

ASBM Canadian Prescribers Survey

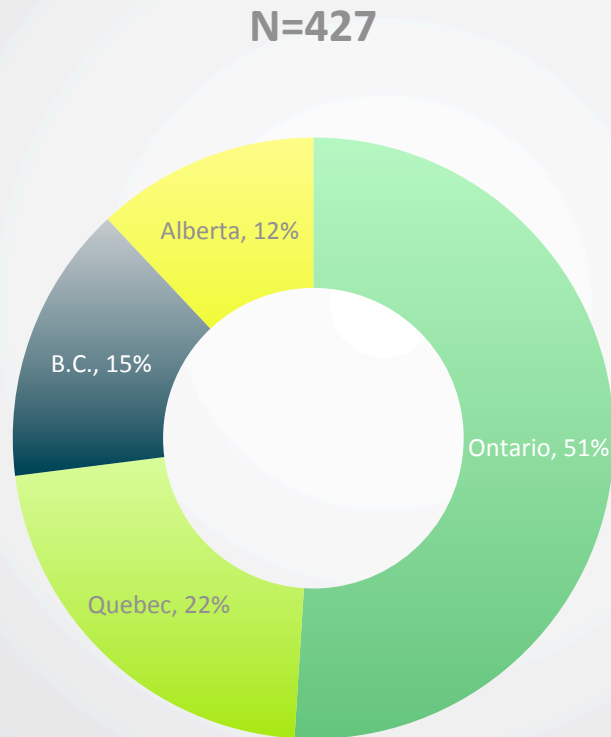
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- 427 Prescribers were recruited from 4 provinces in Canada
 - Alberta (n=53)
 - British Columbia (n=63)
 - Ontario (n=217)
 - Quebec (n=94)
- 15 minute web-based survey

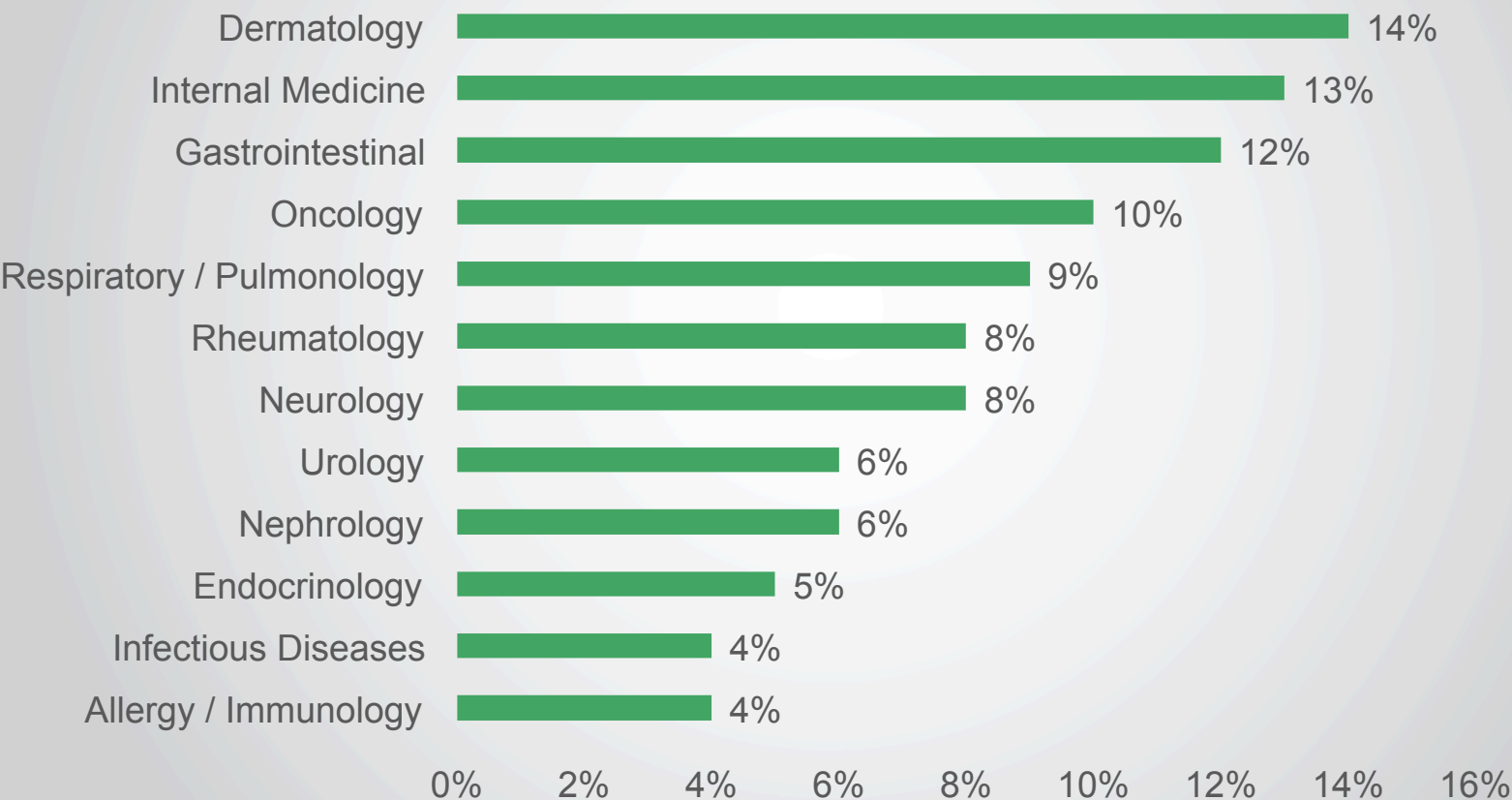
Demographic Data

SAMPLE CHARACTERISTICS



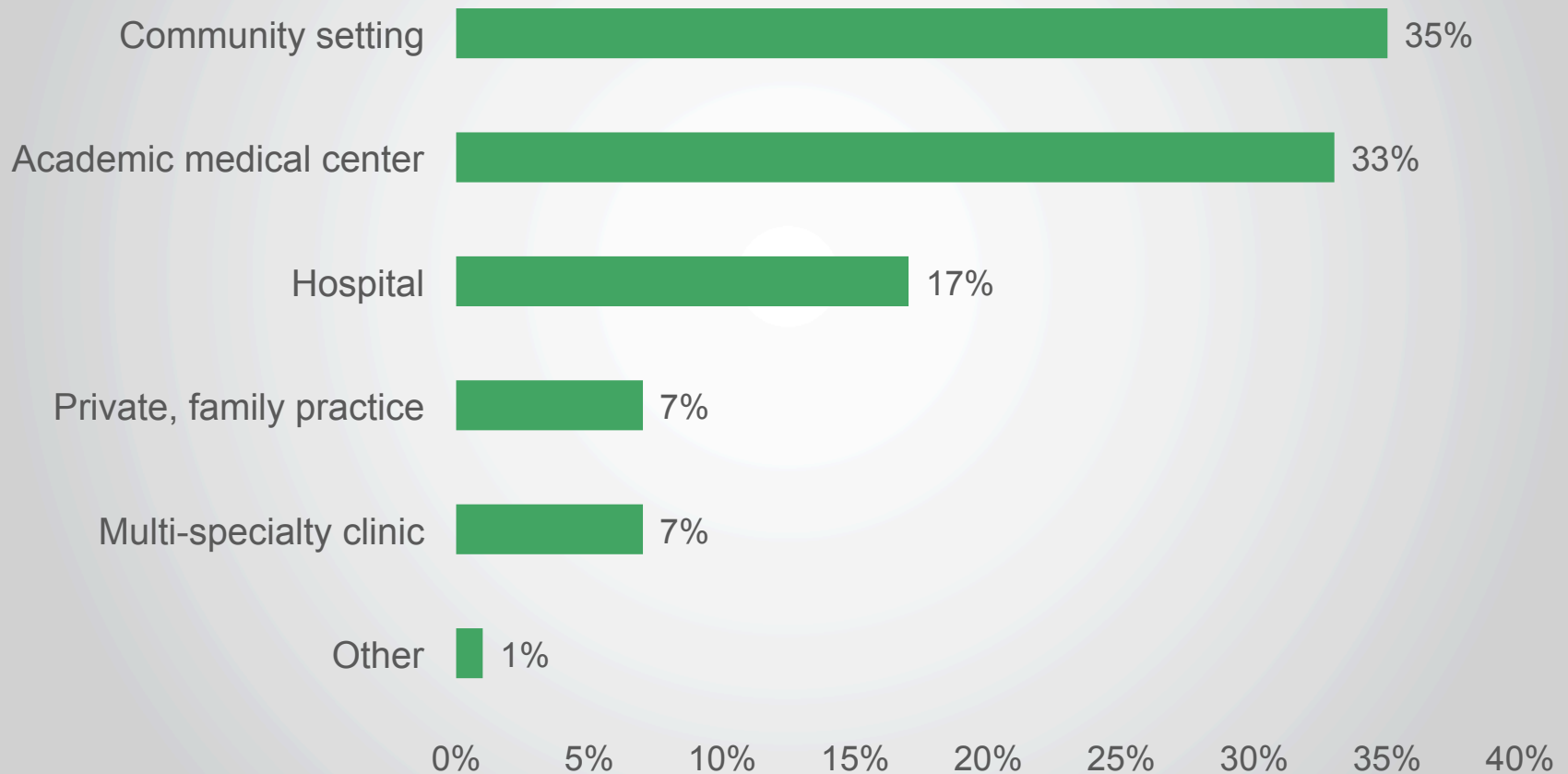
Primary therapeutic area

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



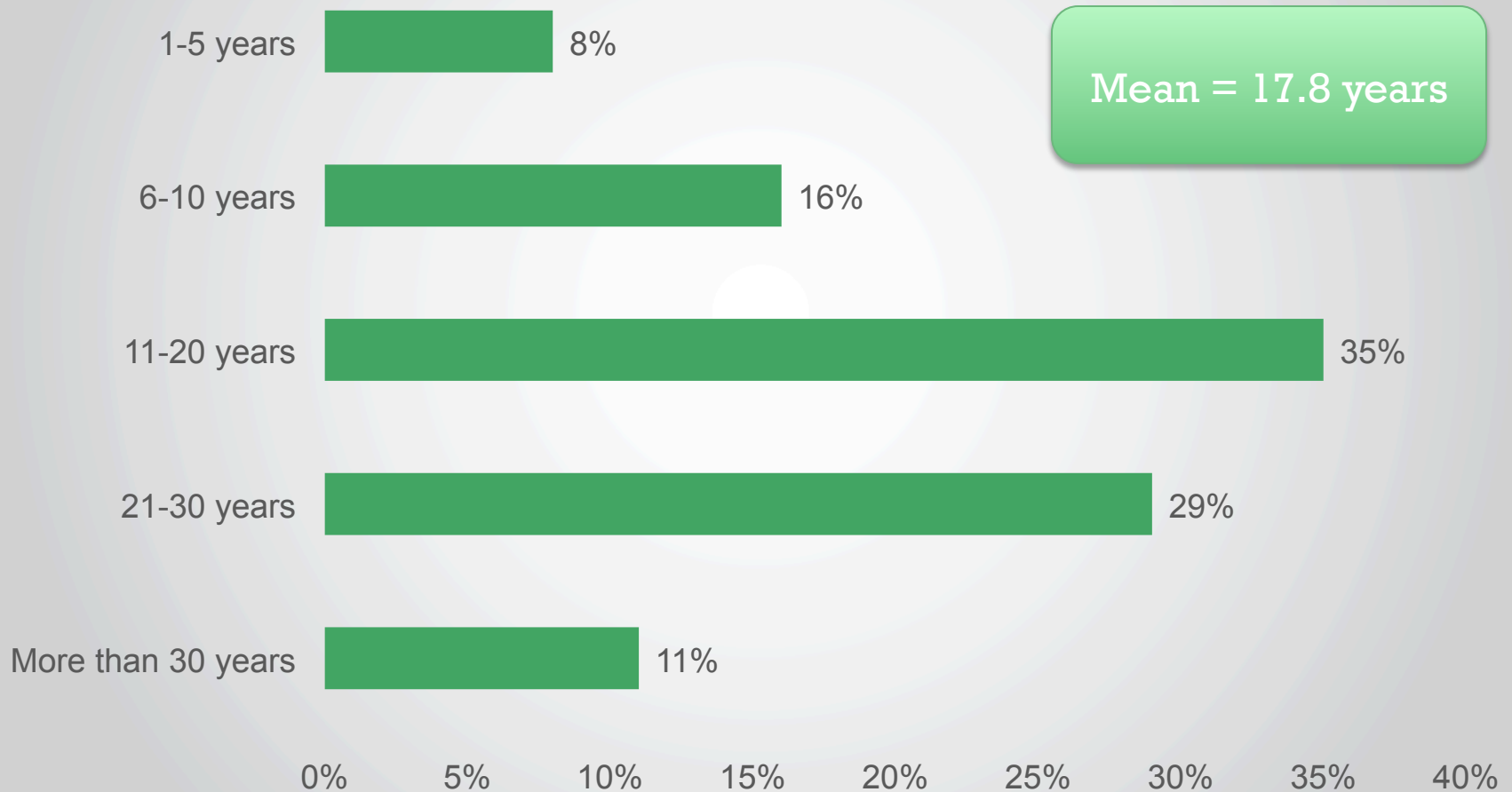
Practice setting

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

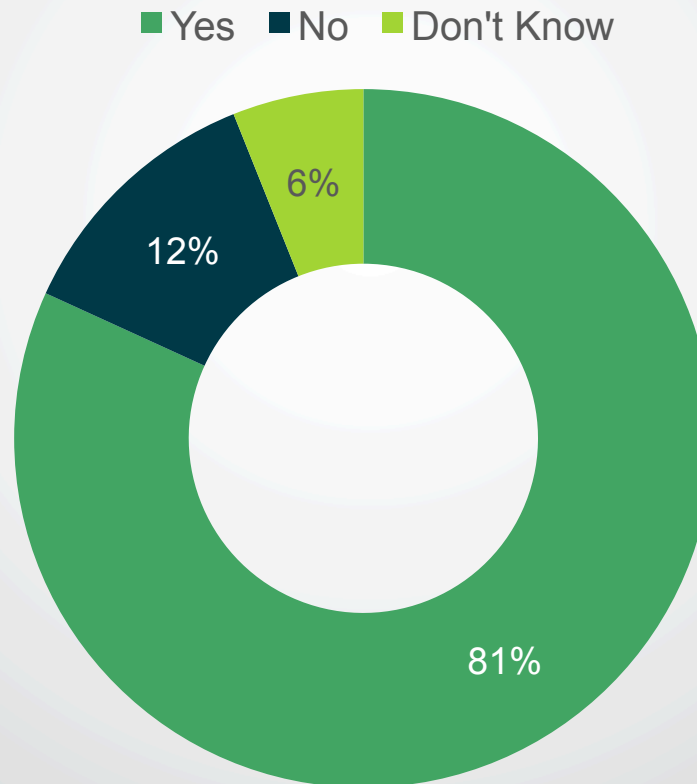


Length of time in healthcare sector

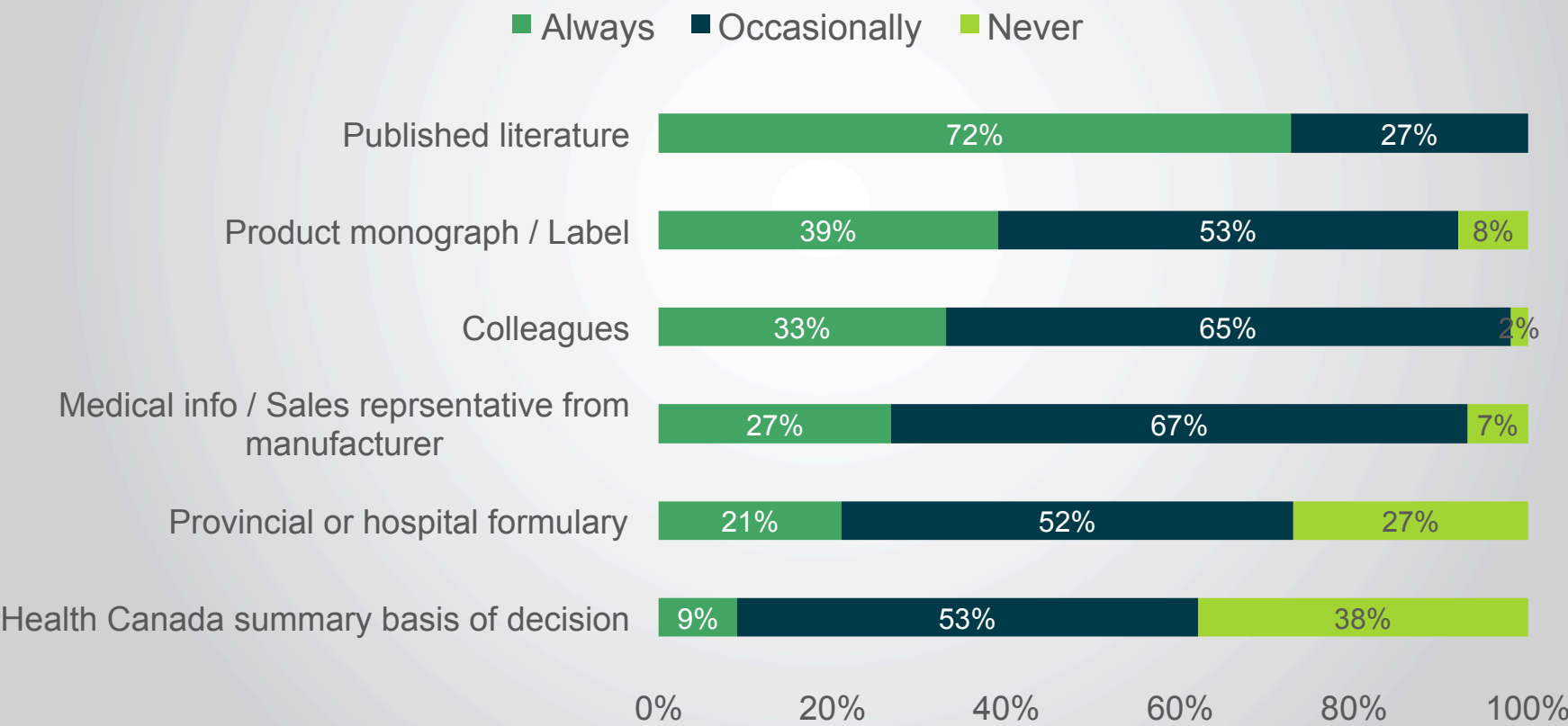
"How long have you been in medical practice?" (N=427)



“Do you commonly treat patients who you are aware are being prescribed biologic medicines by another health care provider?” (N=427)



“How often do you use each of the following sources to learn about the details of a medicine for prescribing and monitoring?” (N=427)

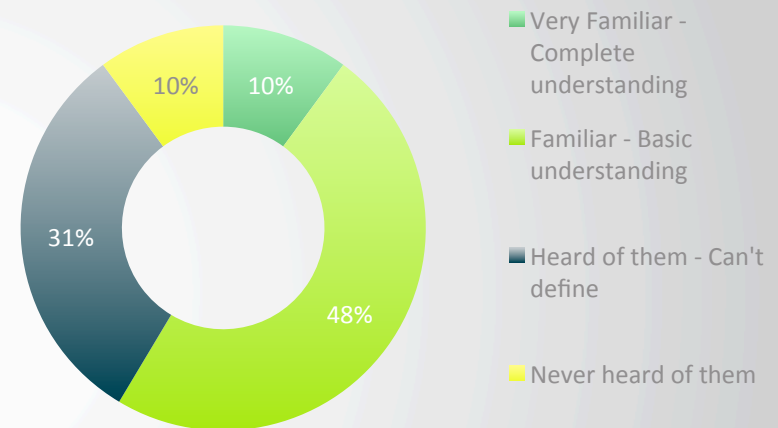


EXECUTIVE SUMMARY

SEB Knowledge

- A need for SEB education is evident - 41% of prescribers do not consider themselves familiar with these medicines.
- Nearly half of all prescribers are unaware that clinical trials for a single indication lead to approval for multiple indications.

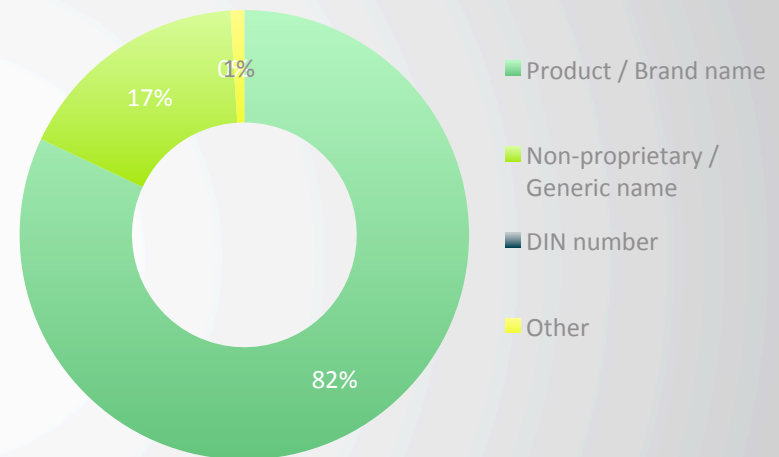
Familiarity with SEBs



Identifying the Drug

- Canadian prescribers overwhelmingly (82%) report identifying drugs in patient records by their brand name.
- When reporting AEs, 70% use brand names.

Identifying Drugs



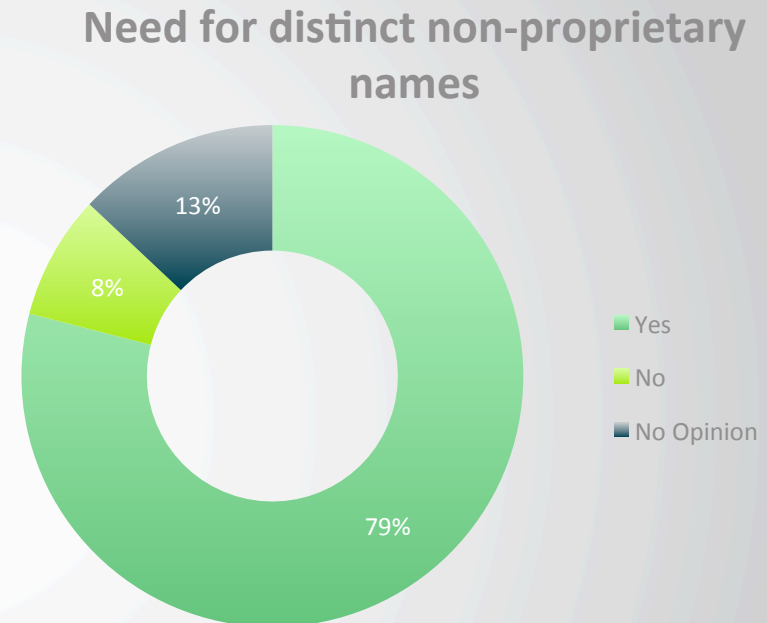
Naming

“If two medicines have the same non-proprietary scientific name, does this suggest to you or imply...

- Structurally identical – Yes = 64%
- Receive either with the same results – Yes = 62%
- Safely switch during treatment, with the same results – Yes = 49%
- Approved for the same indications – Yes = 76%

Naming, cont.

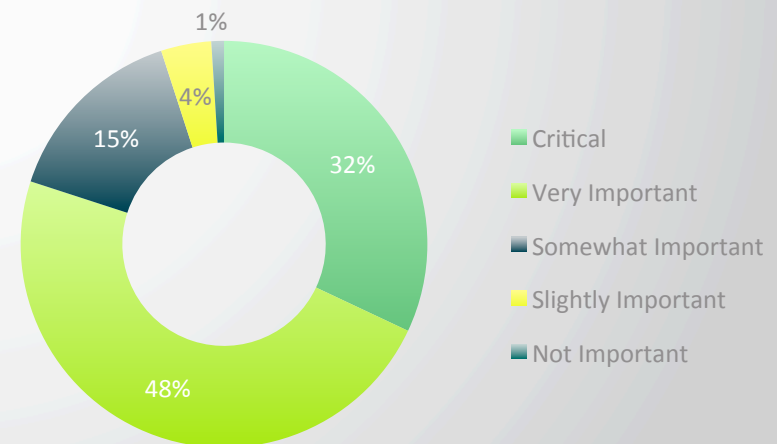
- 79% believe Health Canada should insist on distinct non-proprietary names.
- Most (54%) believe a completely different INN is most appropriate.



Pharmacy Substitution

- 87% of prescribers consider it “Critical” or “Very Important” that prescribers decide which biologic is most suitable.
- 80% regard DAW authority as “Critical” or “Very Important.”

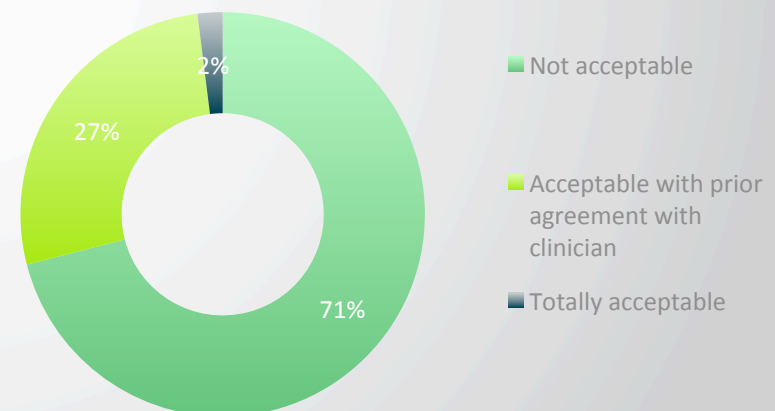
Importance of DAW



Notification

- 85% consider it “Critical” or “Very Important” to receive notification of a switch.
- 2% consider pharmacy level substitution totally acceptable.
- 27% consider switching to a biosimilar acceptable, pending agreement of the prescriber.

Pharmacist Decision Making



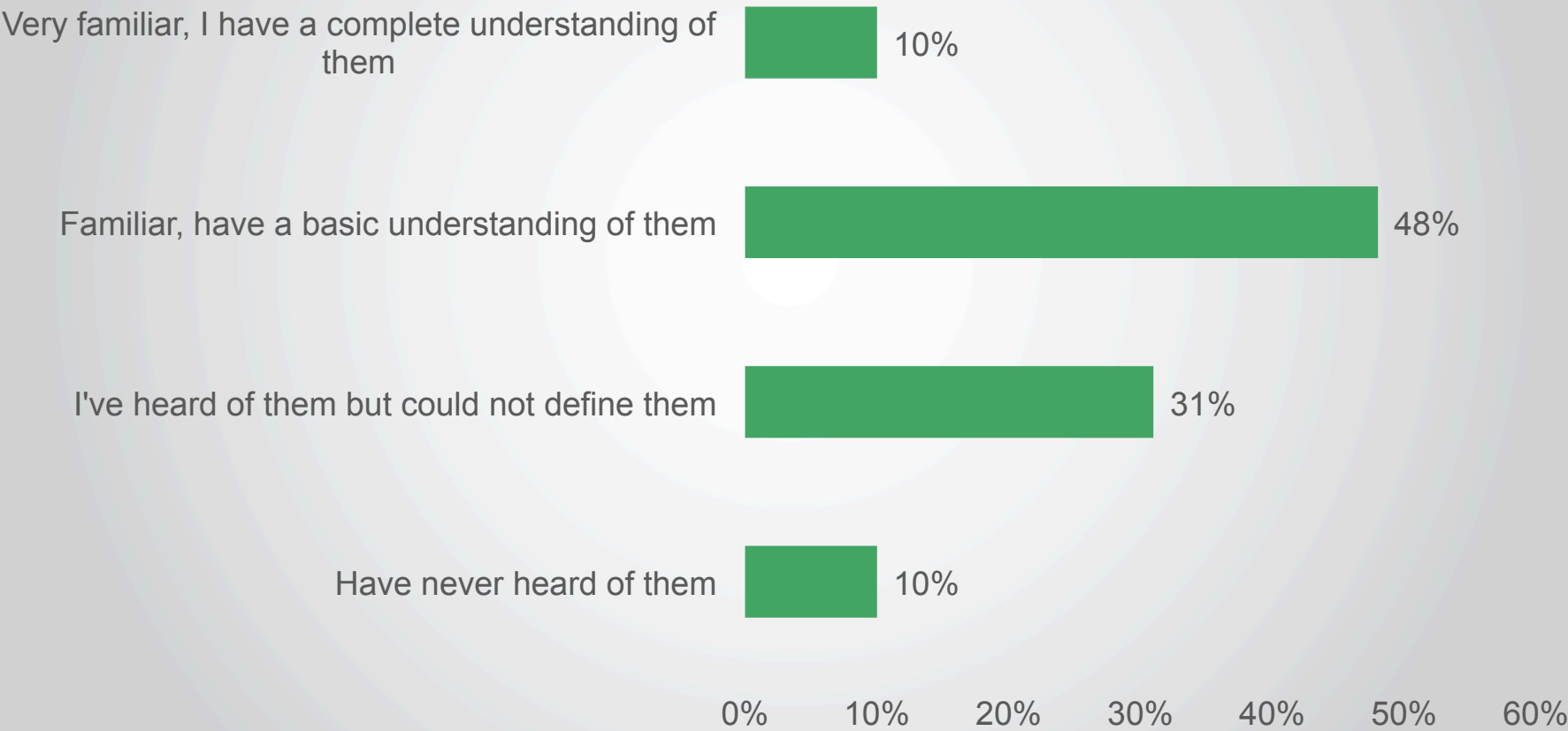
Study Data

FAMILIARITY

- ISR has provided regional statistical significance tests for each question
- When highlighting the existence of segment differences, ISR uses the following format: Each column (country) 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 SEBs.
 - How to read table: Physicians in Quebec (D: 62%) are more likely to answer “No” than physicians in Alberta (A: 32%), British Columbia (B: 44%), and Ontario (C:44%)

	Total N=427	Alberta N=53 A	B.C. N=63 B	Ontario N=217 C	Quebec N=94 D
No	47%	32%	44%	44%	62% ABC
Yes	53%	68% D	56% D	56% D	38%

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



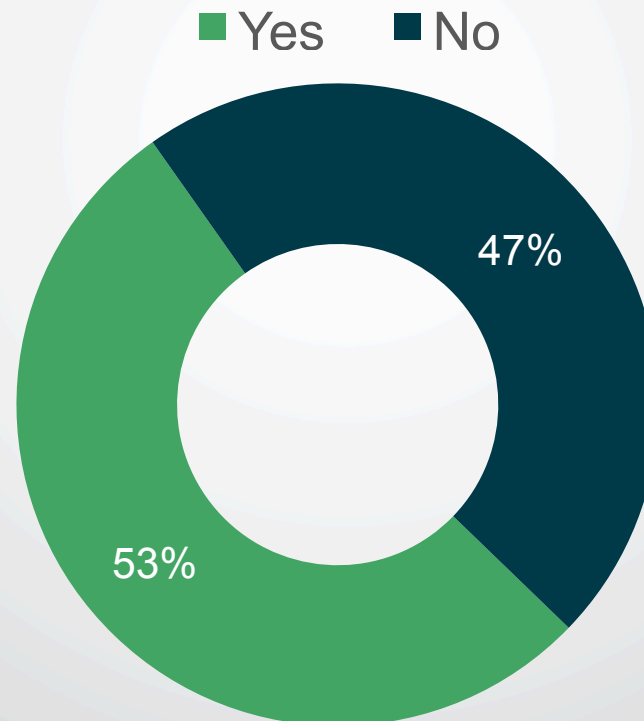
Significance: Familiarity with Subsequent Entry Biologic medicines

- Prescribers in Alberta are more likely to be “very familiar” with biologic medicines than others, especially those in Ontario.
- Prescribers in Quebec indicate a lower level of awareness than most.

	Total N=427	Alberta N=53 A	B.C. N=63 B	Ontario N=217 C	Quebec N=94 D
Very Familiar	10%	23% C	11%	7%	11%
Familiar	48%	45%	54%	50%	41%
I've heard of them	31%	21%	30%	34%	31%
Have never heard of them	10%	11%	5%	9%	17% BC

Biosimilar approval awareness

“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)



Significance: Biosimilar approval awareness

- Overall, about half of prescribers are aware of this dynamic.
- Prescribers in Quebec show significantly lower levels of awareness than others.

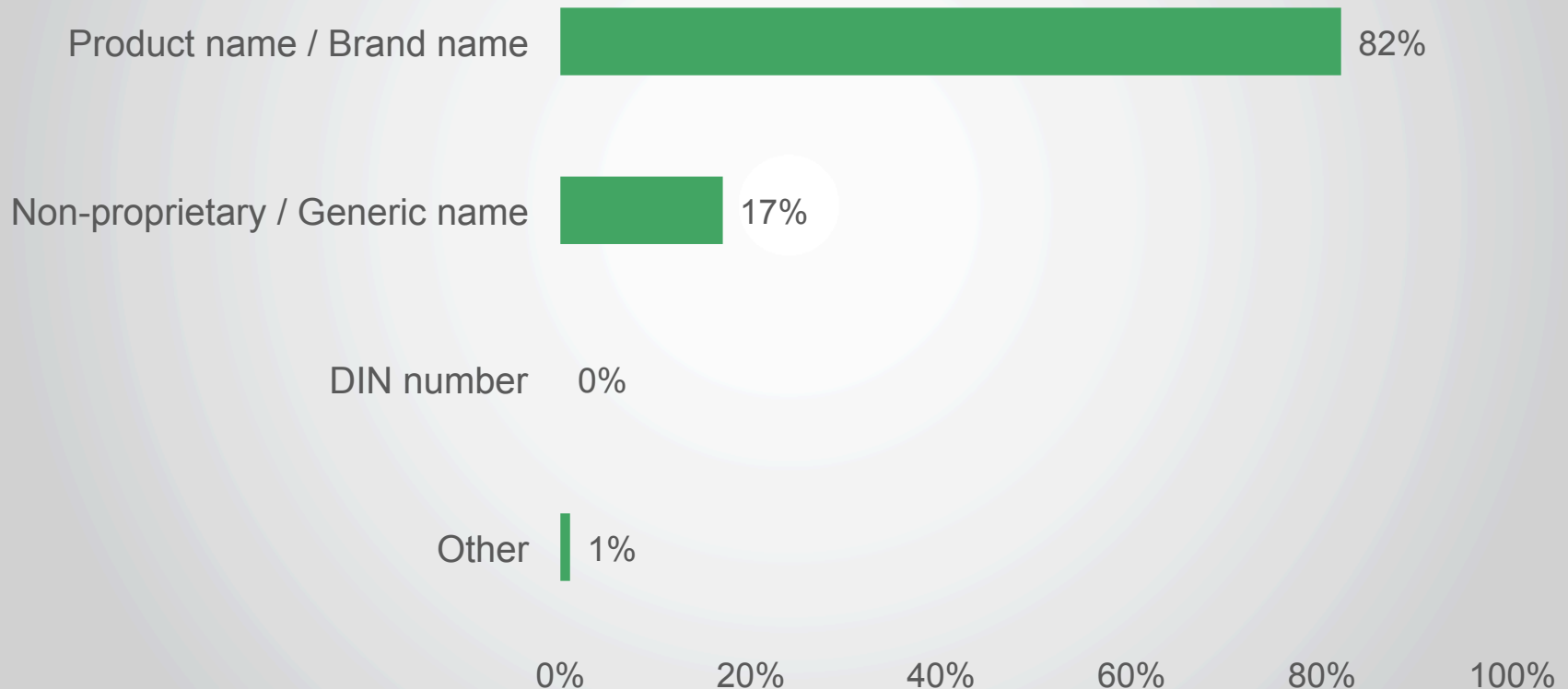
	Total N=427	Alberta N=53 A	B.C. N=63 B	Ontario N=217 C	Quebec N=94 D
No	47%	32%	44%	44%	62% ABC
Yes	53%	68% D	56% D	56% D	38%

Study Data

PRESCRIBING, RECORDING, & REPORTING

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)



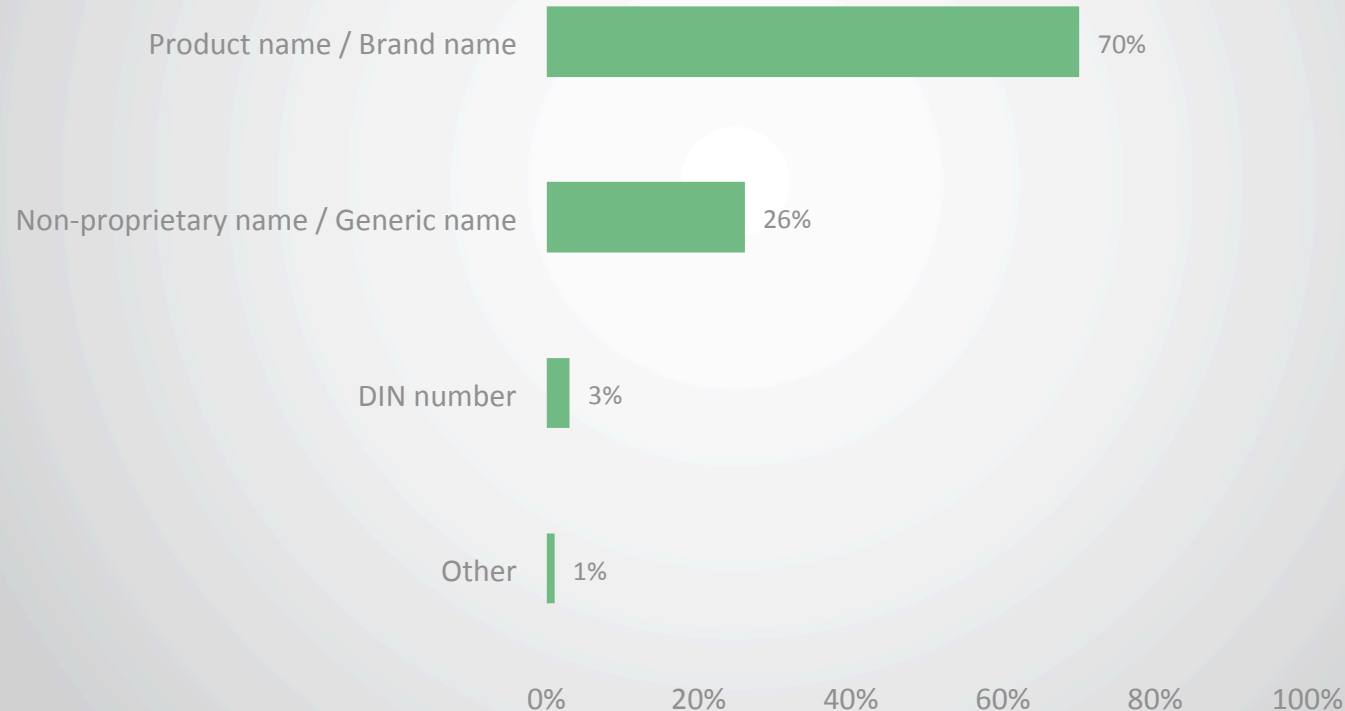
Significance: Biologic recording – Patient record

- About 80% of prescribers record these products by brand name.
- No regional differences are evident.

	Total N=427	Alberta N=53 A	B.C. N=63 B	Ontario N=217 C	Quebec N=94 D
Product name / Brand name	82%	79%	76%	82%	85%
Other	1%	0%	0%	1%	1%
DIN number	0%	0%	0%	0%	0%
Non-proprietary / Generic name	17%	21%	24%	16%	14%

Biologic recording – Adverse events

“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)



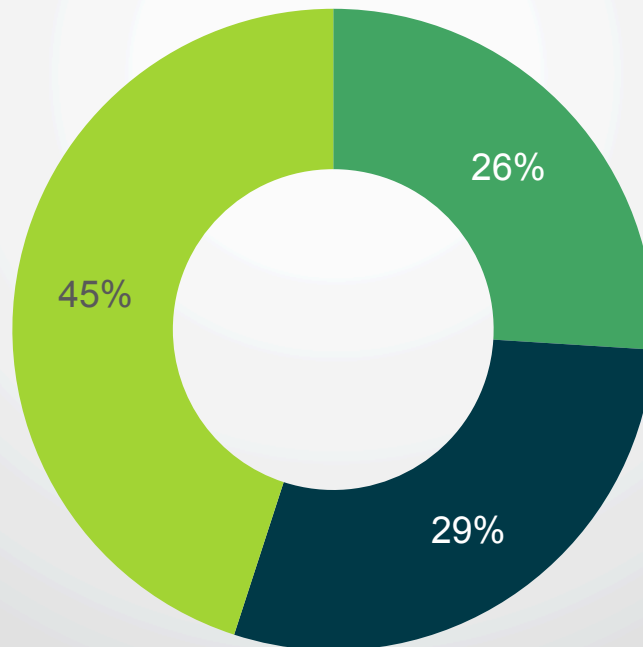
Significance: Biologic recording – Adverse events

- About 70% of prescribers record these products by brand name for AE reporting purposes.
- Prescribers in British Columbia are less likely to do so, and significantly more likely than others to report by non-proprietary / generic name.

	Total N=427	Alberta N=53 A	B.C. N=63 B	Ontario N=217 C	Quebec N=94 D
Product name / Brand name	70%	72%	57%	74% B	71%
DIN number	3%	4%	0%	3%	4%
Non-proprietary name / Generic name	26%	25%	43% ACD	22%	23%
Other	1%	0%	0%	2%	1%

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

■ Always ■ Sometimes ■ Never



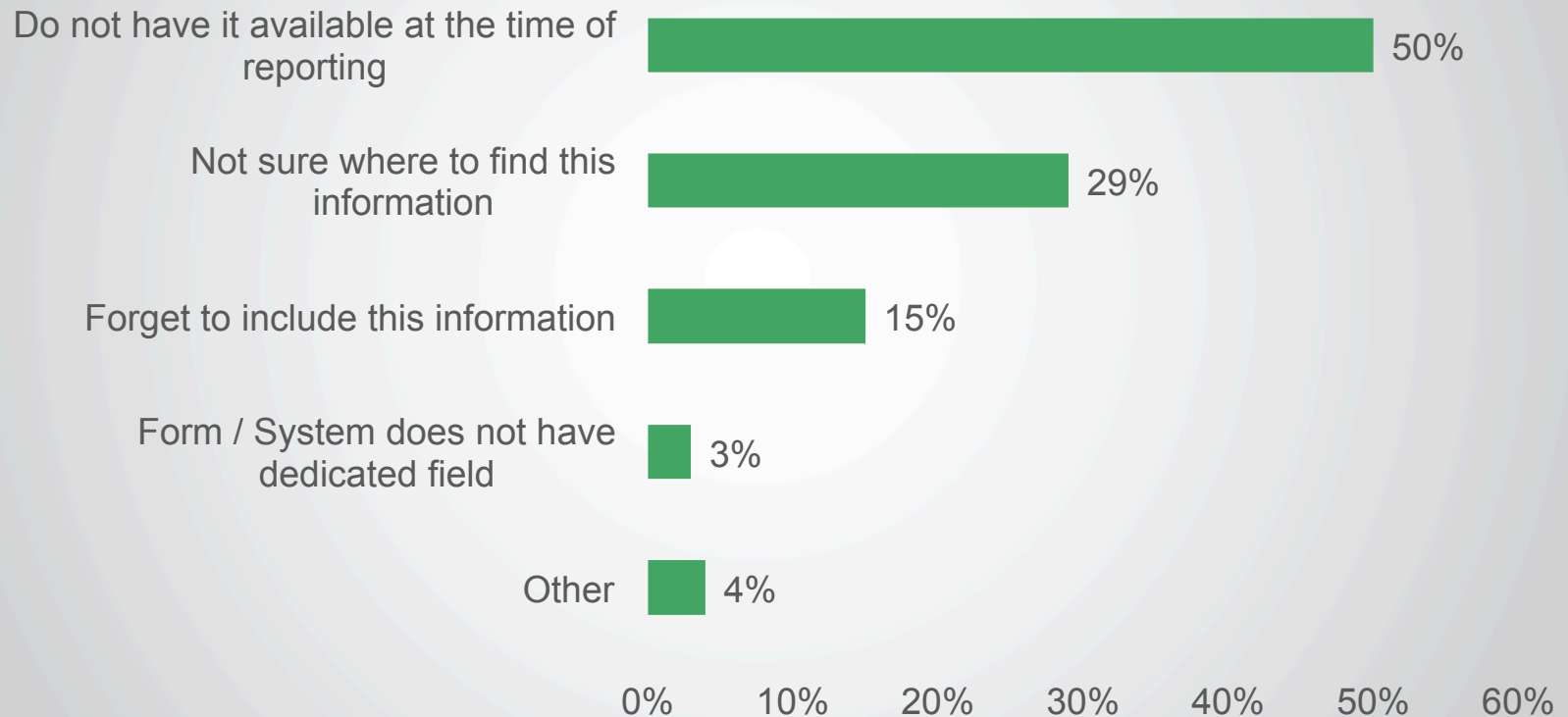
Significance: Batch number inclusion

- Prescribers in Alberta are more likely to “Always” include batch numbers.
- Those in Ontario and Quebec are more likely to “never” include batch numbers.

	Total N=427	Alberta N=53 A	B.C. N=63 B	Ontario N=217 C	Quebec N=94 D
Always	26%	43% CD	29%	21%	26%
Sometimes	29%	25%	37%	29%	26%
Never	45%	32%	35%	50% AB	49% A

Reason for not including batch number

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



Significance: Reason for not including batch number

- Overall, about half of respondents report not having access to the data at the time of reporting.
- Alberta prescribers are less likely to report simply forgetting the information.

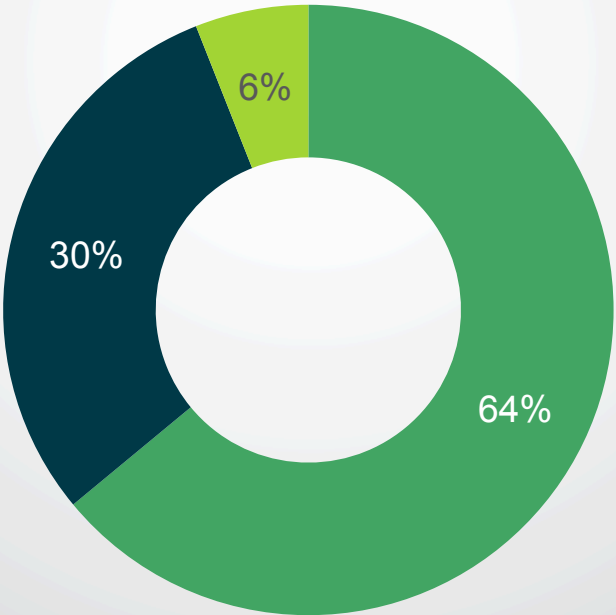
	Total N=317	Alberta N=30 A	B.C. N=45 B	Ontario N=172 C	Quebec N=70 D
Do not have it available at the time of reporting	50%	60%	51%	48%	51%
Forget to include this information	15%	0%	13%	13% A	26% AC
Form / System does not have dedicated field	3%	3%	4%	3%	0%
Not sure where to find this information	29%	37%	27%	31%	20%
Other	4%	0%	4%	5%	3%

Study Data

NAMING

“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)

■ Yes ■ No ■ No Opinion



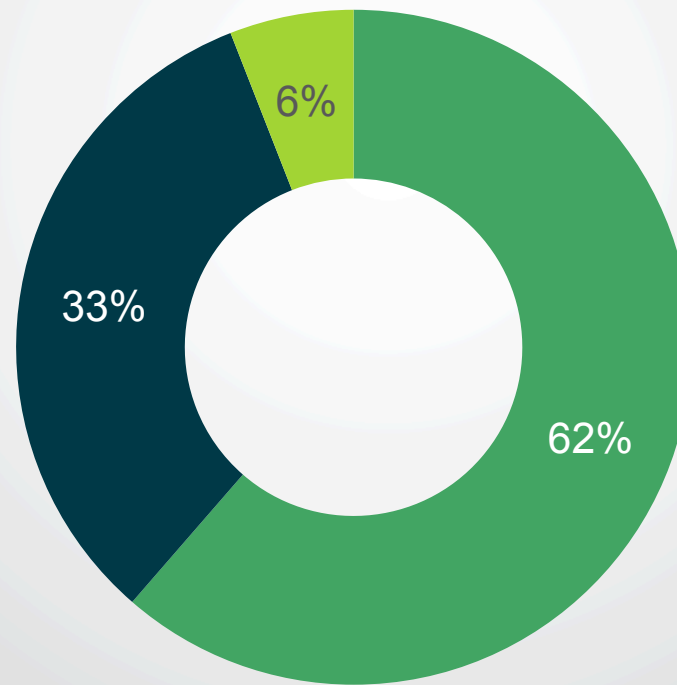
Significance: Non-proprietary name implications – Structurally Identical?

- Overall, about 2/3 of respondents believe the products would be structurally identical.
- No regional differences are evident.

	Total N=427	Alberta N=53 A	B.C. N=63 B	Ontario N=217 C	Quebec N=94 D
No	30%	25%	30%	30%	30%
Yes	64%	70%	68%	63%	61%
No opinion	6%	6%	2%	6%	10%

“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)

■ Yes ■ No ■ No Opinion



Significance: Non-proprietary name implications – Same results?

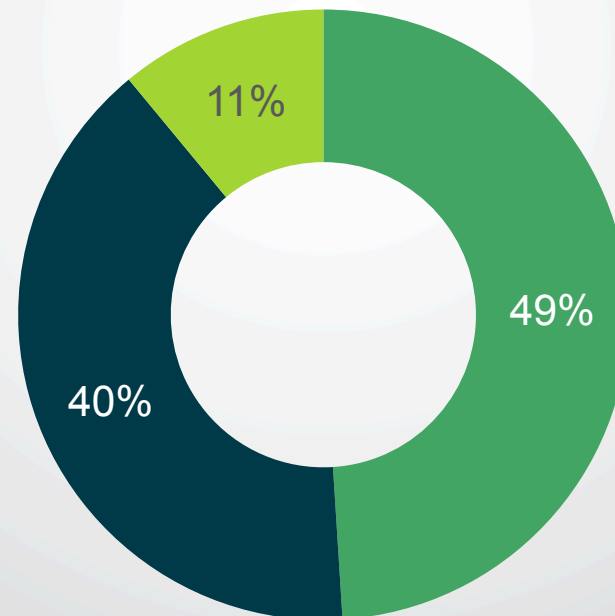
- Overall, about 2/3 of respondents believe the products would achieve similar results, if switched.
- No regional differences are evident.

	Total N=427	Alberta N=53 A	B.C. N=63 B	Ontario N=217 C	Quebec N=94 D
No	33%	38%	27%	32%	34%
Yes	62%	57%	71%	61%	60%
No opinion	6%	6%	2%	6%	6%

Non-proprietary 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)

■ Yes ■ No ■ No Opinion



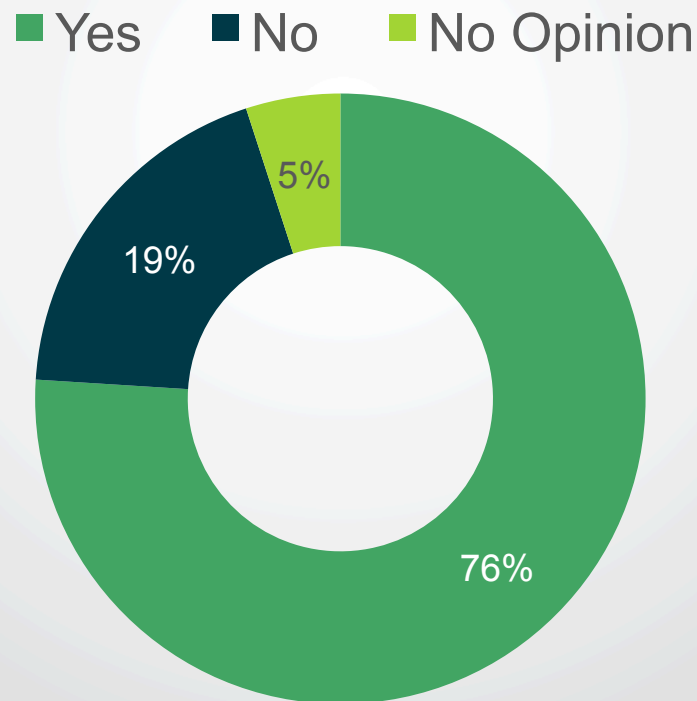
Significance: Non-proprietary name implications – Substitution during course of treatment

- No regional differences are evident.

	Total N=427	Alberta N=53 A	B.C. N=63 B	Ontario N=217 C	Quebec N=94 D
No	40%	42%	41%	37%	43%
Yes	49%	49%	54%	50%	46%
No opinion	11%	9%	5%	13%	12%

Non-proprietary 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)

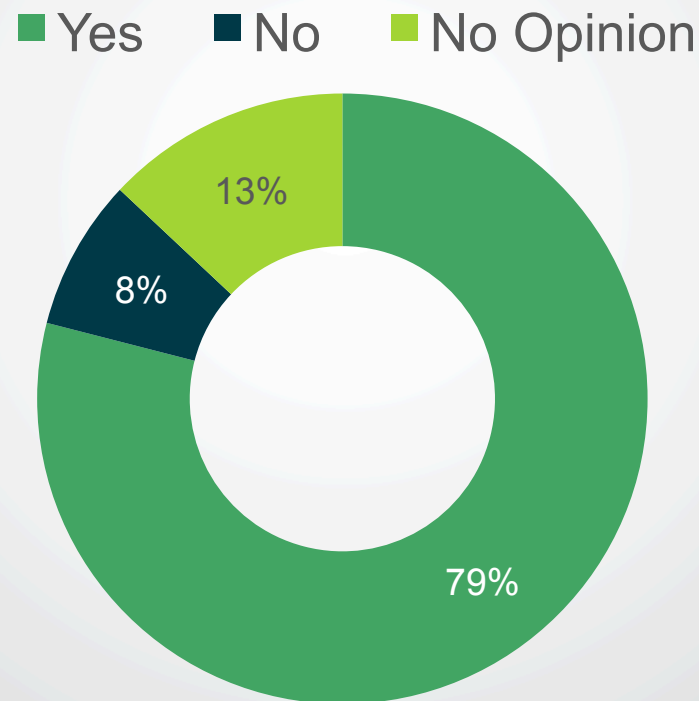


Significance: Non-proprietary name implications – Approved for same indications?

- No regional differences are evident.

	Total N=427	Alberta N=53 A	B.C. N=63 B	Ontario N=217 C	Quebec N=94 D
No	19%	15%	19%	19%	22%
Yes	76%	81%	78%	76%	73%
No opinion	5%	4%	3%	6%	4%

“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)

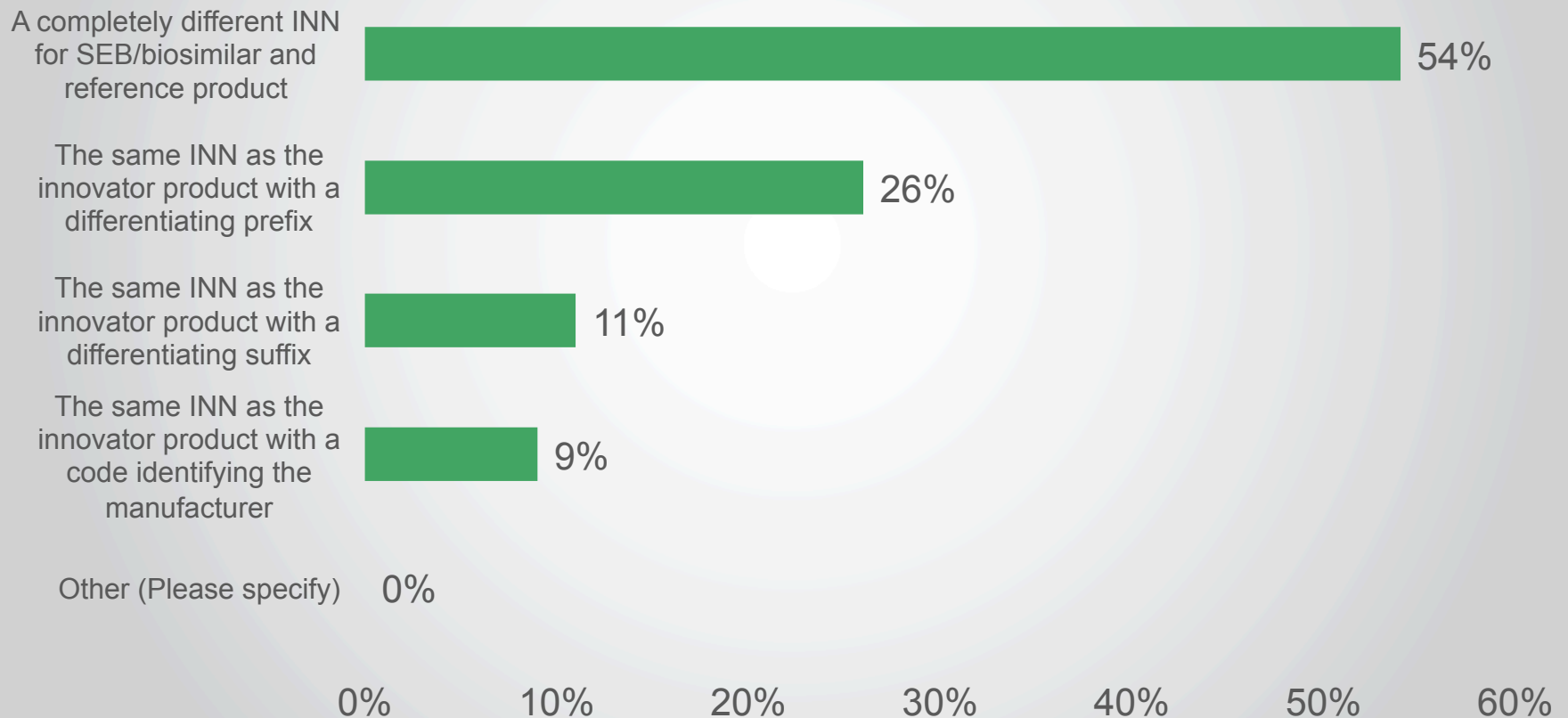


- Prescribers in Quebec are more likely than those in Ontario to believe Health Canada should insist on distinct non-proprietary names for every biologic or SEB approved.

	Total N=427	Alberta N=53 A	B.C. N=63 B	Ontario N=217 C	Quebec N=94 D
No	8%	8%	8%	9%	9%
Yes	79%	85%	75%	75%	86% C
No opinion	13%	8%	17% D	16% D	5%

Differentiating SEB from Innovator Products

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



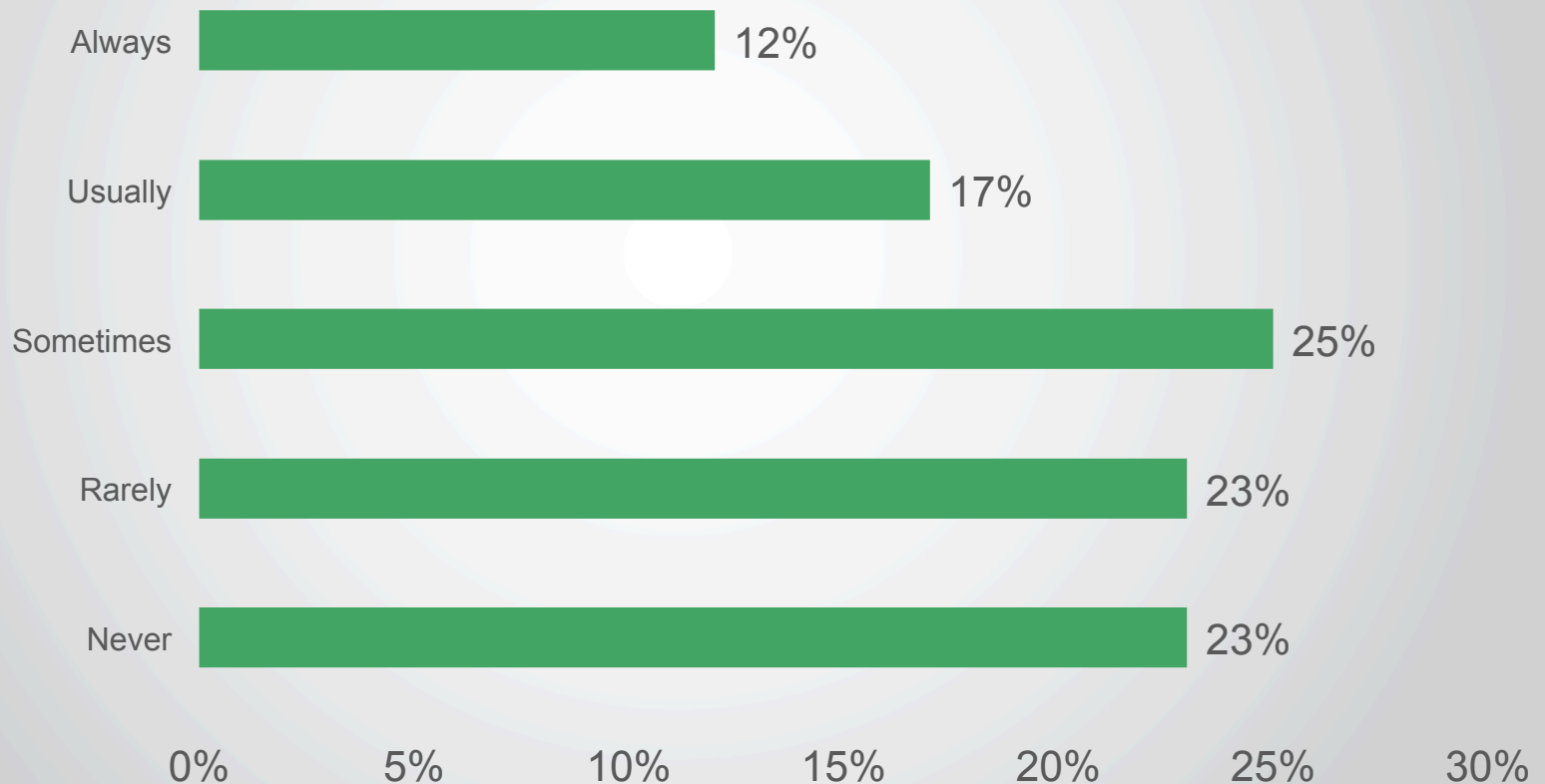
- Prescribers in Alberta are more likely to prefer a different suffix than those in Ontario, who are more likely to prefer a manufacturer code.

	Total N=427	Alberta N=53 A	B.C. N=63 B	Ontario N=217 C	Quebec N=94 D
Completely different INN	54%	58%	49%	55%	53%
Different prefix	26%	19%	33%	25%	27%
Different suffix	11%	17% C	16%	8%	11%
Manufacturer code	9%	6%	2%	12% B	10%
Other	0%	0%	0%	1%	0%

Study Data

PHARMACY SUBSTITUTION

“Health Canada has specified that SEBs 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=427)



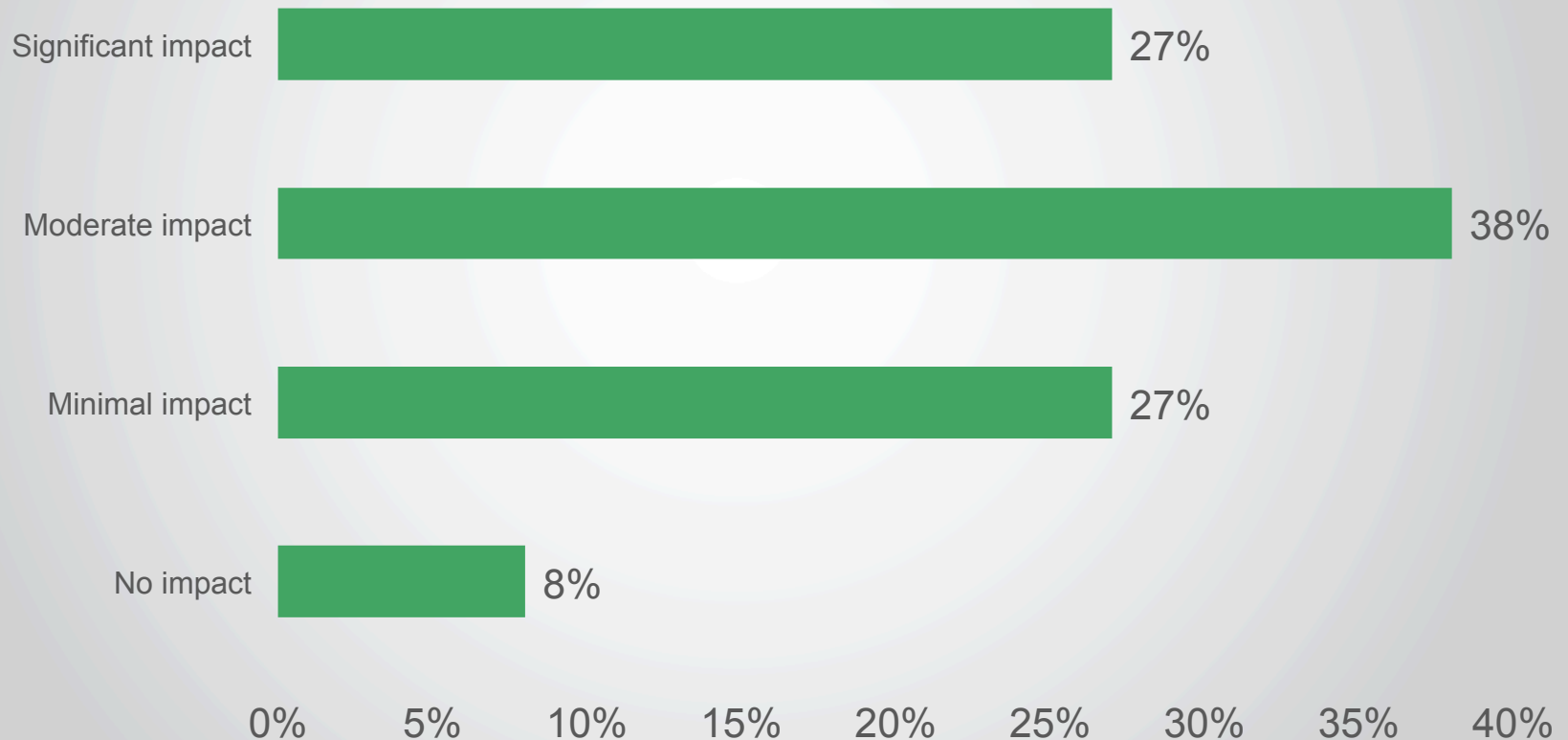
Significance: Frequency of DAW

- Prescribers in Alberta are more likely to “Always” designate DAW.

	Total N=427	Alberta N=53 A	B.C. N=63 B	Ontario N=217 C	Quebec N=94 D
Always	12%	23% CD	11%	12%	10%
Usually	17%	9%	21%	16%	21%
Sometimes	25%	17%	22%	26%	27%
Rarely	23%	25%	25%	21%	24%
Never	23%	26%	21%	25%	18%

Impact of Health Canada's Position on Interchangeability

"How much impact will Health Canada's science-based position on interchangeability have on your practice? (N=427)"

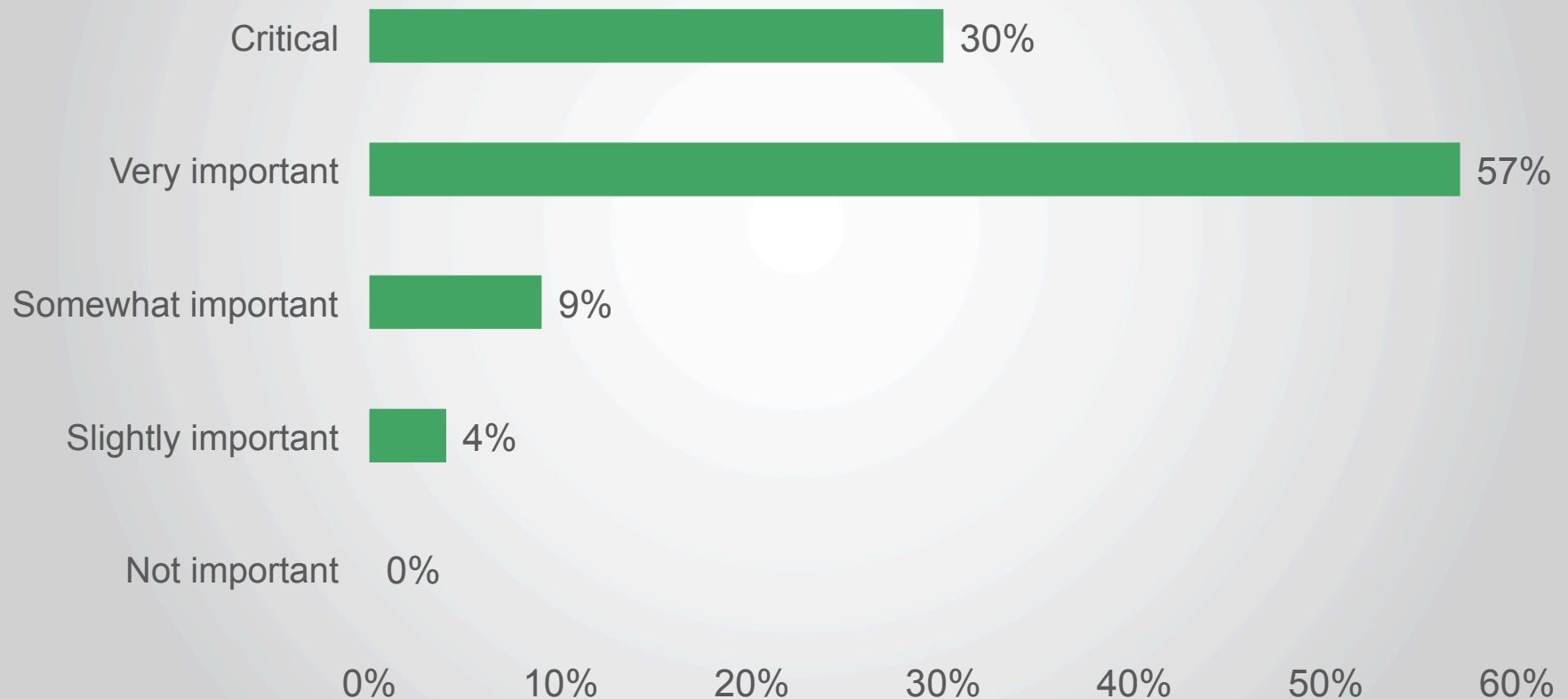


- No regional differences are evident.

	Total N=427	Alberta N=53 A	B.C. N=63 B	Ontario N=217 C	Quebec N=94 D
Significant impact	27%	28%	22%	28%	29%
Moderate impact	38%	38%	43%	37%	39%
Minimal impact	27%	23%	29%	28%	26%
No impact	8%	11%	6%	8%	6%

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)



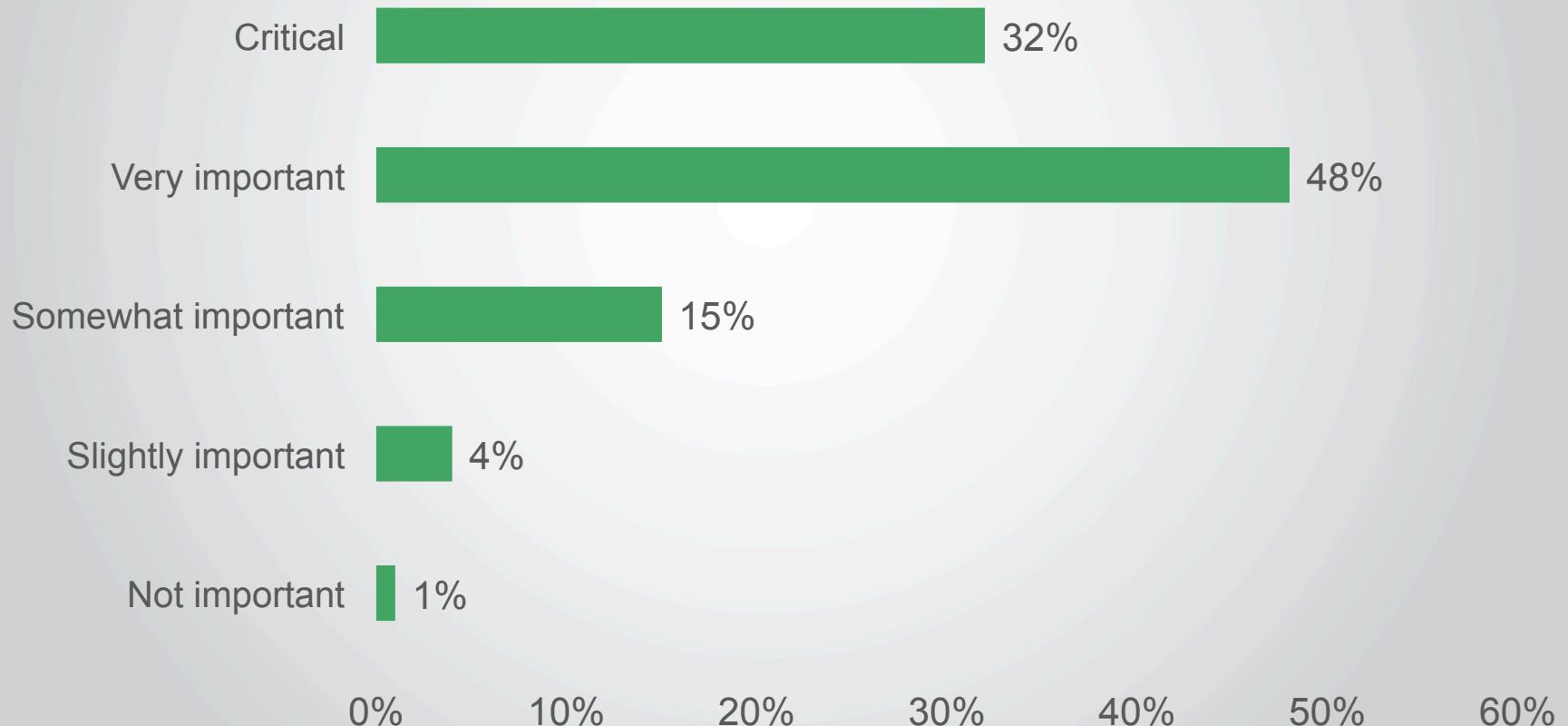
Significance: Importance of prescribing authority

- Prescribers in Alberta and Ontario are more likely to designate this as “Critical” than those in Quebec.

	Total N=427	Alberta N=53 A	B.C. N=63 B	Ontario N=217 C	Quebec N=94 D
Critical	30%	38% D	30%	34% D	17%
Very important	57%	51%	57%	55%	64%
Somewhat important	9%	6%	5%	9%	12%
Slightly important	4%	4%	8% C	2%	7% C
Not important	0%	2%	0%	0%	0%

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)



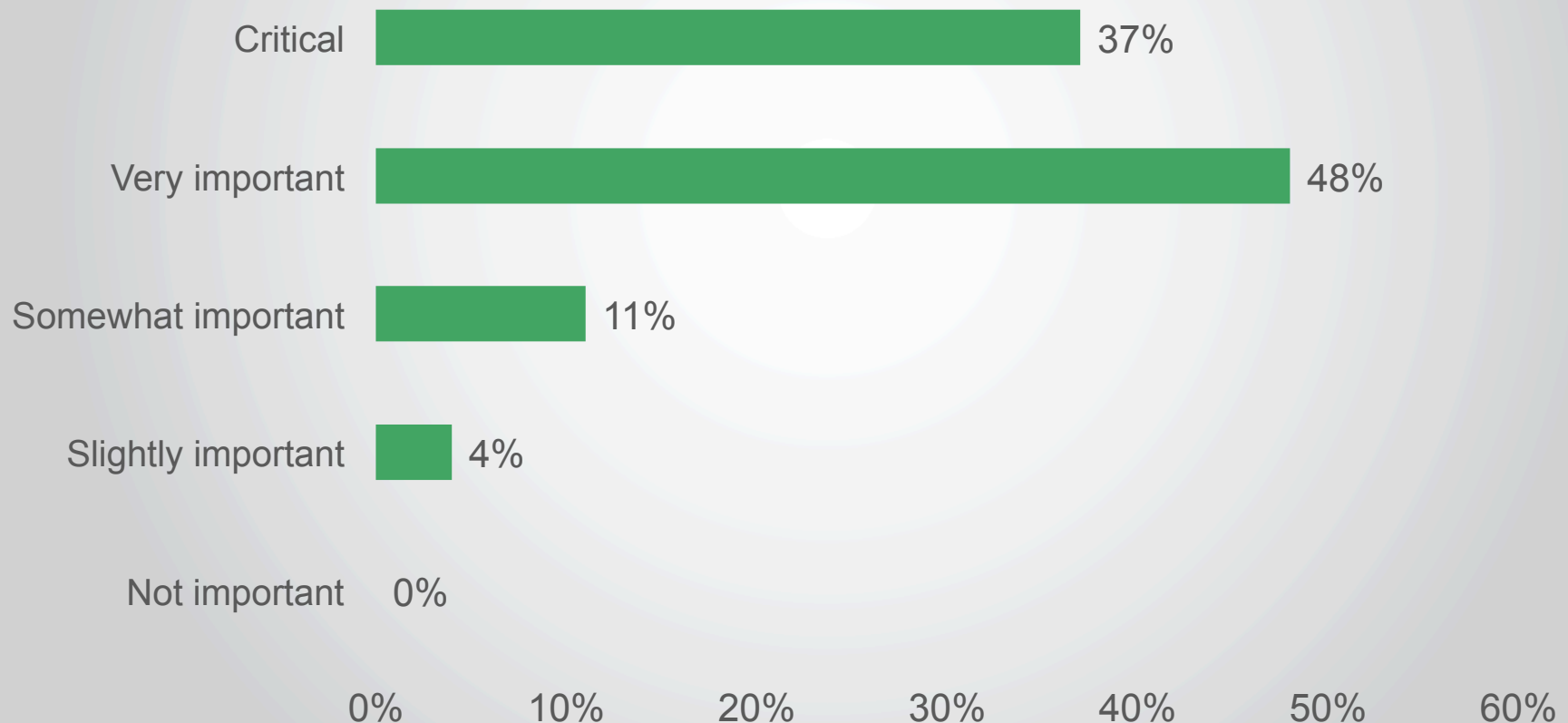
Significance: Importance of DAW

- Prescribers in Alberta are more likely than those in Quebec to believe DAW authority is “Critical.”

	Total N=427	Alberta N=53 A	B.C. N=63 B	Ontario N=217 C	Quebec N=94 D
Critical	32%	42% D	35%	33%	23%
Very important	48%	43%	43%	53%	41%
Somewhat important	15%	11%	16%	10%	27% AC
Slightly important	4%	2%	6%	3%	7%
Not important	1%	2%	0%	0%	1%

Importance of substitution notification

“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)



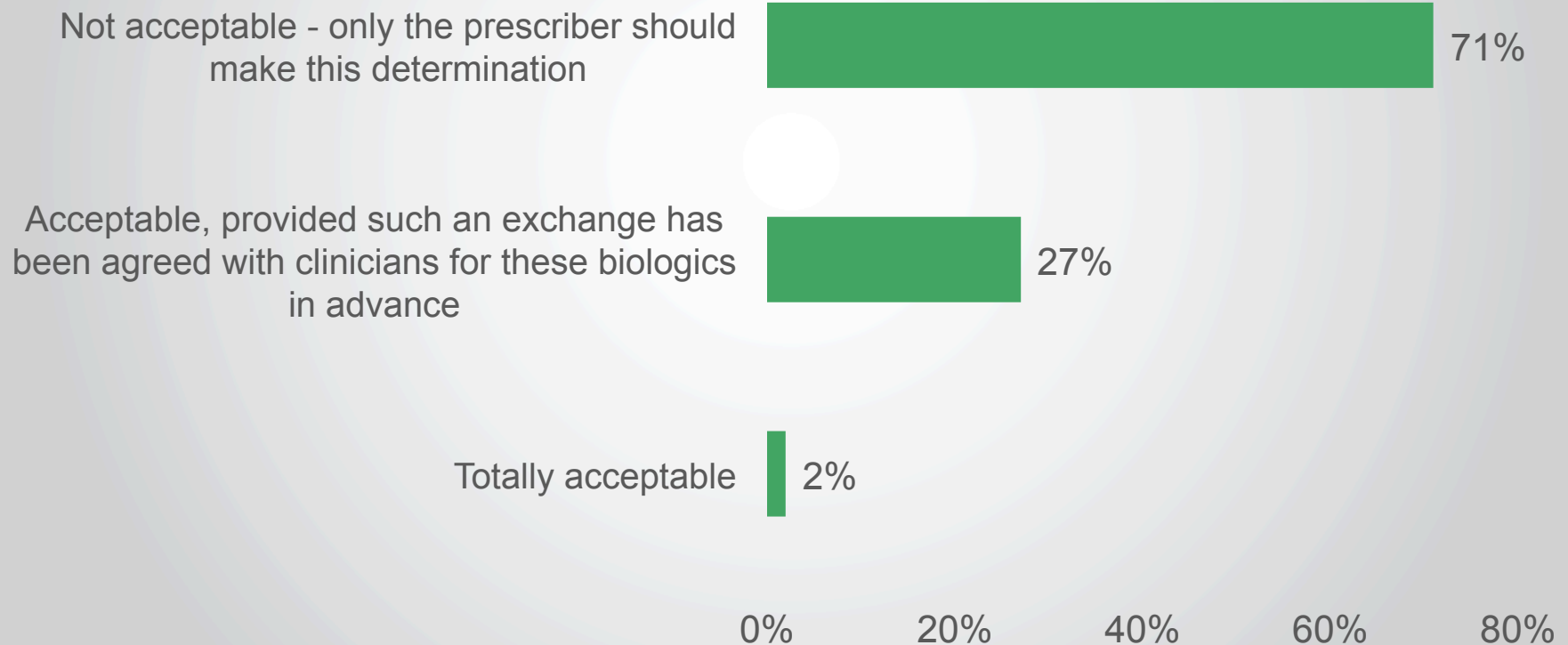
Significance: Importance of substitution notification

- Notification is important across provinces.
- Prescribers in Quebec feel less strongly than most.

	Total N=427	Alberta N=53 A	B.C. N=63 B	Ontario N=217 C	Quebec N=94 D
Critical	37%	47% D	41% D	38% D	26%
Very important	48%	42%	43%	50%	52%
Somewhat important	11%	9%	6%	11%	14%
Slightly important	4%	0%	10% AC	1%	7% AC
Not important	0%	2%	0%	0%	1%

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)



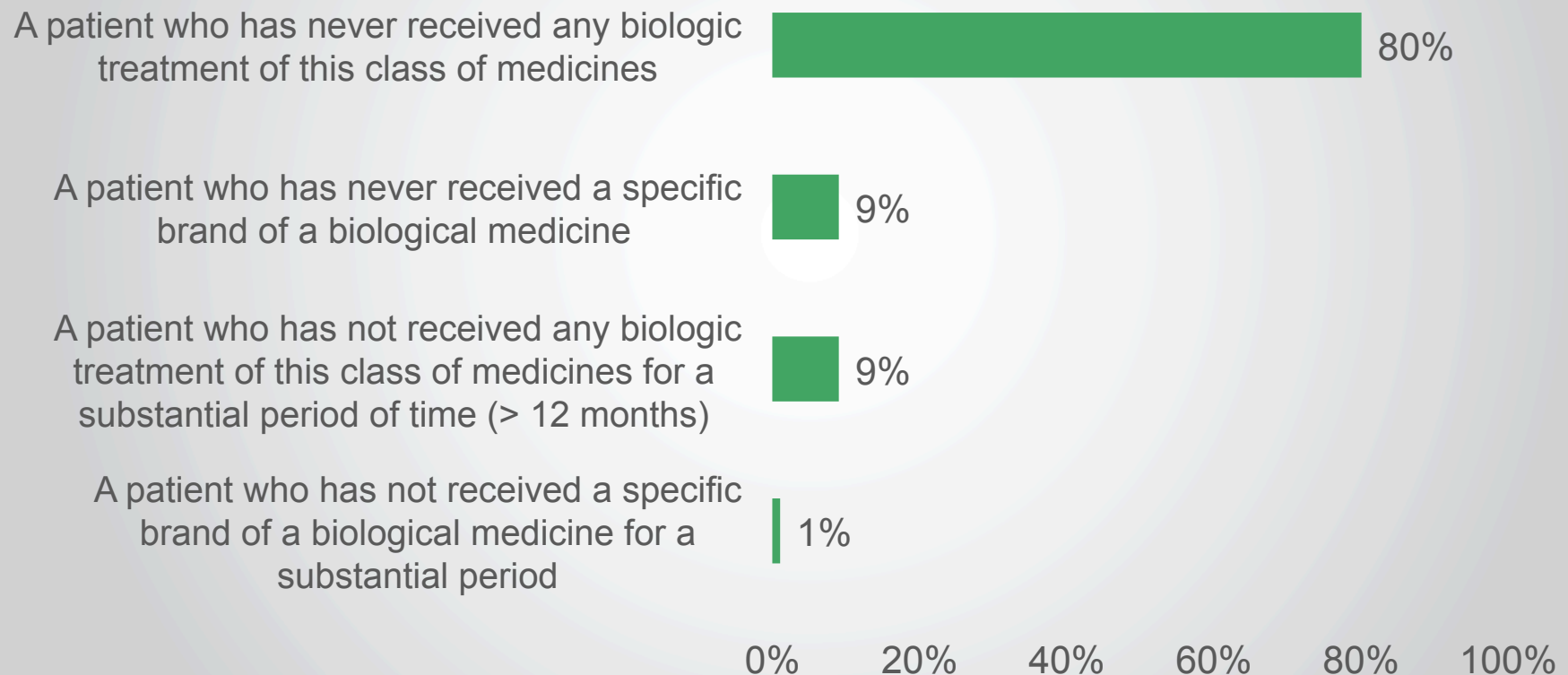
Significance: Acceptability of pharmacist determination

- Unilateral decision making at the pharmacy is not acceptable to most prescribers. This sentiment is strongest among those in Alberta and Ontario.

	Total N=427	Alberta N=53 A	B.C. N=63 B	Ontario N=217 C	Quebec N=94 D
Totally acceptable	2%	2%	3%	0%	5% C
Acceptable, provided such exchange has been agreed with clinicians for these biologics in advance	27%	19%	37% AC	23%	36% AC
Not acceptable	71%	79% BD	60%	77% BD	59%

Defining “bio-naïve”

“How do you define “bio-naïve” patients with respect to biologics?” (N=427)



Significance: Defining “bio-naive”

- Most believe this means “a patient who has never received any biological treatment of this class.”

	Total N=427	Alberta N=53 A	B.C. N=63 B	Ontario N=217 C	Quebec N=94 D
A patient who has never received a specific brand of biological medicine	9%	6%	13%	8%	13%
A patient who has never received any biological treatment of this class	80%	85% B	68%	85% BD	71%
A patient who has not received a specific brand of a biological medicine for a substantial period of time	1%	2%	0%	1%	2%
A patient who has not received any biologic treatment of this class of medicines for a substantial period of time	9%	8%	19% C	5%	14% C
Other	0%	0%	0%	1%	0%