Drugs/Substances– Consultation Summary

Background

<u>Overview</u>

The College has been moving forward with the process to identify, research and recommend changes to the schedules of drugs/substances that are available to naturopaths in the General Regulation under the *Naturopathy Act, 2007*. This work is being led by the Scheduled Substances Review Committee (SSRC) on behalf of the College's Council. The process involves multiple stages and components that are outlined below.

<u>Process</u>

In 2018, the Council approved a list of "priority 1" drugs/substances proposed by the SSRC. At that time, Council also directed the SSRC to conduct additional pharmacological and technical research to confirm evidence that would support the "priority 1" additions. The SSRC had created the proposed lists based on feedback and stakeholder submissions received from its 2017 consultation asking for proposed additions.

The College contracted the Ontario Pharmacists Association's Drug Information and Resource Centre (DIRC) to conduct an independent review and provide the SSRC with a formal third party analysis and report on the approved list of drugs, substances and tests being proposed.

The DIRC report received by the SSRC reviewed and summarized data pertaining to the efficacy, safety, and dosage/administration of the identified drugs and substances. The report included the following information, where available, for each drug or substance

- Efficacy of use in the proposed indications.
- All potential routes of administration, including information about dosage forms not commercially available in Canada.
- Safety information including contraindications, warnings and precautions as well as black box warnings and recent (within one year) recalls and/or safety alerts.
- Monitoring parameters including measures of efficacy, lab monitoring requirements, and indicators of harm.
- Prescribing restrictions, such as recommended practice setting for administration, or type of practitioner who should prescribe.
- Situations that warrant co-management of the patient with a physician.

The SSRC met on in the fall of 2018 and reviewed the DIRC reports as well as the original stakeholder submissions received from the public consultation conducted by the College in 2017. (Note: all stakeholder submissions were anonymized to remove any potential conflict of interest).

Using a decision guidance tree, the SSRC reviewed all priority 1 drugs, substances and drafted proposed amendments to Tables 2, 3, 4, 5, and 6 of <u>Ontario Regulation 168/15</u>.

On January 31, 2019, the College Council approved these proposed amendments. Because proposed changes to regulations and legislation must be consulted on before they can be sent to the Ministry of Health and Long-Term Care for consideration, the College launched a new 60-day consultation on the changes.

Summary of drugs/substances

The table below summarizes the recommendations being proposed by the SSRC with regards to the 22 drugs and substances authorized by Council for further investigation. The specific changes are attached in the downloads below.

Drug/Substance	**Recommendation**
Alpha Lipoic Acid	Add to Table 2 with limitation.
B Complex	Amend route of administration of Biotin, Vitamin B1, Vitamin B2, Vitamin B3, Vitamin B5, and Vitamin B6 in Table 2 to include intramuscular.
Carnitine	No change necessary. Already included on Table 3, 4, 5 & 6.
Cortisone	Add to Table 3, 4, & 6 in oral form.
Dehydroepiandosterone (DHEA)	Add to Table 3, 4, 5 & 6 in topical or oral form.
Dextrose	No change. Already included on Table 2 for IVIT. However should be considered later with Lidocaine and Procaine etc....
Estrogens	Remove (bioidentical) and current limitation from Table 3, 4, 5 & 6.
Glycyrrhizic Acid	No change. Insufficient information to support amendment.
Hydrocortisone Acetate	Add to Table 3, 4, 5 & 6 in topical form.
Iron Dextran	Add to Table 2 with limitation.
Levothyroxine (T4)	Add to Table 3, 4, & 6.
Liothyronine (T3)	Add to Table 3, 4 & 6.
Magnesium Sulphate	No change. Already included on Table 2 for IVIT and IM.
Methionine	No change. Already included on Table 2 for IVIT. insufficient information to support amendment.
NADH 1, 4 – Dihydronicotinamide Adenine Dinucleotide	No change. More information needed.
Oral Micronized Progesterone	Remove (bioidentical) and current limitation

	from Table 3, 4, 5 & 6.
Phosphatidylcholine	Add to Table 2.
Pyridoxine	Amend route of administration to include: intramuscular, subcutaneous.
Silybinin and its salts	No change. Information does not support the addition.
Testosterone	Add to Table 3, 4, & 6 in topical form.
L-Tyrosine	Add to Table 2 with limitation.
Vanadium	No change. Already included on Table 2 for IVIT. insufficient information to support amendment.

What we want to know:

- Feedback and recommendations about the proposed changes to the tables of drugs/substances, and
- any recommendations with regards to limitations or restrictions that should be added..

Have your say

Feedback can be provided in the following ways **by no later than Sunday, April 7, 2019**:

1. Email: info@collegeofnaturopath.on.ca
2. Mail: College of Naturopaths of Ontario
   attn.: SSRC
   150 John Street, 10th Floor
   Toronto, ON M5V 3E3
3. Fax: 416-583-6011

All feedback is carefully considered, even that which is not reflected in the College's final recommendations or documents.

Next steps

The SSRC will review the information submitted, as well as information from conversations with stakeholder groups, and make recommendations to the College Council. If accepted, the College will formally submit the proposed lists to the Ministry of Health and Long-term Care for approval.

DOCUMENTS FOR DOWNLOAD

ONTARIO REGULATION 168/15

GENERAL

TABLE 1

PRESCRIBED SUBSTANCES THAT MAY BE ADMINISTERED BY INHALATION

Substance	Limitations
Acetylcysteine	No limitation specified.
Glutathione	No limitation specified.
Ipratropium Bromide	Administered to a patient by the member in his or her office only in emergency circumstances. In an emergency, administer a maximum daily dose of 0.5 mg but only after the member has administered Salbutamol to the patient.
Salbutamol	Administered to a patient by the member in his or her office only in emergency circumstances. In an emergency, administer a maximum of two doses, each dose 2.5 mg.
Saline	No limitation specified.
Therapeutic Oxygen	No limitation specified.

TABLE 2

PRESCRIBED SUBSTANCES THAT MAY BE ADMINISTERED BY INJECTION

Substance	Route of Administration	Limitation
Acetylcysteine	Intravenous	Must be in combination with other amino acids.
Adenosine triphosphate	Intravenous	No limitation specified.
Alanine	Intravenous	Must be in combination with other amino acids.
Alpha Lipoic Acid	Intravenous	Maximum daily dose of 600 mg racemic or maximum daily dose of 300 mg R.
Arginine	Intravenous	Must be in combination with other amino acids.
Aspartic Acid	Intravenous	Must be in combination with other amino acids.
Atropine	Intravenous	Administered to a patient by the member in his or her office only in emergency circumstances. In an emergency, administer 0.5-1 mg q3-5 min. Dose must be 0.5 mg or higher but must not exceed 2 mg.
Biotin	Intravenous, Intramuscular	No limitation specified.
Calcium Chloride	Intravenous	No limitation specified.
Calcium Gluconate	Intravenous	No limitation specified.
Calcium Glycerophosphate	Intravenous	No limitation specified.
Carbohydrates in sodium chloride solution	Intravenous	No limitation specified.
Chromium	Intravenous	No limitation specified.
Copper Sulfate	Intravenous	No limitation specified.
Cupric Chloride	Intravenous	No limitation specified.
Dextrose Injection	Intravenous	No limitation specified.
Diphenhydramine Hydrochloride	Intravenous, Intramuscular	Administered to a patient by the member in his or her office only in emergency circumstances with a maximum dose of 100 mg.
Epinephrine Hydrochloride	Intramuscular	Administered to a patient by the member in his or her office only in emergency circumstances with a maximum dose of 1.5 mg.
Ferrous Sulphate	Intramuscular	Must be administered by z-track only.
Folic Acid	Intravenous, Intramuscular	No limitation specified.
Glutamine	Intravenous	Must be in combination with other amino acids.
Glutamic Acid	Intravenous	Must be in combination with other amino acids.
Glycine	Intravenous	Must be in combination with other amino acids.
Glutathione	Intravenous, Intramuscular	No limitation specified.

Histidine	Intravenous	Must be in combination with other amino acids.
Hydrochloric Acid	Intravenous	In ratio of 1:1000 or 1:500.
Iron Dextran	Intramuscular	Must be administered by z-track only.
Isoleucine	Intravenous	Must be in combination with other amino acids.
L-Tryptophan	Intravenous	No limitation specified.
Lactated Ringer's Solution	Intravenous	No limitation specified.
Leucine	Intravenous	Must be in combination with other amino acids.
Levocarnitine and its salts	Intravenous	No limitation specified.
Lysine	Intravenous	Must be in combination with other amino acids.
Magnesium Sulfate	Intravenous, Intramuscular	Must never be administered by the member for the treatment of eclampsia or pre-eclampsia.
Magnesium Chloride	Intravenous, Intramuscular	Must never be administered by the member for the treatment of eclampsia or pre-eclampsia.
Manganese	Intravenous	No limitation specified.
Methionine	Intravenous	Must be in combination with other amino acids.
Molybdenum	Intravenous	No limitation specified.
Ornithine	Intravenous	Must be in combination with other amino acids.
Phenylalanine	Intravenous	Must be in combination with other amino acids.
Phosphatidylcholine	Intravenous	No limitation specified
Potassium Chloride	Intravenous	In dosage form not more than 0.3 mEq/kg/hr. Must never be administered as a single agent or by intravenous push.
Potassium Phosphate	Intravenous	In dosage form not more than 0.3 mEq/kg/hr. Must never be administered as a single agent or by intravenous push.
Proline	Intravenous	Must be in combination with other amino acids.
Ringer's Solution (sodium, chloride, potassium and calcium)	Intravenous	No limitation specified.
Saline Solution	Intravenous, Intramuscular	No limitation specified.
Selenium	Intravenous	No limitation specified.
Serine	Intravenous	Must be in combination with other amino acids.
Sodium Bicarbonate	Intravenous	No limitation specified.
Sodium Iodide	Intravenous	Must be in combination with other minerals.
Sterile Water	Intravenous, Intramuscular	Must be in combination with other substances.
Strontium and its salts	Intravenous	No limitation specified.
Taurine	Intravenous	No limitation specified.
Threonine	Intravenous	Must be in combination with other amino acids.
Tyrosine (L-tyrosine)	Intravenous	Must be in combination with other amino acids.
Vanadium	Intravenous	Must be in combination with other minerals.
Viscum Album	Intravenous, Subcutaneous	No limitation specified.
Vitamin A	Intravenous	Maximum daily dose of 10,000 International Units.
Vitamin B1	Intravenous, Intramuscular	No limitation specified.
Vitamin B2	Intravenous, Intramuscular	No limitation specified.
Vitamin B3	Intravenous, Intramuscular	No limitation specified.
Vitamin B5	Intravenous, Intramuscular	No limitation specified.
Vitamin B6	Intravenous, Intramuscular, Subcutaneous	No limitation specified.
Vitamin B12	Intravenous, Intramuscular	No limitation specified.
Vitamin C	Intravenous	Must administer no more than 15 g per day when patient's G6PD is deficient.

Vitamin D	Intravenous, Intramuscular	No limitation specified.
Vitamin E	Intravenous	No limitation specified.
Vitamin K1	Intramuscular	No limitation specified.
Zinc Chloride	Intravenous	No limitation specified.
Zinc Sulphate	Intravenous	No limitation specified.

TABLE 3

DRUGS THAT MAY BE PRESCRIBED

Drug	Limitations, routes of administration, dosages
Adenosine triphosphate	Only if prescribed for intravenous injection to be administered by the member in his or her office to the patient.
Calcium Chloride	Only if prescribed in injectable form for intravenous injection to be administered by the member to the patient.
Calcium Gluconate	Only if prescribed in injectable form for intravenous injection to be administered by the member to the patient.
Colchicine	Must not be prescribed unless the drug is botanical colchicine, compounded from the corm of colchicum autumnale.
Cortisone	Only if prescribed in oral form.
Dehydroepiandrosterone (DHEA)	Only if prescribed in topical or oral form.
Dextrose Injection	May only be prescribed when in concentrated solutions for intravenous injection to be administered by the member to the patient.
Digitalis Purpurea and its glycosides	Only if prescribed in conjunction with monitoring of patient's serum levels by member.
Estrogen ~~(bioidentical)~~	~~Only if prescribed in topical or suppository form.~~ No limitation, etc. specified
Folic Acid	Only if prescribed in oral dosage containing more than 1.0 mg of folic acid per dosage or, where the largest recommended daily dosage would, if consumed by a patient, result in the daily intake by that patient of more than 1.0 mg of folic acid.
Hydrocortisone Acetate	Only if prescribed in topical form.
L-Tryptophan	Only if prescribed for patient's use in oral dosage form at a concentration of more than 220 mg per dosage unit or per daily dose. Recommended daily dose must not exceed 12g and must be provided. May be prescribed as a single ingredient intended for intravenous injection.
Levocarnitine and its Salts	Only if prescribed for the treatment of primary or secondary levocarnitine deficiency.
Liothyronine or its salts	No Limitation etc., specified
Nitroglycerin	Administered to a patient by the member in his or her office only in emergency circumstances and only for angina pectoris. Dosage: 1 to 2 metered doses (0.4 or 0.8 mg nitroglycerin) administered on or under the tongue, without inhaling. The mouth must be closed immediately after each dose (up to 3 doses in total, at least 5 minutes apart). A sublingual tablet may be used (0.3 or 0.6 mg for initial dose). Maximum dose of 1.8 mg.
Pancreatin	Only if prescribed in a dosage form that provides more than 20,000 USP units of lipase activity per dosage unit or for the treatment of pancreatic exocrine insufficiency.
Pancrelipase	Only if prescribed in a dosage form that provides more than 20,000 USP units of lipase activity per dosage unit or for the treatment of pancreatic exocrine insufficiency.
Pilocarpine and its salts	Must not be prescribed unless, 1. the drug is botanical pilocarpus, compounded from the leaves of pilocarpus microphyllus, 2. the member monitors his or her patient's drug levels during treatment with the drug and, 3. the drug is never prescribed to treat a patient with glaucoma.
Podophyllotoxin	Must not be prescribed unless, 1. the drug is botanical podophyllotoxin compounded from podophyllum peltatum and, 2. the drug is never prescribed to treat a patient with rheumatoid arthritis.
Progesterone ~~(bioidentical form)~~	~~Only if prescribed in a topical or suppository form.~~ No limitation, etc. specified
Rauwolfia	No limitation, etc., specified.
Testosterone	Only if prescribed in topical form.
Thyroid	No limitation, etc., specified.
Thyroxin or its salts	Including but not limited to levothyroxine and its salts
Vitamin A	Only if prescribed in oral dosage form containing more than 10,000 International Units of Vitamin A per dosage or, where the largest daily dosage would, if consumed by a patient, result in the daily intake by that patient of more than 10,000 International Units of Vitamin A.
Vitamin D	Only if prescribed in oral dosage containing more than 1,000 International Units of Vitamin D per dosage or, where the largest daily dosage would, if consumed by a patient, result in the daily intake by that patient of more than 1,000 International Units of Vitamin D.
Vitamin K1	Only if prescribed in oral dosage when the maximum daily dose is more than 0.120 mg.
Vitamin K2	Only if prescribed in oral dosage when the maximum daily dose is more than 0.120 mg.
Yohimbine and its salts	Must not be prescribed unless the drug is botanical yohimbine, compounded from the bark of pausinystalia yohimbine.

TABLE 4

DRUGS THAT MAY BE DISPENSED

Drug	Limitations, routes of administration, dosages
Colchicine	Must not be dispensed unless the drug is botanical colchicine, compounded from the corm of the colchicum autumanle.
Cortisone	Only if dispensed in oral form.
Dehydroepiandrosterone	Only if dispensed in oral or topical form.
Digitalis Purpurea and its glycosides	Only if dispensed in conjunction with monitoring of patient's serum level by the member.
Estrogen ~~(bioidentical)~~	~~Only if dispensed in topical or suppository form.~~ No limitation, etc. specified
Folic Acid	Only if dispensed in oral dosage containing more than 1.0 mg of folic acid per dosage or, where the largest daily dosage would, if consumed by a patient, result in the daily intake by that patient of more than 1.0 mg of folic acid.
Hydrocortisone Acetate	Only if dispensed in topical form.
L-Tryptophan	Only if dispensed for patient's use in oral dosage form at a concentration of more than 220 mg per dosage unit or per daily dose. Recommended daily dose must not exceed 12g and must be provided in 3 to 4 equally divided doses.
Levocarnitine and its salts	Only if dispensed for the treatment of primary or secondary levocarnitine deficiency.
Liothyronine or its salts	No limitation, etc. specified
Pancreatin	Only if dispensed in a dosage form that provides more than 20,000 USP units of lipase activity per dosage unit or for the treatment of pancreatic exocrine insufficiency.
Pancrelipase	Only if dispensed in a dosage form that provides more than 20,000 USP units of lipase activity per dosage unit or for the treatment of pancreatic exocrine insufficiency.
Pilocarpine and its salts	Must not be dispensed unless, 1. the dispensed drug botanical pilocarpus compounded from the leaves of pilocarpus microphyllus, 2. the member monitors his or her patient's drug levels during treatment with the drug and, 3. the drug is never dispensed to treat a patient with glaucoma.
Podophyllotoxin	Must not be dispensed unless, 1. the dispensed drug is botanical podophyllotoxin compounded from podophyllum peltatum and, 2. the drug is never dispensed to treat a patient with rheumatoid arthritis.
Progesterone ~~(bioidentical form)~~	~~Only if dispensed in a topical or suppository form.~~ No limitation, etc. specified
Rauwolfia	No limitation, etc., specified.
Testosterone	Only if dispensed in topical form.
Thyroid	No limitation, etc., specified.
Thyroxin or its salts	Including but not limited to levothyroxine and its salts
Vitamin A	Only if dispensed in oral dosage containing more than 10,000 International Units of Vitamin A per dosage or, where the largest daily dosage would, if consumed by a patient, result in the daily intake by that patient of more than 10,000 International Units of Vitamin A.
Vitamin D	Only if dispensed in oral dosage containing more than 1,000 International Units of Vitamin D per dosage or, where the largest recommended daily dosage would, if consumed by a patient, result in the daily intake by that patient of more than 1,000 International Units of Vitamin D.
Vitamin K1	Only if dispensed in oral dosage when the maximum daily dose is more than 0.120 mg.
Vitamin K2	Only if dispensed in oral dosage when the maximum daily dose is more than 0.120 mg.
Yohimbine and its salts	Must not be dispensed unless the dispensed drug is botanical yohimbine compounded from the bark of pausinystalia yohimbine.

TABLE 5

DRUGS THAT MAY BE COMPOUNDED

Drug	Limitations, routes of administration, dosages.
Adenosine triphosphate	Only if compounded for intravenous injection.
Colchicine	Must not be compounded unless the drug is botanical colchicine compounded from the corm of colchicum autumnale.
Dehydroepiandrosterone (DHEA)	Only if compounded in topical form.
Dextrose Injection	Only if compounded when in concentrated solution for intravenous injection.
Digitalis Purpurea and its glycosides	Only if compounded in conjunction with monitoring of the patient's serum levels by the member.
Estrogen ~~(bioidentical)~~	~~Only if compounded in topical or suppository form.~~ No limitation, etc. specified
Folic Acid	Only if compounded in oral dosage containing more than 1.0 mg of folic acid per dosage or, where the largest daily dosage would, if consumed by a patient, result in the daily intake by that patient of more than 1.0 mg of folic acid.
Hydrocortisone Acetate	Only if compounded in topical form
L-Tryptophan	Only if compounded for patient's use in oral dosage form at a concentration of more than 220 mg per dosage unit or per daily dose. Recommended daily dose must not exceed 12g and must be provided in 3 to 4 equally divided doses.

	May also be compounded as a single ingredient intended for intravenous injection.
Levocarnitine and its Salts	Only if compounded for the treatment of primary or secondary levocarnitine deficiency.
Pancreatin	Only if compounded in a dosage that provides more than 20,000 USP units of lipase activity per dosage unit or for the treatment of pancreatic exocrine insufficiency.
Pancrelipase	Only if compounded in a dosage that provides more than 20,000 USP units of lipase activity per dosage unit or for the treatment of pancreatic exocrine insufficiency.
Pilocarpine and its salts	Must not be compounded unless, 1. the drug is botanical pilocarpine, compounded from the leaves of pilocarpus microphyllus, 2. the member monitors his or her patient's serum levels during treatment with the drug and, 3. the drug is never compounded to treat a patient with glaucoma.
Podophyllotoxin	Must not be compounded unless, 1. the drug is botanical podophyllotoxin, compounded from podophyllum peltatum and, 2. the drug is never compounded to treat a patient with rheumatoid arthritis.
Progesterone ~~(bioidentical)~~	~~Only if compounded in topical or suppository form.~~ No limitation, etc. specified
Rauwolfia	No limitation, etc., specified.
Thyroid	No limitation, etc., specified.
Vitamin A	Only if compounded in oral dosage containing more than 10,000 International Units of Vitamin A per dosage or, where the largest daily dosage would, if consumed by a patient, result in the daily intake by that patient of more than 10,000 International Units of Vitamin A.
Vitamin D	Only if compounded in oral dosage containing more than 1,000 International Units of Vitamin D per dosage or, where the largest daily dosage would, if consumed by a patient, result in the daily intake by that patient of more than 1,000 International Units of Vitamin D.
Vitamin K1	Only if compounded in oral dosage where the maximum daily dose is more than 0.120 mg.
Vitamin K2	Only if compounded in oral dosage where the maximum daily dose is more than 0.120 mg.
Yohimbine and its salts	Must not be compounded unless the drug is botanical yohimbine, compounded from the bark of pausinystalia yohimbine.

TABLE 6

DRUGS THAT MAY BE SOLD

Drug	Limitations, routes of administration, dosages.
Colchicine	Must not be sold unless the drug is botanical colchicine, compounded from the corm of colchicum autumnale.
Cortisone	Only if sold in oral form.
Dehydroepiandrosterone	Only if sold in oral or topical form.
Digitalis Purpurea and its glycosides	Only if sold in conjunction with monitoring of the patient's serum levels by the member.
Estrogen ~~(bioidentical)~~	~~Only if sold in topical or suppository form.~~ No limitation, etc. specified
Folic Acid	Only if sold in oral dosage containing more than 1.0 mg of folic acid per dosage or, where the largest daily dosage would, if consumed by a patient, result in the daily intake by that patient of more than 1.0 mg of folic acid.
Hydrocortisone Acetate	Only if sold in topical form.
L-Tryptophan	Only if sold for patient's use in oral dosage form at a concentration of more than 220 mg per dosage unit or per daily dose. Recommended daily dose must not exceed 12g and must be provided in three to four equally divided doses.
Levocarnitine and its Salts	Only if sold for the treatment of primary or secondary levocarnitine deficiency.
Liothyronine or its salts	No limitation, etc. specified
Pancreatin	Only if sold in a dosage form that provides more than 20,000 USP units of lipase activity per dosage unit or for the treatment of pancreatic exocrine insufficiency.
Pancrelipase	Only if sold in a dosage form that provides more than 20,000 USP units of lipase activity per dosage unit or for the treatment of pancreatic exocrine insufficiency.
Pilocarpine and its salts	Must not be sold unless, 1. the drug is botanical pilocarpine, compounded from the leaves of pilocarpus microphyllus, 2. the member monitors his or her patient's serum levels during treatment with the drug and, 3. the drug is never sold to treat a patient with glaucoma.
Podophyllotoxin	Must not be sold unless, 1. the drug is botanical podophyllotoxin, compounded from podophyllum peltatum and, 2. the drug is never sold to treat a patient with rheumatoid arthritis.
Progesterone ~~(bioidentical form)~~	~~Only if sold in topical or suppository form.~~ No limitation, etc. specified
Rauwolfia	No limitation, etc., specified.
Testosterone	Only if sold in topical form.
Thyroid	No limitation, etc., specified.
Thyroxin or its salts	Including but not limited to levothyroxine and its salts
Vitamin A	Only if sold in oral dosage containing more than 10,000 International Units of Vitamin A per dosage or, where the largest daily dosage would, if consumed by a patient, result in the daily intake by that patient of more than 10,000 International Units of Vitamin A.

Vitamin D	Only if sold in oral dosage containing more than 1,000 International Units of Vitamin D per dosage or, where the largest daily dosage would, if consumed by a patient, result in the daily intake by that patient of more than 1,000 International Units of Vitamin D.
Vitamin K1	Only if sold in oral dosage where the maximum daily dose is more than 0.120 mg.
Vitamin K2	Only if sold in oral dosage where the maximum daily dose is more than 0.120 mg.
Yohimbine and its salts	Must not be sold unless the drug is botanical yohimbine compounded from the bark of pausinystalia yohimbine.