Health Canada
Santé Canada

Health Products and Food Branch
Direction générale des produits de santé et des aliments

Biologic and Radiopharmaceutical Drugs Directorate
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[redacted]

Dear [redacted]

The purpose of this letter is to provide guidance on the regulatory considerations of mixing Solvent Detergent (S/D) plasma and red blood cells (RBCs) for the practice of intrauterine "exchange" transfusions (IUT), which was raised at our bilateral meeting in May 2023. Health Canada is aware that S/D plasma is becoming more widely used at hospitals in lieu of transfusable plasma manufactured at Canadian Blood Services (CBS).

Health Canada does not consider mixing RBCs and S/D plasma to be a transformation activity as per the *Blood Regulations*. S/D plasma is classified as a drug, and mixing it with RBCs for IUT falls under the practice of medicine. Any adverse reactions as defined in the *Blood Regulations* resulting from this activity would still need to be reported as Adverse Recipient Reactions as required under the *Blood Regulations*.

For additional information, please contact:

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Yours sincerely,

Sophie Sommerer
Director General

Cc:
Kelly Robinson, Director General, Marketed Health Products Directorate (MHPD)