Newfoundland and Labrador Pharmacy Board

A Guide to Understanding the Provincial Drug Schedules

February 2019

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INTRODUCTION

General

In November 2014, changes were made to the Newfoundland and Labrador Drug Scheduling process in accordance with the new Pharmacy Regulations, 2014 (see Appendix A). As such, changes to the provincial drug schedules are now reviewed and approved by the Newfoundland and Labrador Pharmacy Board rather than the Minister of Health and Community Services.

This approval process will still be based on the recommendations of the National Drug Scheduling Advisory Committee, as described below. Once a recommended change is received by the Newfoundland and Labrador Pharmacy Board, it is added to the agenda for the next Board meeting for review and approval. ***A recommended change is NOT effective until it has received Board approval.***

National Drug Scheduling Advisory Committee

In May 1995, the National Association of Pharmacy Regulatory Authorities (NAPRA) approved a national scheduling model and, to ensure ongoing review and maintenance of the drugs listed in the model schedules, established the National Drug Scheduling Advisory Committee (NDSAC) in August 1995. NDSAC includes experts from across Canada as well as other relevant representatives and is mandated to advise the provincial regulatory authorities on matters relating to the placement of drugs within the national scheduling model and to continually evaluate and maintain the drug scheduling factors within the model (see Appendix B).

NDSAC meets several times throughout the year to review and analyse submissions from sponsors requesting scheduling additions or revisions, generally in response to:

- A federal government proposal to deregulate a federal prescription status drug;
- A new drug approved for sale in Canada on a non-prescription basis; or
- A request from a manufacturer, the public or other stakeholder to reassess or review the current recommended schedule status of a drug.

SCHEDULE I – PRESCRIPTION SALE ONLY

Schedule I drugs require a prescription for sale and are provided to the public by the pharmacist following the diagnosis and professional intervention of a practitioner. They are subject to the same conditions as the drugs listed in the Prescription Drug List established in accordance with section 29.1 of the Food and Drugs Act and its accompanying Regulations (Canada).

Some drugs on this schedule may appear to be non-prescription drugs since there is no "Pr" symbol directly on the product. Pharmacists must be aware of these products to prevent possible sale without a prescription.

The following table provides a current list of Schedule I drugs. **Recent changes are indicated with BOLD UNDERLINE**. Examples of the Brand Names of products containing these drugs are also provided. Please note that the list of Brand Names is not necessarily inclusive and are provided for reference only.

Chemical name as it appears in the Schedule	Examples of common Brand Names
allergy serums and extracts	
alpha 1-proteinase inhibitor (human)	
alverine and its salts for parenteral use	
amino acid solutions for parenteral use	
aminopromazine [proquamezine] and its salts	
bacillus Calmette-Guerin vaccine	
bacitracin and its salts and derivatives for parenteral use	
calcium chloride in injectable form for parenteral nutrition	
calcium gluconate in injectable form for parenteral nutrition	
cetirizine and its salts when sold in concentrations greater than 8.5 mg cetirizine base per dosage unit	• Reactine 20mg tablet
cholera vaccine except oral, inactivated, when used for prophylaxis against Traveler's Diarrhea due to enterotoxigenic escherichia coli [ETEC]	
chromium chloride (chromic chloride) in injectable form for parenteral nutrition	
cimetidine and its salts in concentrations greater than 100mg of cimetidine per dosage unit	
clotrimazole and its salts (except in preparations for topical or vaginal use)	
copper chloride (cupric chloride) in injectable form for parenteral nutrition	
copper sulphate in injectable form for parenteral nutrition	
cromoglycic acid and its salts (except sodium cromoglycate in solutions for ophthalmic or nasal use in concentrations of 2% or less)	
cyclopentolate and its salts in preparations for parenteral or ophthalmic use (except when sold for use in diagnostic procedures to an optometrist registered in a province of Canada)	
cytomegalovirus immune globulins	
dextrose injection in concentrate solutions for parenteral nutrition	
diiodohydroxyquin (except in preparations for topical use on the skin)	
encephalitis vaccine (Japanese)	
ephedrine and its salts in preparations containing more than 8 mg per unit dose, or with a label recommending more than 8 mg/dose or 32 mg/day, or labelled or implied for use exceeding 7 days, or if indicated for other than nasal congestion	
epinephrine and its salts (other than in pre-filled syringes intended for emergency administration by injection in the event or anaphylactic reactions to allergens)	
erythrityl tetranitrate	
esomeprazole or its salts, except when sold for the 14-day treatment for frequent heartburn at a daily dose of 20 mg in package sizes of no more than 280 mg of esomeprazole	
ethylpapaverine and its salts	
famotidine and its salts (except when sold in concentrations of 20 mg or less per oral dosage unit and indicated for the treatment of heartburn)	
fluconazole (except when sold in a concentration of 150 mg per oral dosage unit and indicated for the treatment of vaginal candidiasis)	

Chemical name as it appears in the Schedule	Examples of common Brand Names
flumazenil	
fluoride and its salts (see sodium fluoride) in solid oral dosage forms containing more than 1 mg of fluoride ion	
fluticasone propionate, except when sold for the treatment of allergic rhinitis in a nasal spray that delivers 50 microgram/spray for those 18 years of age and older	
folic acid in preparations containing more than 1 mg of folic acid per dosage form or, where the largest recommended daily dosage shown on the label would, if consumed by a person, result in the daily intake by that person of more than 1.0 mg folic acid	
hepatitis A vaccine	
hepatitis B adult vaccine	
hepatitis B immune globulin	
herpes zoster (shingles) vaccine	
homatropine and its salts for ophthalmic or parenteral use or in preparations for oral use containing more than 2 mg per dosage unit	
hydrocortisone or hydrocortisone acetate, when sold in a concentration that provides 1% or less hydrocortisone in preparations for topical use on the skin in adults and children 2 years of age and over in package sizes containing more than 30g	
hydrocortisone or hydrocortisone acetate, when sold in a concentration that provides 1% or less hydrocortisone in preparations for topical use on the skin in children under 2 years of age	
ibuprofen or its salts, except when sold in an immediate release form for oral administration in a concentration of 400 mg or less per dosage unit or when sold in a modified release oral dosage form that provides 600 mg or less per dosage unit	
iodochlorohydroxyquin (except in preparations for topical use on the skin)	
isopropamide and its salts	
isosorbide and its salts	• Imdur • generic brands
ketoconazole and its salts (except in preparations for topical use as a shampoo)	
levallorphane and its salts	
lipid solutions in injectable form for parenteral nutrition	
Lyme Disease vaccine	
magnesium sulphate in injectable form for parenteral nutrition	
manganese and its salts in injectable form for parenteral nutrition	
meclizine and its salts when sold in concentrations greater than 25mg per dosage unit	
metaraminol bitartrate	
methacholine and its salts	
miconazole and its salts (except in preparations for topical or vaginal use)	
minoxidil (except in solutions for topical use in concentrations of 5% or less)	
mometasone furoate for the treatment of allergic rhinitis in a nasal spray that delivers 50 mcg/spray for those 12 years of age and older	• Nasonex • generic brands
mupirocin	• Bactroban • Taro-mupirocin
naloxone or its salts, including, but not limited to naloxone hydrochloride, EXCEPT when indicated for emergency use for opioid overdose	
naproxen and its salts (with the exception of naproxen sodium 220 mg per oral dosage unit)	• Anaprox • Naprosyn • generic brands
nicotine and its salts, for human use (except: (a) in natural substances; (b) in the form of a chewing gum containing 4 mg or less of nicotine per dosage unit; (c) in the form of a transdermal patch with a delivery rate of 22 mg or less of nicotine per day; or (d) in a form to be administered orally by means of an inhalation device delivering 4 mg or less of nicotine per dosage unit); or (e) in the form of a lozenge containing 4 mg or less of nicotine per dosage unit.)	

Chemical name as it appears in the Schedule	Examples of common Brand Names
nicotinic acid when sold in (a) a modified-release oral dosage form that provides 500 mg or more per dosage unit or per daily dose; or (b) an immediate-release oral dosage form that provides more than 500 mg per dosage unit or per daily dose	
nicotinyl-tartrate	
nikethamide	
nitroglycerin (except for sublingual immediate release dosage forms)	• Minitran • Nitro-Dur • Transderm-Nitro • Trinipatch
nizatidine and its salts (except when sold in an oral dosage form containing not more than the equivalent of 75 mg of nizatidine)	• Axid • generic brands
nystatin and its salts and derivatives (except preparations for topical use on the skin)	
omeprazole or its salts, when sold for the 14-day treatment for frequent heartburn at a daily dose of 20mg, in package sizes of more than 280mg of omeprazole	• Losec • generic brands
orphenadrine hydrochloride	
pancreatic enzymes in products for the treatment of established pancreatic insufficiency	
pancreatin in products for the treatment of established pancreatic insufficiency	
pancrelipase in products for the treatment of established pancreatic insufficiency	
papaveretrine and its salts	
papaverine and its salts	
pentaerythritol tetranitrate	
phenylephrine and its salts in preparations for parenteral use or ophthalmic use in concentrations greater than 2.5%	
physostigmine salicylate (except preparations for oral or topical use only)	
polymyxin B and its salts and derivatives (except for topical use or for local action in the oral cavity or nasal passages)	
potassium para-aminobenzoate (except in preparations for topical use on the skin)	
potassium salts in preparations for injection	
proquamezine [aminopromazine] and its salts for internal use	
quinidine salts	
rabies immune globulin	
rabies vaccine	
ranitidine and its salts (except when sold in concentrations of 150 mg or less per oral dosage unit and indicated for the treatment of heartburn)	
rho D immune globulin	
selenium in injectable form for parenteral nutrition	
sodium acetate in injectable form for parenteral nutrition	
sodium chloride in injectable form for parenteral nutrition	
sodium iodine in injectable form for parenteral nutrition	
sodium phosphate in injectable form for parenteral nutrition	
tioconazole and its salts (except in preparations for topical or vaginal use in humans)	
tetanus immune globulin	
tropicamide and its salts in preparations for parenteral or ophthalmic use (except when sold for use in diagnostic procedures to an optometrist registered in a province of Canada)	
tubocurarine and its salts	
typhoid vaccines / salmonella typhi vaccines	
vaccines (except those part of a routine immunization program in most/all provinces & territories: cholera vaccine (oral, inactivated) when used for prophylaxis against traveller's diarrhea and due to enterotoxigenic escherichia coli (ETEC); diphtheria toxoid, haemphilus influenzae type b, hepatitis B pediatric, influenza, measles, mumps, pertussis, pneumococcus, poliomyelitis, rubella, tetanus toxoid; and those requiring special enhanced public access due to disease outbreaks: meningococcus)	

Chemical name as it appears in the Schedule	Examples of common Brand Names
varicella vaccine (chicken pox)	
varicella zoster immune globulin	
vitamin A in oral dosage forms containing more than 10,000 IU per dosage form or, where the largest recommended daily dosage shown on the label would, if consumed by a person, result in the daily intake by that person of more than 10,000 IU of Vitamin A	
vitamin D in oral dosage form containing more than 1,000 International Units of Vitamin D per dosage form or, where the largest recommended daily dosage shown on the label would, if consumed by a person, result in the daily intake by the person of more than 1,000 International Units of Vitamin D	
vitamin K (except Vitamin K1 and Vitamin K2 sold (a) for external use in humans; or (b) in an oral dosage form for use in humans if the maximum recommended daily dose is 0.120 mg or less)	
vitamins in injectable form for parenteral nutrition	
yellow fever vaccine	
zinc chloride in injectable form for parenteral nutrition	
zinc sulphate in injectable form for parenteral nutrition	

SCHEDULE II – SALE ONLY FROM A NO PUBLIC ACCESS AREA OF A DISPENSARY

Schedule II drugs, while less strictly regulated, do require professional intervention from the pharmacist at the point of sale and possibly referral to a practitioner. While a prescription is not required, the drugs are available only from the pharmacist and must be retained within an area of the pharmacy where there is no public access and no opportunity for patient self-selection.

Pharmacists have a professional responsibility to ensure patients are knowledgeable about the appropriate selection of a Schedule II drug depending on symptoms, compatibility with other drugs being used, efficacy, possible adverse drug reactions, expected outcomes and what to do if outcomes are not achieved.

The following table provides a current list of Schedule II drugs. **Recent changes are indicated with <u>BOLD UNDERLINE</u>**. Examples of the Brand Names of products containing these drugs are also provided. Please note that the list of Brand Names is not necessarily inclusive and are provided for reference only.

Chemical name as it appears in the Schedule	Examples of common Brand Names
acetarsol	
acetylcysteine	
acetylsalicylic acid (ASA) and its salts (in oral preparations containing 80 mg or less per dosage unit and intended for pediatric use OR rectal preparations containing 150 mg or less per dosage unit, in package sizes containing no more than 1.92 g of acetylsalicylic acid)	• Asaphen Chewable 80mg • Asatab 80mg Chewable • generic brands
adiphene and its salts for parenteral use	
allethrins	
amylocaine and its salts (for ophthalmic or parenteral use)	
anisotropine and its salts	
anthralin	
antihemophilic factor, human	
antipyrine (except otic preparations)	
apomorphine and its salts	
arginine and its salts	
artemisia, its preparations, extracts and compounds (except in trace amounts in homeopathic preparations)	
belladonna alkaloids and their salts and derivatives (except in preparations for topical use or in trace amounts in homeopathic preparations)	
benoxinate hydrochloride (oxybuprocaine) for ophthalmic or parenteral use	
bentiromide	
benzalkonium and its salts (liquid preparations in concentrations greater than 2%)	
benzethonium chloride (liquid preparations in concentrations greater than 1%)	
benzocaine and its salts (for ophthalmic or parenteral use)	
benzyl benzoate	
boric acid and its salts (in preparations for systemic or ophthalmic use in concentrations greater than 2%, except in contact lens solutions intended to be rinsed off prior to insertion in the eye.)	
buclizine	
bufexamac	
bupivacaine and its salts (for ophthalmic or parenteral use)	
butacaine and its salts (for ophthalmic or parenteral use)	
calcium disodium edentate	
camphor (in oleaginous vehicles and in liquid forms in concentrations greater than 11%)	
cantharides, their preparations and derivatives	
charcoal (activated) for use in poisoning treatment	
chloroprocaine and its salts (for ophthalmic or parenteral use)	
cholecystokinin	
cholera vaccine (oral, inactivated) when used for prophylaxis against Traveler's Diarrhea due to enterotoxigenic escherichia coli [ETEC]	• Dukoral
choline bitartrate (for parenteral use)	

Chemical name as it appears in the Schedule	Examples of common Brand Names
chymopapain (for parenteral use)	
chymotrypsin (for ophthalmic and parenteral use)	
cinchocaine (dibucaine) and its salts (for opthalmic or parenteral use)	
clidinium and its salts	
clobetasone butyrate (when sold in a concentration of 0.05% clobetasone butyrate in cream preparations for topical use on the skin)	• Specto EczemaCare Medicated Cream
coal tar (in concentrations greater than 10%)	• Odans Liquor Carbonis Detergens
codeine and its salts (in preparations exempted from the Regulations to the Controlled Drugs and Substances Act – i.e. not more than 8 mg or its equivalent of codeine phosphate per solid form or not more than 20 mg or its equivalent of codeine phosphate per 30 mL in a liquid preparation) (Please Note: These preparations should be stored in accordance with the Regulations to the Controlled Drugs and Substances Act)	• Robaxacet-8 • generic and store brands
collagenase (as a debriding agent)	
crotamiton	• Eurax
cyclandelate	
cyclazocine and its salts	
cyclomethacaine and its salts (for ophthalmic or parenteral use)	
cyclopentamine and its salts	
cyclopentolate and its salts (except in products for ophthalmic or parenteral use)	
cyproheptadine and its salts	
desoxyribonuclease [pancreatic dormase]	
dextrose (sclerosing agents)	
diclofenac diethylamine when sold as a single medicinal ingredient for topical use on the skin for not more than 7 days - in concentrations greater than 1.16% and less than or equal to 2.32% - in package sizes containing greater than 2.6g of diclofenac diethylamine	• Voltaren Emulgel Extra Strength products (in package sizes greater than 112 gm)
dicyclomine and its salts (except for topical use and lozenges)	
dihydroquinidine and its salts (except phenylbarbiturate)	
diiodohydroxyquin (for topical use on the skin)	
dimenhydrinate and its salts (for parenteral use)	• Gravol IM injection
diperodon and its salts (except for topical use)	
diphenhydramine and its salts and preparations (for parenteral use)	
diphenhydramine and its salts and preparations (for topical use in concentrations of greater than 2%)	
diphtheria toxoid	
dyclonine (except for topical use on mucous membranes)	
ephedrine and its salts in single entity products (in preparations containing no more than 8 mg per unit dose, with a label recommending no more than 8 mg/dose or 32 mg/day and for use for not more than 7 days, and indicated for nasal congestion)	
epinephrine and its salts (in pre-filled syringes intended for emergency administration by injection in the event of anaphylactic reactions to allergens.)	• Epipen / Epipen Jr.
esdepallethrin/piperonyl butoxide	
ethanolamine oleate	
ethoheptazine and its salts	
ethyl chloride (except in trace amounts)	
fibrin	
fibrinolysin	
fluticasone propionate, when sold for the treatment of allergic rhinitis in a nasal spray that delivers 50 mcg/spray for those 18 years of age and older, in package sizes containing more than 120 metered sprays	
gentian violet (for application to skin or mucous membranes)	
glucagon	
glycopyrrolate and its salts	
hemophilus influenzae type B vaccine	
heparin and its salts (except for topical use)	
hepatitis B pediatric vaccine	

Chemical name as it appears in the Schedule	Examples of common Brand Names
histamine and its salts (except for topical use)	
homatropine and its salts (for oral use in concentrations of 2 mg or less per dosage unit)	
human insulin	
human papillomavirus vaccine	
hyaluronic acid and its salts (preparations in concentration of 5% or more)	
hyaluronidase	
hydroquinone (topical preparations)	
hydroxyephedrine and its salts	
hyoscine and its salts and derivatives (except for parenteral use)	• Buscopan tablets
hyoscyamine and its salts and derivatives (except for topical use)	
influenza vaccine	
insulin	
iodinated glycerol	
iodine and its salts and derivatives (except in topical preparations or in oral doses of 1 mg or less per day)	
iodochlorhydroxyquin (for topical use)	
ipecac & its extracts & derivatives (when used as an emetic)	
iron and its salts and derivatives (in preparations with more than 30mg elemental iron per unit or 5ml liquid) <u>30mg elemental iron equals:</u> ferrous ascorbate 250mg ferrous fumarate 92mg ferrous gluconate 257mg ferrous sulphate 150mg	• Feramax products • Neo-Fer / Neo-Fer Cf • Palafer capsules / suspension / Palafer CF • generic & store brand ferrous fumarate, ferrous gluconate and ferrous sulphate
levargorphane and its salts	
levonordefrine	
levonorgestrel (when sold in concentrations of 0.75 mg per oral dosage unit (except when labelled to be taken as a single dose of 1.5 mg and in package sizes containing no more than 1.5 mg levonorgestrel, packaged and labelled for emergency contraception.))	
lidocaine and its salts (for ophthalmic or parenteral use or topical use on mucous membranes except lozenges)	• Xylocaine Viscous
lindane	
loperamide and its salts in products marketed for pediatric use – under 12 years of age	
magnesium sulphate (for parenteral use)	
mannitol and its salts	
measles vaccine	
meningococcus vaccine	
mepivacaine and its salts (for ophthalmic or parenteral use)	
metathoheptazine and its salts	
methantheline	
methdilazine and its salts	
methenamine and its salts (except for topical use)	
metheptazine and its salts	
methocarbamol (for parenteral use)	
methyl salicylate (in liquid dosage forms in concentrations greater than 30%	
methylene blue (for parenteral use)	
monobenzone	
monoethanolamine oleate	
mumps vaccine	
naloxone hydrochloride injection, when indicated for emergency use for opioid overdose naloxone hydrochloride nasal spray, when indicated for emergency use for opioid overdose (Please Note: See Appendix C for Guidelines on the Sale of Naloxone Injection in Community Pharmacies)	

Chemical name as it appears in the Schedule	Examples of common Brand Names
naphazoline and its salts (in nasal preparations for pediatric use)	
niacin [nicotinic acid] (in extended release formulations)	
nitroglycerin (sublingual immediate release dosage forms)	• Nitrolingual Pumpspray • Nitrostat 0.3mg / 0.6mg tablets • generic brands
norepinephrine and its salts [levarteronol, noradrenaline]	
omeprazole or its salts, when sold for the 14-day treatment for frequent heartburn at a daily dose of 20mg, in package sizes of no more than 280mg of omeprazole	• Heartburn Control (Apotex) • Omep
oxymetazoline and its salts (in nasal preparations for pediatric use)	
oxyquinoline	
paroxypropione	
pentagastrin and its salts	
permethrin and its derivatives	• Kwellada-P cream rinse / lotion • Nix cream rinse / Nix dermal cream
pertussis vaccine	
phenol (preparations with concentrations greater than 20%)	
phenoxybenzamine and its salts	
phenylephrine and its salts and preparations (in nasal preparations in concentrations of 2.5% or less for pediatric use)	
physostigmine salicylate (for oral or topical use)	
piperazine and its salts	
pneumococcal polysaccharide vaccine	
pneumococcal 7-valent conjugate vaccine	
pneumococcal 13-valent conjugate vaccine	
poliomyelitis vaccine	
polyacrylamide	
potassium salts (in preparations containing greater than 5 mmol per dose)	
povidone-iodine (vaginal preparations, except in concentrations of 5 % or less	
pramoxine and its salts (for ophthalmic or parenteral use)	
prilocaine and its salts (for ophthalmic or parenteral use)	
procaine and its salts (for ophthalmic or parenteral use)	
promethazine and its salts (except for topical use)	
propantheline and its salts	
proparacaine and its salts (for ophthalmic or parenteral use)	
propylhexidine	
protamine and its salts	
pseudoephedrine and its salts and preparations in single entity products	
pyrantel and its salts	• Combantrin products
pyrethrins	
pyrethrins/piperonyl butoxide	• R&C Shampoo with Conditioner
pyrivinium and its salts	
racemethionine	
rose bengal	
rotavirus vaccine	
rubella vaccine	
rue and its preparations and extracts	
salicylic acid and its salts (in topical preparations in concentrations greater than 40%)	
silver nitrate	
sincalide	
sodium acetate (for parenteral use)	
sodium biphosphate (for parenteral use)	
sodium chloride (single ingredient solutions for parenteral or ophthalmic use in concentrations greater than 0.9%) [Does not apply to contact lens products intended to be rinsed off prior to insertion in the eye.]	
sodium citrate (for parenteral use)	
sodium iodide (for sclerosing)	
sodium phosphate (for parenteral use)	

Chemical name as it appears in the Schedule	Examples of common Brand Names
sodium picosulphate for oral purgatives, 10 mg per pack (when found in preparations with magnesium oxide 3.5g and citric acid 12g)	• Pico-Salex • Purg-Odan
sodium tetradecyl sulphate	
stramonium, its preparations, extracts and compounds	
streptokinase (as a debriding agent)	
strontium and its salts (for parenteral use)	
sutilains	
tetanus toxoid	
tetracaine and its salts (for ophthalmic and parenteral use)	
tetrahydrozoline (in nasal preparations for pediatric use)	
thrombin	
thyroglobulin	
thyrotropin	
triamcinolone acetonide in an aqueous nasal spray that delivers 55mcg per metered spray for adults and children 12 years of age and older, in package sizes containing more than 120 metered sprays	
urea in topical preparations in concentrations greater than 25%	
vaccines. which are part of a routine immunization program in most/all provinces and territories	
vitamins (any parenterals not included in Schedule I)	
xylometazoline and its salts (in nasal preparations for pediatric use (0.05%))	
xylose	

SCHEDULE III – PHARMACY SALE ONLY

Schedule III drugs may present risks to certain populations in self-selection. Although available without a prescription, these drugs are to be sold from the self-selection area of the pharmacy which is operated under the direct supervision of the pharmacist. Such an environment is accessible to the patient and clearly identified as the "professional services area" of the pharmacy. The pharmacist is available, accessible and approachable to assist the patient in making an appropriate self-care selection.

The following table provides a current list of Schedule III drugs. **Recent changes are indicated with <u>BOLD UNDERLINE</u>**. Examples of the Brand Names of products containing these drugs are also provided. Please note that the list of Brand Names is not necessarily inclusive and are provided for reference only.

Chemical name as it appears in the Schedule	Examples of common Brand Names
acetaminophen in sustained release formulations (in strengths of greater than 650 mg per unit or in package sizes of more than 50 units)	• Tylenol Arthritis Pain 8H (100's, 170's, 200's) • Tylenol Muscle & Body 8H (72's, 110's) • generic and store brands
acetylsalicylic acid and its salts (in products intended for oral adult use in strengths of 81mg per dosage unit and 650mg or greater per dosage unit, and in rectal preparations containing more than 150 mg per dosage unit)	• Aspirin 81mg Daily Low Dose / 81mg Quick Chews • Entrophen 81mg Daily Low Dose / 81mg Chewable • Novasen 650mg • generic and store brands
aloe vera latex, its extracts and derivatives [except aloin] (dosage forms for systemic use containing more than 300 mg per dosage unit)	
aluminum oxide	
amylocaine and its salts (in preparations for topical use on mucous membranes except lozenges)	
anethole trithione	
antazoline and its salts	• Refresh Eye Allergy Relief
antipyrine (for otic use)	• Auralgan
bacitracin and its salts and derivatives (for ophthalmic use)	
belladonna alkaloids, their salts and derivatives (for topical use)	
benzocaine and its salts (for topical use on mucous membranes for teething)	
benzonatate	
berberis vulgaris (Barberry)	
bisacodyl and its salts (except when sold in concentrations of 5mg or less per oral dosage unit or 10mg or less per rectal dosage unit/suppository in package sizes containing no more than 50mg of bisacodyl)	• Carter's Little Pills (in package sizes of greater than 10 tablets) • Dulcolax (in package sizes of greater than 10 tablets or 5 suppositories) • generic brand tablets & suppositories (in package sizes of greater than 10 tablets or 5 suppositories)
brompheniramine and its salts as a single entity for the treatment of allergies	
bupivacaine and its salts (for topical use on mucous membranes except lozenges)	
calcium polycarbophil	
carbinoxamine and its salts	
casanthranol	
cerapon	
cetirizine and its salts (in concentrations of 10 mg equivalent to 8.5 mg or less of cetirizine base per dosage unit) in products marketed for pediatric use (under 12 years of age)	• Reactine Children's Liquid / Fast Melt
chlophedianol and its salts	
chloroprocaine and its salts (for topical use on mucous membranes except lozenges)	
chlorzoxazone and its salts	• Acetazone Forte
cimetidine and its salts (in concentrations of 100 mg or less per dosage unit)	
clemastine and its salts	

Chemical name as it appears in the Schedule	Examples of common Brand Names
clotrimazole and its salts (in preparations for vaginal use)	• Canesten vaginal products • Clotrimaderm vaginal creams
danthron	
dehydrocholic acid and its salts	
deoxycholic acid and its salts	
desloratadine and its salts and preparations in products marketed for pediatric use (under 12 years of age)	• Aerius Kids Syrup
dexbrompheniramine and its salts	
dexchlorpheniramine and its salts	
dextromethorphan and its salts	• Balminil DM products / Night-Time • Benylin All in One Cold & Flu products / "Cough" products / DM products / Mucus & Phlegm Relief products / Tickly Throat Cough • Buckley's Complete products / Daytime & Nighttime Cold and Sinus • Coricidin Cold & Flu Extra Strength • Dimetapp DM Cough & Cold • Jack & Jill Cough & Cold Liquid • NeoCitran Extra Strength Total Cold / Ultra Strength Total Flu • Robitussin Complete / Cough & Cold / Cough Control / CoughGels / Total Cough, Cold & Flu • Tylenol "Cough" products / Cold Daytime & Nighttime / Plus Mucus Relief / Flu Daytime & Nighttime • Vicks Children's Nyquil Cold & Cough / Dayquil Cold & Flu / Dayquil "Cough" products / Nyquil Cold & Flu / Nyquil "Cough" products • generic and store brand DM & "Cough" syrups and tablets
diclofenac diethylamine when sold as a single medicinal ingredient for topical use on the skin for not more than 7 days - in concentrations greater than 1.16% and less than or equal to 2.32% - in package sizes containing no more than 2.6g of diclofenac diethylamine	• Voltaren Emulgel Extra Strength (in package sizes less than 112gm)
dimenhydrinate and its salts (for oral or rectal use) (Please Note: Pharmacists are advised that in areas here there is evidence of abuse or a particular concern about abuse, dimenhydrinate products should not be located in a self-selection area of the pharmacy. See Appendix D for Guidelines Regarding the Sale of Dimehydrinate)	• Gravol products • generic and store brands
dimethothiazine	
dimeticone 100 cSt solution 50% w/w for topical use in the treatment of head lice	• NYDA
diphenhydramine and its salts and preparations for topical use in concentrations of 2% or less when sold in containers of greater than 300mg of diphenhydramine hydrochloride	• Benadryl cream / spray • Calamine lotion + antihistamines • generic and store brands
diphenhydramine and its salts and preparations (except for parenteral use)	• Advil Cold & Flu / Nighttime • Aleve Nighttime • Benadryl oral products • Benylin All in One Cold & Flu Night / Night for Children / Sleep Time • Buckley's Night Time Mixture • Jack & Jill Bedtime • Neo Citran Total Cold Night • Nytol products except Nytol Natural Source • Sinutab Sinus Nighttime Extra Strength • Sleep-Eze products except V Natural • Tylenol Children's Cold & Cough Nighttime / Complete Cold, Cough & Flu Nighttime / Nighttime • Unisom products except Unisom-2 • ZZZ-Quil • generic and store brand "Allergy Medications" or "Sleep Aids"
diphenylpyraline	

Chemical name as it appears in the Schedule	Examples of common Brand Names
doxylamine and its salts (except those sold for nausea and vomiting of pregnancy)	• Buckley's Complete Nighttime / Nighttime Cold & Sinus • Robitussin Complete Nighttime • Tylenol Cold & Flu Nighttime • Vicks NyQuil Cold & Flu Nighttime / Complete Cold & Flu / Cough / Sinus Liquicaps • generic and store brands
dyclonine and its salts (for topical use on mucous membranes except lozenges)	
electrolyte solutions (for oral rehydration)	• Gastrolyte • Pedialyte products • generic brands
ephedrine and its salts in combination products (in preparations containing no more than 8 mg per unit dose, with a label recommending no more than 8 mg/dose or 32 mg/day and for use for not more than 7 days, and indicated for nasal congestion) [Note: Pharmacists are advised that in areas where there is evidence of abuse or particular concern about abuse, ephedrine products should NOT be located in a self- selection area of the pharmacy]	
esomeprazole or its salts, when sold for the 14-day treatment for frequent heartburn at a daily dose of 20 mg, in package sizes of no more than 280 mg of esomeprazole	• Nexium 24HR
famotidine and its salts, when sold in concentrations of 20 mg or less per oral dosage unit and indicated for the treatment of heartburn, in package sizes containing more than 600 mg of famotidine	
fexofenadine hydrochloride (in products marketed for paediatric use (under 12 years of age))	
fluconazole when sold in a concentration of 150 mg per oral dosage unit and indicated for the treatment of vaginal candidiasis, in package sizes containing no more than 150 mg of fluconazole	• CanesOral • Diflucan One • Monicure • generic brands
fluoride and its salts (oral preparations containing 1 mg or less of fluoride ion per dosage unit) (1mg fluoride ion equals 2.2mg sodium fluoride)	
fluticasone propionate, when sold for the treatment of allergic rhinitis in a nasal spray that delivers 50 mcg/spray for those 18 years of age and older, in package sizes containing no more than 120 metered sprays	
fractar	
glyceroargentinate	
gramicidin and its salts and derivatives (for ophthalmic use)	• Optimyxin eye/ear drops • Polysporin Eye and Ear drops
ibuprofen and its salts, containing 400mg or less per oral dosage unit (when sold in package sizes exceeding 18,000mg)	• Advil single-entity 200mg products (more than 90 tablets) • Advil single-entity 400mg products (more than 45 tablets) • Motrin single-entity 200mg products (more than 90 tablets) • Motrin single-entity 300mg products (more than 60 tablets) • Motrin single-entity 400mg products (more than 45 tablets) • generic and store brands
ibuprofen or its salts, when sold in a modified-release oral dosage form that provides 600 mg or less per dosage unit	• Advil 12 Hour
haloprogin	
heparin and its salts (for topical use)	
hydrocortisone or hydrocortisone acetate, when sold in a concentration that provides 1% or less hydrocortisone in preparations for topical use on the skin in adults and children 2 years of age and over in package sizes containing no more than 30g	
iodine and its salts and derivatives (for topical use)	
isopropyl myristate in concentration of 50% (for use in the treatment of head lice)	• Resultz
lactic acid (preparations in concentrations of more than 10%)	
lactulose	

Chemical name as it appears in the Schedule	Examples of common Brand Names
levonorgestrel (when sold in concentrations of 0.75 mg per oral dosage unit to be taken as a single dose of 1.5 mg, packaged and labelled for emergency contraception, in package sizes containing no more than 1.5 mg of levonorgestrel)	• Plan B • generic brands
lidocaine and its salts (for otic use)	• Polysporin Plus Pain Relief ear drops
lidocaine and prilocaine (eutectic mixture)	• EMLA cream and patches
loratadine and its salts and preparations in products marketed for pediatric use (under 12 years of age)	• Claritin Kids Syrup
magnesium citrate (cathartics)	
magnesium salicylate (except oral dosage forms which also contain choline salicylate)	
meclizine and its salts (when sold in concentrations of 25mg or less per dosage unit)	
mepivacaine and its salts (for topical use on mucous membranes except lozenges)	
methocarbamol (except for parenteral use)	• Motrin Platinum Muscle and Body • Robax Platinum / Robaxacet / Robaxin / Robaxin 750 / Robaxisal • Tylenol Extra Strength Back Pain / Body Pain Night • generic and store brands
miconazole and its salts (for vaginal use)	• Monistat vaginal products • generic and store brands
mineral tar (except shampoos with concentrations less than 5%)	
naproxen sodium 220 mg per oral dosage unit (when sold in products labelled with a recommended maximum daily dose of 440 mg, and in package sizes exceeding 6,600 mg)	• Aleve (100 tablets or more)
narcotine and its salts (noscapine)	
nystatin and its salts and derivatives (in topical preparations for use on the skin)	• Nyaderm cream • generic brands
orphenadrine citrate	
oxethazine	
oxybuprocaine and its salts (for topical use on mucous membranes except lozenges)	
phenyltoloxamine and its salts	
polymyxin B and its salts and derivatives (for ophthalmic use)	• Optimyxin eye/ear drops • Polysporin Eye and Ear drops
povidone - iodine (in topical preparations, except in concentrations of 5% or less)	• Betadine ointment / solution
pramoxine and its salts (for topical use on mucous membranes except lozenges)	
prilocaine and its salts (for topical use on mucous membranes except lozenges)	
procaine and its salts (for topical use on mucous membranes except lozenges)	
promethazine and its salts (for topical use)	
proparacaine and its salts (for topical use on mucous membranes except lozenges)	

Chemical name as it appears in the Schedule	Examples of common Brand Names
pseudoephedrine and its salts and preparations in combination products (Please Note: Pharmacists are advised that in areas where there is evidence of abuse or particular concern about abuse, pseudoephedrine products should NOT be located in a self-selection area of the pharmacy)	• Advil Cold & Sinus products / Children's Advil Cold / Cold & Flu • Aerius Dual Action 12 Hour • Allegra D • Benadryl Total • Benylin All-in-One Cold & Flu / Cough & Chest Congestion / "D" products / Mucous & Phlegm Plus Cold products • Buckley's Complete Cough & Cold / Cough, Cold & Flu / Daytime Plus Mucus / Nighttime / Cold & Sinus • Claritin Allergy + Sinus • Entex LA • Motrin Cold & Sinus Pain • NeoCitran Flu with Mucous Relief / Flu Night • Reactine Complete • Robitussin Cough & Cold / Total Cough, Cold & Flu • Sinutab Sinus / Sinus & Allergy • Sudafed Head Cold & Sinus / Sinus / Sinus Advance Cold & Allergy softchews / Cough & Cold softchews • Tylenol Cold & Sinus / Complete Cold, Cough & Flu • Tylenol Children's Cold / Cold & Cough / Cold & Stuffy Nose / Complete Cold, Cough & Fever • generic and store brands
ranitidine and its salts, when sold in concentrations of 150mg or less per oral dosage unit & indicated for the treatment of heartburn, in package sizes containing more than 4,500mg of ranitidine	
sodium biphosphate (cathartics)	
sodium cromoglycate (in solutions in concentrations of 2% or less for ophthalmic or nasal use)	• Cromolyn eye drops • Opticrom • Rhinaris-CS Anti-Allergic Nasal Mist
sodium phosphate (cathartics)	
tetracaine and its salts (for topical use on mucous membranes except lozenges)	
tioconazole and its salts (in preparations for vaginal use)	
triethanolamine oleate	
triethanolamine salicylate (in concentrations greater than 20%)	
tripelennamine and its salts	
triprolidine	
tyrothricine	
triamcinolone acetonide in an aqueous nasal spray that delivers 55mcg per metered spray for adults and children 12 years of age and older, in package sizes containing no more than 120 metered sprays	• Nasacort Allergy 24HR
vegetable tar (except shampoos in concentrations of 5% or less)	

UNSCHEDULED DRUG PRODUCTS

Many drugs have been reviewed by the National Drug Scheduling Advisory Committee (NDSAC) but have not been assigned any place in the above schedules. As well, many drugs that are included in the schedules are included based on specific parameters such as strength and dosage form. That same drug in another strength or dosage form may be considered "Unscheduled".

Unscheduled drugs can be sold without professional supervision. Adequate information is available for the patient to make a safe and effective choice and labelling is deemed sufficient to ensure the appropriate use of the drug. These drugs may be sold from any retail environment.

The following table lists all drugs that are currently specifically recommended for unscheduled status by NDSAC. It is not intended to reflect all drugs not otherwise captured by the Provincial Drug Schedules. **Recent changes are indicated with <u>BOLD UNDERLINE</u>**. Examples of the Brand Names of products containing these drugs are also provided. Please note that the list of Brand Names is not necessarily inclusive and are provided for reference only.

Chemical name	Examples of common Brand Names
acetaminophen (in immediate release tablets, capsules, suppositories or liquid)	• Atasol Forte • Tempra products • Tylenol products • generic and store brands
acetaminophen in sustained release formulations (up to and including 650 mg per unit, in package sizes containing no more than 50 units)	• Tylenol Arthritis Pain 8H • Tylenol Muscle & Body 8H • generic and store brands
acetylsalicylic acid and its salts (in products for oral use in strengths of 325mg and 500mg per dosage unit)	• Alka-Seltzer products • Anacin products • Aspirin Regular / Extra Strength • Novasen 325mg • generic and store brand products in 325mg or 500mg strengths
aloin	
ammonium hydroxide	
attapulgite (active)	
bacitracin and its salts (for topical use)	• Bacitin ointment • Band Aid adhesive bandages plus antibiotic • Ozonol Antibiotics Plus • Polysporin Antibiotic ointment / Triple Antibiotic ointment / Complete • generic and store brand "Antibiotic Ointments"
benzocaine and its salts (for topical application on the skin)	• Lanacane Antibacterial First Aid spray
benzoyl peroxide (preparations of 5% or less as a single ingredient)	• Advantage Acne Control Kit • Benzagel products • Clean & Clear Persa-Gel 5 • Clearasil Daily Clear Acne Treatment Cream BP Plus • Continuous Control Acne Cleanser • Deep Pore Acne Vanishing Treatment • Emergency Acne Vanishing Facial Cleanser • Spectro AcneCare Wash • "Stubborn Acne" products
bile salts	
bioflavanoids	
bisacodyl when sold in concentrations of 5mg or less per oral dosage unit or 10mg or less per rectal dosage unit/suppository, in package sizes containing no more than 50mg of bisacodyl	• Dulcolax (in pkg sizes of 10 tablets or less / 5 suppositories or less) • generic brand tablets & suppositories (in pkg sizes of 10 tablets or less / 5 suppositories or less)
boric acid and its salts (in ophthalmic preparations in concentrations up to and including 2%, and in contact lens solutions intended to be rinsed off prior to insertion into the eye.	

Chemical name	Examples of common Brand Names
brompheniramine and its salts in combination products for the relief of cough and cold symptoms	• Dimetapp liquid • Robitussin Children's Cold
butenafine (1% cream)	
camphor (in oleaginous vehicles and in liquid forms in concentrations up to and including 11%)	
caprylic acid	
capsaicin	
cascara sagrada and its extracts and derivatives	
cetirizine and its salts (in concentrations of 10 mg equivalent to 8.5 mg or less of cetirizine base per dosage unit) in products marketed for adult use (12 years of age and older)	• Reactine 10mg tablets (single-entity) • generic & store brands
charcoal (activated) except for use in poisoning treatment	
chloral hydrate (for topical use)	
chlorpheniramine and its salts and preparations	• Benylin Cold & Sinus Night • Chlor-Tripolon • Tylenol Extra Strength Sinus Nighttime
cinnamedrine	
clotrimazole and its salts (in preparations for topical use)	• Canestan 1% Topical Cream • generic brands
coal tar (in concentrations up to and including 10%)	
desloratidine and its salts and preparations (in products marketed for adult use – 12 years and older)	• Aerius tablets
diclofenac diethylamine when sold as a single medicinal ingredient for topical use on the skin in concentrations of not more than 1.16% for not more than 7 days	• Voltaren Emulgel regular strength products
digestive enzymes (from plant sources)	
diphenhydramine and its salts and preparations for topical use in concentrations of 2% or less when sold in containers of 300 mg or less of diphenhydramine hydrochloride	• Benadryl Itch Relief Stick
docosanol 10% for topical use	• Abreva ointment
docusate and its salts	• Colace products • Senokot S • Soflax products • Various generic and store brands
famotidine and its salts, when sold in concentrations of 20mg or less of famotidine per oral dosage unit and indicated for the treatment of heartburn, in package sizes containing no more than 600mg of famotidine	• Pepcid AC 10mg (60 tablets or less) • Pepcid AC Maximum Strength 20mg (30 tablets or less)
fexofenadine HCl (in products marketed for adult use – 12 years and older)	• Allegra 12 hour / 24 hour
glutamic acid and its salts (gastric acidifiers)	
gramicidin and its salts (for topical use)	• Polysporin Cream / Complete / Plus Pain Relief / For Kids / Triple Antibiotic Ointment • generic and store brand "Antibiotic Creams"
guaifenesin	• Balminil Expectorant • Benylin "E" / Mucous & Phlegm • Robitussin Mucus & Phlegm
ibuprofen and its salts, containing 400mg or less per oral dosage unit (when sold in package sizes of up to 18,000mg)	• Advil single-entity 200mg products (90 tablets or less) • Advil single-entity 400mg products (45 tablets or less) • Motrin single-entity 200mg products (90 tablets or less) • Motrin single-entity 300mg products (60 tablets or less) • Motrin single-entity 400mg products (45 tablets or less) • Various generic and store brands
inositol niacinate	
ipecac and its extracts and derivatives (for use other than as an emetic)	
iron and its salts and derivatives (in preparations containing 30 mg or less elemental iron per dosage unit or 5 ml oral liquid)	

Chemical name	Examples of common Brand Names
ketoconazole and its salts (as a shampoo)	• Nizoral 2% shampoo
lidocaine and its salts (for topical use on the skin, including lozenges)	• After Sun Soothing Spray • Afterburn • Bactine First Aid Spray • Band-Aid Brand Antiseptic Wash • Ozonol Antibiotics Plus • Polysporin Complete / For Kids / Plus Pain Relief • Solarcaine First Aid Lidocaine Spray / Medicated First Aid Lotion / Medicated Lidocaine Gel
loperamide and its salts in products marketed for adult use – 12 years and older)	• Imodium products • generic and store brand tablets
loratadine and its salts and preparations in products marketed for adult use (12 years of age and older)	• Claritin adult products (single entity) • generic & store brands
methyl salicylate (in liquid dosage forms in concentrations up to and including 30%)	
miconazole and its salts (for topical use)	• Micatin Cream / Spray • Monistat Derm Cream
minoxidil, when sold in preparations for topical use in adults in concentrations of 5% or less, for human use only	
naphazoline and its salts (in nasal preparations for adult use and in ophthalmic products)	• Albalon • Clear Eyes / Clear Eyes Allergy / Extra Strength Redness Relief • Naphcon A • Opti-Tears Allergy • Refresh Redness Relief • Soothe Allergy / Redness • Visine for Allergy with Antihistamine
naproxen sodium 220 mg oral dosage unit (when sold in products labelled with a recommended maximum daily dose of 440 mg, and in package sizes of up to 6,600 mg)	• Aleve (24's)
niacin (in immediate release formulations)	
niacinamide (oral)	
niacinamide (for topical use)	
nicotine and its salts, for human use (a)in natural substances; (b) when sold as a chewing gum containing not more than the equivalent of 4mg of nicotine per dosage unit; (c) when sold as a transdermal patch with a delivery rate of not more than the equivalent of 22mg; (d) when sold in a form to be administered orally by means of an inhalation device delivering 4mg or less of nicotine per dosage unit; or (e) when sold in a form to be administered orally as a lozenge containing 4 mg or less of nicotine per lozenge	• Habitrol products • Nicoderm products • Nicorette products • Nicotinell products • Nicotrol products • Thrive products • Generic and store brand transdermal nicotine patches
oxiconazole (1% for topical use)	
oxymetazoline (in nasal preparations for adult use and in ophthalmic products)	• Claritin Allergy Decongestant nasal spray • Dristan Long Lasting nasal sprays • Drixoral nasal sprays
pancreatic enzymes, pancreatin, pancrealipase (except in products for the treatment of established pancreatic insufficiency)	
papain (as a debriding agent)	
pepsin	
peptone	
pheniramine	• Dristan Nasal Mist • Naphcon-A • NeoCitran Cold & Sinus Night / Cold & Sore Throat Night • Opti-Tears Allergy • Soothe Allergy • Visine for Allergy with Antihistamine

Chemical name	Examples of common Brand Names
phenylephrine and its salts and preparations (for oral use, in nasal preparations for adults and in ophthalmic preparations in concentrations of 2.5% or less)	• Benylin Cold & Sinus / Cold & Sinus Plus caplets • Dayquil Sinus • Dimetapp liquid • Dristan Tablets / Nasal Mist • NeoCitran Cold & Congestion / Cold & Sinus Night / Cold & Sore Throat Night • Robitussin's Children's Cold
polyethylene glycol (topical administration)	
polyethylene glycol 3350 as a single ingredient oral product indicated as a laxative to treat occasional constipation	• Clearlax • Lax-A-Day • Pegalax • Purelax • Restoralax
polymyxin and its salts and derivatives (topical)	• Band aid adhesive bandages plus antibiotic • Ozonol Antibiotics Plus • All Polysporin topical products • generic and store brand "Antibiotic" ointments and creams
pramoxine and its salts for topical application on the skin and including lozenges	• Aveeno Anti-Itch Lotion • Gold Bond Anti-Itch lotion / Medicated Anti-Itch cream • Polysporin Itch Relief / Poly-To-Go
propylene glycol (topical application)	
pyrilamine	• Menstrual Midol Complete / PMS Midol Complete
ranitidine and its salts, when sold in concentrations of 150mg or less per oral dosage unit and indicated for the treatment of heartburn, in package sizes containing no more than 4500mg of ranitidine	• Zantac 75 • Zantac 150 • generic brands
salicylic acid and its salts (in topical preparations in concentrations up to and including 40%)	
senna and its extracts and derivatives	• Ex-Lax products • Senokot S
sodium tartrate	
tetrahydrozoline (for ophthalmic use and in nasal preparations for adults)	• Clear Eyes Triple Action Relief • Visine Allergy / Multi-Symptom / Original / Red Eye
tioconazole and its salts (in preparations for topical use)	
triethanolamine salicylate (in concentrations up to and including 20%) [trolamine]	• Aspercreme • Myoflex products
trypsin	
ubiquinone	
xylometazoline and its salts (in nasal preparations for adults(0.1%))	• Balminil Decongest spray • Otrivin Cold & Allergy products • Various generic and store brands

APPENDIX A
PROVINCIAL REGULATIONS

DRUG SCHEDULES

13. (1) The board may adopt the drug schedules established under the National Association of Pharmacy Regulatory Authorities National Drug Schedules System.

(2) Notwithstanding subsection (1), a pharmacist in charge may, where he or she considers it necessary, exercise a higher degree of control over a particular drug than what is contemplated in the schedules.

APPENDIX B
SCHEDULING CRITERIA

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.

APPENDIX C
GUIDELINES REGARDING THE SALE OF NALOXONE INJECTION IN COMMUNITY PHARMACIES

1) Introduction

In response to significant increases in the incidence of opioid overdose, the large majority of which result in death, steps are being taken across Canada to provide greater access to naloxone, an opioid antagonist indicated for the complete or partial reversal of opioid overdose, including its consequences: respiratory depression, sedation and hypotension.

In March 2016, Health Canada revised its listing for naloxone on the Prescription Drug List (PDL) such that naloxone or its salts ("naloxone") no longer required a prescription when indicated for emergency use for opioid overdose.

National Drug Scheduling Advisory Committee (NDSAC) subsequently reviewed this change and made recommendations regarding the scheduling of naloxone hydrochloride injection[1] and naloxone hydrochloride nasal spray[2] when indicated for emergency use for opioid overdose, As per the Pharmacy Regulations, 2014, the Newfoundland and Labrador Pharmacy Board reviewed the NDSAC recommendations on August 22, 2016 and February 18, 2017, and approved the following revisions to the Newfoundland and Labrador Provincial Drug Schedules:

Added to Schedule I:	"Naloxone or its salts, including, but not limited to naloxone hydrochloride, EXCEPT when indicated for emergency use for opioid overdose."
Added to Schedule II:	"Naloxone hydrochloride injection, when indicated for emergency use for opioid overdose."
Added to Schedule II:	"Naloxone hydrochloride nasal spray, when indicated for emergency use for opioid overdose."

Drugs listed in Schedule II of the Provincial Drug Schedules, while less strictly regulated than Schedule I drugs, do require professional intervention from the pharmacist at the point of sale and possibly referral to a practitioner. While a prescription is not required, the drugs are available only from the pharmacist and must be retained within an area of the pharmacy where there is no public access and no opportunity for patient self-selection.

While naloxone is very safe and the only contraindication to the use of naloxone is a known hypersensitivity to the drug, pharmacists are expected to meet certain expectations in the provision of this product to their patients.

2) Practice Expectations

2.1 Competency

a) Pharmacists providing naloxone should take reasonable steps to ensure they are competent to do so. This should include the completion of an appropriate education and training program (see section 3 – Additional Resources for examples of appropriate programs).

2.2 Patient Assessment

a) While it would be ideal for the pharmacist to personally consult with the patient (i.e. the person for whom the drug is intended) prior to providing naloxone, considering the nature of the drug and its intended use, this may not always be possible. Consideration should be given to providing naloxone to:

i) any individual who uses opioids for either legitimate medical purposes or for recreational use;

ii) close personal friends or family members of the individuals identified in i); or

iii) any person who knows an opioid user who would like to be prepared in the event of an accidental overdose.

[1] Review completed and scheduling recommendation made on June 26, 2016
[2] Review completed and scheduling recommendation made on December 22, 2016

b) Before providing naloxone, the pharmacist should have sufficient knowledge and understanding of the circumstances such that he or she can be reasonably satisfied that providing naloxone is appropriate.

c) When considering whether or not the sale of naloxone is appropriate, in situations where the patient is identified, the pharmacist should take into account the patient's:

   i) history of opioid use;
   ii) history of past naloxone use;
   iii) allergies and/or sensitivities; and
   iv) pregnancy and lactation status (if applicable).

PLEASE NOTE:	Given the safe and effective nature of naloxone, it is very unlikely that it would not be appropriate to provide the drug to someone who requests it.

2.3 Additional Equipment and Supplies

a) When providing naloxone, pharmacists should provide the product as part of a "kit" that includes:

   i) two 1 mL single-use ampoules or vials of naloxone hydrochloride 0.4mg/ml solution or two doses of naloxone hydrochloride 4mg/0.1ml nasal spray;
   ii) two 3cc syringes with auto-retractable 25G needles attached (1" length recommended) (for injectable naloxone);
   iii) alcohol swabs (for injectable naloxone);
   iv) latex or vinyl gloves;
   v) ampoule opening device (optional);
   vi) rescue breathing barrier with one-way valve (optional); and
   vii) step-wise instructions for recognizing and responding to an opioid overdose including written and visual instructions for administering naloxone administration (see section 3. – Additional Resources for examples of written instructions).

2.4 Documentation and Labelling

a) In accordance with section 3.5 of the *Standards of Pharmacy Operation – Community Pharmacy* (SOPO-Community), each time a pharmacist provides a Schedule II product, it must be documented in the patient's medication profile. Generally speaking, this is also the expectation when providing naloxone.

b) In order to retain traceability and accountability, in cases where:

   i) someone other than the patient is purchasing naloxone,
   ii) the patient is not identified, or
   iii) it is not clear that the patient has consented to the medication being added to their patient profile,

   the pharmacist should create a record indicating that naloxone was provided to an "unknown patient". This record should include the date the naloxone was provided and the identification of the pharmacist who provided the product.

c) In accordance with section 3.6 of the SOPO-Community, each time a pharmacist provides a Schedule II product, it must be appropriately labelled. In the case of naloxone, the label should include, at a minimum:

   i) pharmacy name, phone number and street address (if available, or, if not, a way of uniquely identifying the pharmacy location);
   ii) patient's first and last name (or "unknown patient");
   iii) drug name (i.e. naloxone kit);
   iv) date of provision;

v) the initials of the pharmacist responsible for the sale; and

vi) a cautionary label indicating that the product should be kept out of the reach of children.

2.5 Pharmacist-Patient Consultation

a) Pharmacists are expected to provide counselling prior to each and every sale of naloxone. This interaction will allow the pharmacist to review important education and training points and allow the purchaser the opportunity to ask questions / discuss concerns.

b) In the case of naloxone, such counselling should include:

i) a review of the contents of the naloxone kit;

ii) how to identify an opioid overdose;

iii) the importance of calling 911 immediately for medical assistance due to the short half-life of the drug;

iv) the importance of rescue breathing;

v) when to administer naloxone;

vi) for injectable naloxone:

i. how to prepare the dose for administration by withdrawing the dose of naloxone from the ampoule/vial into the syringe;

ii. how to landmark the thigh and administer an intra-muscular injection; and

iii. how to avoid and manage needle stick injuries;

vii) for intranasal naloxone:

i. how to administer properly, noting that the device does not need to be "primed" and that once the plunger is depressed, the dose has been released;

viii) when to use the second dose of naloxone;

ix) the need to remain with the victim to provide supportive measures and to assess the need for subsequent doses while waiting for emergency first responders to arrive: and

x) any other information the pharmacist deems relevant to the circumstances.

3) Additional Resources

3.1 Education and Training Programs

a) Alberta Pharmacists' Association - Take Home Naloxone - Information for Pharmacists webinar

b) Canadian Pharmacists Association - Naloxone for Opioid Overdose – What Pharmacists Need to Know webinar slides

c) College of Pharmacists of British Columbia - Community Pharmacy Distribution of Naloxone webinar slides

3.2 Other Resources and References

a) Naloxone Injection Training Checklist

b) Naloxone Nasal Spray Training Checklist

c) Product Monograph – Adapt Pharma – Naloxone Nasal Spray Product Monograph (includes Patient Information)

d) Product Monograph – Sandoz Canada – S.O.S. Naloxone Hydrochloride Injection Product Monograph (includes Patient Information)

4) References

a) Alberta College of Pharmacists - Guidance for Pharmacists and Pharmacy Technicians Dispensing or Selling Naloxone as a Schedule 2 Drug

b) College of Pharmacists of Manitoba - Guidelines for Pharmacists Selling Naloxone as a Schedule II Drug

c) Nova Scotia College of Pharmacists - Naloxone for Opioid Overdose Reversal Position Statement

d) Ontario College of Pharmacists - Dispensing or Selling Naloxone

APPENDIX D
GUIDELINES REGARDING THE SALE OF DIMENHYDRINATE

1. As a Schedule III drug, dimenhydrinate may be sold from the self-selection area of the pharmacy. However, even if sold from this location, registrants and other staff should be aware of the sales of dimenhydrinate and the pharmacist-in-charge should be alerted to any potential concerns or issues.
2. If evidence of misuse or abuse of dimenhydrinate is detected, pharmacists-in-charge are encouraged to restrict the sale of dimenhydrinate to Schedule II status (i.e. no patient self-selection, mandatory direct pharmacist involvement in the sale).
3. Dimenhydrinate in package sizes greater than 30 tablets, or 100ml of liquid should not be sold from the self-selection area of the pharmacy and should only be sold pursuant to a prescription, or following pharmacist assessment and documentation on the patient profile.

APPENDIX E
VACCINES AND IMMUNE GLOBULINS QUICK REFERENCE

SCHEDULE I	SCHEDULE II
➢ Bacillus Calmette-Guerin ➢ Cholera (when not used for prophylaxis against Traveler's Diarrhea due to enterotoxigenic escherichia coli [ETEC]) ➢ Hepatitis A ➢ Hepatitis B Adult ➢ Herpes Zoster (shingles) ➢ Japanese Encephalitis ➢ Rabies ➢ Typhoid ➢ Varicella (chicken pox) ➢ Yellow Fever ➢ All Immune Globulins	➢ Cholera (oral, inactivated) (when used for prophylaxis against Traveler's Diarrhea due to enterotoxigenic escherichia coli [ETEC]) ➢ Diptheria toxoid ➢ Haemophilus influenzae Type B ➢ Hepatitis B Pediatric ➢ Human Papillomavirus ➢ Influenza ➢ Measles ➢ Meningococcus ➢ Mumps ➢ Pertussis ➢ Pneumococcal conjugate(7-valent) ➢ Pneumococcal conjugate (13-valent) ➢ Pneumococcal polysaccharide ➢ Poliomyelitis ➢ Rotavirus ➢ Rubella ➢ Tetanus toxoid