Plasma Donation in Canada

(Source: Health-Canada http://www.hc-sc.gc.ca/dhp-mps/brgtherap/activit/fs-fi/plasma-eng.php)

- 1. Canada has one of the safest blood systems in the world, thanks to the strict standards set out in Health Canada's Food and Drugs Act and Regulations for the collection of blood and plasma.
- 2. In Canada, blood used for transfusion is collected solely by the Canadian Blood Services or by Héma-Québec and only from volunteer donors. Canadians are encouraged to donate blood regularly, if possible, as part of maintaining Canada's voluntary donation-based blood transfusion system.
- 3. Whereas plasma used for the manufacturing of plasma products may be collected from paid donors, this is not a new practice. In fact, approximately 70% of the immune globulins available in Canada are made in whole or in part from plasma from paid donors. These lifesaving products are extremely safe, due to advancements in blood manufacturing technology which now includes steps to inactivate any viruses or other contaminants. Paid plasma donors are currently criticalto ensuring a sufficient supply of blood products in Canada.

What is plasma and plasma donation?

- 4. Plasma is the pale-yellow liquid component of blood that normally holds the blood cells in suspension. It makes up about 55% of the total volume of an individual's blood.
- 5. Plasma donation is the process of collecting a donor's blood, separating the plasma portion of the blood from the blood cells, and then returning the blood cells to the donor. This process takes between 2 and 3 hours and is known as plasmapheresis.

What is plasma used for?

- 6. Plasma is the starting material used for the manufacturing of life-saving, commercial drugs known as plasma products.
- 7. Commonly used plasma products include albumin, which is used to treat fluid loss in burn or trauma patients; immune globulins, which are used to treat or prevent infections or immune disorders; and clotting factors, which are used for the treatment of haemophilia as well as other bleeding disorders.

Who collects plasma in Canada?

8. In Canada, both Canadian Blood Services and Héma-Québec collect plasma for manufacturing into plasma products. Under strict regulations enforced by the Food and Drug Act, private companies can also collect plasma for the production of essential plasma products.

Are all plasma products used in Canada made from Canadian plasma?

9. No. Canada is not self-sufficient for plasma products and so some products such as immune globulins need to be purchased from manufacturers that use U.S. sourced plasma. In fact about 70% of the immune globulins distributed in Canada are made from U.S. sourced plasma.

How much plasma is collected worldwide for the manufacture into plasma products and is it enough to meet global needs?

10. Today, about 24-26.5 million litres of plasma is collected globally each year, with the U.S. producing approximately 60% of the global supply and with 70% of the U.S. supply coming from paid donors. It is estimated that the lives of more than 1,000,000 patients worldwide depend on source plasma from the U.S. obtained from paid donors.

Is plasma donation regulated in Canada?

- 11. Yes. The federal law that governs the collection of plasma used for making plasma products is the Food and Drugs Act and the Food and Drug Regulations. Included within these regulations are specific provisions that relate to Human Plasma Collected by Plasmapheresis.
- 12. Any establishment that collects plasma for use in making plasma products must be licensed by Health Canada. The license application must show that its donor screening and testing processes meet the strict requirements under the law. For example, before donors are accepted into a plasma donation program they must be determined to be eligible to donate. In addition to a comprehensive questionnaire and interview, donors must be physically examined for health and disease risk factors. At the time of every donation, donors are re-interviewed and their blood is tested for infectious diseases, including HIV and Hepatitis B and Hepatitis C.

Can plasma donors be paid for their donations?

- 13. Yes. In fact, paid plasma donors are currently critical to ensuring a sufficient supply of plasma products in Canada. While neither Canadian Blood Services nor Héma-Québec pay their donors for either blood or plasma, private clinics and companies may pay plasma donors provided it is permitted by the provincial and territorial laws.
- 14. Payment for plasma donation is even more common in the U.S. Much of the U.S.-sourced plasma used for manufacturing blood products, including those that are sold in Canada, comes from paid donors. The U.S. has the same level of intense safety regulation over plasma donation as in Canada.
- 15. Many Canadians taking plasma products were infected with HIV and hepatitis during the years of the tainted blood crisis. The Krever Inquiry Report recommended that blood donors should not be paid.