Ontario Public Drug Programs Division

Application of Generic Substitution to the Exceptional Access Program - Frequently Asked Questions for Patients

October 7, 2016

1. What are brand name and generic drugs?

Companies that develop brand name drugs hold a patent on the formula. A patent gives the drug maker the sole right to produce and sell the drug.

When the patents expire, other companies can make the drug with the same active ingredient(s) as the brand name drug and has the same effect in every important way. These drugs are called generic drugs.

Generic drugs have a different name and may look or taste different from brand name drugs, but they have the same active ingredient(s). They also cost less.

Both generic and brand name drugs follow the same quality and safety standards. Health Canada monitors the way they are manufactured and ensures that all drugs meet the same standards.

If you would like more information on the effectiveness and safety of generic drugs, please speak with your healthcare professional or visit:

https://www.cadth.ca/sites/default/files/pdf/generic_drugs_questions_answered_e.pdf

2. Why is the ministry applying a Generic Substitution policy to the Exceptional Access Program (EAP)?

Currently where there are generic Off-Formulary Interchangeable (OFI) drug products available for a brand name drug, the ministry's EAP approval allows for the dispensing of the brand name drug or the generic drug. The ministry is now applying a Generic Substitution policy to the EAP in order to increase the use of safe and effective generic alternatives to brand name products. Under the policy, the ministry will only approve the funding of the generic product, unless the Ontario Drug Benefit recipient has a prescription directing the dispensing of the brand product with "no substitution" and the recipient has a documented adverse reaction to at least two (2) generic versions of the

drug.

Generic drugs approved for use by Health Canada are as safe and effective as their brand name counterparts. Increasing the use of generic drug products offers cost savings for our healthcare system to allow for the funding of new innovative drug therapies.

Ontario is the only province in Canada that does not have a generic substitution requirement for drugs that require special authorization.

3. When does the new policy become effective?

The new policy will become effective on **November 1, 2016**.

4. I am currently using a brand product that has been approved under the EAP. Do I have to switch to a generic version beginning November 1, 2016?

Yes, beginning November 1, 2016, Ontario Drug Benefit (ODB) recipients with an approval for an EAP brand drug will be required to switch to a generic alternative, where available. Patients will be required to try two (2) or more generic alternatives before a "no substitution" prescription for a brand name drug will be reimbursed under the ODB program.

5. What if I want to have the brand name drug?

If you have chosen to have a brand name drug when there is a generic alternative available, you will be able to pay the cost difference yourself and have the pharmacy dispense the brand name drug to you.

6. What if I have experienced a side effect to the generic drug?

A very small number of patients may experience side effects with the generic drug upon trial. In these cases, the patient may try another interchangeable generic drug (if available). If you have experienced side effects on two generic drugs, please speak to your doctor or pharmacist regarding obtaining the brand name product and having it reimbursed by the Ontario Drug Benefit Program.

7. Does the new policy apply to biologics?

No, this policy does not apply to biologics.