INTRODUCTION

The purpose of this project was to review the schedule of Chinese medicines listed in Appendix B of the Regulation Amendment Proposal of the College of Traditional Chinese Medicine Practitioners and Acupuncturists of British Columbia.

In July 2015, the College submitted a Regulation Amendment Proposal to the Ministry of Health of British Columbia to request that the Traditional Chinese Medicine Practitioners and Acupuncturists Regulation be amended to conform to the Shared Scope of Practice/Restricted Activities Model under the Health Professions Act, R.S.B.C. 1996, c. 183.

The Regulation Amendment Proposal included a schedule of Chinese medicines (aka restricted Chinese medicines or Schedule I). The Chinese medicines in this schedule are ones that have a high potential for adverse consequences and therefore should require prescription by a qualified and competent health professional. An earlier schedule was originally developed by an Herbal Committee appointed by the Board of the College in 2004 and was subsequently revised in 2009 following consultation with various stakeholders.

In view of advancements in the regulation of Chinese medicines in various jurisdictions around the world, the Chinese Medicine Working Group was formed in July 2016 to review and update the schedule of Chinese medicines. The schedule was reviewed and updated by a group of experienced practitioners working with staff and external resource persons.
**PROCESS AND ACTIVITIES**

The primary steps in the review and update were:

1. Review reference material regarding risk factors in Chinese medicines
2. Develop a list of Chinese medicines potentially fitting the criteria for placement on the Schedule
3. Identify level of risk for adverse consequences for Chinese medicines reviewed
4. Establish minimum level of risk for requiring prescription
5. Review and finalize Chinese medicines that require prescription

**Review Reference Material**

The Chinese Medicine Working Group reviewed references from the following sources:

- Appendix B to the Regulation Amendment Proposal, College of Traditional Chinese Medicine Practitioners and Acupuncturists of British Columbia;
- eHealth Communication tool for use of Chinese herbal medicine, Faculty of Health, University of British Columbia;
- Nomenclature compendium for Chinese herbal medicine, Chinese Medicine Board of Australia (CMBA); and
- Referenced Nomenclature list of commonly used Chinese herbal medicines, Australian Health Practitioner Regulation Agency (AHPRA).

A full list of reference material is available in Appendix A.

**Develop a List of Chinese Medicines for Consideration**

Based on a review of the reference material, the Chinese Medicine Working Group developed a list of Chinese medicines for consideration by combining:

- Appendix B to the Regulation Amendment Proposal; and
- the Poisons Standard (SUSMP), as applied by the Chinese Medicine Board of Australia (CMBA).

This resulted in a list of 102 Chinese medicines identified for consideration.

**Identify Level of Risk for Adverse Consequence**

An online survey was used to capture the Chinese Medicine Working Group members' individual judgement regarding the following on the 102 Chinese medicines:

- frequency of use among practitioners;
- likelihood of adverse effects inherent in the Chinese medicine;
- likelihood of adverse reactions with pharmaceuticals or supplements; and
- likelihood of adverse reaction with patients' pre-existing condition or disease.

Additionally, members were asked to identify Chinese medicines not included in the survey for consideration in an expanded review. Members identified 26 additional Chinese medicines for consideration.
A second online survey was then constructed to capture the members’ individual judgement regarding the same four criteria on the 26 additional Chinese medicines.

The survey results were tabulated and the Chinese medicines that received responses beyond a threshold level were identified for further review. Members reviewed, discussed and updated where appropriate, their responses on all the Chinese medicines identified for further review.

**Establish Minimum Level of Risk for Requiring Prescription**

The survey captured the Chinese Medicine Working Group members’ responses using a five-point scale for likelihood to produce adverse consequences as follows:

1. Very Unlikely
2. Unlikely
3. Somewhat Likely
4. Likely
5. Very Likely

The members established an initial level of risk at ‘4 – Likely’ for a Chinese medicine to require prescription.

**Review and Finalize Chinese Medicines that Require Prescription**

The Chinese Medicine Working Group members reviewed each of the Chinese medicines that received an average response lower than ‘4 – Likely’. The review resulted in a total of 16 adjustments made.

Based on the defined criteria for requiring prescription and the adjustments made by the members, a total of 68 Chinese medicines were identified as requiring prescription. In addition to the defined criteria, members took into consideration the range of severity of risk (e.g. from potential for discomfort to potential to threaten life, limb or function), other reference material (e.g. SUSMP), and other risk potentials not captured by the surveys such as whether a Chinese medicine is identified as being high risk by another regulator.

**CHINESE MEDICINES THAT REQUIRE PRESCRIPTION**

The Chinese Medicine Working Group identified the following 68 Chinese medicines that should require a prescription:

- Ba dou, 巴豆, Croton tiglium
- Bai fan, 白矾, Aluminum potassium sulfate
- Bai fu zi, 白附子, Typhonium giganteum
- Bai guo, 白果, Semen Ginkgo
- Ban bian lian, 半边莲, Lobelia chinensis
- Ban mao, 斑蝥, Cantharis; Lytta vesicatoria
- Ban xia, 半夏, Pinellia ternata
- Bei wu jia, 北五加, Cortex Acanthopanacis Radicis
- Cang er zi, 苍耳子, Fructus Xanthii
- Cao wu, 草乌, Aconitum kusnezoffii
- Chai hu, 柴胡, Radix Bupleuri
Chan su, 蟾酥, Bufo bufo; Bufo melanostictus
Chuan wu, 川乌, Radix Aconiti Preparata
Da Cha Yao Gen, 大戟药根, Radix Gelsemii Elegantis
Da Feng Zi, 大风子, Hydnocarpus anthelminthicus
Dan shen, 丹参, Radix Salviae Miltiorrhizae
Dang gui, 当归, Radix Angelicae Sinensis
Dian qie cao, 颠茄草, Atropa belladonna
Fu zi, 附子, Aconitum carmichaelii
Gan sui, 甘遂, Euphorbia Kansui
Guan mu tong, 关木通, Clematis
Gui Jiu, 鬼臼, Radix Angelicae Sinensis
Hong fen, 红粉, Hydrargyri Oxydum Rubrum
Hong Niang Zi, 红娘子, Huechys
Huang Yao Zi, 黄药子, Cannabis sativa
Huo Yang Le, 火秧果, Euphorbia antiquorum
Ji Ji, 及己, Chloranthus serratus
Jia Zhu Tao, 夹竹桃, Nerium oleander
Ku lian pi, 苦楝皮, Melia azedarach
Ku xing ren, 苦杏仁, Prunus armeniaca; Prunus armeniaca var. ansu; Prunus sibirica
Lang du, 狼毒, Radix Euphorbiae Ebracteolatae
Lei Gong Teng, 雷公藤, Radix Tripterygii Wilfordii
Liu huang, 硫黄, Sulfur
Ma dou ling, 马兜铃, Fructus Aristolochiae
Ma huang, 麻黄, Ephedra intermedia
Ma Liu Ye, 麻柳叶, Pterocarya Stenoptera
Ma qian zi, 马钱子, Strychnos nux-vomica
Mao Gen, 毛茛, Imperata cylindrica
Nao Sha, 砒砂, Sal Ammoniaci
Nao yang hua, 麝羊花, Rhododendron molle
Pi Shi, 砒石, Arsenolite
Pi Shuang, 砒霜, Arsenic sulfide (As2S3)
Qian jin zi, 千金子, Chamaesyce hirta
Qian niu zi, 牵牛子, Ipomoea nil; Ipomoea purpurea
Qing fen, 轻粉, Mercury chloride (Hg2Cl2)
Qing Niang Zi, 青娘子, Lytta Caraganae
Quan xie, 全蝎, Buthus martensii
Ren shen, 人参, Panax ginseng
Shan ci gu, 山慈菇, Cremastra appendiculata; Pleione bulbocodioides; Pleione yunnanensis
Shan dou gen, 山豆根, Sophora tonkinensis
Sheng Yao, 升药, Hydrargyrum Oxydatum Crudum
Shui Yin, 水银, Mercury
Teng Huang, 藤黄, Garcinia Hanburyi
Tian nan xing, 天南星, Arisaema erubescens
Tian xian teng, 天仙藤, Herba Aristolochiae
Tian xian zi, 天仙子, Hyoscyamus niger
Wei ling xian, 威灵仙, Clematis chinensis
Xi xin, 细辛, Asarum sieboldii
Xiang Si Zi, 相思子, Rhizoma Cyperi
Xiong huang, 雄黄, Realgar
Xue Shang Yi Zhi Hao, 雪上一枝蒿, Aconitum brachypodum

Yang jin hua (Man tuo luo), 洋金花 (曼陀罗), Datura metel
Yu Teng, 鱼藤, Derris trifoliata
Zao fan (Lü fan), 皂矾 (绿矾), Melanteritum
Zhi cao wu, 制草乌, Aconitum kusnezoffii
Zhi chuan wu, 制川乌, Aconitum carmichaelii
Zhu sha, 朱砂, Cinnabaris
Zhu ya zao, 猪牙皂, Fructus Gleditsiae Abnormalis

A summary of changes to the schedule of Chinese medicines in the Regulation Amendment Proposal is available in Appendix B.

LIMITATIONS
There are a number of limitations with this review, including the rapidly changing landscape of regulatory models for Chinese medicines across the globe. To the extent possible, attempts were made to include adequate reference material to ensure a reasonable level of reliability in the experienced practitioners’ individual and collective judgment of the potential risk of using certain Chinese medicines.

CONCLUSION AND RECOMMENDATION
A scan of regulatory systems for Chinese medicines confirms that regulators recognize some Chinese medicines may carry a potential for adverse consequences and that those Chinese medicines should only be prescribed by adequately trained health professionals.

Emerging research on the correlation of adverse effects of Chinese medicines when combined with pharmaceutical or supplement use is receiving increased attention by such bodies as the World Health Organization (WHO), which has published guidelines in order to define basic criteria for evaluating the quality, safety, and efficacy of herbal medicines aimed at assisting national regulatory authorities, scientific organizations and manufacturers in this particular area. The Canadian regulatory system is consistent with WHO guidelines for the assessment of herbal medicines for safety purposes. The Chinese Medicine Working Group recommends that the College stay abreast of advances in the knowledge and regulation of the safe use of Chinese medicines by traditional Chinese medicine practitioners in British Columbia.

The Chinese Medicine Working Group recommends that the College update Appendix B of the Regulation Amendment Proposal to the list of 68 Chinese medicines requiring prescription, as listed in this report.
APPENDIX A

Reference Documents

- American Dragon, www.americandragon.com
- Complementary and Alternative Healing University, www.alternativehealing.org
- Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)
- eHealth Communication tool for use of Chinese herbal medicine, October 2015, Faculty of Health, University of British Columbia
- Natural and Non-prescription Health Products Directorate, Health Canada
- Nomenclature compendium for Chinese herbal medicine, October 2015, Chinese Medicine Board of Australia (CMBA)
- Regulation Amendment Proposal, July 2015, College of Traditional Chinese Medicine Practitioners and Acupuncturists of British Columbia
- The Poisons Standard (the SUSMP), Department of Health, Australian Government
- Referenced Nomenclature list of commonly used Chinese herbal medicines, July 2016, Australian Health Practitioner Regulation Agency (AHPRA)
- TCM Wiki, www.tcmwiki.com
- 中华临床中药学（上下）, 1998, 人民卫生出版社
- 现代中药学大辞典, 2001, 人民卫生出版社
APPENDIX B

Changes to Schedule of Chinese Medicines

The names of the following Chinese medicines have been revised in order to bring them into alignment with Health Canada’s Natural Health Products Ingredients Database:

- Sheng Ban Xia, 生半夏, Unprocessed Rhizoma Pinelliae
- Sheng Cao Wu Tou, 生草烏頭 / 生草乌头, Unprocessed Radix Aconiti Kusnezoffii
- Sheng Chuan Wu Tou, 生川烏頭 / 生川乌头, Unprocessed Radix Aconiti
- Sheng Fu Zi, 生附子, Unprocessed Radix Aconiti Lateralis
- Sheng Gan Sui, 生甘遂, Unprocessed Radix Kansui
- Sheng Guan Bai Fu, 生關白附 / 生关白附, UnprocessedRadix Aconiti Coreani
- Sheng Lang Du, 生狼毒, Unprocessed Radix Euphorbiae Fischarianae;Stellerae
- Sheng Qian Jin Zi, 生千金子, Unprocessed Semen Euphorbiae
- Sheng Teng Huang, 生藤黃, Unprocessed Resina Garciniae Morellae
- Sheng Tian Nan Xing, 生天南星, Unprocessed Rhizoma Arisaematis
- Sheng Yu Bai Fu, 生禹白附, Unprocessed Rhizoma Typhonii
- Sheng/Zhi Ma Qian Zi, 生/製馬錢子, 生/制马钱子, Unprocessed/Processed Semen Strychni

The following Chinese medicines have been added to the schedule of Chinese medicine:

- Bai guo, 白果, Semen Ginkgo
- Bei wu jia , 北五加, Cortex Acanthopanacis Radicis
- Cang er zi, 苍耳子, Fructus Xanthii
- Chai hu, 柴胡, Radix Bupleuri
- Dan shen, 丹参, Radix Salviae Miltiorrhizae
- Dang gui, 当归, Radix Angelicae Sinensis
- Dian qie cao, 顏茄草, Atropa belladonna
- Guan mu tong, 關木通, Clematis
- Hong fen, 紅粉, Hydrargyri Oxydum Rubrum
- Ku lian pi, 苦楝皮, Melia azedarach
- Ku xing ren, 苦杏仁, Prunus armeniaca; Prunus armeniaca var. ansu; Prunus sibirica
- Ma dou ling, 马兜铃, Fructus Aristolochiae
- Ma qian zi, 马钱子, Strychnos nux-vomica
- Quan xie, 全蝎, Buthus martensii
Ren shen, 人参, Panax ginseng

Tian xian teng, 天仙藤, Herba Aristolochiae

Wei ling xian, 威灵仙, Clematis chinensis

Yang jin hua (Man tuo luo), 洋金花 (曼陀罗), Datura metel

Zao fan (Lü fan), 皂矾（绿矾）, Melanteritum