Health Canada Santé Canada

Guidance Document

Interim Enforcement Approach for Directed Donations of Sperm and Ova

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Canada

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Introduction

Purpose

This guidance document outlines Health Canada's interim enforcement approach for certain requirements under the directed donation process. It is for:

- health professionals who make use of donor sperm and ova
- establishments that process, import, distribute and/or make use of donor sperm and ova

The *Safety of Sperm and Ova Regulations* (regulations) made under the *Assisted Human Reproduction Act* (act) apply to donor sperm and ova that are used in assisted human reproduction.

The regulations provide multiple donation pathways. One such pathway is the directed donation process. This pathway gives individuals flexibility and autonomy in selecting their donor in cases where the donor and recipient know each other. It also ensures the safety of the donation while allowing sperm or ova from known donors who would be excluded under the regular process to be used.

Recently, Health Canada has been made aware that some requirements set out under the directed donation process do not account for common industry practices. Nor do they consider certain situations involving intended parent(s) who require a surrogate to have children.

It's becoming more common for regulated parties to make use of donor sperm and ova by creating *in vitro* embryos (IVEs) for intended parents before the parents know their surrogate. The reasons for doing so include:

- advances in IVE cryopreservation techniques
- the challenges and timelines associated with choosing a surrogate
- a desire to know there are viable IVEs for the surrogate to carry before an arrangement is made

Gametes from intended parents are sometimes being processed in accordance with the directed donation process. This is being done because the donor(s) will know the recipient (the surrogate) in the future. However, the recipient is not known at the time of making use of the donor sperm or ova.

By proceeding as such, these regulated parties are not complying with:

- certain key requirements of the directed donation process, such as:
    - the donor and recipient must know each other before making use of the sperm or ova
    - certain obligations related to the recipient must be met before making use of donor sperm or ova

The requirement that intended parents know their surrogate before making use of the sperm or ova to create IVEs has several unintended consequences:

- may create an unnecessary and potentially costly burden by requiring intended parents to have their sperm and/or ova retrieved and cryopreserved rather than using fresh gametes to create IVEs
- may cause undue delays in retrieving the gametes (in cases where it's necessary to use fresh gametes), which could impact fertility
- risks limiting access for a specific subset of donors who may not be eligible to donate under the regular process

This is contrary to the intent of the directed donation process, which aims to increase access and flexibility.

Therefore, until the regulations can be amended to address this issue, in the interim, Health Canada will consider certain requirements under the directed donation process of lower priority for enforcement. There are conditions to this caveat.

Policy objectives

Health Canada acknowledges that the regulations must be amended to address situations where intended parents:

- know they will need a surrogate to have children **and**
- wish to create and cryopreserve IVEs using donor gametes processed under the directed donation process **and**
- wish to create IVEs before they know their surrogate

This interim enforcement approach will avoid limiting access to the directed donation process for donors who cannot donate under the regular process. The enforcement approach, which will continue to reduce the risk to human health and safety, is consistent with a key principle underpinning the act. This principle, stated by Parliament, is that "persons who seek to undergo assisted reproduction procedures must not be discriminated against, including on the basis of their sexual orientation or marital status."

Scope and application

This interim enforcement approach applies to:

- health professionals who make use of donor sperm and ova
- establishments that process, import, distribute and use donor sperm and ova processed according to the directed donation process

Conditions for Implementation

Section 30 of the regulations exempts donor sperm and ova from the regular process. They may be processed according to the directed donation process if certain requirements are met. One of these requirements, which is set out in paragraph 30(a), is that the donor and recipient know each other.

For directed donations, section 40 of the regulations requires that before they can make use of sperm or ova, health professionals must document that:

- in their medical opinion the use of sperm or ova will not pose a serious risk to human health and safety **and**
- they have informed the recipient of the risks that the use of the sperm or ova could pose and that they have obtained written consent from the recipient

An interim enforcement approach with conditions is being applied to paragraph 30(a) and section 40 of the directed donation process. This approach will be for cases where intended parent(s) know they will need a surrogate to have a child but wish to:

- make use of sperm and ova to create an IVE **and**
- have 1 or both gametes processed in accordance with the directed donation process before knowing their surrogate

In such situations, Health Canada will consider non-compliances with paragraph 30(a) and section 40 to be of lower priority for enforcement. However, the following conditions for mitigating risk must be met:

- for non-compliances with paragraph 30(a), the donor and recipient must know each other **before the IVE is transferred to the recipient** (surrogate) and
- for non-compliances with section 40, the health professional must meet the following conditions **before transferring the IVE to the recipient** (surrogate):
    - create a document stating that based on the summary document and any risk-mitigating measures with respect to the sperm or ovum used to create the IVE, in their medical opinion the sperm or the ovum would not pose a serious risk to health and safety because of the transfer
    - create a document stating that the health professional:
        - has informed the recipient of the risks to human health and safety that using the sperm or ovum could pose as a result of the transfer of the corresponding IVE and
        - has obtained written consent from the recipient

Health Canada has considered the implications of applying this enforcement approach on the rest of the regulatory framework. If the conditions are met, non-compliance with paragraph 30(a) and section 40 and any other section that may result due to this non-compliance will be given a lower priority for enforcement. However, all other sections of the regulations concerning the directed donation process must be met before the sperm or ovum can be used to create an IVE.

Establishments and health professionals must demonstrate that the conditions were met. Applicable documentation and records, including standard operating procedures, may be verified during an inspection.

This enforcement approach takes effect immediately.

We will review this enforcement approach on a regular basis. We reserve the right to enforce the act and regulations if we identify any potential risks to health and safety.

Notes About Guidance Documents in General

Guidance documents provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. They also provide guidance to Health Canada staff on how mandates and objectives should be met fairly, consistently and effectively.

Guidance documents are administrative, not legal, instruments. This means that flexibility may be applied. However, to be acceptable, alternate approaches to the principles and practices described in this document must be supported by adequate justification. They should be discussed in advance with the relevant program area, in this case with the Biological Product Compliance Program to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

Contact Information

Send any inquiries and information requests about this interim enforcement approach to the Biological Product Compliance Program by email: bpcp-pcpb@hc-sc.gc.ca.