**Ontario Public Drug Programs Division, Ministry of Health and Long-Term Care**

# Notice from the Executive Officer: Application of Generic Substitution to the Exceptional Access Program (EAP)

**October 7, 2016**

The purpose of this notice is to provide you with information regarding upcoming changes to the reimbursement of drug products under the Exceptional Access Program (EAP). Effective **November 1, 2016**, the ministry is introducing the application of generic substitution to the EAP.

Under this new policy, if an EAP drug has an interchangeable generic product designated through the Off-Formulary Interchangeable (OFI) mechanism, the ministry will only approve the funding of the generic product. Where Ontario Drug Benefit (ODB) recipients have had a documented adverse reaction to at least two (2) generic versions, the ministry will reimburse the higher-cost brand product. Similar to products listed on the ODB Formulary, the "No Substitution" policy will apply.

Starting November 1, 2016, pharmacists must dispense an OFI generic product in the pharmacy's inventory to ODB recipients with an EAP approval from the ministry. Pharmacists will be reimbursed the cost of the generic product that is dispensed. Given that inventory selection differs from pharmacy to pharmacy, the Health Network System (HNS) will have system rules in place on November 1, 2016, to reduce the value of the "Amount MOHLTC Pays" for a brand name OFI drug product to that of the highest-cost generic in the interchangeable category. The "Amount MOHLTC Pays" will therefore reflect the maximum price the ministry will pay for the drug under the EAP, unless the brand version is eligible for reimbursement. The ODB electronic formulary (e-Formulary) will have enhancements in October 2016 to show the OFI list with the "Amount MOHLTC Pays" to allow prescribers and dispensers to become familiar with this information in advance.

In order for ODB to reimburse the brand name product, prescribers are required to complete, sign and forward to the pharmacist, a copy of the Health Canada Side Effect Reporting Form for **each** interchangeable drug product trialed, and will continue to be required to write "no substitution" on a written prescription or indicate "no substitution" to the pharmacist in the case of a verbal prescription. The form(s) must be completely filled out noting the details of the adverse reaction(s) and signed by the prescriber.

Upon receipt of a “no substitution” prescription, the pharmacist will continue to:

- Clearly note on each Side Effect Reporting Form(s) – “**ODB No Substitution**”; and
- Fax or mail the completed and signed form(s) to Health Canada’s Canada Vigilance Program if not already submitted by the prescriber; and
- Retain copies of the completed and signed adverse drug reaction form(s) in a readily retrievable format at the pharmacy. Note: Copies must be kept for two (2) years past the last claim that relied on the adverse reaction form.

Health Canada Side Effect Reporting Forms do not have an expiry date and serve as a permanent record.

The pharmacist will continue to be required to mail or fax the completed form(s), where it has not been submitted by the prescriber, to:

Canada Vigilance Program, Marketed Health Products Directorate, Health Canada, Address locator 0701E, Ottawa, Ontario, K1A 0K9 Fax: 1-866-678-6789

If ODB recipients choose to exercise their personal preference for the brand therapy without trying at least two (2) generic drug products, pharmacists may continue to provide them with their choice and it will be the responsibility of the recipient to pay for any cost difference. The same will apply if the ODB recipient’s prescriber does not provide the appropriate Side Effect Reporting Form(s) to the pharmacy.

To further inform healthcare providers and patients, we have included Frequently Asked Questions (FAQs) for reference purposes.

If you have any questions, please contact the ministry by email at: PublicDrugPrgrms.moh@ontario.ca or the Ontario Drug Benefit (ODB) Help Desk at 1-800-668-6641.

**Background**

Currently, EAP approvals for drugs that are not listed on the ODB Formulary do not require generic substitution as is required for drugs that are listed on the ODB formulary. All EAP approvals enable the provision of all generic and brands of that product. This is changing on November 1, 2016, to require the use of at least two (2) generic products before the brand will be reimbursed by the Ministry.

Ontario is the only province in Canada that has not yet moved to a generic substitution requirement for drugs that require special authorization. The requirement to try at least one generic and experience an adverse reaction) has been a condition for “no substitution” brand claims since at least 1996.

Further changes to support the use of generic drugs on the Formulary were introduced on October 1, 2015, through revisions to the “no substitution” policy. Under the revised policy, ODB recipients are required to try at least two generics before the being eligible for the brand drug through the “no substitution” policy. Under the previous policy, ODB recipients were required to try only one generic product before the “no substitution” policy applied.

Health Canada has stringent regulations in place to ensure only safe and effective drug products are marketed in Canada, regardless of whether they are brand or generic drugs. This new policy will enhance the use of safe generic alternatives, resulting in cost savings for our healthcare system to allow for the funding of new innovative drug therapies.