Health Canada Santé Canada

What We Heard Report

A Summary of Feedback from the Consultation: *Toward a Strengthened Assisted Human Reproduction Act*

Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

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Rapport « Ce que nous avons entendu » - Un résumé des commentaires reçus à la suite de la consultation : Vers une Loi sur la procréation assistée renforcée

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Executive Summary

On July 12, 2017, Health Canada launched a 60-day online consultation[1], inviting interested stakeholders to provide comments on the Department's key policy proposals to update and strengthen the Assisted Human Reproduction (AHR) Act. The consultation followed the Department's initial announcement[2], made in October 2016, of its intent to bring into force the dormant sections of the Act and develop supporting regulations, as required.

The online consultation provided Canadians with an opportunity to review and submit feedback on key policy proposals prior to the Department finalizing policy decisions and developing the regulations for: reducing the risks to human health and safety arising from the use of donor sperm and ova (section 10); reimbursement of expenses incurred by donors and surrogates (section 12); and, the administration and enforcement framework (sections 45-58).

The consultation generated 57 sets of comments, representing the views of individual stakeholders as well as consolidated feedback from specific groups of stakeholders, including: an association representing the views of medical professionals in the field of AHR in Canada, representatives of the AHR industry, academics, surrogates, advocacy groups, intended parents, and fertility lawyers. Participants were invited to share their views on the proposals by providing their general feedback and/or by submitting responses to specific policy questions embedded throughout the document.

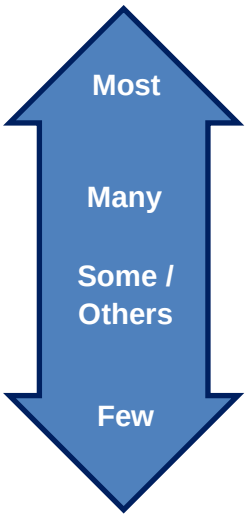
In general, stakeholders were supportive of the Department's intention to strengthen the AHR Act. Stakeholders were pleased that regulations to support section 10 of the Act will result in updated semen regulations and will introduce similar protections for users of donor ova. Furthermore, most stakeholders welcomed the proposed "directed donation" pathway that gives Canadians more flexibility in choosing their donor.

Likewise, there was general support for introducing regulations under section 12 pertaining to the reimbursement of expenses incurred by donors and surrogates. Stakeholders were in agreement that the current lack of reimbursement regulations causes uncertainty with respect to the allowable expenditures. Greater certainty is needed to ensure that Canadians have adequate legal and medical protections.

Most stakeholders were supportive of the need to effectively enforce compliance with the Act and agreed in principle with the proposed administration and enforcement framework outlined in the proposals.

It is important to note that qualitative descriptors such as "most", "many", "some", "others", and "few" have been used throughout the report to describe the stakeholders comments, and a graphical representation has been provided to illustrate the degree of separation between these terms.

The feedback shared in this report comprises the views and reflects the priorities of individuals and groups who chose to participate in the consultation and as such, cannot be generalized to the wider population of Canadians with any known degree of accuracy.



[1] https://www.canada.ca/en/health-canada/programs/consultation-assisted-human-reproduction/document.html
[2] http://www.gazette.gc.ca/rp-pr/p1/2016/2016-10-01/html/notice-avis-eng.php#ne1

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1 Section 10: Safety of donor sperm and ova

Who Responded?

Most of the feedback on the policy proposals related to the safety of donor sperm and ova was submitted by industry stakeholders, including consolidated feedback from a professional medical association representing the views of health professionals working in the field of AHR. A few fertility lawyers as well as members of academia also provided their comments on specific questions embedded in this section of the consultation paper. Additionally, many anonymous comments on section 10 proposals were also submitted for consideration by Health Canada.

What did they say?

The purpose of the section 10 regulations, once drafted, will be to reduce the risks to health and safety arising from the use of donor sperm and ova, including the risk of transmission of infectious and genetic disease. As such, the policy proposals summarized in the consultation paper outlined measures for screening and testing sperm and ova donors and establishing specific requirements for those who process, import, distribute and use donor sperm or ova.

In general, stakeholders were supportive of the proposed infectious disease testing requirements. Some stakeholders suggested additional testing, such as testing for “new or emerging infections” while other industry stakeholders expressed concern with respect to the availability or accessibility of tests, or their relevance in particular geographic regions of Canada. Some also raised concern about the cost and reliability of a few of the currently available tests.

Stakeholders were in agreement with the proposed genetic screening criteria for sperm and ova donors, aimed at reducing the risk of genetic disease transmission. Stakeholders were in support of the embedded flexibility to assess a donor based on genetic diseases known to be prevalent in the donor’s ethnic background, in accordance with recognized medical guidelines. This was further supported by some stakeholders who were especially concerned with the potential ethical considerations of adhering to any specific list of serious genetic diseases given the diversity of donors. A few stakeholders recommended screening for specific conditions, such as severe allergies. Overall, stakeholders agreed with the proposed criteria to not disqualify donors based on their genetic history, and many reiterated that making this information available to the recipient was of primary importance.

The consultation also asked stakeholders whether or not cases of suspected transmission of a genetic disease from donor sperm or ova should be reported to Health Canada. Some stakeholders felt that the Department should play a role in tracking such adverse reactions given that the safety of donor sperm or ova could be compromised and as such, could pose a public health risk if the donor continues to donate. Others suggested that there would be limited benefit from introducing federal oversight and that the additional regulatory burden could prompt the industry to be overly cautious in accepting donations. One group of stakeholders suggested that a donor registry be created to keep track of all third party donors in Canada.

The views were divided on the proposed application of section 10 requirements. Although most stakeholders were in support of the new “directed donation” and “exceptional distribution” pathways, which give Canadians more flexibility in choosing their donor, some

stakeholders were concerned about the increased risk to the health of recipients of directed donations, and the role of the treating physician in authorizing such donations.

With respect to the proposed level of regulatory oversight and establishment requirements for persons engaged in regulated activities, most stakeholders indicated that the level of oversight was appropriate. One group of stakeholders, in particular, agreed with Health Canada's proposed approach to place the highest level of regulatory oversight on processors, due to the health and safety risks associated with their activities. A third of stakeholders also commented on the proposed level of oversight for those who import sperm or ova to Canada, and these stakeholders indicated that every person that imports donor sperm or ova should be bound by the same regulatory requirements. Similarly, most stakeholders agreed with the proposal to require both fertility clinics that process directed donations and establishments that process anonymous donations to register with Health Canada. Some stakeholders requested further details on the precise nature of the requirements.

In order to protect the long-term health and well-being of people born of AHR technologies, some stakeholders suggested that donor records be made available or accessible to the child born of AHR at their age of maturity, and their retention be overseen by the federal government.

Other comments provided by some stakeholders included:

- Request for further clarity on directed donation, and what it means to "know the donor".
- Divided views on the appropriate cut-off age for donations with some stakeholders proposing 40 years of age or higher for semen donors and 34-35 years of age for ova donors while others proposing that no age limit be enforced, but rather require that the recipient be informed of the donor's age and the risks associated with that age.
- Request for clarification on reporting requirements and informed consent process.
- Recommendation to prohibit anonymous donations due to ethical and safety concerns.

2 Section 12: Reimbursement of Donors and Surrogates

Who Responded?

Many stakeholders provided feedback on proposals related to section 12, including: professional associations, academia, fertility lawyers and advocates for surrogates. Additionally, many anonymous comments on section 12 proposals were also submitted for consideration by Health Canada.

What Did They Say?

The majority of stakeholders welcomed the opportunity to comment on the proposed list of expenditures for which donors and surrogates may be reimbursed. Many agreed with the proposals but suggested additional categories of expenditures for the Department to consider.

In terms of the proposed process for reimbursement, the majority of stakeholders stressed the importance of a system that is not overly onerous or bureaucratic, and one which allows for the timely reimbursement of expenditures with real protection for donors and surrogates to ensure that they are not left vulnerable to exploitation through the reimbursement process.

Some stakeholders saw value in the proposal to require signed declaration forms from a compliance enforcement perspective, but suggested that Health Canada should also develop a template for donors and surrogates to use.

With respect to creating and maintaining records, a few stakeholders expressed concern that receipts were not always easily obtainable or available, which would pose an additional burden on donors, surrogates, agencies, and clinics.

Some stakeholder groups, including academics and women's rights organizations, suggested that altruistic donation and surrogacy should continue to be the guiding principle informing the Department's regulatory framework. These groups argued that any compensation beyond reimbursement for expenditures related directly to the donation or surrogacy could undermine the importance of informed decision making and meaningful consent and could lead to the exploitation of women.

However, many stakeholders advocated for a model that would allow for reasonable compensation, suggesting that a definitive itemized list of reimbursable expenses could be too rigid to account for the individual circumstances of each donation and surrogacy arrangement. Despite holding this view, many of the same stakeholders also took the opportunity to propose additional categories of expenditures.

Other comments provided by some stakeholders included:

- Opposition to any form of reimbursement as it was perceived to be equated to "commercial surrogacy".
- The need for the Department to adopt policies regarding reimbursement, such as not to restrict the "generosity and gratitude" displayed by surrogates, donors, and intended parents.
- "Expense neutral" approach for donors and surrogates, meaning that surrogates and donors should neither profit nor lose out financially as a result of their surrogacy or donation.
- Concerns with regards to the difficulty of being able to reimburse for "non-tangible" costs such as time, effort, risk, and commitment.
- Support for all reasonable donor and surrogate compensation or the creation of one generally-worded category that covers any reasonable expense related to surrogacy.
- The need for a complaint mechanism to help resolve any compliance issues.

3 Sections 45-58: Administration and Enforcement

Who Responded?

A smaller number of stakeholders commented directly on the administration and enforcement framework, but they represented a wide cross-section, including professional associations, fertility clinics, academia, fertility lawyers and advocacy organizations.

What Did They Say?

The overwhelming majority of stakeholders who commented on the proposed administration and enforcement regime agreed with the purpose and objectives in principle. However, they suggested that further consideration with respect to the level of regulatory oversight be taken into account as the framework is implemented.

Some stakeholders noted that fertility clinics are also regulated by their respective colleges and that it may be appropriate to apply certain elements of the proposed administration and enforcement regime, such as inspections and seizures, in a different manner between clinical and non-clinical processors and distributors. In particular, these stakeholders indicated that non-clinical processors should be subject to a more frequent inspection cycle than clinical fertility clinics processing solely directed donations, as the latter group are also subject to regular assessment and accreditation by their provincial Colleges.

Moreover, these stakeholders also noted that sperm and ova from directed donors are more similar in nature to sperm and ova obtained for use by the spouse, common-law partner or sexual partner of the donor than sperm and ova obtained from anonymous donors. As a result, they suggested that procedures and policies surrounding seizure and restoration for directed donations should take this difference into account.

Conversely, a few stakeholders were concerned that Health Canada's proposed approach focused primarily on processors, importers, and distributors, and suggested that increased oversight of qualified medical professionals in a clinical setting may be appropriate to ensure adequate oversight of the supply chain.

Other comments provided by stakeholders included:

- The need for greater clarity on how complaints can be made regarding violations of the Act.
- Simplifying the process for restoring seized information and human reproductive material.
- Request for greater clarity on how the Department will enforce the reimbursement regulations.
- Recommending further, and ongoing, engagement with stakeholders as the regulatory regime is implemented.

4 Additional Feedback

Stakeholders also submitted comments on issues that fall outside the scope of the current regulatory project. The Department heard from a few stakeholders about issues that relate to the practice of medicine, which is under provincial rather than federal jurisdiction. For instance, one stakeholder requested enhanced oversight of drugs used at fertility clinics. While important to consider, these particular issues are not under Health Canada's purview.

One group of stakeholders advocated for loosening restrictions on the prohibitions in the AHR Act related to scientific research. Other stakeholders advocated for regulations that respond to the rapidly advancing scientific field of AHR, or follow international standards for scientific research and clinical procedures to keep pace with the changing AHR landscape.

Some stakeholders expressed concern that the existing prohibition on the purchase of gametes encourages the importation of sperm and ova from parts of the world where they are more readily accessible and are subject to less regulatory oversight. A few stakeholders expressed concern about the potential burden imposed on the Canadian healthcare system in arrangements where Canadian surrogates offer their services to international intended parents, given that the medical costs of the surrogate's pregnancy are borne by Canadian taxpayers. This fact, combined with the limitations placed on items that can be reimbursed, may make Canadian surrogates seen as a more economical option, and stakeholders do not want Canada to encourage reproductive tourism, either at home or abroad.

Stakeholders advocating on behalf of surrogates emphasized the importance of regulating persons who make arrangements between surrogates and intended parents (i.e. surrogacy consultants) and requested that more clarity be provided on the legal limits of such arrangements. Health Canada also heard from a few fertility lawyers who commented on the legal aspects of surrogacy, and the importance of strong contracts. These stakeholders would prefer to see more consistency and clarity concerning contract law, to better protect all parties involved.

With regards to the current penalties associated with medical and scientific activities prohibited by the Act, one group of stakeholders questioned whether criminal penalties are appropriate and advocated for a punitive approach with measures in place to ensure compliance. Health Canada also received a comment expressing disappointment that AHR laws currently only set out a maximum penalty for violations and that the actual penalties are solely at the discretion of the courts, thereby making them potentially inadequate.

Other comments provided by stakeholders included:

- Concerns that the policy language used in the consultation document was too product-focused, and technical in nature, making it potentially difficult for some Canadians to provide meaningful feedback.
- Concern about the lack of federally-regulated mandatory standards for embryologists working at fertility clinics.
- Concern about the lack of federal oversight with respect to embryo safety.
- The need for proper counselling for donors and recipients.
- The need for data collection and retention, including reporting success rates for clinics that process directed donations.

5 Conclusion

Health Canada would like to thank all those who submitted their feedback on the key policy proposals to strengthen the AHR Act. Your comments have been taken into consideration and have helped inform the development of regulations needed to bring Section 10, Section 12 and Sections 45-58 of the AHR Act into force.