Quick Facts:
Safety of Donor Sperm and Ova

FACT: There are important health and safety gaps in assisted human reproduction oversight

- Safety of donated ova is currently unregulated in Canada.
- The current regulations for the safety of donor sperm are outdated.
- The ability to oversee the supply chain to help ensure the integrity and quality of donor sperm and ova used by Canadians is limited.

FACT: New regulations will address the health and safety gaps

- The proposed regulations introduce updated requirements for screening and testing sperm donors and new requirements for screening and testing ova donors.
- The new measures aim to reduce the risk of infectious disease transmission from the donor to the recipient and to the child born of assisted human reproduction, as well as the risk of genetic disease transmission from the donor to the child.
- New quality management requirements will help ensure the integrity of donor sperm and ova by reducing the risks of contamination or cross-contamination and infectious disease transmission.

FACT: New regulations will give Health Canada greater oversight of the safety of donor sperm and ova

- Establishments responsible for ensuring that donations are processed in accordance with the regulations prior to their distribution or use will be required to register with Health Canada prior to distributing or making use of donor sperm and ova.
- Establishments that import or distribute donor sperm and ova will be required to notify Health Canada before they conduct those activities.
- The proposed regulations also require the retention of relevant records related to each donation and will ensure measures are in place to ensure that donor sperm and ova can be traced within the distribution chain.
- Every year establishments that process, import or distribute sperm and ova will be required to attest that they are in compliance with regulatory requirements.
- All establishments, including those that process sperm and ova, may be subject to inspection by Health Canada.

Quick Facts:
Donation Options

FACT: New regulations will provide Canadians with more options in building their families

- Health Canada recognizes the right of individuals to make an informed decision to accept certain risks in using donor sperm or ova to build their families, and the important role that their treating physician plays in assessing and communicating those risks.
- The proposed regulations introduce two donation processes:
    - The Regular Process will be the standard way that donor sperm and ova, including all anonymous donations, are assessed.
    - In the case where the donor and recipient know one another, they may choose to follow the Directed Donation Process, which will provide the recipient with more flexibility in selecting their donor, while still considering the safety of the donation.
- The proposed regulations will also allow access to otherwise non-compliant donor sperm or ova under exceptional cases (e.g. to create a genetic sibling).

Quick Facts:
Reimbursement Regulations

FACT: New regulations will provide clarity to Canadians on allowable reimbursement

- The *Assisted Human Reproduction Act* prohibits the purchase of sperm and ova from a donor or person acting on behalf of a donor, and prohibits the payment to a female person to become a surrogate mother.
- The Act allows donors and surrogates to be reimbursed for out-of-pocket expenditures related to their donation or surrogacy, provided the reimbursement is done in accordance with the regulations.
- The new regulations will provide clarity to Canadians by setting out the categories of expenditures (e.g. medical expenses, legal/counselling fees, maternity clothes) for which reimbursement will be allowed.

FACT: New regulations will establish a verifiable process for making reimbursements

- All reimbursements must be for expenditures directly related to the donation or surrogacy or maintenance and transport of an in vitro embryo and must be accompanied by a receipt.
- A person who makes a reimbursement under the regulations will have to obtain a signed declaration from the person requesting the reimbursement that will contain details about the expenditures being reimbursed.
- The person making the reimbursement will be required to maintain records, including the signed declaration forms, receipts and other relevant documents, for a period of six years after the date of reimbursement.
- The new regulations will require a person who has reimbursed to provide, upon request, any record or any additional information related to the reimbursement.

Quick Facts:
Other Steps Being Taken to Strengthen the *Assisted Human Reproduction Act*

FACT: A strengthened Act will provide Health Canada with better enforcement tools

- The administration and enforcement framework will:
  - Allow for the designation of inspectors to administer and enforce the *Assisted Human Reproduction Act*.
  - Provide inspectors with the tools necessary to verify compliance with the Act.

FACT: Minor amendments to the existing consent regulations will improve their clarity

- The proposed amendments to the Consent Regulations will:
  - Help preserve the anonymity of donors who donated on the condition of anonymity.
  - Introduce a 10 year retention requirement for records related to consent.

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