



CHINESE MEDICINE WORKING GROUP

PROJECT REPORT

November 16, 2016



College of Traditional Chinese Medicine Practitioners
and Acupuncturists of British Columbia

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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.

CMWG MEMBERS

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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 Acanthopanax 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, 大茶药根, 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, 關木通, 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, 火秧笏, Euphorbia antiquorum

Ji Ji, 及己, Chloranthus serratus

Jia Zhu Tao, 夾竹桃, 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, 硃砂, Sal Ammoniaci

Nao yang hua, 闹羊花, 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) , Melantheritum

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
- WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues, 2007, World Health Organization
- 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, Unprocessed Radix Aconiti Coreani

Sheng Lang Du, 生狼毒, Unprocessed Radix Euphorbiae Fischerianae; Stellerae

Sheng Qian Jin Zi, 生千金子, Unprocessed Semen Euphorbiae

Sheng Teng Huang, 生藤黃, Unprocessed Resina Garcinia 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 Acanthopanax 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, 颠茄草, Atropa belladonna

Guan mu tong, 關木通, Clematis

Hong fen, 红粉, 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*



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