

Editorial:

ATCM Council has on a few occasions in the past years published the list of prohibited and restricted herbal medicines and products. We have also reported to members about the incidences of adverse effects or toxicity of some Chinese herbal medicines, and informed our members with the warnings on certain prohibited or restricted herbal medicines and products from MHRA. As we have many new members who joined ATCM in recent years, and they may not be well aware about the legal and regulatory situation around Chinese herbal medicines, the council would like to publish this list once again, in order to guide the safe and legal practice for our members, and to prevent any adverse incidences from happening. You are advised to keep this list for future reference.

We should draw your particular attention to the new regulation by MHRA based on EU Directive of Traditional Medicinal Herbal Products, that since April 2014, all manufactured herbal products would need license or THR registration for entering the UK market. It is illegal to sell any unlicensed/unregistered manufactured TCM products in the UK.

March 2015

Republication: List of Prohibited and Restricted Chinese Herbal Medicines

By ATCM Council

March 2010

Traditional Chinese medicine (TCM) has been popular in the United Kingdom for the last few decades. This is because under Section 12 of the Medicines Act 1968, Herbal medicines are exempt from medicinal products licensing, which enable us to use dried herbal medicines and patent herbal products. However, under current legal statutes, our profession does not have statutory recognition, i.e. we are not an authorised healthcare profession; hence some various restrictions apply to our practice. The restrictions are mainly in the following areas:

- The Convention on International Trade in Endangered Species (CITES)
- Under Statutory Instruments
- Under the 1968 MEDICINES ACT
- Prescription Only Medicines (POM)

A: Restricted Under the Convention on International Trade in Endangered Species (CITES)

Herbs which are endangered in the wild are restricted but may be traded with the appropriate CITES certification. In the case of Appendix I this is normally only permitted for scientific purposes if at all. Suppliers can trade in Appendix II herbs but only from authenticated cultivated supply. An example of this is XI YANG SHEN which is available from farmed sources.

APPENDIX I

虎骨 HU GU (Os tigris)
麝香 SHE XIANG (Secreto Moschus)
犀角 XI JIAO (Comu Rhinoceri)

熊胆 XIONG DAN (Vesica Fellea Ursi)
豹骨 BAO GU (Os Leopardis)
玳瑁 DAI MAO (Carapax Ertmochelydis)
云木香 MU XIANG (Saussurea lappa) NOTE: Vladimira species (Chuan Mu Xiang) are permitted as a substitute herb.

APPENDIX II

穿山甲 CHUAN SHAN JIA (Squama Mantis Pentadactylae)
猴枣 HOU ZAO (Calculus Macacae)
羚羊角 LING YANG JIAO (Cornu Antelopis)
龟板 GUI BAN (Chinemys reevesii)
石斛 SHI HU (Dendrobium species)
白芨 BAI JI (Bletilla striata)
天麻 TIAN MA (Gastrodia elata)
狗脊 GOU JI (Cibotium barometz)
芦荟 LU HUI (Aloe ferox)
小叶莲 XIAO YE LIAN (Podophyllum emodii)
肉苁蓉 ROU CONG RONG (Cistanches deserticola)
西洋参 XI YANG SHEN (Panax quinquefolius)
NOTE: Only applies to the whole and sliced root.
胡黄连 HU HUANG LIAN (Picrorrhiza kurroa)

B: Restrictions under Order 1997 SI 2130

These herbs were listed as an addition to the 1968 Medicines Act as being potent and hence in need of dosage regulation. In some cases they are forbidden at any internal dosage.

MD= Maximum single dose MDD=Maximum Daily Dose

附子/ 草乌FU ZI/CAO WU (Aconitum species) NOTE: Permitted to use externally at a dose of 1.3% or below. Internal use prohibited.

石榴皮 SHI LIU PI (Punica granitum) Internal use prohibited.

槟榔 BING LANG (Areca catechu) Internal use prohibited.

麻黄 MA HUANG (Ephedra sinica) MDD 1800 mg. MD: 600 mg.

洋金花 YANG JIN HUA (Datura stramonium) MDD 150 mg. MD: 50 mg.

颠茄草 DIAN QIE CAO (Atropa belladonna) MDD 150 mg. MD: 50 mg.

天仙子 TIAN XIAN ZI (Hyocyamus niger) MDD 300 mg. MD: 100 mg.

C: Restrictions under Order 2002 SI 1841

This ban relates to all Aristolochia species but also includes herbs which have been confused with aristolochic species due to poor quality assurance. The sale, supply and importation of the following are banned:

木通 MU TONG (Aristolochia manshuriensis) NOTE: this ban also applies to Akebia quinata, Akebia trifoliata, Clematis montana and Clematis armandii.

防己 FANG JI (Aristolochia fangji) NOTE: this ban also applies to Stephania tetrandra, Cocculus laurifolius, Cocculus orbiculatus and Cocculus Trilobus

马兜铃 MA DOU LING (Aristolochia contorta, Aristolochia debilis)

天仙藤 TIAN XIAN TENG (Aristolochia contorta, Aristolochia debilis)

青木香 QING MU XIANG (Aristolochia debilis)

D: Restrictions under the 1968 MEDICINES ACT

Under Section 12(1) of the 1968 Medicines Act, 'herbal remedies' which are administered after a one-to-one consultation with a practitioner do not require a medicines licence (marketing authorisation). This legislation was enacted before traditional medicines from non-European cultures, which use non-plant substances, had any significant presence in the UK. Since the term 'herbal remedies' refers to plant materials, the MHRA has stated in its guidance on medicines law that the use of mineral and animal substances which do not have a marketing authorisation is illegal. Section 12(1) is currently under review, which in addition to recommending options for the statutory regulation of herbal medicine, has been asked to advise on changes to section 12 (1). In the course of this review the ATCM is arguing strongly that non-plant materials used in traditional medicines, as long as they are nontoxic and not of endangered species, should be sanctioned on the same basis as plant materials, i.e. so long as they can meet the necessary safety and quality criteria. It is expected that this redefinition of what constitutes a 'herb'

will be clarified in European and UK legislation in the near future to include non plant medicines, provide that our profession is statutorily regulated and we are recognised as an Authorised Healthcare Profession. However, no matter what outcome of medicines act reform, the following must never be used in any form:

朱砂 ZHU SHA (Mercuric sulphur) Cinnabar

青粉 QING FEN (Mercuric chloride) Calomel

红粉 HONG FEN (Mercuric oxide) Realgar

白矾 BAI FAN (Aluminium silicon oxide) Alum

黑锡 HEI XI Lead

E: Prescription Only Medicines (POM)

It is strictly prohibited for herbalists/TCM practitioners to include in the order dispensed any drug which is made available only through prescription by a registered medical doctor. This includes the following:

罂粟壳 YTNG SU KE (Papaver somnifera)

马钱子 MA QIAN ZI (Strychnos nux vomica)

附子(内服) FU ZI Internal use

F: Patent Herbal Formulae

It should be noted that several patent herbal formulae traditionally contain some of the above restricted herbs notably mu tong and toxic minerals. These include the following which may present a health risk if used as a patent.

1 Formulae containing toxic ingredients:

牛黄解毒片 MU HUANG JIE DU PIAN (May contain arsenic)

天王补心丹 TIAN WANG BU XIN DAN (May contain mercuric salts)

龙胆泻肝丸 LONG DAN XIE DAN WAN (May contain Aristolochic Acid)

安宫牛黄丸 AN GONG NIU HUANG WAN (contains several prohibited ingredients)

2, Formulae containing ingredients of animal source:

男宝 NAN BAO

女宝 NU BAN

龟龄集 GUI LING JI

海马补肾丸 HAIMABUSHENWAN

虎骨膏 HU GU GAO, Tiger Bone Plaster

麝香虎骨膏 SHE XIANG HU GU GAO, Musk and Tiger Bone Plaster

G. Herbal Medicines and Products under Alarming Spotlight in Recent Years

From 1990s, TCM has been developed dramatically in the United Kingdom. It was estimated that there were over 3000 TCM clinics across the UK in 2007. As we know that almost all the TCM products are imported into

UK, hence, due to different regulatory policy and quality standards, it has been noticed that some TCM products are legally acceptable in China, but being illegal in the UK. Furthermore, driven by the commercial interests, some business and manufacturers behaviour totally against the law & professional standard both in China and the UK. For instance, adultery - illegal ingredients which are banned in both the UK and China being added to herbal patent medicine; falsely claiming that a 100% natural remedy actually contains chemical or pharmaceutical ingredients. Single herbs, or material medica, are relatively less problematic with a few names coming under spotlight.

1. Materia Medica

Senecio 千里光 **Qian Li Guang**

It came to MHRA's attention in 2002 that a TCM product known as Qian Bai Bi Yan Pian had been supplied in the UK. The products contain a plant Qian Li Guang (Senecio), which is known to cause liver damage in humans. Senecio scandens is reported to contain the unsaturated pyrrolizidine alkaloids, senecionine and seneciphylline. These alkaloids are known to give rise to serious liver damage (hepatic veno-occlusive disease). They have also shown to be carcinogenic and mutagenic in animals. After 3 years consultation, from 1 April 2008, sale, supply or importation of unlicensed medicinal products for internal use which contain Senecio was banned.

Asarum 细辛 **Xi Xin**

Asarum belongs to the Aristolochiaceae family, and this already raises a red flag for those investigating the safety of the herb. The Chinese herb xixin, commonly known as asarum, is mainly derived from *Asarum sieboldii*, *Asarum heterotropoides*. There have been no reports of aristolochic acid in these plants. However, aristolochic acid has been found in some other species of *Asarum* (*Asiasarum*) by Japanese researchers². Although there is no order to ban *Asarum xixin* by MHRA yet, they have been discussing about this and very soon a ban will be in effect. Besides, other TCM professional organisations, such as the Register of Chinese Herbal Medicine (RCHM) have voluntarily banned this ingredient within their organisation.

Psoralea corylifolia 补骨脂 **Buguzhi**

The fruit contains furanocoumarin psoralen which is known to cause phototoxicity and can sensitise the skin to ultra-violet (UV) light. This can result in burning of the skin, even in weak winter sunlight. Reports of severe burning have been received in connection with TCM preparations containing *Psoralea* fruit, used both internally and externally. *Psoralea* preparations should not be used in conjunction with sun bathing or sun beds.

2. Patent Herbal Products

There have been incidents related to patent herbal products. Mainly in the following three areas:

1) Containing prohibited substances

Fu Fang Lu Hui Jiao Nang 复方芦荟胶囊

Containing high levels of mercury (between 11% and 13%). The level of mercury was found to be 117,000 times more than is allowable in food substances in the UK. ³

Jie Jie Wan 解结丸

The product was manufactured by Guangzhou Bai Yun Shan pharmaceutical manufactory which contains Aristolochic Acids.

Qian bai Bi Yan Pian 千柏鼻炎片

Containing Senecio 千里光 qian li guang. See above for details.

2) Containing pharmaceutical substances

Shu Bao 蜀宝

Slimming pills. The products were found to contain a highly toxic derivative of the substance called fenfluramine – banned both in UK and China.

Li Da Dai Dai Hua 丽达代代花

Slimming Aids, contains sibutramine, a prescription only medicine..

Mei Zi Tang 美姿堂

Slimming Aids, contains sibutramine.

Jia Yi Jian 加伊健

The product was manufactured by HUNAN AIMIN Pharmaceutical Ltd, contains dangerously high levels of Tadalafil and Sibutramine.

3) Adverse-effects

Shou Wu Pian 首乌片, Shou Wu Wan 首乌丸, Shen Min 神民

Up to 30 March 2006, seven reports of suspected adverse reactions associated with He Shou Wu, *Polygonum multiflorum* have been reported to the MHRA through the Yellow Card Scheme. All seven reports are of liver reactions and comprise one report of abnormal liver function, seven reports of jaundice, two reports hepatitis and one report of jaundice and hepatitis. The patients were taking He Shou Wu *Polygonum multiflorum* for hair loss. All the patients had recovered or were recovering after stopping He shou Wu *Polygonum multiflorum*.

H. Toxic herbs according to Chinese Pharmacopoeia

The herbs listed below are commonly used in the UK. They are legally available from the wholesale market and in TCM clinics. However, the Chinese pharmacopoeia states that they are "toxic" or "slightly toxic". Although there have not been any reports of incidences caused by the toxicity or side-effects of these herbs, caution should

be given when using them in our practice. Generally speaking, a dose of these herbs within 10 grams (within 3 grams for Wu Zhu Yu) per day in decoction for adults, with no longer than 3-4 weeks of administration, should be safe.

半夏 Ban Xia Rhizoma Pinelliae
苍耳子 Cang Er Zi Fructus Xanthii
重楼 Chong Lou Rhizoma Paridis
川楝子 Chuan Lian Zi Fructus Meliae tosendan
苦杏仁 Ku Xing Ren Semen Armemiaceae Amarum
山豆根 Shan Dou Gen Radix Sophorae tonkinensis
蛇床子 She Chuang Zi Fructus Cnidii
吴茱萸 Wu Zhu Yu Fructus Evodiae
仙茅 Xian Mao Rhizoma Curculiginis

Conclusion

Of course, as long as the current lack of statutory regulation and recognition for herbal medicine and TCM practice exists, the list of restricted and troublesome or controversial TCM products will keep growing. In fact, the MHRA receives complaints against TCM products from healthcare professionals and the general public every month. It is quite likely the officers from the MHRA come to inspect your clinic or practice at any time. To avoid unwanted uncertainty and concerns over safety, it is advisable that practitioner members should obtain herbal medicines and products from reputable

suppliers. Simply because those suppliers may already have a normal communication channel with MHRA and comply with the legal requirements when they import their products. ATCM has joined RCHM's scheme of herbal medicine suppliers approval and the list of approved suppliers is already published to the members of both organisations. For those herbal products claiming to have an almost instant effect such as "Herbal Viagra", or "100% Natural Slimming Tea", you must be aware that these may contain some undeclared or illegal ingredients. Besides, it is also advisable for member to keep orders, receipts and invoices of your herbal medicines as the proof id source, because this may be useful for any future inspection.

References:

- (1) B. Calman. Inside the Chinese medicine minefield <http://www.dailymail.co.uk/health/article-453398/Insidechinese-medicine-minefield.html>
- (2) Hashimoto K, et al., Quantitative analysis of aristolochic acids, toxic compounds, contained in some medicinal plants, *Journal of Ethnopharmacology* 1999; 64(2): 185-189.
- (3) Traditional Chinese medicine containing mercury: Fufang Lu Hui Jiaonang www.mhra.gov.un/publication

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