- “In what province / territory is your office location?” (n=403)

Use of information sources



Questions

- “How often do you use each of the following sources to learn about the details of a medicine for prescribing and monitoring?” (n=403)
- “Are there other sources you use to learn about the details of a medicine for prescribing and monitoring? If so, please specify.” Verbatim responses included in the attached Excel file below.



OTHER sources



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STUDY DATA

Understanding statistical significance

- ISR has provided regional statistical significance tests for each question.
- When highlighting the existence of segment differences, ISR uses the following format: Each column (province) has been assigned a letter (A thru D) and when a statistically significant difference occurs between segments, it is noted by one of these letters.
- Below are the regional statistical significance results of the question asking about prescribers' knowledge of the approval process for biosimilars.
 - How to read table: Physicians in B.C. (B: 78%) and Ontario (C: 74%) are more likely to answer “Yes” than physicians in Quebec (D: 57%). Similarly, physicians in Quebec (D: 43%) are more likely to answer “No” than physicians in B.C. (B: 22%), and Ontario (C:26%)

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Yes	70%	64%	78%D	74%D	57%
No	30%	36%	22%	26%	43%BC



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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 medicine'). 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 now becoming available in Canada. Unique to Canada, the patient support program for a biologic is paid for by the manufacturer and a change in biologic medications means a change in programs if the manufacturer is different.

STUDY INTRODUCTION

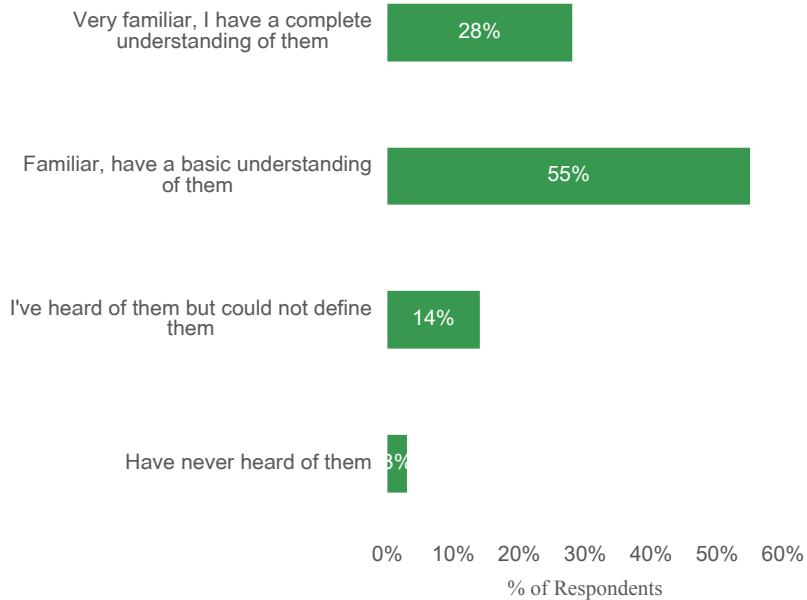


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BIOSIMILARS FAMILIARITY, KNOWLEDGE, ATTITUDES AND BELIEFS

Familiarity with biosimilars



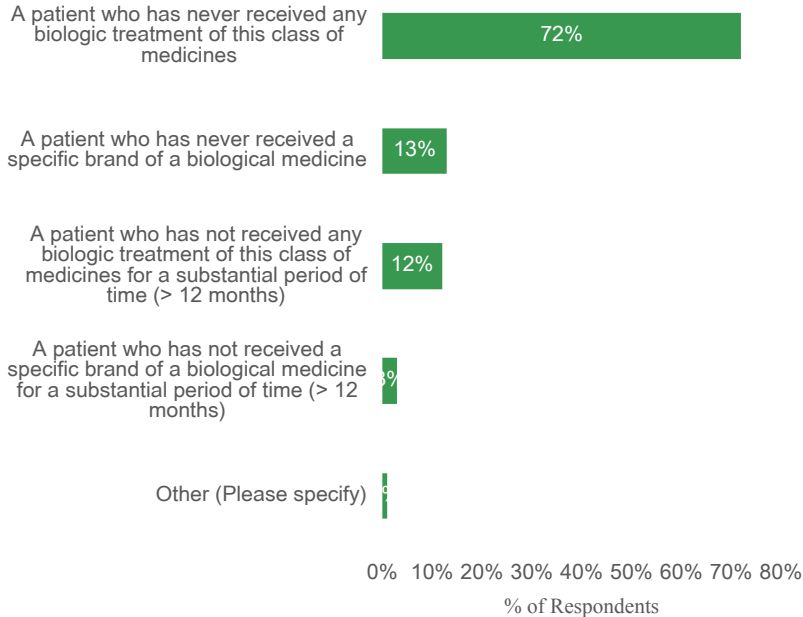
- Question
 - “How familiar are you with biosimilars?” (n=403)

Familiarity with biosimilars

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Very familiar	28%	38%	28%	27%	23%
Familiar	55%	47%	61%	58%	49%
Heard of them	14%	13%	11%	13%	22%
Never heard of them	3%	2%	0%	2%	7%

- Question
 - “How familiar are you with biosimilars?”

Defining “bio-naïve”



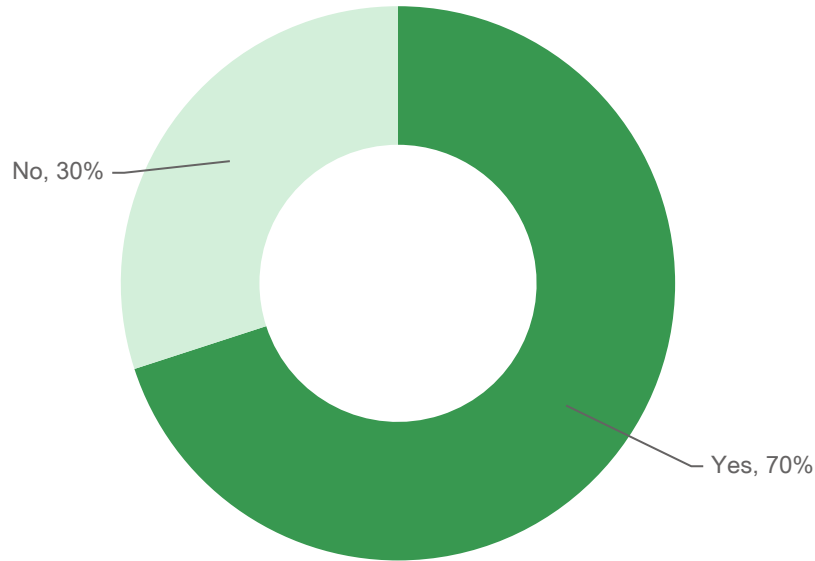
- Question
 - “How do you define “bio-naïve” patients with respect to biologics?” (n=403)

Defining “bio-naïve”

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
A patient who has never received a specific brand of biological medicine	13%	13%	20% ^C	9%	19% ^C
A patient who has never received any biological treatment of this class	72%	64%	69%	76%	68%
A patient who has not received a specific brand of a biological medicine for a substantial period of time	3%	4%	2%	3%	0%
A patient who has not received any biologic treatment of this class of medicines for a substantial period of time	12%	19%	9%	10%	14%
Other	1%	0%	0%	1%	0%

- Question
 - “How do you define “bio-naïve” patients with respect to biologics?”

Awareness of biosimilars approval process



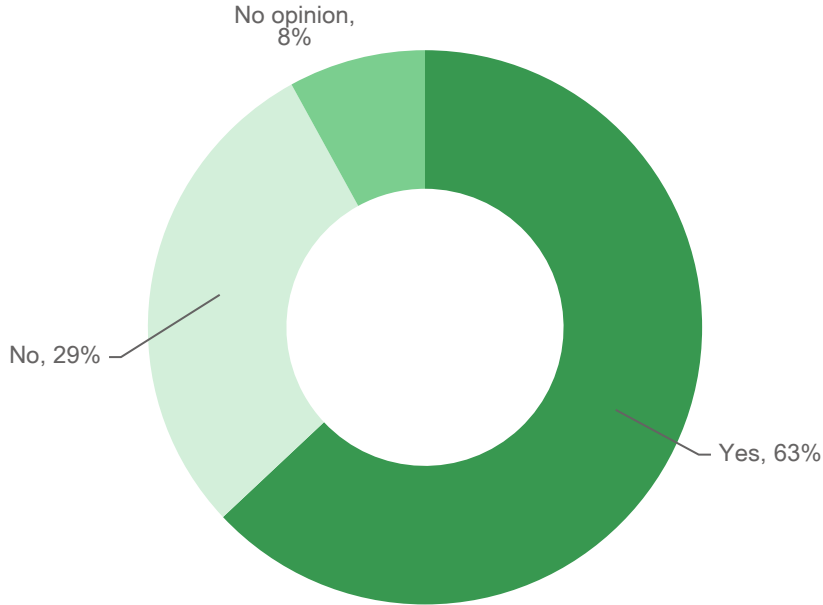
- Question
 - “Are you aware a biosimilar may be approved for several or all indications of the reference product on the basis of clinical trials in only one of those indications?” (n=403)

Awareness of biosimilars approval process

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Yes	70%	64%	78%D	74%D	57%
No	30%	36%	22%	26%	43%BC

- Question
 - “Are you aware a biosimilar may be approved for several or all indications of the reference product on the basis of clinical trials in only one of those indications?”

Approved for the same indications?



- Question

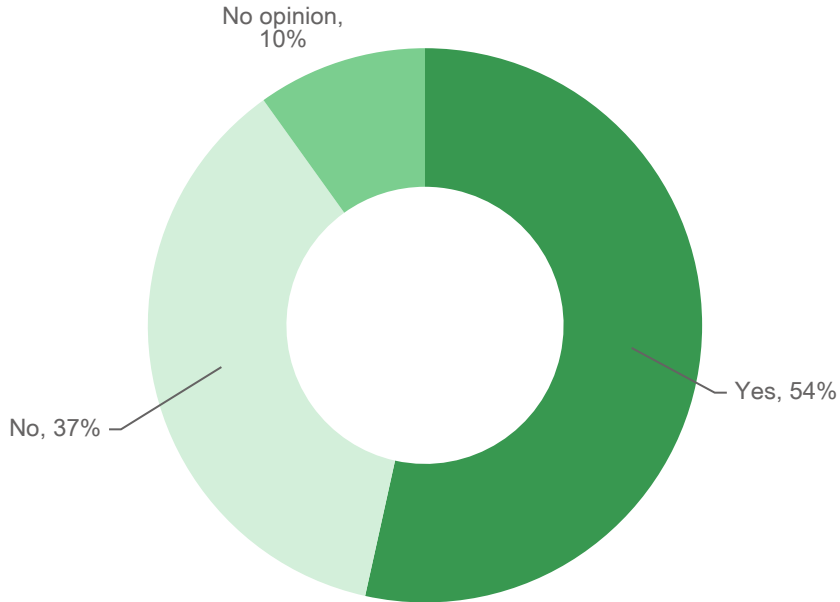
- If two biologic medicines have the same non-proprietary scientific name, does this suggest to you or imply that:
- ...the medicines are approved for the same indications?" (n=403)

Approved for the same indications?

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Yes	63%	62%	59%	65%	61%
No	29%	32%	35%	27%	28%
No opinion	8%	6%	6%	8%	11%

- Question
 - If two biologic medicines have the same non-proprietary scientific name, does this suggest to you or imply that:
 - ...the medicines are approved for the same indications?”

Identical?



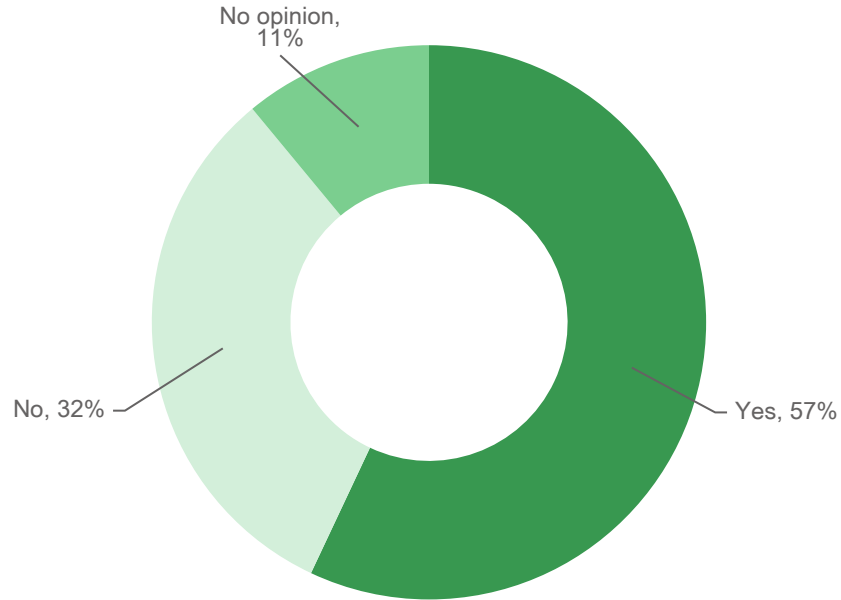
- Question
 - If two biologic medicines have the same non-proprietary scientific name, does this suggest to you or imply that:
 - ...the medicines are identical?" (n=403)

Identical?

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Yes	54%	68% ^C	52%	50%	55%
No	37%	25%	41%	39%	36%
No opinion	10%	8%	7%	11%	8%

- Question
 - If two biologic medicines have the same non-proprietary scientific name, does this suggest to you or imply that:
 - ...the medicines are identical?"

Receive either?

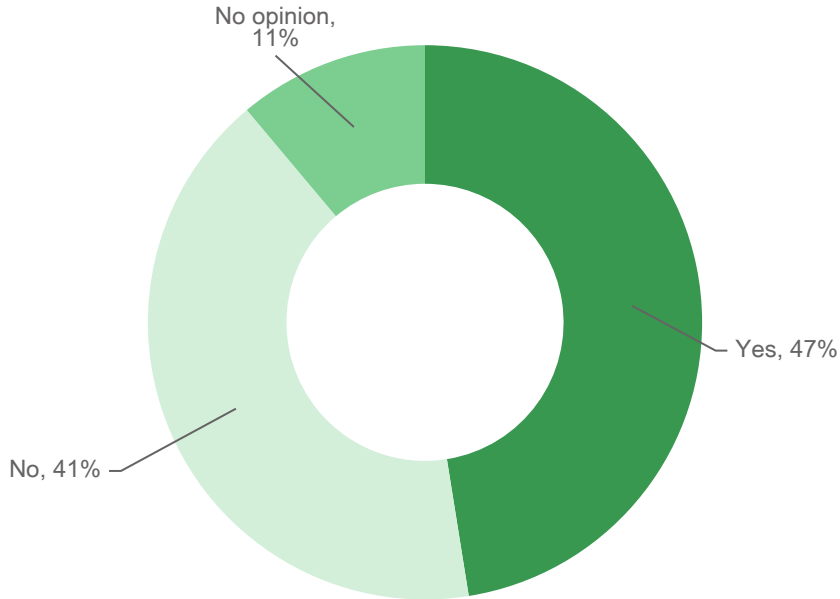


- Question
 - If two biologic medicines have the same non-proprietary scientific name, does this suggest to you or imply that:
 - ...a patient could receive either biologic drug and expect the same result?" (n=403)

Receive either?

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Yes	57%	66%	48%	55%	65%
No	32%	23%	46% ^{AD}	35% ^D	19%
No opinion	11%	11%	6%	10%	16%

- Question
 - If two biologic medicines have the same non-proprietary scientific name, does this suggest to you or imply that:
 - ...a patient could receive either biologic drug and expect the same result?"



- Question
 - If two biologic 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 a biosimilar during a course of treatment and expect the same result as with either of the products?" (n=403)

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Yes	47%	57%	39%	47%	47%
No	41%	34%	52%	40%	45%
No opinion	11%	9%	9%	14%	8%

- Question
 - If two biologic 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 a biosimilar during a course of treatment and expect the same result as with either of the products?"

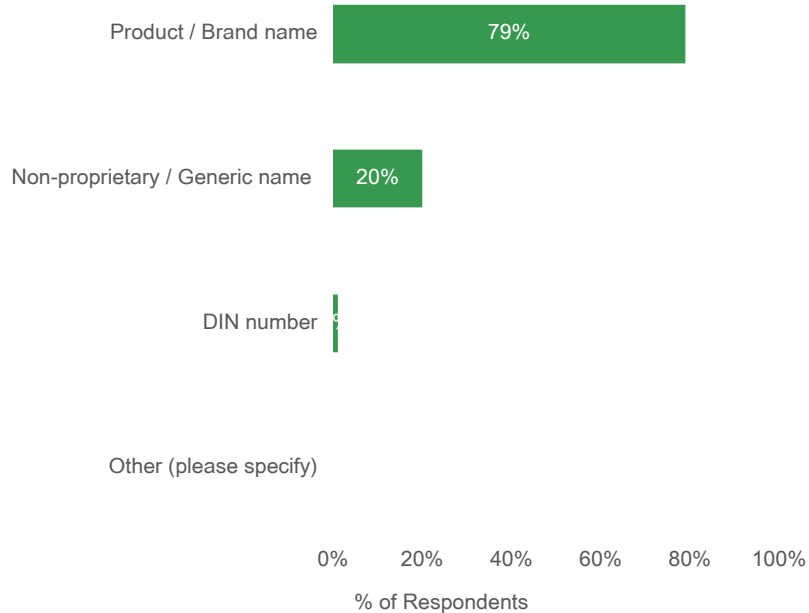


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REPORTING AND NAMING

How biologics are identified



- Question
 - “When you identify the prescription of a biologic drug in your patient record, are you likely to identify the medicine by:” (n=403)

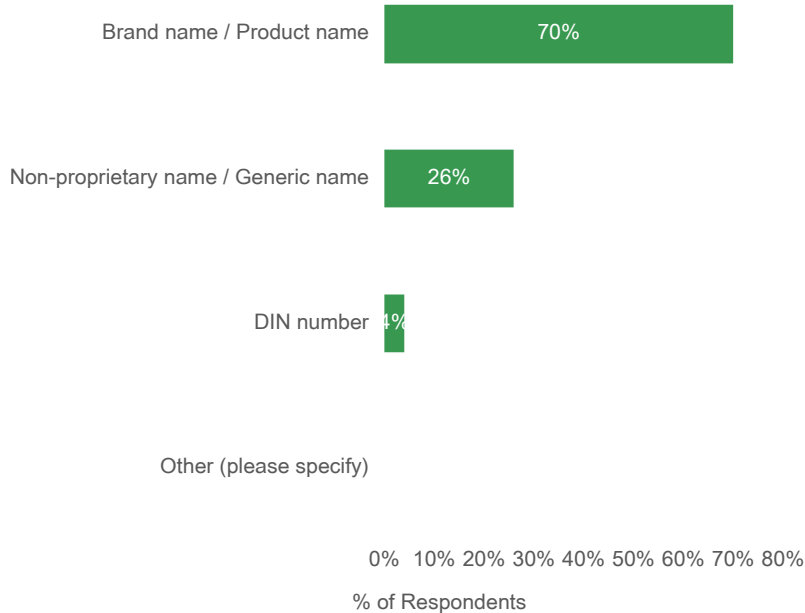
How biologics are identified

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Product / Brand name	79%	81%	65%	80%B	86%B
Non-proprietary / Generic name	20%	19%	31%D	20%	12%
DIN number	1%	0%	2%	0%	1%
Other	0%	0%	2%	0%	0%

- Question
 - “When you identify the prescription of a biologic drug in your patient record, are you likely to identify the medicine by:”



How biologics are identified – Adverse events



- Question
 - “In the context of identifying a biologic for the purposes of reporting an adverse event, how do you identify the medication?” (n=403)

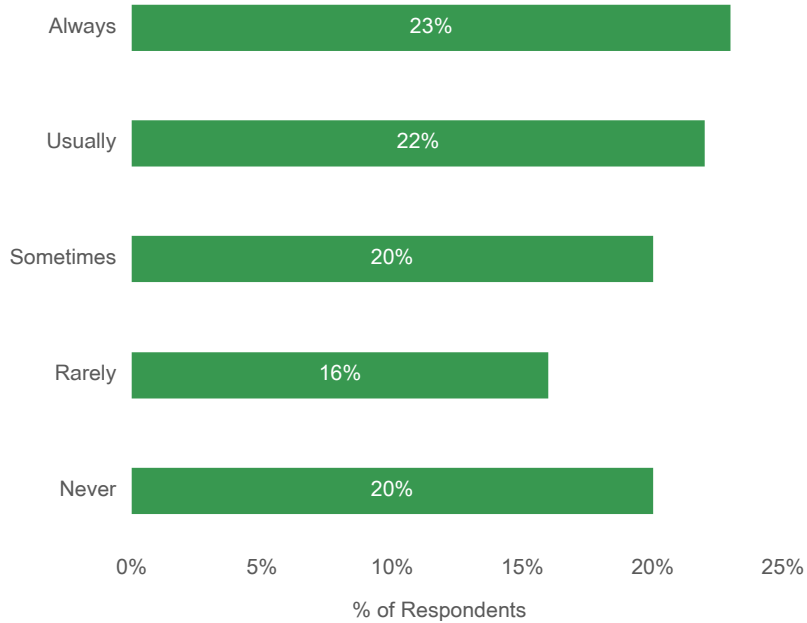
How biologics are identified – Adverse events

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Product / Brand name	70%	68%	52%	74%B	76%B
Non-proprietary / Generic name	26%	23%	43%ACD	24%	22%
DIN number	4%	9%C	6%	2%	3%
Other	0%	0%	0%	0%	0%

- Question

- “In the context of identifying a biologic for the purposes of reporting an adverse event, how do you identify the medication?”

Batch numbers?



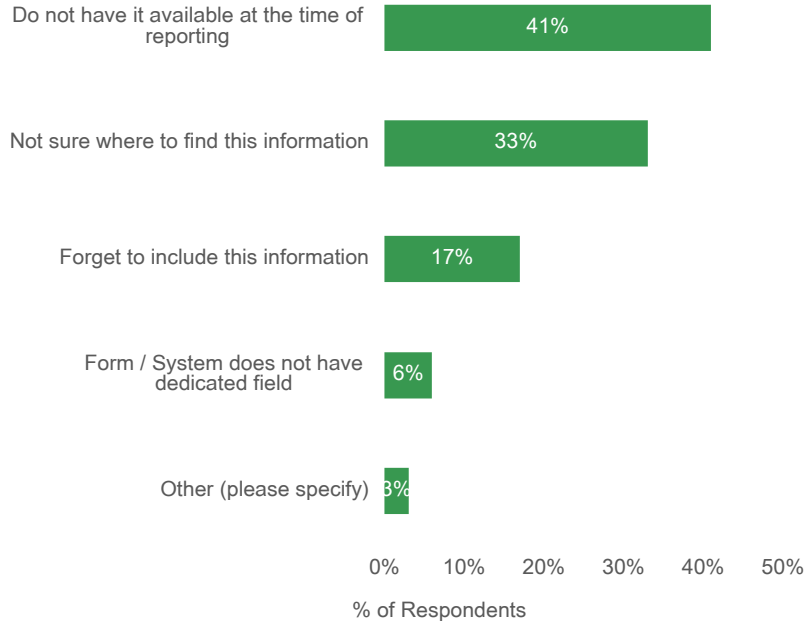
- Question
 - “How often do you include the batch number when reporting adverse events?” (n=403)

Batch numbers?

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Always	23%	36% BD	19%	25% D	12%
Usually	22%	26%	26%	20%	19%
Sometimes	20%	19%	20%	20%	22%
Rarely	16%	9%	28% AC	15%	15%
Never	20%	9%	7%	21% B	32% ABC

- Question
 - “How often do you include the batch number when reporting adverse events?”

Batch numbers?

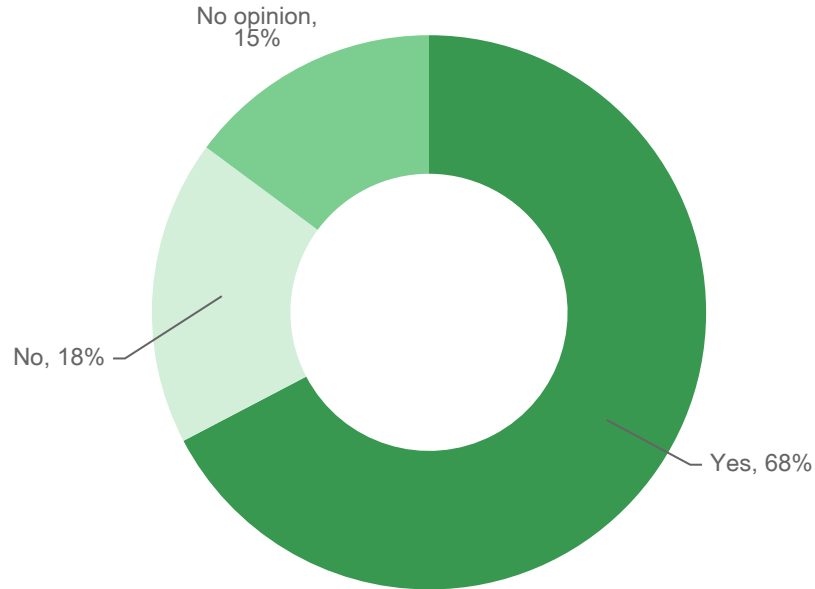


- Question
 - “What are the main reasons for not reporting the batch number?” (n=226)

Batch numbers?

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Not available	41%	25%	33%	45%	41%
Not sure where to find	33%	40%	57% ^{CD}	29%	25%
Forget	17%	25%	10%	17%	20%
Form / System does not have field	6%	10%	0%	4%	12%
Other	3%	0%	0%	4%	2%

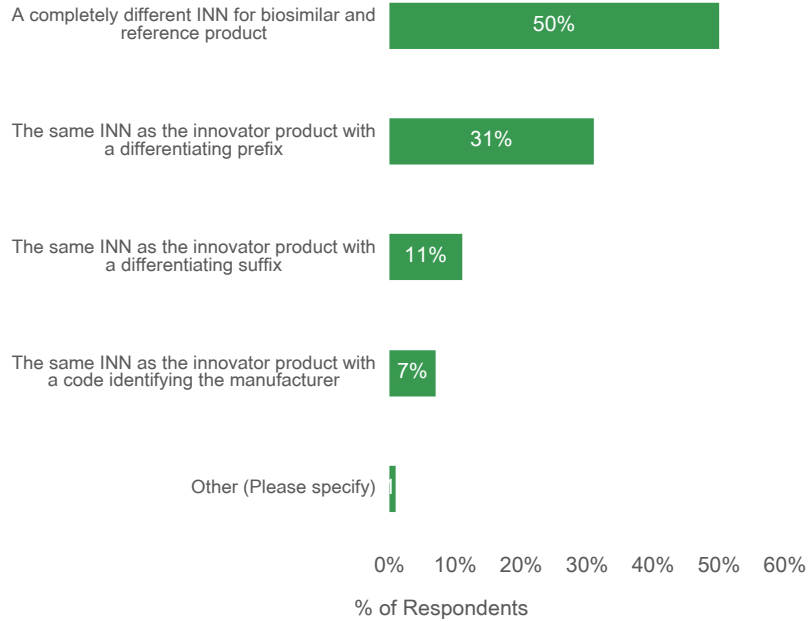
- Question
 - “What are the main reasons for not reporting the batch number?” (n=226)



- Question
 - “In your opinion, should the Health Canada insist on a distinct non-proprietary / generic name for every biologic or biosimilar approved by them?” (n=403)

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Yes	68%	68%	83% ^{CD}	65%	65%
No	18%	19%	15%	21% ^D	9%
No opinion	15%	13% ^B	2%	15% ^B	26% ^{BC}

- Question
 - “In your opinion, should the Health Canada insist on a distinct non-proprietary / generic name for every biologic or biosimilar approved by them?”



- Question
 - “What is the best way for Health Canada to differentiate a biosimilar medicine from the innovator biologic product?” (n=403)

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Different INN	50%	51%	50%	49%	53%
Same INN, different prefix	31%	34%	30%	30%	32%
Same INN, different suffix	11%	4%	17%	12%	11%
Same INN, manufacturer code	7%	9%	4%	8%	4%
Other	1%	2%	0%	2%	0%

- Question

- “What is the best way for Health Canada to differentiate a biosimilar medicine from the innovator biologic product?”



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SUBSTITUTION ATTITUDES & BELIEFS



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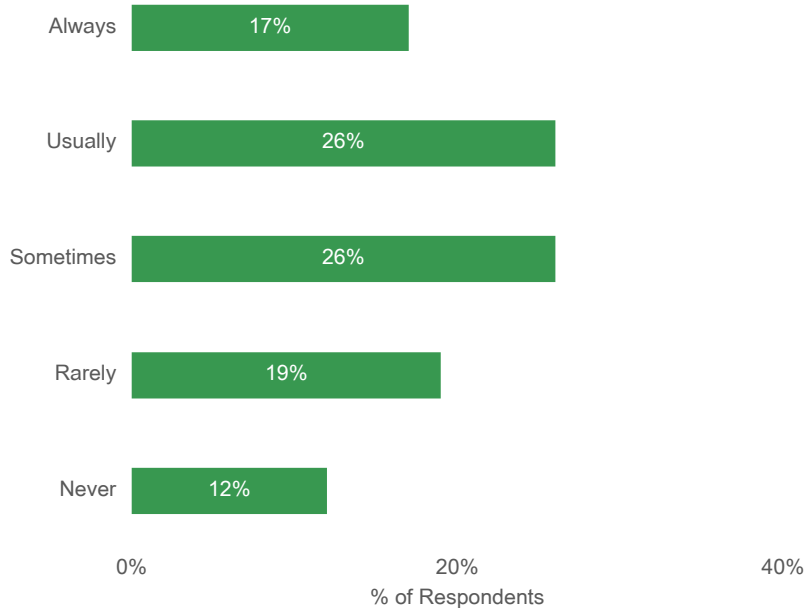
Health Canada has stated, biosimilars are not “generic biologics”... authorization of a biosimilar is not a declaration of pharmaceutical equivalence, bioequivalence or clinical equivalence to the reference biologic drug. – Health Canada Biosimilar Guidance Document, November 2016.

While provinces have the authority to determine interchangeability and automatic substitution of medicinal products, Health Canada advises against this practice in the case of biosimilars.

Health Canada has also recommended that a decision to switch a patient being treated with a reference biologic drug (innovator product) to a biosimilar should be made by the treating physician in consultation with the patient and taking into account available clinical evidence and any policies of the relevant jurisdiction. - Health Canada Biosimilar Fact Sheet, August 2017.

INTRODUCTION TO SUBSTITUTION

DAW, No substitution frequency



- Question
 - “Health Canada has specified that biosimilars are not identical to their comparator and should not be deemed interchangeable. When you prescribe a biologic drug, how often do you write “dispense as written” or “no substitution” on your prescriptions?” (n=403)

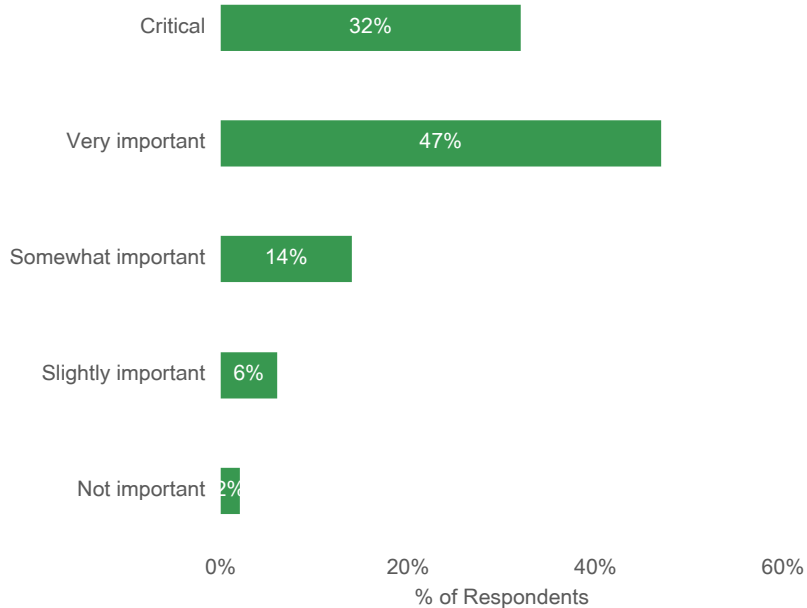
DAW, No substitution frequency

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Always	17%	28% ^{CD}	20%	15%	12%
Usually	26%	23%	24%	27%	26%
Sometimes	26%	26%	22%	29%	23%
Rarely	19%	13%	24%	18%	20%
Never	12%	9%	9%	11%	19%

- Question

- “Health Canada has specified that biosimilars are not identical to their comparator and should not be deemed interchangeable. When you prescribe a biologic drug, how often do you write “dispense as written” or “no substitution” on your prescriptions?”

Importance of DAW



- Question
 - “In a situation where substitution by a pharmacist is 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=403)

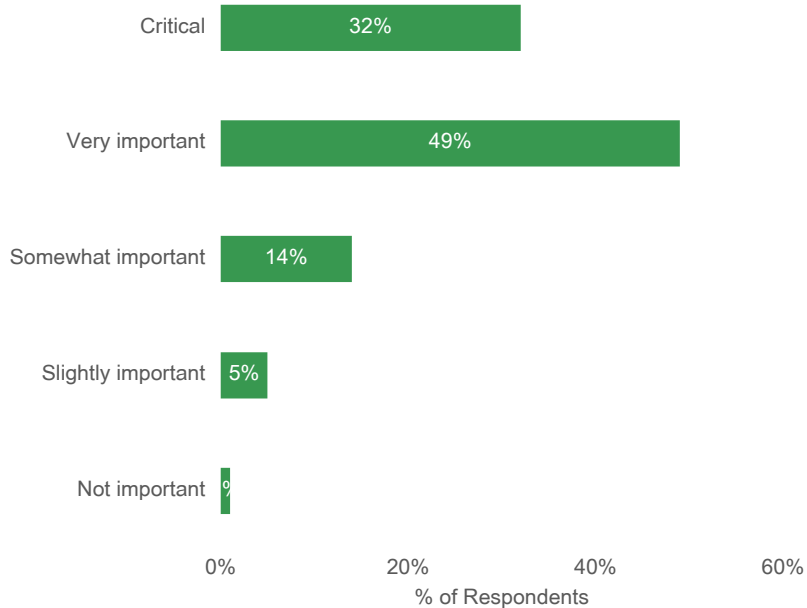
Importance of DAW

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Critically important	32%	36%D	31%D	38%D	12%
Very important	47%	40%	46%	49%	49%
Somewhat important	14%	19%	17%	10%	18%
Slightly important	6%	4%	6%	2%	18%AC
Not important	2%	2%	0%	1%	4%

- Question

- “In a situation where substitution by a pharmacist is 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"?”

Importance of DAW



- Question
 - “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 biosimilar, 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=403)

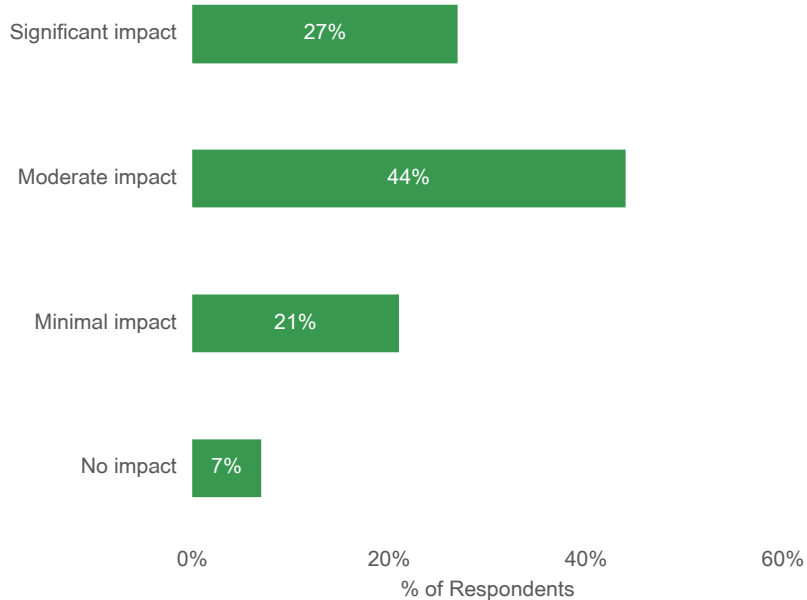
Importance of DAW

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Critically important	32%	32%	39%D	35%D	20%
Very important	49%	53%	43%	50%	45%
Somewhat important	14%	11%	11%	12%	23%C
Slightly important	5%	2%	7%	2%	12%AC
Not important	1%	2%	0%	0%	0%

- Question

- “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 biosimilar, how important would it be to you to have the authority to designate a biologic medicine as "DISPENSE AS WRITTEN" or "DO NOT SUBSTITUTE"?”

Impact of Health Canada position



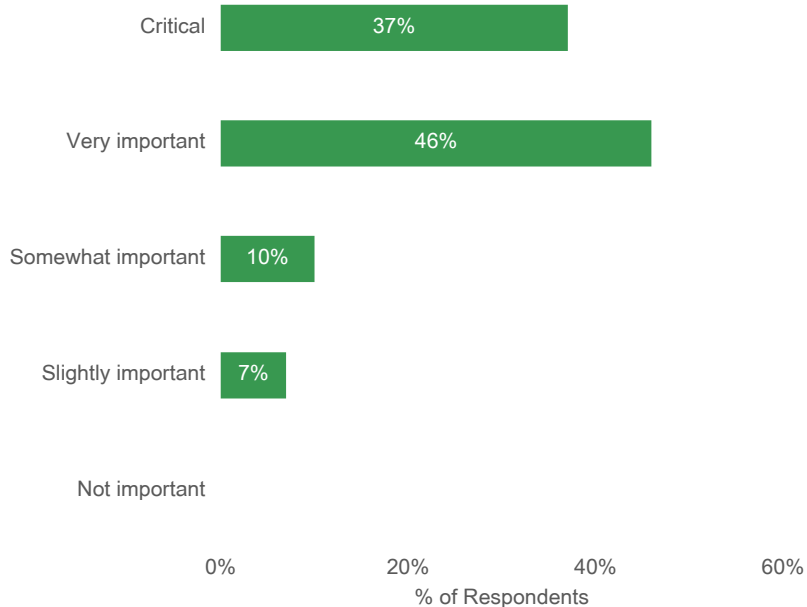
- Question
 - “How much impact will Health Canada’s science-based position on interchangeability have on your practice?” (n=403)

Impact of Health Canada position

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Significant impact	27%	38%	24%	27%	23%
Moderate impact	44%	43%	50%	44%	42%
Minimal impact	21%	15%	22%	23%	18%
No impact	7%	4%	4%	6%	18% ^{ABC}

- Question
 - “How much impact will Health Canada’s science-based position on interchangeability have on your practice?”

Importance of decision authority



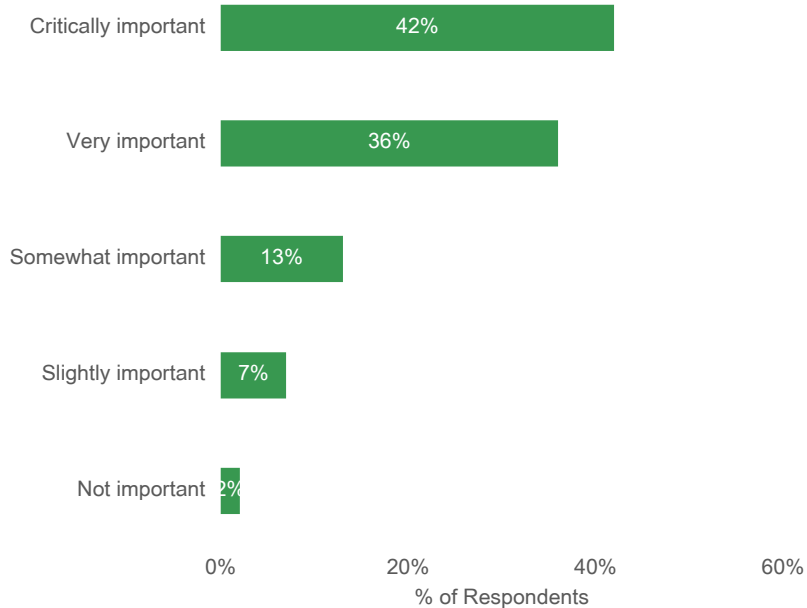
- Question
 - “How important is it to you as a prescribing physician to decide the most suitable therapeutic biologic for your patients?” (n=403)

Importance of decision authority

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Critically important	37%	45%D	35%	41%D	22%
Very important	46%	32%	48%	51%AD	36%
Somewhat important	10%	21%C	13%	6%	14%C
Slightly important	7%	2%	4%	2%	27%ABC
Not important	0%	0%	0%	0%	1%

- Question
 - “How important is it to you as a prescribing physician to decide the most suitable therapeutic biologic for your patients?”

Importance of notification



- Question

- “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=403)

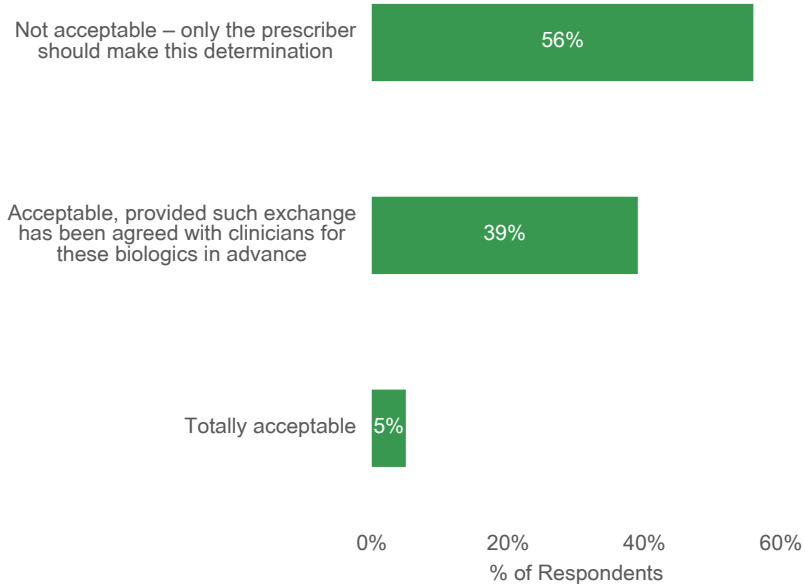
Importance of notification

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Critically important	42%	40%	54%D	45%D	24%
Very important	36%	45%D	33%	37%	28%
Somewhat important	13%	11%	9%	14%	14%
Slightly important	7%	2%	4%	2%	27%ABC
Not important	2%	2%	0%	1%	7%C

- Question

- “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?”

Pharmacist switching



- Question
 - “How acceptable would it be for you if the pharmacist made the determination which biologic (innovator or biosimilar) to dispense to your patient on initiation of treatment?” (n=403)

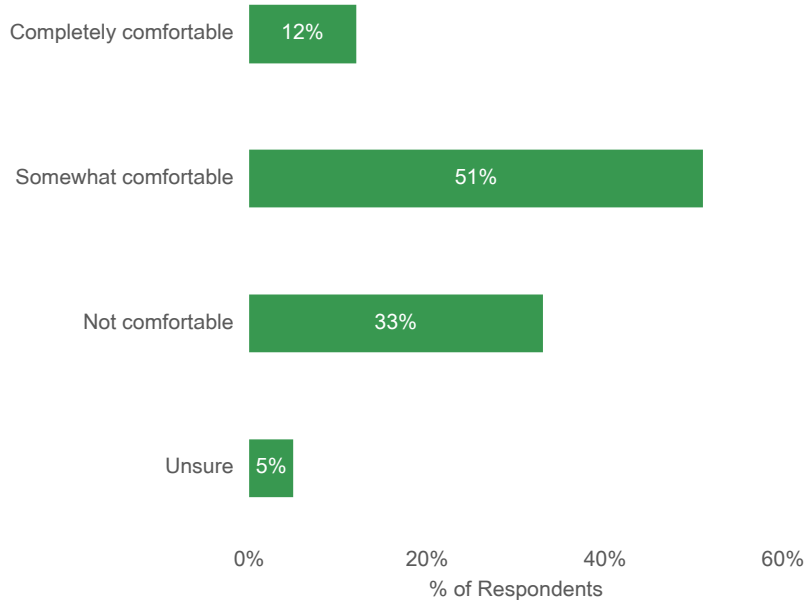
Pharmacist switching

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Not acceptable	56%	51%	63% ^D	59% ^D	43%
Acceptable with advanced agreement	39%	47%	33%	35%	50% ^C
Totally acceptable	5%	2%	4%	5%	7%

- Question

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

Non-medical switching



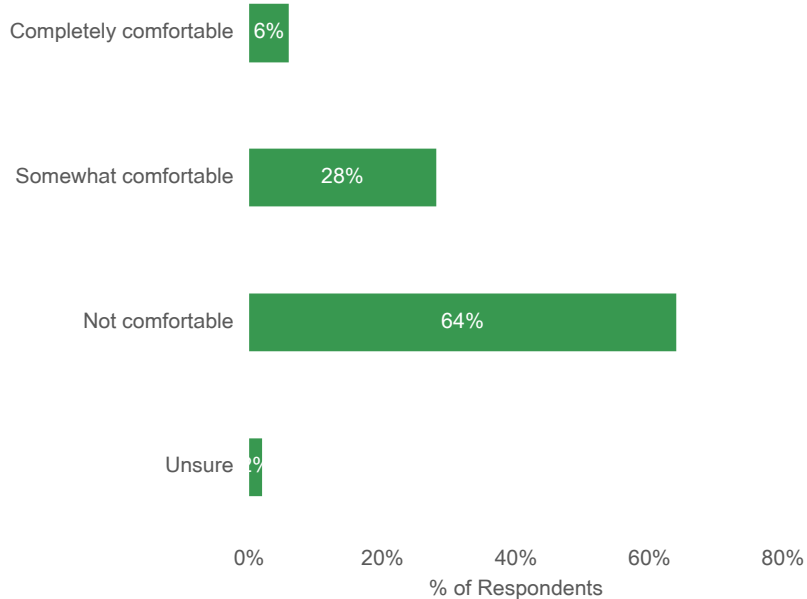
- Question
 - “How comfortable are you with switching your patient to a biosimilar for non-medical reasons (i.e., coverage)?” (n=403)

Non-medical switching

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Completely comfortable	12%	11%	20% ^D	11%	8%
Somewhat comfortable	51%	49%	50%	52%	49%
Not comfortable	33%	38%	26%	32%	38%
Unsure	5%	2%	4%	5%	5%

- Question
 - “How comfortable are you with switching your patient to a biosimilar for non-medical reasons (i.e., coverage)?”

3rd party non-medical switching



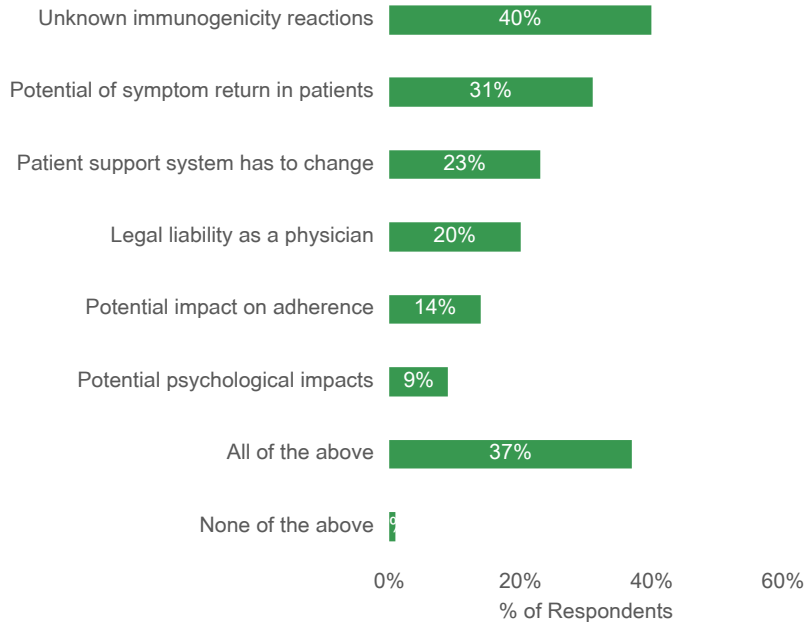
- Question
 - “How comfortable are you with a third-party switching your patient to a biosimilar for non-medical reasons (i.e., coverage)?” (n=403)

3rd party non-medical switching

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Completely comfortable	6%	6%	11%	5%	5%
Somewhat comfortable	28%	36%	26%	28%	26%
Not comfortable	64%	58%	59%	66%	65%
Unsure	2%	0%	4%	1%	4%

- Question
 - “How comfortable are you with a third-party switching your patient to a biosimilar for non-medical reasons (i.e., coverage)?”

Non-medical switching



- Question

- “What concerns you about non-medical switching to a biosimilar?” (n=371)

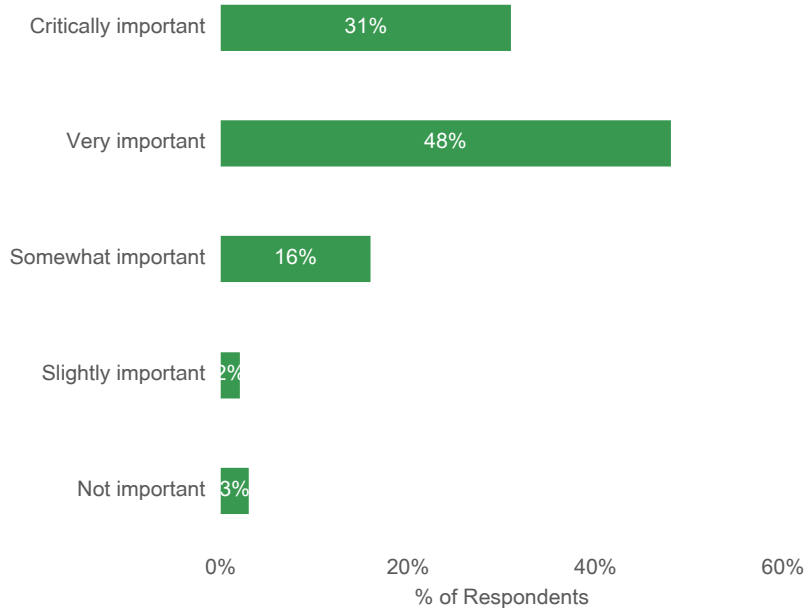
Non-medical switching

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Immunogenicity reactions	40%	33%	43%	38%	46%
Symptom return	31%	31%	31%	32%	28%
Patient support system change	23%	31%B	10%	23%B	28%B
Legal liability	20%	20%	27%	18%	25%
Adherence	14%	22%D	18%	12%	9%
Psychological impact	9%	16%C	12%	6%	7%
All of the above	37%	39%	41%	37%	35%
None of the above	1%	1%	0%	1%	0%

- Question

- “What concerns you about non-medical switching to a biosimilar?” (n=371)

Importance of informed consent



- Question

- “How important do you believe it is for a patient to provide informed consent before a biosimilar is automatically substituted at the pharmacy level?” (n=403)

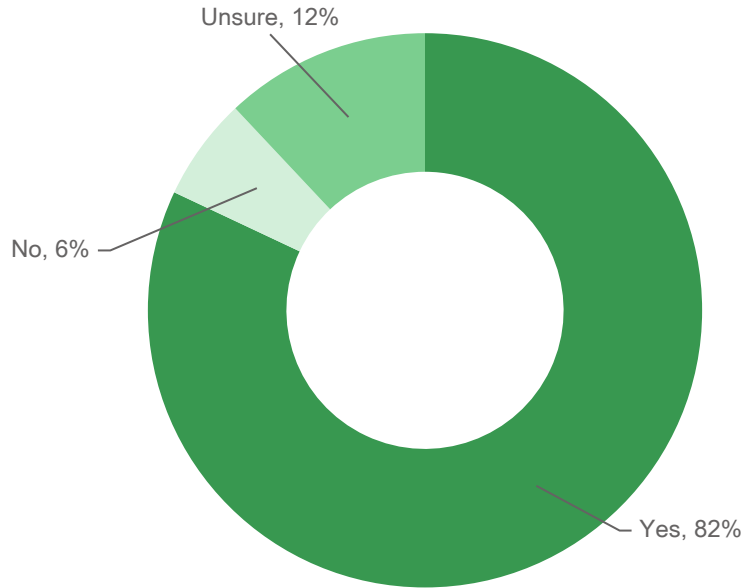
Importance of informed consent

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Critically important	31%	36%	22%	33%	26%
Very important	48%	43%	61% ^C	46%	49%
Somewhat important	16%	17%	13%	15%	22%
Slightly important	2%	2%	2%	3%	0%
Not important	3%	2%	2%	3%	4%

- Question

- “How important do you believe it is for a patient to provide informed consent before a biosimilar is automatically substituted at the pharmacy level?”

Need for switching studies?



- Question

- “While provinces have the authority to determine interchangeability and automatic substitution of medicinal products, Health Canada advises against this practice in the case of biosimilars. Prior to deciding whether automatic substitution should be allowed by a pharmacist or payer, do you believe studies should be conducted that measure the effects of switching on patient safety and product efficacy?” (n=403)

Need for switching studies?

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Yes	82%	77%	85%	83%	78%
No	6%	11% ^C	7%	4%	5%
Unsure	12%	11%	7%	12%	16%

- Question

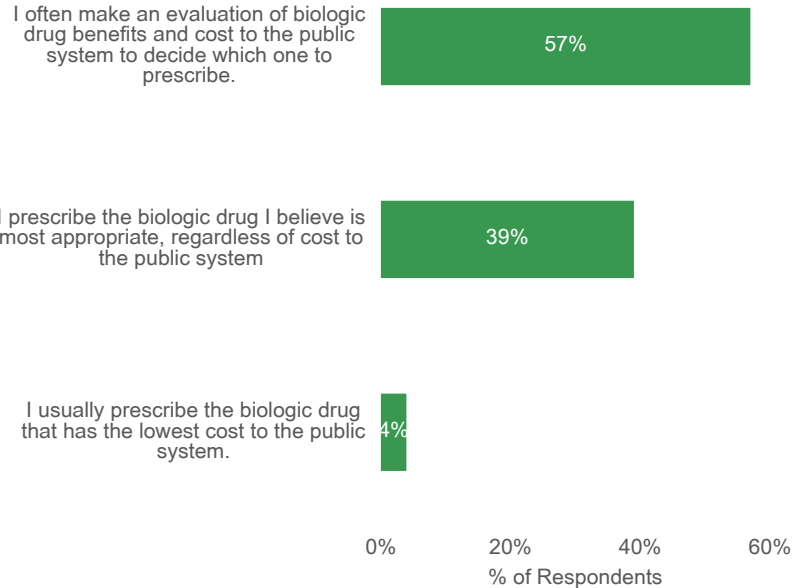
- “While provinces have the authority to determine interchangeability and automatic substitution of medicinal products, Health Canada advises against this practice in the case of biosimilars. Prior to deciding whether automatic substitution should be allowed by a pharmacist or payer, do you believe studies should be conducted that measure the effects of switching on patient safety and product efficacy?”



Smarter questions ∴ Smarter answers

ASBM

PRESCRIBING INFLUENCERS

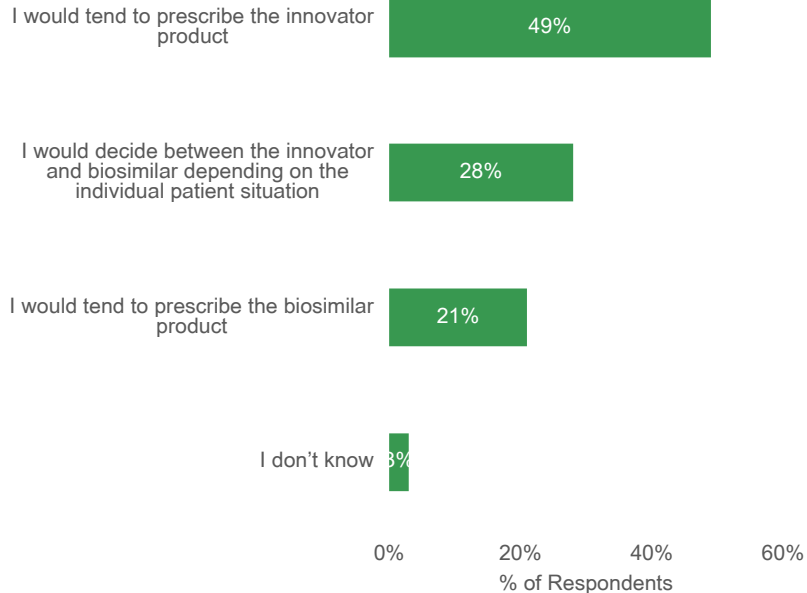


- Question
 - “How do costs to the public system impact which biologic drug you prescribe?” (n=403)

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
I often make an evaluation of biologic drug benefits and cost to the public system to decide which one to prescribe.	57%	68%	63%	53%	55%
I prescribe the biologic drug I believe is most appropriate, regardless of cost to the public system	39%	32%	30%	43%	39%
I usually prescribe the biologic drug that has the lowest cost to the public system.	4%	0%	7%	3%	5%

- Question
 - “How do costs to the public system impact which biologic drug you prescribe?”

Preference for brand



- Question
 - “If cost to the public system were not a factor, how would that impact your choice of innovator vs biosimilar prescription?” (n=246)

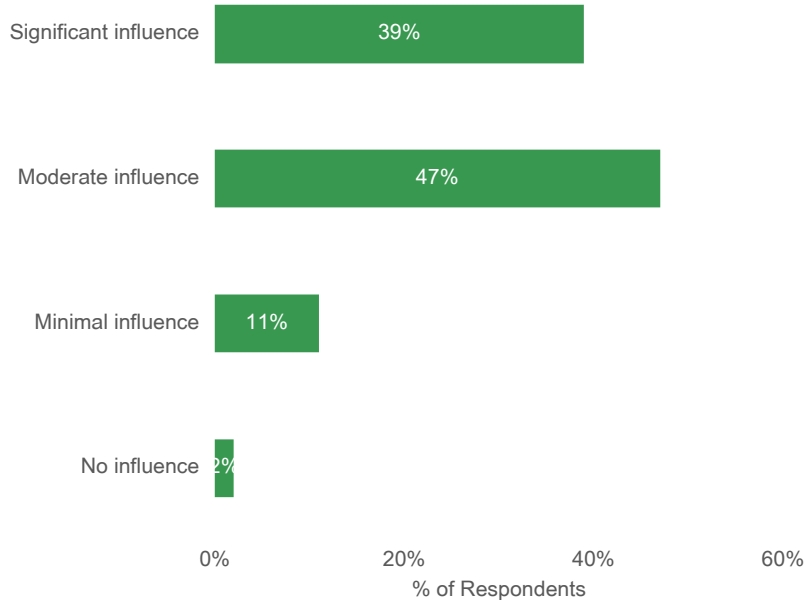
Preference for brand

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
I would tend to prescribe the innovator product	49%	47%	50%	48%	51%
Depends on individual patient	28%	25%	26%	32%	20%
I would tend to prescribe the biosimilar	21%	28%	21%	17%	24%
I don't know	3%	0%	3%	3%	4%

- Question

- “If cost to the public system were not a factor, how would that impact your choice of innovator vs biosimilar prescription?” (n=246)

Patient support



- Question
 - “What influence does the quality of a biologic’s patient support program have on which biologic you prescribe?” (n=403)

Patient support

	Total	Alberta (A)	B.C. (B)	Ontario (C)	Quebec (D)
Significant influence	39%	45%B	26%	40%	42%
Moderate influence	47%	45%	48%	49%	45%
Minimal influence	11%	4%	24%ACD	10%	9%
No influence	2%	6%	2%	1%	4%

- Question
 - “What influence does the quality of a biologic’s patient support program have on which biologic you prescribe?”