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## Revised Fact Sheet on Xenotransplantation

### What is xenotransplantation ?

Xenotransplantation is the transfer of living cells, tissues, and/or organs from one species to another. In this document it refers to animal-to-human transplantation. An example is the transplant of a kidney from a pig into a human.

### What are the potential benefits of xenotransplantation?

Xenotransplantation could potentially provide an unlimited supply of cells, tissues, and organs for humans. Any disease that is treated by human-to-human transplantation could potentially be treated by xenotransplantation. Organ xenotransplants could include whole hearts, lungs, livers, kidneys or pancreases. Tissue xenotransplants could include skin grafts for burn patients, corneal transplants for the visually impaired, or bone transplants for limb reconstruction. Cellular xenotransplants may provide treatment for people with diabetes, Alzheimer's or Parkinson's diseases.

### Have animal organs or tissues been used for transplants before?

Medical science already uses animal parts for various therapeutic reasons, such as replacement heart valves from pigs. However, these therapeutic products have been chemically treated and are not functional, living tissue. This distinguishes them from the viable organs used in xenotransplantation.

### What are the potential risks of xenotransplantation?

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### What are the potential risks of xenotransplantation?

The most serious risk of xenotransplantation appears to be cross-species transmission of undetected or unidentified animal infectious agents to patients that could, in turn, be transmitted to the general public. The worst-case scenario would be a major new epidemic. The potential risk of cross-species infection is largely compounded by the

practices of patient immunosuppression for transplantation. Some of the other scientific concerns surrounding xenotransplantation include immune rejection, uncertain efficacy/viability (whether it will work), and whether high levels of immunosuppression will leave the patient vulnerable to more frequent infectious diseases or cancer. Scientists are attempting to overcome immune rejection by inserting human genes into animal cells to make them more acceptable to a patient's immune system. Some experts believe that moving to clinical trials is the only way the uncertainties surrounding xenotransplantation can be answered. Others say experimental results show that a clinical trial at present would be premature and that these trials should be undertaken only if and when the risks have been shown to be minimal.

#### **What is the regulatory status of xenotransplantation in Canada?**

Xenotransplants - the live cells, tissues, and organs from animal sources - are considered therapeutic products (drugs or medical devices) and are subject to the requirements of the Food and Drugs Act, and the Food and Drug Regulations or the Medical Devices Regulations. Pursuant to these regulations, sponsors of human clinical trials involving xenotransplants would be required to submit an application to Health Canada for approval before a clinical trial may proceed. No clinical trials involving xenotransplantation have been approved by Health Canada to date.

#### **What is a clinical trial?**

A clinical trial is medical research undertaken with informed and consenting human subjects in a controlled environment. The intent of a clinical trial is for the sponsoring company or research institute to gather information on the safety and effectiveness of new drugs or therapies prior to seeking approval of a procedure or product for use by the Canadian public.

#### **How soon could xenotransplants be carried out in Canada?**

To date, no requests for clinical trials involving xenotransplants have been received or approved by Health Canada.

#### **What animals would be used for xenotransplants?**

While it may seem logical to choose animals that are genetically similar to humans, such as apes or baboons, it is becoming clear that more distant mammals may be preferred. Pigs have been viewed as the preferred choice of source animal due to the fact that they are inexpensive and easy to breed, have relatively large litters, have organs that are about the right size, and may confer less risk of infection to humans than non-human primates. The pigs would be raised in specially designed facilities and would be used only for transplantation procedures.

#### **What have other countries done about xenotransplantation?**

In the United States, the regulatory responsibility lies with the Food and Drug Administration (FDA) which has updated its "Public Health Service Guidelines on Infectious Disease Issues in Xenotransplantation" that were first released in September 1996. Clinical trials involving xenotransplantation have been approved by the FDA.

In Great Britain, a moratorium on clinical trials was introduced in January 1997, but clinical trial applications may now be submitted for review to the United Kingdom Xenotransplantation Interim Regulatory Authority (UKXIRA). UKXIRA was established in May 1997, to advise the UK Health departments on actions necessary to regulate xenotransplantation and to advise on the acceptability of clinical trial applications. UKXIRA has not approved any clinical trials to date.

The World Health Organization, in its efforts to foster international consensus on issues related to human health, hosted a consultation with international experts and published guidelines in 1998 on preventing and managing infectious diseases associated with xenotransplantation.

In January 1999, the Council of Europe's Parliamentary Assembly called for a moratorium on xenotransplantation until this new technology is evaluated and guidelines are established and agreed. The Assembly also asked the Council of Europe Public Health and Bioethics Committees to work hand in hand with the World

Health Organisation on a strategy which balances ethical, medical, scientific, legal, social and public health issues before human clinical trials continue.

### **Have there been xenotransplants in other countries?**

According to the Organisation for Economic Co-operation and Development, limited clinical trials involving xenotransplantation are planned or ongoing in some countries, such as the U.S., Belgium, Spain, and Germany.

### **What has Health Canada done to address the issue of xenotransplantation in Canada ?**

In November 1997, Health Canada sponsored a National Forum on Xenotransplantation - Clinical, Ethical, and Regulatory Issues. The Forum Report included several important recommendations, such as the need to inform and involve the public on issues related to xenotransplantation, and to develop safety standards that can be used to regulate xenotransplants, if and when they are approved for use in Canada. An Expert Working Group on Xenotransplantation Standards was established by Health Canada to develop such safety standards. In July 1999, as a result of this work, Health Canada released, for public comment, the draft Proposed Canadian Standard for Xenotransplantation.

Both a Notice to Interested Parties: Intent to Develop a Regulatory Framework for Xenografts (February, 1999) and Notice to Hospitals: Clinical Use of Animal Cells, Tissues, or Organs to Treat Patients (March, 1999) were issued to communicate 1) the current federal regulatory requirements concerning the clinical use of xenotransplants, 2) Health Canada's intent to develop appropriate regulations for xenotransplants, and 3) that applications under the Special Access Program of Health Canada for the use of xenotransplants are not being considered.

In the fall of 1999, an Expert Advisory Committee on Xenograft Regulation was formed "to provide Health Canada with timely advice on medical, scientific, ethical and communication issues related to the regulation of xenografts".

In March 2000, Health Canada sponsored a Xenotransplantation Surveillance Workshop: Infection Control Database and Sample Archiving, which brought together infectious disease and other experts to discuss issues concerning xenotransplantation surveillance for Canada.

In response to recommendations identifying the need for public consultation, Health Canada developed a Public Involvement Plan for xenotransplantation and sponsored, in April 2000, a Planning Workshop to obtain input to the Plan. As a step toward implementing the Plan, Health Canada funded the Canadian Public Health Association to form a Public Advisory Group and to conduct a public consultation on xenotransplantation.

Canada's involvement in xenotransplantation discussions and initiatives has not been limited to the national scene. Canada is a member country of the Organisation for Economic Co-operation and Development (OECD). Together with the World Health Organization (WHO), Health Canada initiated an Electronic Discussion Group on International Xenotransplantation Policy Considerations to provide a forum for global discussions on xenotransplantation public policy considerations. Health Canada is also represented as observer on the Council of Europe's Working Party on Xenotransplantation, which had been tasked with preparing a report on the state of the art in the field of xenotransplantation by the end of year, 2001.

### **What are the next steps?**

The views and concerns of Canadians are important considerations, among others, that will help guide the future development of government policy on xenotransplantation. In addition to carefully reviewing the report of results from the public consultation, Health Canada has established a Working Group and is conducting complementary analyses to the report. Some of these analyses include a key issues paper, an international overview, a report on the status of risk associated with xenotransplantation, a legal analysis, and an analysis of potential policy and regulatory options. On the basis of these analyses and all input from the public, a policy decision will be made as to whether or not clinical trials involving xenotransplantation shall be allowed to proceed.

**To forward comments or request further information**

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