

POLICY STATEMENT

Mandatory Patient Package Inserts

June 2000

In a July 21, 1999 communication, Health Canada has advised that Patient Package Inserts have been made mandatory as part of the marketing authorizations, Notice of Compliance (NOC) and/or Drug Identification Number for the drugs listed below. The mandatory documents would have been submitted to the Therapeutic Products Program by the manufacturer with its application to market a drug product, and reviewed as part of the submission.

The patient information material supplied by the manufacturer should be dispensed with:

1. Prescription Drugs:
 - a. Drugs delivered with the assistance of a device (i.e. inhalers, transdermal patches)
 - b. Isotretinoin and other oral tretinoids, except those used in oncology
 - c. Methotrexate for rheumatoid arthritis
 - d. Nonsteroidal anti-inflammatory drugs (NSAIDS)
 - e. Oral contraceptives
 - f. Ticlopidine

2. Biologicals – all drugs intended for self-administration including:
 - a. Erythropoietin
 - b. Gonadotropins
 - c. Human Growth Hormone
 - d. Insulins
 - e. Interferons
 - f. Wound Healing Factors

3. All drugs where the Product Monograph or Prescribing Information indicates that a patient information document is available.