About Health Canada

- Activities & Responsibilities
- Advisories, Warnings & Recalls
- Branches, Regions & Agencies
- Conferences & Events
- Estimates, Plans & Performance
- International Activities
- Media Room
- Minister
- Public Involvement & Consultations
- Funding
- Legislation & Guidelines
- Reports & Publications

Consumer Product Safety

Diseases & Conditions

Drugs & Health Products

Emergencies & Disasters

Environmental & Workplace Health

First Nations & Inuit Health

Food & Nutrition

Health Care System

Healthy Living

Science & Research

Government Health Partners

Need Larger Text?

Home > About Health Canada > Media Room > News Releases > 2005

News Release

2005-115
October 26, 2005
For immediate release

Tissue recall in the United States

OTTAWA - Health Canada is advising Canadians of a voluntary recall in the United States of tissue products used in implants and grafts that were imported into Canada. These tissues were recovered by Biomedical Tissue Services Limited in the United States from tissue donors who may not have met Health Canada donor eligibility requirements and who may not have been properly screened for certain infectious diseases. At this time, tissues that have been implicated include processed human bone, skin and tendons. The implicated products represent a small percentage of the tissue supply in Canada.

Health Canada currently estimates that approximately 300 tissue products originating from Biomedical were imported into Canada. Most of the implicated bone and skin products would have been implanted or grafted during dental procedures. Other bone products and tendons would have been transplanted in orthopedic procedures. The risk from use of these products is considered to be low, as tissues are routinely processed using methods that help to reduce the risk of infectious disease. However, the actual infectious risk is unknown. To date, no known adverse events from these products have been reported in Canada or the United States.

Health Canada requirements to determine donor eligibility include important steps to ensure that donors do not harbor infections that could be transmitted to recipients. These steps include testing for relevant infectious diseases, physically assessing the donor, and reviewing the donor's medical history and other factors that may place them at an increased risk of infections that could then unintentionally be transmitted to recipients through the tissues.

While the risk is believed to be low, Health Canada has taken a number of precautionary measures. Health Canada sent a letter to the Canadian importers of these tissue products, advising them to notify all end users who received these products. End users would include, among others, hospitals, physicians, and dental offices. Health Canada is advising them in turn to notify all patients who received these tissue products and to provide access to infectious disease testing. The relevant infectious diseases for which tissue donors are required to be tested in Canada are: HIV-1 and 2 (the viruses that cause AIDS), hepatitis B virus (HBV), hepatitis C virus (HCV), human T-cell lymphotropic virus (HTLV I and II) and syphilis. As well, physicians who still have concerns or questions should contact the health care facility where the procedure was performed.

In addition, Canada's Public Health Agency of Canada has notified the chief medical officers of Health for the provinces and territories of this issue and has provided them with Health Canada's recommendation to the importers of products originating with Biomedical for patient notification.

Biomedical has sold products to a number of U.S. companies that have exported tissues to Canada. These companies have all initiated voluntary

recalls for all products that were produced using tissues from Biomedical. Products were imported into Canada from the following companies: Tutogen Medical Incorporated, which has sold products in Canada to Zimmer Dental of Mississauga, Ontario, and Mentor Medical Systems Canada Inc. of Oshawa, Ontario; LifeCell Corporation, which has sold products in Canada to BioHorizons of Markham, Ontario, and Biogenics Inc. of Toronto, Ontario; and Regeneration Technologies Incorporated, which has sold products in Canada to Laswell of Milton, Ontario, and Medtronic of Canada Ltd. of Mississauga, Ontario.

Although the risk is believed to be low, Health Canada advises that Canadians who think they might be affected by this recall should speak with their health care professional.

Health Canada will continue to work with the United States Food and Drug Administration on a priority basis to obtain more information about the extent of the problem, the risk and those impacted in order to monitor the recall in Canada. Further public health updates will be issued as needed.

-30-

Media Enquiries:
Nathalie Lalonde
Health Canada
(613) 957-1803

Public Enquiries:
(613) 957-2991
1-866 225-0709