Newfoundland and Labrador Pharmacy Board

On August 7, 2017, the Newfoundland and Labrador Pharmacy Board approved the following change to the Provincial Drug Schedules:

To reflect the NDSAC recommendation of June 11, 2017, finalized on July 20, 2017:

Delete from Schedule III:	minoxidil (for topical use in concentrations of 5% or less)
Add to the Unscheduled List:	minoxidil, when sold in preparations for topical use in adults in concentrations of 5% or less, for human use only

Discussion:

Applicable Scheduling Factors[1]: #III-3

The committee discussed the overall best fit for this drug. It was agreed that some factors applicable in 2014 are no longer applicable. The drug and its formulations are not new to the Canadian market or to self-care. The sponsor presented all adverse events reported in Canada from 2010 to 2016, as well as a Canadian label comprehension study. Although one of the Schedule III factors still applies, the committee agreed that the best fit for these products is Unscheduled status.

[1] See Appendix for description of Scheduling Factors

Appendix
Scheduling Factors

FACTORS FOR THE INCLUSION OF DRUGS IN SCHEDULE I

1. Indications for use of the drug are identifiable only by the practitioner. Diagnosis of the indication requires intervention by the practitioner before the drug is used.
2. Use of the drug requires adjunctive therapy or evaluation. Adjunctive therapy could include other drugs, non-pharmacologic measures, or specialized drug delivery devices. Evaluation could include indicated laboratory or clinical assessments.
3. Use of the drug may produce dependency. The drug may cause addiction or become habit forming. Control of access and duration of therapy by a health care professional is required.
4. Serious adverse reactions to the drug are known to occur or have a recognized potential to occur at normal therapeutic dosage levels. Adverse experiences require special monitoring or intervention by a health care professional.
5. There exists a narrow margin of safety between the therapeutic and toxic dosages of the drug, either in the general population, or in identified subpopulations, or in patients with multiple medical problems. Safe use requires the involvement and intervention of a health care professional.
6. Serious interactions of the drug are known to occur. Such interactions (drug-drug, drug-food, drug-disease) require special monitoring or intervention by a health care professional.
7. Use of the drug has contributed to, or is likely to contribute to, the development of resistant strains of microorganisms. Appropriate use, and/or the decision to continue treatment, requires evaluation by the practitioner.
8. The mechanism of action of the drug is known but the consequences of widespread use are not adequately established. Unexpected effects of the drug must be evaluated and reported by a health care professional.
9. The therapeutic effects of a newly released drug are based on new or unknown mechanisms of action, but the consequences of widespread use are not adequately established. Close monitoring of the patient is required by a health care professional for unanticipated effects.

FACTORS FOR THE INCLUSION OF DRUGS IN SCHEDULE II

1. The initial need for a drug is normally identified by the practitioner, in addition chronic, recurrent, or subsequent therapy must be monitored by the pharmacist. A prescription should not be required to obtain a drug if the patient can understand directions for continued use through the intervention of the pharmacist. Therefore, the patient should have access to the drug for subsequent treatment and use following the first diagnosis and prescription by the practitioner. This collaborative approach enhances patient care.
2. The drug must be readily available under exceptional circumstances when a prescription is not practical. Such a drug might be required for a serious medical situation and the patient should have access to it to prevent a possible health emergency. An example of such an exceptional circumstance is availability of injectable epinephrine for anaphylactic reactions.
3. The drug is intended for administration in a health care setting or under direction of a health care professional, or is in an injectable dosage form and is not otherwise included in Schedule I. Examples include preoperative or diagnostic agents and products used for immunization or desensitization.
4. Evidence of abuse of the drug has been reported, due to its inherent pharmacological action which has the potential for abuse. Monitoring by a health care professional is necessary.
5. The selection of the drug requires intervention by the pharmacist to confirm that an appropriate self-assessment has been made by the patient. Dosage form, for example, may be an important consideration.

6. Use of the drug may delay recognition or mask the symptoms of serious disease. Intervention by the pharmacist is necessary to ensure appropriate referral to the practitioner.
7. The drug may cause important adverse reactions, including allergies, or interacts with other drugs, foods, or disease states that cannot be adequately addressed through product labelling. Intervention by the pharmacist is necessary to assess patient risk to prevent such problems for an individual patient through interpretation and clarification of labelling.
8. Use of the drug requires reinforcement or an expansion of the directions for use, through pharmacist - patient dialogue. Such reinforcement and expansion may include the explanation of the use of a drug delivery system.
9. The drug is a new ingredient for self-medication and monitoring by the pharmacist is necessary to facilitate observation and reporting of any unexpected event.
10. The maximum labelled dosage directions exceed the generally accepted or usual limits for Schedule III status.

FACTORS FOR THE INCLUSION OF DRUGS IN SCHEDULE III

1. The initial need for a drug is normally identified by the patient, physician, or pharmacist, but chronic, recurrent, or subsequent therapy can be monitored by the pharmacist.
2. The maximum recommended duration of use of the drug is limited and specified on the product label. The pharmacist is available to explain that the consequences of not following the period of use may be serious and that persistence of symptoms may suggest an underlying ailment.
3. The maximum recommended duration of use of the drug is not specified on the label, but continued use may delay recognition or mask the symptoms of serious disease. The pharmacist is available to help in interpretation of symptoms, to assist in selection of alternative therapy, or to provide appropriate referral.
4. The drug is used to treat a persistent, chronic or recurring condition and the availability of the pharmacist to provide advice can promote appropriate use. The pharmacist should be available to direct the patient to a practitioner for assessment if the treatment period has been inappropriate or the therapy has been ineffective.
5. The drug is used for self-treatment of self-limiting ailments; however, where product selection has been identified as likely to cause patient confusion and the availability of the pharmacist to provide advice can promote appropriate use. Many product selections may be confusing for the patient. These choices are further complicated by the different forms of available therapy or dosage forms.
6. The drug demonstrates adverse effects, including allergies, or interacts with other drugs, foods, or disease states that can be identified in product labelling, but appropriate product selection and explanation of risk may require the advice of the pharmacist. For example, individuals taking a traditional monoamine oxidase inhibitor are aware that certain drugs should be avoided (e.g., cold products) but might require assistance in selecting a safe product to use.
7. The drug is a new ingredient for self-selected self-medication and the availability of the pharmacist to provide advice can promote appropriate use. The pharmacist is available to answer questions about this new ingredient.
8. The drug has inherent pharmacologic action which has the potential for non-medical use which may result in adverse patient outcomes.
9. The maximum labelled dosage directions exceed the generally accepted or usual limits for unscheduled status.