SECURING CANADA'S PLASMA FOR IMMUNOGLOBIN SUPPLY

WHAT WE HEARD REPORT

For Canadian Blood Services

February 24, 2022

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Abiding by the Code of Ethics of the International Association of Public Participation (IAP2), the Dialogue Partners team has aimed to reflect the themes and summary of participant input from the stakeholder engagement activities in a manner that captures the essence of what was shared. Any errors or omissions made in this summary report are based solely on our interpretation and analysis of that input.

Dialogue Partners Team

WHY THIS, WHY NOW?

Canadian Blood Services operates the blood and plasma supply system in all provinces and territories except Québec, which has its own similar system and blood operator. The organization is regulated by Health Canada and funded primarily by provincial and territorial ministers of health, who are also its corporate members.

Background: A global shortage of immunoglobulins and COVID-19 pandemic dynamics

Use of immunoglobulins has been growing in health systems around the world for many years. The growth in demand has been consistently strong for the last several years, and blood supply systems and the global commercial plasma industry are challenged with keeping pace to collect enough plasma to meet demand.

In August of 2019, the American Food and Drug Administration declared a shortage of immunoglobulins. The U.S. supplies much of the world with plasma for plasma protein products, so an American shortage has serious ramifications globally. This shortage has been made more acute by the COVID-19 pandemic, which has disrupted supply chains around the world, keeping both donors and pharmaceutical industry workers at home. Patients in the U.S. and Europe continue to be affected by this shortage.

To date, Canadian Blood Services has been able to leverage its national supply chain and bulk buying practices — as well as its national emergency planning measures alongside governments and hospitals across the country — so that patients in Canada have not gone without immunoglobulin, although some have been required to switch between product brands and vial sizes.

Risk-Based Decision-Making Framework

As part of Canadian Blood Services' responsibility to manage plasma sufficiency for immunoglobulin (Ig), the organization is undertaking a comprehensive analysis using the Risk-Based Decision-Making

Framework for Blood Safety, developed by the Alliance of Blood Operators – it can be found on-line at allianceofbloodoperators.org.

The Framework's objectives are to:

- Optimize safety of the blood supply while recognizing that elimination of all risk is not possible
- Allocate resources in proportion to the magnitude and seriousness of the risk and the effectiveness of the interventions to reduce risk
- Assess and incorporate the social, economic, and ethical factors that may affect decisions about risk.

2021-2022 Risk-Based Decision-Making – Canada's plasma sufficiency for immunoglobulin security of supply

A risk-based decision-making analysis was initiated to focus on Canada's plasma sufficiency for immunoglobulin security of supply, including risks across both collection and fractionation capacity. In 2016, a similar exercise was conducted assessing emerging risks related to the security of supply for immunoglobulins for Canada patients.

The risk-based decision-making analysis requires, and is informed by, a robust stakeholder engagement process. Within this context, Canadian Blood Services contracted Dialogue Partners to conduct stakeholder engagement activities on the issue of securing Canada's plasma sufficiency for immunoglobulin (Ig). Engagement activities provided stakeholders with opportunities to share their views on risk mitigation pertaining to securing a more robust domestic supply of Ig. In a continued effort to reduce the spread of COVID-19, Canadian Blood Services hosted virtual engagement opportunities, providing a virtual engagement platform to provide input in both written submissions and virtual dialogue formats.

The engagement process was designed to better understand the perspectives of patients living with primary and secondary immunodeficiency disorders, autoimmune disorders, neurological and other disorders for which immunoglobulins are a vital part of treatment. Canadian Blood Services sought to understand the level of concern patients and their treaters have and understand their priorities in securing supply. This patient community bears the greatest burden of risk brought about by any supply challenge.

The objectives of the current analysis will be to project the next five-year scenario and to evaluate the options for mitigating the risks, with decision drivers focusing on:

- **Patient need:** To ensure an adequate supply of immunoglobulin for Canadian patients who rely on this therapeutic product; to create certainty and security of domestic supply.
- **Affordability:** To deliver an adequate supply of immunoglobulin for Canadian patients at an affordable cost to Canadian healthcare systems.
- **Sustainability of blood and plasma collection network in Canada:** To maintain donor engagement and access to a sustained supply of plasma necessary to serve the transfusion needs of all Canadian patients; to maintain donor well-being and trust; to maintain value proposition for workforce. This RBDM analysis includes assessments on security of supply, health economics and outcomes, operational impacts, and contextual factors (e.g., social, legal, and ethical), along with development of a participation strategy.

This report summarizes participant input shared through written submissions received and notes taken at the virtual engagement sessions hosted on January 19th and 20th, 2022 and represents Dialogue Partners' professional summary of what was heard. Comments on this report can be directed to info@dialoguepartners.ca.

HOW WE ENGAGED AND WHAT WE ASKED

Stakeholder participation is crucial to ensuring various perspectives are heard and contribute to informing the overall analysis and decision-making in this process.

Seventy-nine invitations to participate in virtual engagement sessions were extended (a list of which is provided in Appendix A). To support designing and planning the dialogue sessions, Dialogue Partners invited stakeholders to provide their thoughts on the topics to be discussed as part of the ensuing sessions. Twelve written submissions were received and themes arising from these written submissions supported the introduction of views from many stakeholder perspectives. Of those stakeholders invited to participate, a total of 24 attended virtual engagement sessions hosted on January 19th (17 participants) and January 20th (7 participants). A list of engagement participants who attended the virtual engagement sessions can be found in Appendix B.

Participants joined the sessions via Zoom. A facilitator from Dialogue Partners guided the sessions while Canadian Blood Services' senior leaders walked participants through background on the status of plasma collection globally and domestically, the impacts of COVID-19 on Ig sufficiency, and the need to expand plasma collection to secure immunoglobulin (Ig) sufficiency. They also introduced the Risk-Based Decision-Making framework and steps in the process to define, assess and propose recommendations on how to mitigate risks related to plasma sufficiency and security of Ig supply.

Following these presentations, participants were engaged in facilitated discussion on the following questions:

1. In a post-pandemic world, what value do you place on domestic security of supply of immunoglobulin?
2. How does security of domestic supply of immunoglobulin directly impact the patient population you represent?
3. What should be considered when determining an "adequate supply of immunoglobulin"?
    a. From your patient population's perspective?
    b. From a system-wide perspective?
4. What should be considered when determining "sustainability"?
    a. From your patient population's perspective?
    b. From a system-wide perspective?
5. What considerations should be kept in mind as these ideas are pursued on their own or in combination?

On January 19th, stakeholder dialogue occurred in small break-out groups to provide all participants the opportunity to express their thoughts. Dialogue Partners facilitators guided the break-out conversations and a dedicated notetaker captured participant input. Representatives from provincial and territorial governments attended as observers. Representatives from Canadian Blood Services also attended to present the issues and answer questions.

On January 20th, due to a smaller number of participants, the discussion was held in plenary format. Again, participants were supported by a Dialogue Partners facilitator and a dedicated notetaker. Representatives from provincial and territorial government and Canadian Blood Services also attended this discussion.

Both sessions' plenary formats were recorded to assist with preparing this report.

Participants were encouraged to utilize the Zoom chat function to share ideas, opinions, and thoughts throughout both sessions.

WHAT WE HEARD

The views outlined in the section below represent those from patient groups, advocacy groups, and clinicians who prescribe Ig products and support patients across Canada. Participants shared their thoughts through written submission and virtual engagement opportunities helping to address key questions related to Ig sufficiency and the need to expand plasma collection to secure Ig.

A diversity of participant views and thoughts were shared around key questions, almost all participants placed a high value on domestic security of supply. Through discussion, key patient-perspective insights emerged around adequate supply and the importance of guaranteed supply and access to preferred products. Guaranteed access to preferred products was considered essential, as disruptions often impact patients' standards of care and overall wellbeing. When considering a systems perspective, participants brought forward key considerations around understanding need and demand, how to better forecast demand of Ig products by tracking and assessing Ig utilization factors, and building partnerships and coordinating policy approaches to achieve greater security of the product. Other key themes included sustainability costs, donor incentives, and plasma collection and production methods. While there was a recognized need to increase efforts to grow and develop a pool of plasma donors to support efforts to increase supply, opinions diverged when considering the potential role commercial collection plays in achieving this overall increase. Despite differences in some approaches, there was seen to be value in creating opportunities for greater collaboration between system partners and driving security through new and innovative solutions.

Input gathered will be used by Canadian Blood Services to inform its analysis of the key risks discussed and continue to inform and influence ongoing deliberations and policy discussions with governments on domestic security of immunoglobulin supply to meet patient needs in Canada.

Q1: In a post-pandemic world, what value do you place on domestic security of supply of immunoglobulin?

Participants placed a high value on domestic security of supply of immunoglobulin (Ig). As per participant written submissions and views shared during the dialogue sessions, there was consensus that Canada must adopt strategies quickly to ensure greater security of the domestic supply of Ig through increased plasma collection. Participants shared views that security of supply was an ongoing concern prior to the pandemic, with some noting they have been working with Canadian Blood Services on domestic security of Ig issues for many years. Participants shared their thoughts on current and future barriers, challenges, and considerations that will impact domestic security of supply.

Key Themes

Patient Care

Participants shared that insecure supply of Ig directly impacts patients who require the treatment. Supply shortages can result in patients and their clinicians needing to switch Ig products and treatment plans, which could potentially impact their health condition and quality of care. Clinicians and patients who participated in the conversation shared that supply shortages may have high social, emotional, physical and mental health impacts on patients who rely on Ig.

Demand, Supply and Production

One participant suggested that the pandemic has caused delayed diagnoses of new patients, and that once health systems begin to recover, these patients may be diagnosed, leading to increasing demand for—and therefore a more restricted supply of—Ig.

Supply was seen to be deeply connected not only to the collection of plasma, but also to the production cycle of plasma-based products such as Ig. Some participants noted that a lack of domestic fractionators in Canada limits the country's ability to manufacture Ig products.

Affordability

Participants viewed the notion of affordability from a personal lens and shared that patient access to second-line or long-term therapies can be hindered due to cost barriers stemming from limited insurance and formulary coverage. This, in turn, can induce a heavier reliance on first-line therapies like Ig, which are more easily prescribed and accessible across all health systems.

Sector Innovation and Funding

Other suggestions offered by participants included monitoring potential opportunities for innovative therapies in the sector that could reduce dependence on Ig. While innovations are welcomed by participants, there was recognition that the sector is years away from realizing the benefits of novel therapies. Participants shared insights on how current resource allocation strategies may deter innovations that could reduce future reliance on Ig products, citing the need for a review of current practices to create more efficient investments.

Tensions

There was recognition that Ig products currently available to patients are safe. One participant expressed concerns regarding the safety of plasma collected through commercialized remunerated models, particularly those located outside of Canada.[i] However, the majority of participants, in particular those representing patients receiving Ig and other plasma product treatments, offered counterpoints on this point and noted there being no difference in the level of safety if the product is collected through not-for-profit or commercialized models. Patient organizations also provided that they have not experienced any safety concerns of manufactured plasma products for many years.

Q2: How does security of domestic supply of immunoglobulin directly impact the patient population you represent?

Participants had a range of direct and indirect connections to the supply and use of Ig in Canada. Patient groups, advocacy groups, and clinicians who prescribe Ig products and support patients were represented. Some participants noted that, while they do not directly serve patients that rely on immunoglobulin therapies themselves, the domestic collection of plasma helps secure other plasma-derived products of interest to them. Some also noted that broadening plasma product fractionation to include other plasma-derived products could potentially lower or leverage Ig production costs overall.

Key Themes

Participants noted the following implications for patients when faced with product insecurity. These included:

- Product availability anxiety and increased stress leading to impacts on mental health
- Anxiety and stress can also negatively impact a patient's condition
- Inconvenient infusion mechanisms
- Adverse side effects when required to repeatedly change Ig products
- Reduced quality of life, work attendance, family support, social interaction and potentially death

In addition to the above implications, Ig prescribers (i.e., clinicians) shared that insecurity of products can negatively impact the ability of prescribers and clinical staff to provide appropriate care to their patients.

Overall, there was repeated recognition that Ig shortages and insecurity of supply pose significant emotional, physical, and mental health impacts for those who rely on Ig products, especially those without alternative treatment pathways.

Tensions

No tensions were noted.

Q3: What should be considered when determining "adequate supply of immunoglobulin"?

A. From your patient population's perspective?

B. From a system-wide perspective?

Key Themes - Patient Perspective

Guaranteed Supply

There was agreement that patients should have access to a guaranteed supply of Ig products. Access to prescribed treatments was consistently discussed as a fundamental consideration around envisioning an adequate supply.

Preferred Product and Accessibility

While access to Ig products that meet the needs of patients was critically important, participants viewed patient access to their *preferred* product as equally important. This means ensuring that patients and their providers have access to Ig products in the size and modality that matches patient treatment plans, as well adequate access to a variety of product brands, as some patients may potentially respond well to some brands and not others.

Overall, participants shared that adequate supply not only means patients and providers have access to Ig products they need, but that they have access to the preferred products that support optimal treatment outcomes.

Key Themes - Systems Perspective

Defining Need and Demand

Participants expressed in determining what adequate supply looks like, the sector needs to better understand what Ig usage, patient need, and demand look like across Canada.

In written submissions, "need" and "demand" were cited as unique in their own definition, with "need" being more aligned to patient's treatment requirements, as determined by a clinician. Where "demand" was aligned with how the supply is managed and monitored across health systems. Participants noted the importance of prioritizing supply according to patient need rather than market demands.

Collection and Production

Throughout stakeholder engagement activities, participants acknowledged that there is growing demand for Ig nationally and globally. There was recognition that it is important to ensure Canada remains competitive in securing an adequate supply of Ig. Participants' comments indicated a need not only to bolster efforts around the collection of plasma, but to consider how the sector can increase its ability to manufacture Ig products domestically.

Ig Utilization Factors

Participants called on health systems to pursue opportunities to improve demand forecasting for Ig products to more accurately predict and plan for adequate supply. Participants noted that this will require the sector to better assess, track and monitor need, demand, and supply, which may require more coordinated approaches to collecting data on drivers of Ig usage locally and nationally – across

all health systems. Those who submitted written feedback indicated that to achieve this, it would be important to:

- Establish mechanisms to identify, monitor and measure real-time trends in usage
- Evaluate and understand if, how, and to what degree misuse and lack of adherence to standards drives demand and supply issues for Ig products
- Evaluate the usage needed in contingency conditions to sustain patient needs in the event of a shortage.

Managing Shortages and Establishing a Management Framework

Written submissions noted that it may be helpful to establish a framework to support standardized management and usage of Ig, particularly one that prioritizes patients whose health is dependent on Ig-based therapies. Other feedback called for protocols for managing supply shortages while building the needed infrastructure to enhance capacity. This was also viewed as an opportunity to reduce supply risks associated with over-reliance on global supplies.

Building Partnerships and Coordinated Policy Approaches

Participants highlighted the need for more coordinated policy approaches to achieve greater security of plasma supply and the current system managed by Canadian Blood Services. Provincial and territorial governments recognized a "lack of policy overseeing the engagement with commercial plasma collectors", and that future national policy should "address the existing, and future, commercial plasma collection sector" in Canada. Alternatively, those against the use of commercial collectors shared that increasing capacity through not-for-profit collection would be needed to address current gaps.

Healthcare Funding

Clinician participants noted that Ig usage can sometimes be driven by formulary funding, siloed healthcare funding, and costs and reimbursement strategies. Limiting funding of alternative therapies was also seen to stifle innovation. Other participants noted that health system partners in general must find a better way to coordinate and collaborate on issues like siloed funding to reduce the barriers faced by patients and clinicians in finding optimal treatments and therapies.

Donors

Participants noted that donor input is an essential consideration when determining how to increase plasma collection in Canada to ensure an adequate supply of Ig. Participants raised the need to gather and understand donor views on increasing plasma collection, remunerated vs non-remunerated collection models, and commercially operated vs health funded national blood system operated. There was also interest in better understanding donor reaction on ethics and health considerations of plasma donors to support an adequate supply of plasma to ensure Ig security.

Tensions

Sustainability concepts pivoted on how stakeholders defined Ig “need” and “demand.” Some stakeholders noted that patient needs must always be prioritized over market demand. It is unclear if there is a collective sense of agreement regarding how competing needs are or should be prioritized in relation to the use of Ig products.

Additionally, while all participants agree that securing an adequate supply of Ig is important, differences of opinion remained regarding how this should be achieved. A couple of participants maintained strong opposition to using commercialized collection models to secure an adequate supply of Ig, however current Ig product users, other patient group representatives and some clinicians expressed support for utilizing both commercial and not-for-profit collection models to increase supply.

Some participants indicated that to achieve adequate supply, there is a need to enhance sector capacity through commercial and voluntary collection models, as well as global supplies.

Q4: What should be considered when determining "sustainability"?

A. From your patient population's perspective?

B. From a system-wide perspective?

Key Themes – Patient Perspective

When discussing what should be considered when determining sustainability, participants again noted the importance of patients having access to Ig products when they are needed and ensuring that supply keeps pace with the projected growth of need. Participants also shared that the following factors should be considered when framing sustainability from a patient perspective:

- Patients must have continued undisturbed access to treatment and therapy as prescribed
- Innovative therapies are monitored and invested in to support future needs
- A greater diversity of Ig suppliers should be engaged and supported by longer contracts with sufficient flexibility to be able to change to newer/innovative therapies as they become available
- Patients value a sustainable and secure supply of Ig, whether it be achieved through not-for-profit, commercialized, or public/private partnership collection models.

Confidence in the safety of the product provided to patients was also seen as critical.

Key Themes – Systems Perspective

Supply, Demand and Costs

Participants expressed the view that patient need, and product demand should be better understood. This includes better understanding what products are being used and are requested by patients and clinicians and how patients respond to varying treatments and therapies. In addition to understanding need and demand, participants noted that plasma collection efforts should be cost-effective, which will require health systems to look at affordable collection models that achieve the best value.

Donor Incentives

While donation incentivization was not framed as a core discussion issue (specifically related to the Risk-Based Decision-Making process), many participants noted that, for them, it plays a key role in determining future sustainability. In general, participants expressed a desire to further explore if and

what role donor incentivization could play in increasing plasma donations. Participants raised various perspectives on this topic, noting that stakeholders sought further discussion on this topic.

Plasma Collection and Product Development Factors

Participants noted that collection of plasma and production of finished Ig products are deeply connected. Given this, there was discussion around the need for taking steps towards vertical integration between collection and production. If sustainability of supply is to be achieved, increasing collection efforts, such as the development of supporting collection infrastructure, should be coupled with increasing the development of domestic fractionization capacity within Canada.

Participants also expressed a need to increase efforts to grow and develop a pool of plasma donors, which includes increasing citizen education, donor awareness and engagement, and outreach to promote the purpose of plasma in treating patients and value of donating plasma. There was collective recognition that this would require significant public investment. Provincial and territorial governments, as stewards of public dollars, indicated that collection models must be cost-effective and sustainable.

Integrity of Collection Practices and Processes

Participant submissions noted that it is important to uphold and secure "the integrity of our system." For some, this means ensuring that Canadian Blood Services and health systems are not collecting plasma from vulnerable groups (e.g., those who are impoverished). For others, it means protecting the donor base of not-for-profit collection systems from commercial remunerated collection models that were seen to commodify plasma and jeopardize the sustainability of supply in Canada.

Need for Greater Collaboration

Throughout the discussions, participants stated that current approaches to managing Ig issues are disjointed. Participants pointed to the need for greater coordination and collaboration between federal, provincial, and territorial governments, health authorities, nor-for-profits (e.g., Canadian Blood Services), patients, and clinicians to fully understand current dynamics surrounding insecurity of supply while planning future sustainability.

Other

Some participants noted that Canadian Blood Services can play an advocacy role to communicate patient and hospital needs. A consideration expressed by a participant was the concept of revisiting formulary reimbursement for products and investment in the patient care side of Ig usage and management – this related back to discussion among patient organizations on the need for a comprehensive care model.

Participants reiterated the need for health systems to remain open to innovation (e.g., develop innovative technology in manufacturing of plasma protein products or in using alternative non-plasma-dependent processes).

Lastly, patient advocate participants emphasized the significant role comprehensive care plays in developing the sustainability of Ig supply. Comprehensive care benefits both patients and systems by decreasing product waste, improving service and system-level budgetary efficiency, and enhancing the quality of care provided to Ig patients. Noting that all costs associated (a comprehensive view) with assessing, delivering, and administering products to patients must be considered.

Tensions

As in other sections, there is a clear divide in how respondents envision the potential role of commercial collection. Some submissions indicated that commercial collection models where donors are paid creates instability for not-for-profit collection models. Others indicated that sustainability and affordability go together. Overall, participants acknowledged that to develop a more secure and sustainable supply of Ig, the models in which the sector procures these limited products must be cost-effective and deliver value overall. For some, this means leveraging both commercial and not-for-profit collection models, while others oppose the utilization of commercial collection models and pushed to increase and expand capacity within the public system.

Within written feedback, some participants expressed support for greater use of utilization management approaches to conserve plasma-derived supplies and products. However, during virtual engagement sessions, those closest to current utilization management approaches pointed to there being is no evidence to suggest that Ig is being misused. Resulting in diverging opinions among participants on how much value any additional utilization management approaches could have in conserving and managing Ig within the sector.

Q5: What considerations should be kept in mind as these ideas are pursued on their own or in combination?

Key Themes

Increase Plasma Collection and Purchase More Ig

Participants agree that increasing plasma collection is critical to securing a greater domestic supply of Ig in Canada. Themes resulting from group discussions included:

- Both the commercial and not-for-profit sectors must establish a steady base of plasma donors to build an adequate supply of Ig. It will be important that Canadian Blood Services continues to engage and educate the public on the growing need for plasma donations in Canada, as well as creating hassle-free and accessible plasma collection experiences.
- Several participants acknowledged that not-for-profit collection models have not yet been able to meet their collection/supply targets independently. Noting that establishing a sustainable supply may require looking at use of a mix of not-for-profit, commercial, and public/private partnerships to expand domestic collection capacity.
- Several participants also pointed to the need to explore donor incentives to quickly securing and sustaining an expanded plasma donor base. Participants proposed exploring alternative donor incentive solutions such as: charitable tax receipts, tax credits, etc.

Optimizing Use and Utilization Practices

In written submissions, participants noted concerns around Ig being overused in Canada. In the virtual sessions, clinicians noted that there is not much evidence of inappropriate use and perceived efforts to restrict clinicians' ability to prescribe Ig were not productive and created tensions. Additionally,

some noted that the screening requirements were onerous and limited clinicians' time spent on patient care.

Some participants indicated support for using evidence-based utilization approaches to better manage the supply and demand for Ig in Canada. Provincial and territorial governments indicated a commitment to pursuing optimized, evidence-based utilization as a management strategy to address potential scarcity in supply and growing demands. In virtual sessions, some participants indicated that additional practices, increased monitoring, or management efforts around optimizing use and utilization of Ig would not likely yield significant reduction in overall usage.

Data Collection to Plan Supply

Participants explored the establishment of a systems-level approach to tracking, monitoring and reporting the use of Ig to inform planning around adequate supply. Participants noted that a broader priority for better data collection and analysis could help understand drivers of usage while streamlining communication actions to address Ig needs between system and service level actors. Some participants pointed to the need for greater transparency in reporting product usage and inventory data.

Donor Compensation/Incentives

While some participants expressed opposition to use of commercialized renumerated collection models, other participants supported it. As in other discussion questions, participants noted the need to find ways to encourage individuals to donate plasma, which includes understanding if and how different compensation methods can help increase plasma collection efforts. One written submission noted that Canadian Blood Services could consider pursuing non-cash compensation models to incentivize donations, which may address the concerns of those who object to direct cash remuneration. These included:

- Credits to offset the cost of post-secondary education for students who donate plasma
- Non-refundable tax credits for people who donate plasma
- "Points" to augment pensions through the Canada Pension Plan who donate plasma

Some participants who identified as Ig patients, patient advocates, and clinicians expressed their support for donors to be compensated. Some acknowledged that legislation would need to be amended if donor compensation practices were considered desirable.

Plasma Safety

In written submissions, several participants pointed to the need to ensure the ongoing safety and quality of plasma-derived products. Those opposed to procuring plasma from commercial suppliers shared concerns related to the robustness of screening measures and processes to control infection risks among these operators. Patient organizations representing long-standing users of plasma products shared a different view about the safety of plasma products provided to Canadian patients, explaining that there have not been concerns related to the safety of these plasma products among patients for many years.

Sustainability Through Innovation

Several written submission responses indicated that "research initiatives to develop modern technology for the manufacture of plasma proteins by alternative, non-plasma-dependent processes,

such as recombinant technology" would also support efforts to achieve longer-term plasma sustainability in Canada.

Tensions

As indicated in previous sections describing diverging views opinions among participants, or tensions, there were mixed views on how to achieve an adequate and sustainable supply of immunoglobin in Canada.

Prior to group discussions, facilitators shared key insights from written submissions. One key theme that emerged was the perceived need for greater monitoring, assessment, and management of Ig products within Canada. This included the potential need to establish mechanisms to better track and measure real-time trends in usage, as well as to better evaluate if, how, and to what degree misuse or over-prescription of Ig drives demand and supply issues. During group discussions, participants noted that there is significant misinformation regarding the misuse of Ig in Canada and that discussions on optimizing use have limited benefit, given that minimal misuse is occurring. Participants called for sharing more detailed information and data on usage.

As noted in previous sections, there continue to be diverging perspectives about the use of donor incentives and commercial suppliers in the collection of plasma in Canada. Some participants were opposed to providing incentives/compensation to donors. Reasons shared by these participants included concerns that incentive-based models pose risks for vulnerable populations who may donate too frequently for their health, for financial incentives. Additionally, these participants felt strongly against using commercial collection models to secure Ig, citing concerns around product safety and the belief that not-for-profit models could meet supply targets with government funding. Other participants saw greater balance being achieved through a mixed approach model that utilizes both commercial and not-for-profit collection models while still maintaining a connection to the global Ig supply chain. Those in support of a mixed approach believe this approach is more likely to be able to meet supply targets, in a timely manner, and that it will be more cost-effective.

WHAT'S NEXT

Canadian Blood Services has informed Dialogue Partners that stakeholder input gathered will inform its analysis of the key risks discussed.

We have also been advised that stakeholder input will continue to inform and influence ongoing deliberations and policy discussions with governments on domestic security of immunoglobulin supply to meet patient needs in Canada. Canadian Blood Services will be reporting to stakeholders on these developments, and how they are shaped by the input provided through this engagement process.

APPENDIX A – INVITATION LIST

Organization / Affiliation
Alpha-1 Canada
Answering TTP Foundation
Aplastic Anemia and Myelodysplacia Association of Canada (AAMAC)
Association of Hemophilia Clinic Directors of Canada (AHCDC)
Atypical Hemolytic Uremic Syndrome (aHUS)
BloodWatch
Canadian Apheresis Group
Canadian Association of Nurses in Hemophilia Care (CANHC)
Canadian Dermatology Association
Canadian Fanconi Anemia Research Fund
Canadian Federation of Nurses Unions (CFNU)
Canadian Health Coalition (CHC)
Canadian Hemophilia Society (CHS)
Canadian Hereditary Angioedema Network (CHAEN)
Canadian Immunodeficiencies Patient Organization (CIPO)
Canadian Immunodeficiency Patient Organization Medical Science Advisory Committee
Canadian Immunodeficiency Patient Organization Nurse Advisory Committee
Canadian MPN Network (Myeloproliferative neoplasms)
Canadian Neurological Society (CNS)
Canadian Organization for Rare Disorders (CORD)
Canadian Rheumatology Association
Canadian Society of Allergy and Clinical Immunology (CSACI)
Canadian Society of Hematology
Canadian Society of Immunology
Canadian Society of Transfusion Medicine
Clinical Immunology Network Canada (CINC)
Friends of Medicare
GBS/CIDP/MMN Foundation of Canada
Immunodeficiency (IG) Working Group
Immunodeficiency Canada
Myasthenia Gravis Society of Canada
Myeloma Canada
Network of Rare Blood Disorders Organization (NRBDO)
Platelet Disorder Support Association (immune thrombocytopenia)

Provincial and Territorial Ministry Representatives & Observers
British Columbia
Alberta
Saskatchewan
Ontario
Health Canada
Prince Edward Island
Nova Scotia

National Advisory Committee on Blood and Blood Products
Dr. Alan Tinmouth
Dr. Andrew Shih
Dr. Charles Musuka
Dr. Jason Quinna
Dr. Jennifer Fesser
Dr. Katerina Pavenski
Dr. Lakshmi Rajappanair
Dr. Lucinda Whitman
Dr. Oksana Prokopchuk-Gauk
Dr. Robert Coupland
Dr. Robert Liwski
Dr. Ryan Lett
Dr. Shabani-Rad Meer-Taher
Dr. Susan Nahirniak
Dr. Vincent Laroche

APPENDIX B – LIST OF ENGAGEMENT PARTICIPANTS

January 19, 2022, Session

Participant Name	Organization
Angela Diano	Alpha-1 Canada
Kat Lanteigne	Blood Watch
Dr. Gail Rock	Canadian Apheresis Group
Dr. Michele Bril-Edwards	Canadian Health Coalition - Board Member
Pauline Worsfold	Canadian Health Coalition - Chair of Board
David Page	Canadian Hemophilia Society (CHS)
Whitney Goulstone	Canadian Immunodeficiencies Patient Organization (CIPO)
Dr. Bruce Ritchie	Canadian Immunodeficiency Patient Organization Medical Science Advisory Committee
Dr. Steven Peters	Canadian Neurological Society (CNS)
Dr. Durhane Wong-Rieger	Canadian Organization for Rare Disorders (CORD)
Dr. Ophir Vinik	Canadian Rheumatology Association (CRA)
Chris Gallaway	Friends of Medicare
Steven Staples	Canadian Heath Coalition
Dr. Katerina Pavenski	National Advisory Committee on Blood Products
Dr. Charles Musuka	National Advisory Committee on Blood Products
Dr. Alan Tinmouth	National Advisory Committee on Blood Products
Dr. Oksana Prokopchuk-Gauk	National Advisory Committee on Blood Products

January 20, 2022, Session

Participant Name	Organization
Dr. Hans Katzberg	GBS/CIDP/MMN Foundation of Canada Medical Advisor
Caroline Herzberg	Canadian Dermatology Association
Donna Hartlen	GBS/CIDP/MMN Foundation of Canada
Dr. Vera Bril	Immunodeficiency (IG) Working Group
Dr. Susan Nahirniak	National Advisory Committee for Blood and Blood Products
Jennifer van Gennip	Network of Rare Blood Disorders Organization (NRBDO)
Jennifer DiRaimo	Platelet Disorder Support Association (immune thrombocytopenia)

References

[i] One participant shared a link to a report on plasma collection during one of the dialogues. The resource was not discussed further and the link is included in this report as part of the engagement record. Dialogue Partners cannot comment on the report's accuracy. https://www.europeanbloodalliance.eu/wp-content/uploads/2013/04/eba_online.pdf