Policy Issues
From the Drugs Directorate

April 4, 1990
900404.EXT

LABELLING OF SPECIAL CONTAINERS

This policy provides labelling guidelines for special containers that are too small to accommodate a full label and containers whose design causes their label to be destroyed during use.

The packages concerned fall into two groups:

- multiple-dose packs, such as blisters, strips, push-through cards, ampoules or vials attached by a plastic strip, etc.; and
- single-dose packs, such as sachets, pouch-type packs, individual dose vials of liquid, etc.

These packages should contain the information outlined below as a minimum requirement.

For multiple-dose packs:

- the brand name (if no brand name, then proper or common name plus manufacturer’s name);
- the potency of the drug except where, in the case of a drug with more than one medicinal ingredient, the name used is unique for a particular potency of the drug; and
- the lot number and expiry date.

The above information should be presented in a manner that ensures that the package can be identified after units have been removed. This can be done by printing in a repetitive manner or by embossing on the edge of each card.

The regulatory requirements for small containers specified in section C.01.004 of the Food and Drug Regulations apply, except for syringes and pipettes in a delivery system of 1 ml or less.

For single-dose packs:

- the brand name, (if no brand name, proper or common name and manufacturer’s name);
- the potency of the drug except where, in the case of a drug with more than one medicinal ingredient, the name used for that drug is unique for a particular potency of the drug;

. the lot number; and

. if space permits, the expiry date.

E. Somers