CADTH

pCPA • APP pan-Canadian Pharmaceutical Alliance
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National Consultation on the Use and Implementation of Biosimilars

ONLINE CONSULTATION SUMMARY REPORT

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Background and Context

CADTH was engaged by the pan-Canadian Pharmaceutical Alliance (pCPA) in August 2019 to undertake a multi-stakeholder engagement process. The process was designed to give stakeholders the opportunity to provide input to jurisdictions that may be considering policy options to increase the appropriate use of biosimilars to maximize the savings that can be reinvested into the health care system. The research design for this consultation was focused on three key phases:

- more than 25 **key informant interviews** that gathered the perspectives of key organizations on the issue of biosimilar use and implementation. CADTH reached out to organizations representing each of five priority therapeutic areas — gastroenterology, rheumatology, endocrinology, dermatology, and ophthalmology — and other key stakeholder groups (including industry associations) to request their participation in a structured hour-long interview.
- an **in-person consultation** on November 18, 2019 in Toronto that brought together more than 100 attendees for a full-day session divided into two components — a morning session of presentations and open discussions followed by an afternoon of small breakout discussions, which the pharmaceutical industry did not participate in. Stakeholders for the morning session included patient and clinical associations from each of the five targeted therapeutic areas, public and private payers, group purchasing organizations, and members of the associations representing biosimilar manufacturers and a broad range of pharmaceutical companies, including both biosimilar and innovator manufacturers. A summary report from the November 18 event was prepared and shared with those who participated in the in-person consultation, as well as on a public website established for the purposes of this consultation. This report was used to inform the development of the online survey.
- an **online survey** conducted from December 10, 2019 to January 13, 2020 designed to provided organizations, in particular, with an opportunity to respond to a core set of questions that built on the consultation summary report. The survey questionnaire is attached as Appendix A.

This report provides an overview of the key highlights and insights from the online survey specifically. Its primary goal is to identify the similarities and differences between the views of survey respondents and the four key conclusions that emerged from the in-person consultation.

Survey Highlights

The survey was open for more than a month and all respondents were provided with a copy of the summary report from the consultation. This allowed them to review the core themes that emerged from the November 18th session as they responded to the survey. The survey included 14 questions across five sections that were based on the core themes from the summit. The sections included:

- Policy Frameworks
- Education and Information Support
- Collection and Use of Real-World Evidence and Monitoring
- Savings and Reinvestment
- Other (for additional comments).

In total, 65 survey entries were submitted. However, due to incomplete and duplicate submissions, the total number of distinct surveys was 36. The table that follows categorizes the responses in greater detail:

Table 1: Summary Responses by Categories

Responses	Number of Responses
Total complete responses	36
Total incomplete responses	27
Total duplicate responses	2
Total Responses	**65**
Total Complete Responses by Stakeholder Type	
Patient group	14
Industry	10
Clinician organization	6
Individual clinician or academic	6
Total Complete Respondents	**36**

Key Themes and Survey Insights

Four key themes that emerged from the November 18th summit. The majority of responses to the online consultation were aligned with these four themes. As a result, the information that follows focuses on outlining where respondents either diverged in opinion or provided new information relevant to the topic.

1. Biosimilars are safe and effective treatments for new starts, but views on other policy options remain divided.
2. Biosimilar reimbursement decisions should be harmonized, and savings should be reinvested in patient care.
3. Ongoing and transparent monitoring of biosimilar outcomes by a neutral third party is important.
4. Standardized and wide-reaching patient and clinician education is key, built on consistent and clear messaging.

1. Biosimilars are safe and effective treatments for new starts, but views on other policy options remain divided.

During the online consultation, respondents were provided an opportunity to rank four policy options from “most preferred” to “least preferred.” Some participants rejected the premise of the question and opted not to answer. The following reflects the most common ranking of those four policy options:

- controlled switching, ranked #1
- tiering, ranked #2
- quotas, ranked #3
- tendering, ranked #4.

This exercise, as well as other questions related to implementation options, provided the following insights:

- **A Loud Call for New Starts Only (i.e., Naive-Only Policy).**
  A number of respondents rejected all of the options beyond a naive-only policy, stating that the current system is working fine; they argued that biosimilar uptake in Canada is increasing and that there is not enough clinical evidence to support more aggressive implementation measures.
- **An Interesting Divergence on Quotas.** Almost 80% of respondents from the pharmaceutical industry (together with one patient group) noted that quotas would be a preferable option, as this would provide the most opportunity for physician input in the prescribing and medication management process.[1] Industry specifically noted that any quota policy would only succeed if it incorporated new physician incentives. However, some clinician organizations outlined problems with using quotas as an approach, arguing that it is fundamentally unfair to patients given the fact that some — but not all — patients would be required to switch.
- **A Preference for Made-in-Canada Real-World Evidence (RWE).** Many respondents reiterated the importance of RWE in the development of any policy initiative. Some suggested that focusing on the European experience is useful but should only be treated as supplemental, and that Canadian-based RWE should be gathered because current clinical trial data on its own are not sufficient to justify any policy change.
- **A Recognition of the Cost of Ineffective Biosimilar Policies.** Most respondents — particularly clinician organizations — recognized the importance of some kind of biosimilar policy and noted that only a sufficiently robust biosimilars market can lower the price of a given biologic molecule in a long-term, sustainable way. Clinician representatives seemed to understand that while originator pricing is dropping from the arrival of biosimilars, the price drop could be temporary without a robust biosimilar market in place.
- **A Preference for a Slow Implementation.** Timing was a concern for most respondents. Many did not appear to be comfortable with only six months for transition and felt that a year was more appropriate, particularly in the context of controlled switching.
- **A Strong Focus on Getting Exceptions Right.** Numerous survey participants provided some further details on what an exemption policy should look like and the conditions for its development, particularly in the context of controlled switching. They also flagged the importance of involving all stakeholders — especially physicians and patients — to ensure its successful design. Some participants suggested modelling the exemption policy off of current polices for generic drugs, whereby patients are only switched back to the originator drug if there is a proven intolerance or loss of effect. There were also suggestions that other patient cohort details should be considered, such as an automatic exemption for populations seen as more vulnerable or at “higher risk,” such as pediatric patients and pregnant. women. Many seemed to support exception criteria that could broadly fit into three categories:
  - the clinical and medical needs of the patient
  - vulnerable population status (e.g., pediatric, elderly, pregnant women)

[1] Note: All company industry respondents and one association ranked quotas highest; however, in most cases this was indicated with the caveat that a naive-only policy is the only option that should be implemented. Most patient groups refused to rank the options. Only two patient groups showed a preference for controlled switching.

- unique instances that could disrupt care (e.g., the location of infusion clinics in certain regions).

2. Biosimilar reimbursement decisions should be harmonized, and savings should be reinvested in patient care.

While respondents agreed on the importance of harmonizing listings between provinces, they were more divided in the survey on how savings should be reinvested. Clinician organizations in particular reiterated the desire to have savings reinvested back into individual therapeutic areas or into new models of care. This was a common position from patient groups, but not one that came out as clearly from clinician organizations during the summit.

Other respondents noted that provincial drug budgets are all consistently under pressure and that greater savings in drug budgets could benefit patients overall by providing greater opportunities to publicly fund new drugs. Some even felt that savings should be redirected into building a data collection and reporting system to capture further knowledge on biosimilars, benefiting both patients and clinicians. The survey responses make it clear that stakeholders desire further consultation on how best to optimize the impact of the savings that will come from the expanded use of biosimilars.

Almost all respondents agreed that accountability would be a key component of a successful reinvestment strategy and that governments should be held to any commitments regarding reinvestment. A related challenge was the difficulty of ensuring consistency across provinces, given the fact that reinvestment decisions would be the responsibility of individual provinces.

3. Ongoing and transparent monitoring of biosimilar outcomes by a neutral third party is important.

Many respondents provided ideas for the data that should be captured in a monitoring and reporting system. These ranged from existing clinical indicators such as adverse reactions and side effects to more qualitative indicators that track patient experience, such as measuring the nocebo effect. It was also noted that most of the indicators available to date are “lagging” indicators (i.e., emergency room visits), and that an adequate monitoring and reporting system would also need to be based on more predictive factors such as workforce participation and satisfaction with the education being provided by the clinician. This is an area of great interest to clinicians in particular and one that would benefit from additional research in the future.

Almost all respondents reiterated the importance of monitoring and reporting being conducted by a neutral and credible third party — a point that was also clearly made at the consultation. Some even suggested specific approaches, such as one national registry or consistent provincial registries that report outcomes to payers. A few respondents specifically highlighted the OBRI–Ontario Best Practices Research Initiative as a favoured and trusted option. They seemed to feel that OBRI already maintains registries of similar data and therefore has much experience in this area. Policy-makers should consider how best to research and engage existing organizations with the capacity to handle this type of work.

4. Standardized and wide-reaching patient and clinician education is key, built on consistent and clear messaging.

Respondents reiterated the need for clear and consistent messaging, but also provided some further insight into what this should look like. Many respondents believed that educating clinicians is best done through professional associations or organizations such as the Canadian Medical Association, whereas the education of patients should be done from a separate organization that is free from bias. Most felt that much of the educational materials disseminated to date have come from industry — particularly educational material for clinicians — and that the perception of industry bias was too strong. Some also felt that both private and public payers can play a role in disseminating education, but that this would need to be in partnership with clinicians.

Ultimately, many respondents felt that there is a significant current gap in education and that the void is being filled by misinformation that may be contributing to polarizing viewpoints on the implementation of biosimilars. Many felt that more evidence-based education is needed. A number of respondents also noted that that there is not enough current education aimed at helping clinicians to have conversations with their patients about biosimilars at the point of the clinical encounter. It appears that much of the education currently available is about biosimilars overall and less about the specific needs of the treating clinician.

Limitations

While there was a significant degree of alignment and consistency between the perspectives expressed on November 18th and the views shared through the on-line survey, it is worth highlighting a number of potential limitations to this survey:

- The majority (65%) of responses were from the pharmaceutical industry, patient groups, and individual clinicians. Additional insight from associations representing clinicians might have resulted in a more nuanced assessment.
- Although a number of the individual respondents identified with a specific academic centre, it was difficult to verify whether their views reflected those of their institutional home. Thus, the assumption was made that the responses are those of the respondent alone.
- The variability in how some questions were answered by some respondents suggests differences in the interpretation of the question, disagreement about the reasonableness of the options presented, or — in a very small number of respondents — a requirement for additional information.

Finally, there were changes in the biosimilars policy landscape in Canada, which may have influenced interest in responding to the survey and/or the content of survey responses.

Conclusion

The CADTH online survey served as the final component in the CADTH biosimilars consultation process. The insights and perspectives previously outlined provide further insights for provinces exploring how best to move forward with biosimilar implementation decisions. With the majority of responses to the online survey fitting within the four key themes from the November 18th summit, payers and policy-makers should feel even more confident that the conclusions reached at the consultation are the strongest cornerstones upon which to build a new biosimilars policy framework.

Appendix A: Survey Questions

Policy Frameworks

There are multiple potential policy options that could be implemented to increase the use and implementation of biosimilars: naive-only, tiering, quotas, tendering, and switching. While these are presented as discrete choices, in reality the implementation of them does not have to be. With that in mind together with the experience and perspective of your organization regarding biosimilar products, please respond to the following questions:

1. What is the most significant barrier to the implementation of biosimilars and why?
2. What steps can be taken to address that barrier by policy-makers or by others?
3. Beyond "New Starts Only," attendees at the CADTH consultation discussed four policy frameworks: tiering, quotas, switching, and tendering. Rank these from most to least desirable and describe the reasons why for your most and least desirable option.
4. How should an exceptions policy for a biosimilar policy framework be developed?
5. At the November 18 in-person biosimilar consultation event, it was noted that manufacturers may be able to match the price of biosimilars and that this, rather than the policy options that were discussed, might be a preferred approach. On the other hand, it was also noted that improving biosimilar uptake is important for generating competition, ensuring long-term sustainability of the biosimilar market in Canada, as well as enhancing patient choice. What is your organization's perspective on this issue and why?

Education and Information Support

6. Are there gaps in the currently available education and information support with respect to biosimilars? If yes, what are they? What type of organization or group is best positioned to fill them?
7. Thinking about the tools and resources that you are aware of that support education and information about biosimilars, which are the most and least helpful and why?
8. Which stakeholders should be responsible for developing or preparing educational and information support material on biosimilars? Would the provider/source depend on the type of information?
9. How well do you believe that existing educational information about biosimilars is being disseminated? Could anything be done differently or better to enhance distribution?

Collection and Use of Real-World Evidence and Monitoring

10. What types of outcomes data or measures are the most important to capture for biosimilars?
11. If a mechanism is established to capture, analyze, and report on outcomes related to biosimilars, what criteria or conditions should be in place to make the information useful for stakeholders and policy makers?
12. How could real-world evidence from other jurisdictions with more experience with biosimilars be used to support policy decisions in Canada?

Questions About Reinvestment

13. What should be a priority for the reinvestment of savings generated by the use of biosimilars and why?

Other

14. Is there anything that you haven't been asked that you would like to comment on with respect to biosimilars?