



## THE SAFETY OF HUMAN INSULINS

### The Issue

Human insulins are used worldwide for controlling diabetes. However, recent media reports have claimed that human insulins are not safe. Demands have been made for a public inquiry into how they were approved and for animal insulins to be made more available.

### Background

The first human genetically engineered insulin, called a recombinant or DNA-derived insulin, was manufactured by Eli Lilly and approved for sale in Canada in 1983. Another recombinant human insulin, made by Novo Nordisk, was approved in 1993. These human insulins have largely replaced animal insulins because they are more effective and have an excellent drug safety record, both in Canada and in other countries. They have proven so popular that Eli Lilly and Novo Nordisk have stopped selling beef-pork insulin worldwide. Health Canada has no authority to force manufacturers to continue marketing a product.

### The Benefits of Human Insulins

Prior to human insulins being approved and marketed in Canada, a thorough review of their effectiveness was done. The results of clinical trials, some conducted in Canada, were studied and post-marketing experiences from other countries were examined. The conclusion was that the benefit-risk balance of human insulins was appropriate.

The problem with introducing any foreign matter such as insulin into the body, is that the body recognizes it as foreign and begins manufacturing antibodies to fight it. These antibodies combat the insulin, meaning that more and more insulin must be taken to control the diabetes.

The major advantage of human insulins is that there are fewer anti-insulin antibodies formed than with animal insulins. This means a lower risk of adverse allergic reactions and a lower possibility the patient will need higher and higher doses of insulin.

More than 200,000 diabetics in Canada and millions worldwide use human insulins every day, proof of their effectiveness and safety. However, all insulins can result in hypoglycemia, (too low blood sugar) if the dose taken is more than your body needs at the time. Hypoglycemia can lead to sweating, disturbed behavior and even loss of consciousness or death. Hypoglycemia can happen whether you are using animal or human insulins.

## How Health Canada Monitors Insulins

Health Canada has monitored the adverse effects that have been reported with human insulins. There does not appear to be any unusual trend with human insulins. The number of adverse incidents is proportionally the same as with animal insulins. Regulators in other international jurisdictions have confirmed similar findings.

## The Effects of Switching Insulins

The harder it is for you to control your blood sugar, the more likely you are to suffer a variety of reactions, not only to your disease, but also to your insulin. That is why it is so important for you to understand the symptoms and signs of hypoglycemia, which can sometimes be very subtle and hard to recognize, regardless of the type of insulin you use.

Changing from one brand of insulin to another can cause difficulties in controlling your blood sugar level until the correct dose is found. The same is true when switching from animal to human insulins.

Although almost all diabetics use human insulins successfully, there are a few who have more difficulty making the change. It is critical when switching from animal to human insulins, that both you and your doctor take particular care to control your blood sugar.

## Insulin Availability

The original human insulins approved for sale in Canada are made by Eli Lilly and Novo Nordisk. Newer versions are also now available. Fast acting insulins are sold by Eli Lilly and Novo Nordisk, and basal or long-acting insulin is sold by Aventis Pharma. These new versions may help provide better control of blood sugar.

Animal insulins are also still available. Eli Lilly manufactures pork insulin. Beef insulin can be imported from a source in the UK via the Special Access Program of Health Canada by calling (613) 941-2114.

The best choice of insulin for you is a decision that should be made after a discussion between you and your doctor.

## Need More Info?

For more information about Diabetes, visit Health Canada's Diabetes Web page at:

<http://www.hc-sc.gc.ca/english/diseases/diabetes.html>

For additional Publications from Health Canada on Diabetes See:

DIABETES SERVICES (GUIDELINES)

THE MANY FACES OF DIABETES: DIABETES AND ITS COMPLICATIONS KILL MORE PEOPLE EACH YEAR THAN AIDS..... GET SERIOUS ABOUT DIABETES

ABORIGINAL DIABETES INITIATIVE FIRST NATIONS ON-RESERVE AND INUIT IN INUIT COMMUNITIES (PROGRAM FRAMEWORK JULY 5 2000)