PRODUCT SELECTION

(Adapted from College of Pharmacists of British Columbia document dated August 2004)

Product selection decisions may be based on Health Canada's Declaration of Equivalence, as indicated by the identification of a Canadian Reference Product on a Notice of Compliance for a generic drug.

Pharmacists may also use their professional judgment in interchanging other products if the products meet the definition of a pharmaceutically equivalent drug.

- "Pharmaceutically equivalent" means a drug product that, in comparison with another drug, contains identical amounts of the identical medicinal ingredients, in comparable dosage forms, but that does not necessarily contain the same non-medicinal ingredients.

Advantages of this approach to product selection:

1. When a new generic product is approved for sale in Canada, it can immediately be dispensed in place of the pharmaceutically equivalent brand name product. There will be no delays in determining interchangeability.

2. The definition of a pharmaceutically equivalent drug permits you to interchange drug products.

   For example, if a physician prescribes Altace® for a client with hypertension, you may provide an alternate supplier's generic version of Ramipril.

   Similarly, if new information in the medical literature demonstrates that a generic product meets the definition of a pharmaceutical equivalent drug with a brand name product, those products can be interchanged even if the brand name product was not listed as the Canadian Reference Product on the generic product's Notice of Compliance.

3. This approach eliminates the provincial review process to determine interchangeability. .

Q & A

Q. How will I know if a generic drug is pharmaceutically equivalent with a certain brand name product?

A. Most generic products approved by Health Canada have a declaration of equivalence with the comparator brand name product. This is identified as the Canadian Reference Product on the Notice of Compliance.

A more detailed description of Health Canada's approach to generic drug approval is in the endnotes.[1]

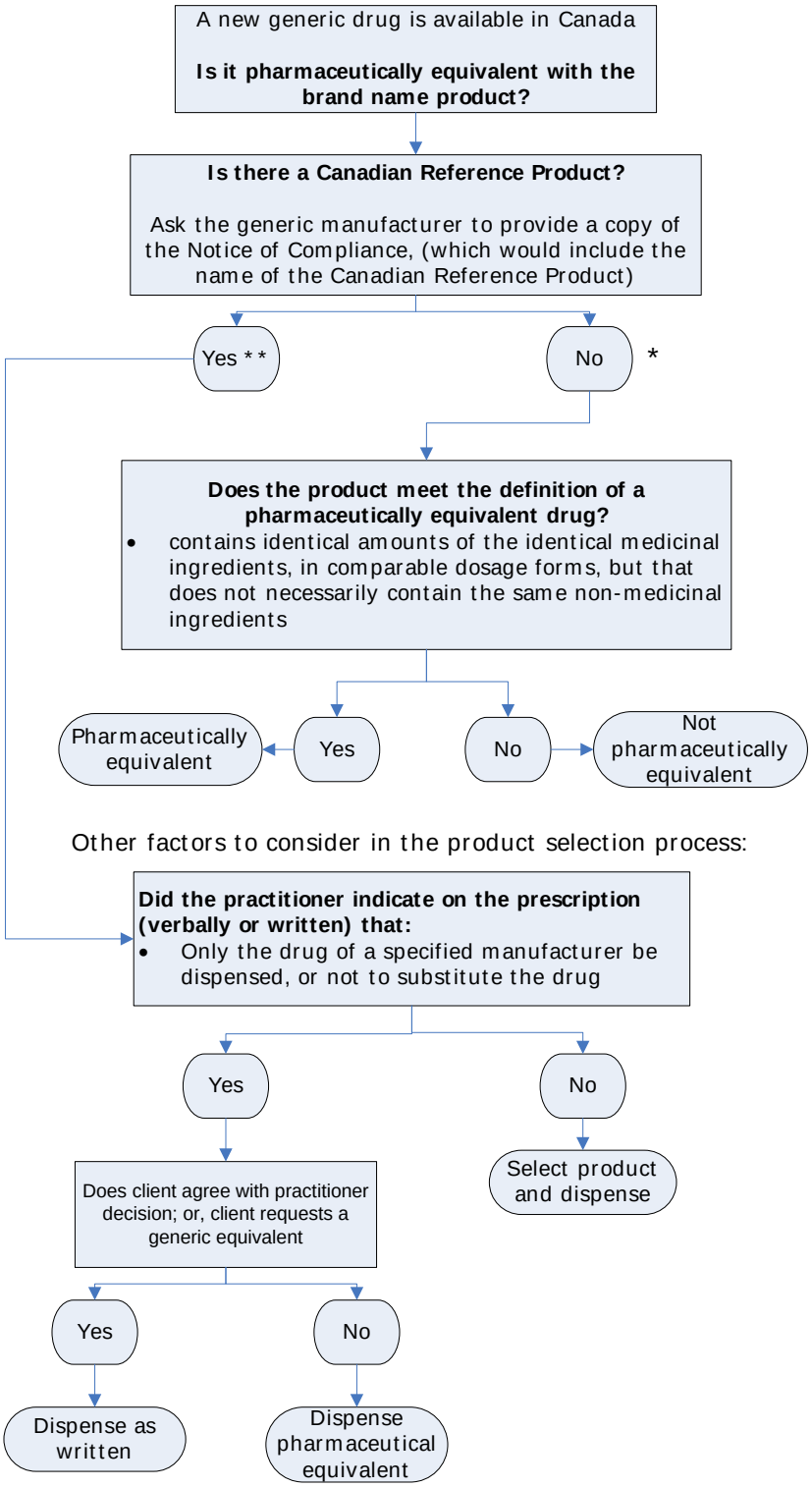
Q. How can I be sure what the Canadian Reference Product is for a generic drug?

A. When a pharmaceutical manufacturer contacts you about a new generic product, ask them to provide you with a copy of the Notice of Compliance. You can be confident that the generic product can be interchanged with the Canadian Reference Product, as listed on the Notice of Compliance. If your head office makes purchasing decisions, you may ask your head office to provide you with this information.

It will not be necessary for you to determine the Canadian Reference Product for existing generic products you are familiar with using. Since every generic product approved since 1995 was compared to a Canadian Reference Product, they are pharmaceutically equivalent. Similarly, generic drugs marketed in the future will likely have been compared to a Canadian Reference Product, so they will be pharmaceutically equivalent as well.

Nevertheless, if you are unsure about a generic product, there are a number of ways that you can confirm that the product can be automatically substituted. Figure 1 also describes the process to determine if a generic drug is pharmaceutically equivalent.

Figure 1: Product Selection Process



* It may also be useful to check the NB Formulary for products deemed to be equivalent prior to July 1, 2014

* * Information regarding subsequent entry biologics is emerging. Until further evidence is available, consult with Health Canada and the manufacturer concerning pharmaceutical equivalence

Q. Does my liability for product selection change as a result of this policy?

A. The issue of liability is covered in the Pharmacy Act and Regulations:

From the Pharmacy Act, 2014:

Product selection
128(1) A pharmacist may dispense a pharmaceutically equivalent, a pharmaceutical alternative or a therapeutic equivalent, all as defined in this Act or in the regulations, unless otherwise directed by the prescriber, or requested by the client.

No liability for dispensing pharmaceutically equivalent products

129 No action or other proceeding lies or shall be instituted against a prescriber, pharmacist or any member under the supervision of a pharmacist, on the grounds that a pharmaceutically equivalent or a pharmaceutical alternative other than the one prescribed was dispensed in accordance with this part.

From the Regulations, 2014:

Substitution
17.6(1) Where a prescription, either written or verbal, contains a direction by the prescriber that the prescribed brand of the drug is not to be substituted, the person dispensing the drug shall not make a substitution, unless requested by the client.

17.6(2) Any substitution must be recorded and forms part of the prescription record.

Based on the legislation,

1. If a practitioner has not made the indication described in 17.6(1), a pharmacist may dispense a pharmaceutically equivalent drug.
2. An indication from a practitioner under 17.6(1) must be made by the practitioner to a pharmacist either
   (a) orally, or
   (b) in writing
   at the time a prescription is issued.

3. No action for damages or any other proceeding may be brought against a pharmacist solely because a pharmaceutically equivalent drug was dispensed in accordance with Regulation section 129.

That means that as long as you are interchanging in compliance with the legislation above and are dispensing products that have been approved by Health Canada and received a Notice of Compliance with a Canadian Reference Product or products that meet the definition of a pharmaceutical equivalent, no action may be brought against you.

Q. Is this process used by any other jurisdictions?

A. Currently, British Columbia and Quebec follow this approach.

ENDNOTES:

1. How new drugs are authorized for sale in Canada:

New drugs are regulated under Part C, Division 8 of the *Food and Drug Regulations*. Companies are granted market authorization by Health Canada in several ways. Regardless of the method of authorization, a manufacturer receives a Notice of Compliance (NOC) when it has met Health Canada's regulatory requirements for the safety, efficacy and quality of a product. The following provides a brief overview of three of the most common routes by which new drugs are authorized for sale in Canada.

1. **Innovator drugs ("brand name drugs")**: Manufacturers receive authorization to sell these products in Canada by submitting a New Drug Submission (NDS) pursuant to section C.08.002 of the Food and Drugs Regulations.

2. **Subsequent entry drugs ("generic drugs")**: Health Canada often authorizes manufacturers to market these drugs by requiring them to submit an Abbreviated New Drug Submission (ANDS) pursuant to section C.08.002.1 of the Food and Drug Regulations. These products will receive a declaration of bioequivalence to a *Canadian Reference Product* (pursuant to Section C.08.004 (4)), which will be stated on the NOC.

3. **The Health Canada** *Changes in Manufacturer's Name and/or Product Name Policy* outlines another option for manufacturers wishing to receive authorization through an NOC to market brand name and generic drug products. This policy applies to eligible drug submissions submitted to Health Canada for a change in the manufacturer's name and/or product name subsequent to a merger, buy-out or other corporate restructuring or the establishment of a licensing agreement.

Products that receive an NOC according to one of these mechanisms have met Health Canada's regulatory requirements for safety, efficacy and quality.

Canadian Reference Product

Canadian reference product is defined in C.08.001.1 of the *Food and Drug Regulations* as:

a. " a drug in respect of which a notice of compliance is issued pursuant to section C.08.004 and which is marketed in Canada by the innovator of the drug,
b. a drug, acceptable to the Minister, that can be used for the purpose of demonstrating bioequivalence on the basis of pharmaceutical and, where applicable, bioavailability characteristics, where a drug in respect of which a notice of compliance has been issued pursuant to section C.08.004 cannot be used for that purpose because it is no longer marketed in Canada, or
c. a drug, acceptable to the Minister, that can be used for the purpose of demonstrating bioequivalence on the basis of pharmaceutical and, where applicable, bioavailability characteristics, in comparison to a drug referred to in paragraph a ".

Since 1995, every generic product approved by Health Canada has gone through a process called an "Abbreviated New Drug Submission." A generic drug approved through an Abbreviated New Drug Submission must be a pharmaceutical equivalent,[2] bioequivalent, have the same route of administration and the same conditions for use as the brand name product.[3] A generic product that meets this definition receives a Notice of Compliance that indicates which brand name product it was compared to. This brand name product is called the Canadian Reference Product. The generic drug would be considered pharmaceutically equivalent with the Canadian Reference Product.

2. Food and Drug Regulations C.08.001
"Pharmaceutical equivalent" means a new drug that, in comparison with another drug, contains identical amounts of the identical active medicinal ingredients, in comparable dosage forms, but that does not necessarily contain the same non-medicinal ingredients.

3. Food and Drug Regulations C.08.002.1(1)
A manufacturer of a new drug may file an abbreviated new drug submission for the new drug where, in comparison with a Canadian reference product,

a. The new drug is the pharmaceutical equivalent of the Canadian reference product;
b. The new drug is bioequivalent with the Canadian reference product, based on the pharmaceutical and, where the Minister considers it necessary, bioavailability characteristics;
c. The route of administration of the new drug is the same as that of the Canadian reference product; and
d. The conditions of use for the new drug fall within the condition of use for the Canadian reference product.