



PLEASE NOTE

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For more information concerning the history of these regulations, please see the [Table of Regulations](#).

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CHAPTER D-15

DRUG PRODUCT INTERCHANGEABILITY AND PRICING ACT INTERCHANGEABLE DRUG PRODUCT PRICING REGULATIONS

Pursuant to section 15 of the *Drug Product Interchangeability and Pricing Act* R.S.P.E.I. 1988, Cap. D-15, Council made the following regulations:

1. In these regulations,
 - (a) “Act” means the *Drug Product Interchangeability and Pricing Act* R.S.P.E.I. 1988, Cap. D-15; Definitions
Act
 - (b) “category” means a category of interchangeable drug products, all of which may be substituted for the same original drug product; category
 - (c) “manufacturer’s list price” means the published price at which a drug product is sold by a manufacturer; manufacturer’s list price
 - (d) “Notice of Compliance” means a Notice of Compliance issued for a drug product under the *Food and Drug Regulations* under the *Food and Drug Act* (Canada); Notice of Compliance
 - (e) “original drug product” means the drug product in a drug category in the particular strength and dosage form for which the original Notice of Compliance was issued. (EC315/12) original drug product
2. (1) For the purposes of subsection 13(1) of the Act,
 - (a) in respect of an interchangeable drug product in a category for which a Notice of Compliance has been issued on or before July 1, 2012, the prescribed date shall be April 11, 2011; and
 - (b) in respect of an interchangeable drug product for which a Notice of Compliance has not been issued on or before July 1, 2012, the prescribed date shall be the date on which a Notice of Compliance is issued for that interchangeable drug product.Prescribed date
- (2) For the purposes of subsection 13(2) of the Act, the Minister may set a maximum cost per unit of an interchangeable drug product or a category from the manufacturer to an operator of a pharmacy that exceeds the percentage set by Minister pursuant to subsection 13(1) of the Act where
 - (a) one or more of the manufacturers provide documentation satisfactory to the Minister that supports the setting of a higher Exception – circumstances

maximum cost per unit, including but not limited to documentation showing that

- (i) the manufacturer's list price for the original drug product on which the maximum cost of the interchangeable drug product or category is based has risen,
- (ii) the original drug product for which the interchangeable drug products in the category may be substituted is no longer marketed in Canada, or
- (iii) a higher maximum cost per unit is justified having regard to a change in market conditions; or

(b) the Minister is satisfied that a higher maximum cost per unit for the interchangeable drug product or category is justified in order to maintain access to the interchangeable drug product or category.

Pricing –
circumstances and
criteria

(3) For the purposes of subsection 13(3) of the Act, the Minister shall, not more than once in each calendar year, consider evidence, whether provided by one or more manufacturers or adduced by the Minister on the Minister's own initiative, respecting the setting of a new percentage, including but not limited to evidence that

- (a) prices for original drug products on which the maximum cost of interchangeable drug products are based have changed;
- (b) the All-Items Consumer Price Index for Prince Edward Island has changed; or
- (c) a different percentage is justified in order to maintain access to interchangeable drug products. (EC315/12)