PROGRAMME DES PRODUITS THÉRAPEUTIQUES
THERAPEUTIC PRODUCTS PROGRAMME

Medical Device Problem Reporting by Healthcare Facilities, Medical Professionals and other device users

Introduction

Medical device problem reporting is an essential element in the continued efforts of the Therapeutic Products Programme (TPP) of Health Canada to protect the health and safety of Canadians. Although manufacturers and importers are required to report medical device problems, the TPP encourages anyone purchasing, using or maintaining these products to report problems.

Why is it important to report device problems to the TPP?

Reporting of problems can result in the prevention of similar problems and in some cases has led to product modifications, redesign, recalls, or improvements in directions for use. In addition, this information could lead to the issuance of a warning or Medical Device Alert. Failure to notify the manufacturer and the TPP could place patients at risk at other facilities that are not aware of the problem. In general, medical device problem reporting contributes to an increased level of device safety, effectiveness and quality.

What types of problems should be reported?

Any concerns that relate to the safety, effectiveness or quality of a medical device that have been detected during use or identified during device examination and testing prior to use should be reported. The problems include deficiencies in the design of the device, defects arising from the manufacturing and inadequacy or errors in labeling such as directions for use.

Why are problem reports from device users so critical?

Most postmarket device problems are discovered in a healthcare facility by the actual user. The user's description and perspective of the nature of the problem is invaluable especially considering their understanding of the procedures and conditions under which the problem occurred.

What happens after an incident has been reported?

After the details of the incident have been verified with the user, the information will be entered into the national incident database. Depending on the problem report details, a Health Canada inspector may visit the user to examine the device and to take samples, if necessary. The Health Canada Regional Office that is responsible for the manufacturer or importer of the medical device in question will be notified. They will follow-up with the manufacturer or importer as needed depending on the level of risk associated with the continued use of the device.

What are the benefits of reporting incidents to TPP?

The TPP acts as a central clearing house for problem report data, and can link isolated reports to identify problems that would otherwise go unnoticed or dismissed as an isolated incident. Once assessed by the manufacturer in consultation with the TPP, all affected facilities and professionals can be promptly informed of the situation and required actions.

In addition, the TPP:

- provides inspectors across Canada to assist users in investigating medical device problems;
- monitors the manufacturer's investigation and steps taken to correct the problem to ensure they are adequate to establish the safety and effectiveness of the device;
- provides assistance from the TPP's scientific, medical and engineering staff to identify the cause of problems and possible solutions, which may include testing of devices;

- provides access to Health Canada's expertise in risk identification and management;
- assists in determining device compliance with other regulatory requirements such as medical device licensing;
- issues Medical Devices Alerts to advise healthcare facilities and other users of problems with a medical device, when intervention is required; and
- in cases where a manufacturer is not prepared to take sufficient steps to correct a problem, the TPP will take action to ensure that the safety of users and patients is not jeopardized.

How do I report an incident?

Call the Medical Device Hotline number to reach a Medical Device Inspector in your Region. After reviewing the details of the incident, the inspector may ask you to complete the TPP's problem reporting form and fax it to their office. This form along with a guidance document on Voluntary and Mandatory Problem Reporting are available on the TPP website.

Medical Device Hotline 1-800-267-9675

TPP website: www.hc-sc.gc.ca/hpb-dgps/therapeut

October 2000

The Therapeutic Products Programme is the national authority that evaluates and monitors the safety, effectiveness, and quality of drugs, medical devices and other therapeutic products available to Canadians.

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