



## REGISTER OF CHINESE HERBAL MEDICINE

### RESTRICTED SUBSTANCES LIST – April 2019

*All previous versions should be destroyed or marked obsolete*

**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**

BAO GU (Os Leopardis)  
CHUAN SHAN JIA (Squama Mantis Pentadactylae)  
DAI MAO (Carapax Ertmochelydis)  
HU GU (Os tigris)  
MU XIANG (Saussurea lappa) NOTE: Vladimira species are permitted as substitute herb.  
SHE XIANG (Secreto Moschus)  
XI JIAO (Cornu Rhinoceri)  
XIONG DAN (Vesica Fellea Ursi)

#### **APPENDIX II**

BAI JI (Bletilla striata)  
GOU JI (Cibotium barometz)  
GUI BAN (Chinemys reevesii)  
HOU ZAO (Calculus Macacae)  
HU HUANG LIAN (Picrorrhiza kurroa)  
LING YANG JIAO (Cornu Antelopis)  
LU HUI (Aloe ferox)  
ROU CONG RONG (Cistanches deserticola)  
SHI HU (Dendrobium species)  
TIAN MA (Gastrodia elata)  
XI YANG SHEN (Panax quinquefolius) NOTE: Only applies to the whole and sliced root.  
XIAO YE LIAN (Podophyllum emodii)

## **B: RESTRICTIONS UNDER STATUTORY INSTRUMENTS:**

### **SI 2130 1997 – NB this has now become schedule 20, under regulation 241 of the Human Medicines Regulations 2012 No.1916 (14<sup>th</sup> August 2012)**

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

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

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

BING LANG (Areca catechu) Pharmacy use only

DA FU PI (Areca catechu) Pharmacy use only

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

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

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

TIAN XIAN ZI (Hyocyanus niger). MDD: 300 mg. MD: 100 mg.

NOTE: SI 2130 also applies to other herbs not employed in Chinese medicine.

### **SI 1841 2002**

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 is banned:

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

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

MA DOU LING (Aristolochia contorta, Aristolochia debilis)

TIAN XIAN TENG (Aristolochia contorta, Aristolochia debilis)

QING MU XIANG (Aristolochia debilis)

### **SI 548 2008**

All species of Senecio are prohibited for internal use due to the presence of toxic pyrrolizidine alkaloids (PA). This mainly applies to the use of Senecio scandens QIAN LI GUANG

## C: RCHM VOLUNTARY RESTRICTIONS AND CAUTIONS:

### **i) Continued restriction on herbs containing pyrrolizidine alkaloids (PAs)**

In February 2016 all RCHM members were notified that the RCHM and other professional associations within the EHTPA had learnt of concerns of the Food Standards Agency (FSA) and the Medicines and Healthcare Products Regulatory Agency (MHRA) about PA contamination/intake. In view of the strong opinion from an EHTPA commissioned panel of internationally known experts that PA containing herbs should not be prescribed internally by herbal practitioners and the increasing scientific data showing long term risks of developing cancer and veno-occlusive disease from PA intake, the RCHM and all other Professional Associations that comprise the EHTPA, have concluded that **for now** we should advise members not to prescribe any PA bearing herbs internally.

The EHTPA, continues to monitor research on the toxicity of PA generating herbs. There is no evidence to cause the Association to change its current advice: prescriptions containing PA-generating herbs should not be issued under any circumstances for internal use; preparations containing PA-generating herbs can be used externally for a maximum of three weeks. The long-awaited Food Standards Agency review of PAs in food law is apparently imminent but will support recommendations made in 2017 by the MHRA in accordance with European Medicines Agency (EMA) and European Food Standards Agency enforced limits. The EMA has kept current maximum limits for exposure to *PA contaminants* at the same level (1 mcg/day) for another two years (due to issues with ability of herbal product manufacturers to meet the reduced, recommended limits).

**Here is the list of the herbs that are in current use by various traditions in the UK so that it is clear that you know to which plants we are referring. These herbs may, if appropriate, still be used externally, clearly labelled 'for external use only' for a maximum of three weeks.**

### **PA-generating herbs – BHMA-EHTPA working list 12<sup>th</sup> April 2019**

*Adenostyles alliarae* (alpendost)

*Alkanna tinctoria* [alkanet]

*Anchusa officinalis* *A. italica* [alkanet]

*Arnebia euchromia*, *A. guttata* [ruan zi cao, huang hua ruan zi cao] **Can be used externally for a maximum of 3 weeks**

*Borago officinalis* [borage]

*Chromolaena odorata* [ropani]

*Cordia dichotoma*, *C. rothii* [shleshmaataka]

*Crotolaria spp* [shana]

*Cynoglossum officinale et spp* [e.g. houndstongue]

*Echium plantagineum*, *E. vulgare* [e.g. viper's bugloss]

*Emilia sonchifolia* [zi bei cao]

***Eupatorium cannabinum*, *E. fortunei*, *E. japonicum*, *E. triplinerve* [hemp agrimony, pei lan, ayapana]**

*Gynura spp* [jian feng wei]

*Heliotropium spp* [shash]

*Ligularia fischeri* [gomchwi]

***Lithospermum erythrorhizon et spp* [zi cao – also *Arnebia euchromia*] **Can be used externally for a maximum of 3 weeks****

*Lolium temulentum* [mochani]

*Mikania cordata et spp* (guaco)

*Myosotis scorpioides* [forget-me-not]

*Onosma spp*

*Packera aurea* (*syn Senecio aureus*) [golden groundsel]

*Petasites hybridus* [butterbur]  
*Pulmonaria officinalis* [lungwort]  
*Senecio spp* [ragworts – quian li guang]  
*Symphytum spp* [comfrey root and leaf] Can be used externally for a maximum of 3 weeks  
*Tussilago farfara* [coltsfoot, kuan dong hua] Can be used externally for a maximum of 3 weeks  
*Trichodesma spp* [adhapuspi]

#### ii) LEI GONG TENG (*Tripterygium wilfordii*)

RCHM members **must not** use Lei Gong Teng unless they are appropriately qualified, i.e. have been specifically trained in its use by an experienced practitioner. This is because it can suppress white blood cell formation, disrupt the menstrual cycle, may be teratogenic and can significantly affect sperm count in males. If you are uncertain about whether your training is adequate please contact the RCHM for clarification.

In the event of a complaint or an insurance claim against an RCHM member which involves his or her prescribing of Lei Gong Teng, the RCHM will not support that member if he or she has not been specifically trained in its use and has not used it with the appropriate care.

#### iii) XI XIN (Asarum species)

Due the presence of Aristolochic Acid in Asarum species the RCHM has issued a voluntary ban on the use of Xi Xin

**iv) BAI YING (*Solanum lyatrum*):** If you intend to use this herb, you must contact the RCHM to ensure that you have sufficient training in identification of the correct herb from potential substitution.

#### D: RESTRICTIONS UNDER THE 1968 MEDICINES ACT

Under Section 12(1) of the 1968 Medicines Act, (which now forms Paragraphs (2), (6) and (9) of Regulation 3 of the Human Medicines Regulation 2012 No.1916 (14<sup>th</sup> August 2012), ‘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 and the RCHM is working to re-establish the use of animal and mineral products. It is also 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.

**In the meantime, members are warned that the use of these products may result in legal action by the MHRA and absence of insurance cover in the case of a claim. Hence all animal and mineral products should not be used until otherwise informed by the RCHM.**

Whatever the outcome of this process, the following must never be used in any form:

ZHU SHA (Mercuric sulphide) Cinnabar  
QING FEN (Mercuric chloride) Calomel  
HONG FEN (Mercuric oxide) Realgar

HEI XI Lead

### **PRESCRIPTION ONLY MEDICINES (POM)**

It is strictly prohibited to include any drug which is made available only through prescription by a registered medical doctor.

This includes the following:

YING SU KE (Papaver somnifera)

MA QIAN ZI (Strychnos nux vomica)

STEROIDS Including external use in creams such as PI YAN PING or 999 SKIN CREAMS. FU ZI Internal use

### **E: CLARIFICATION ON PATENT FORMULAE (i.e. manufactured unlicensed herbal medicines)**

The Medicines Act 1968 is no longer in use (except for some minor sections) and the THMPD has been transposed into UK legislation, and now forms Part 7 of the Human Medicines Regulations 2012.

This European Traditional Herbal Medicinal Products Directive (THMPD) 2004/24/EC came into effect on 30 April 2011. The Directive established a regulatory approval process for herbal medicines in the European Union (EU). It required each EU Member State to set up a traditional herbal registration scheme for manufactured traditional herbal medicines that are suitable for use without medical supervision. **Companies are no longer able to sell manufactured unlicensed herbal medicines (patents) unless they have an appropriate product licence, either:**

a full **marketing authorisation (MA)** based on the safety, quality and efficacy of the product, as with any regular medicine, or a **traditional herbal registration (THR)** based on the safety, quality and **evidence of traditional use** of the product.

Any medicine that is not licensed by the Medicines and Healthcare Products Regulatory Agency (MHRA) is known as an unlicensed medicine. The vast majority of herbal medicines are unlicensed.

### **Buying patents over the internet**

The same restrictions apply to medicine bought online. Patent medicines without a full license or a THR are no longer legal for use.

### **F: ANIMAL AND MINERAL PRODUCTS**

According to the Human Medicines Regulations 2012 No.1916 (14<sup>th</sup> August 2012), the definition of a herb substance means *'a plant or part of plant, algae, fungi or lichen, or an unprocessed exudate of a plant, defined by the plant part used and the botanical name of the plant, either fresh or dried, but otherwise unprocessed'*

The legal interpretation is that animal and mineral products are not, **and have never been considered as herbs under UK medicines law**. For these reasons, these RCHM has no legal argument for their medicinal use until such time as they can be included in a new definition of a herbal substance. An attempt to use them as foods, will impose other regulation as applied to foods.

## **G: SUPPLIERS**

We have sought advice from insurance providers regarding the responsibility to ensure a safe herbal product in the event of an adverse reaction. Their reply was that members must ensure that they have used a 'bone fide' supplier. This is open to interpretation, but ordering on the internet direct from China will not be considered safe practice. In order to protect members, the RCHM operates an audited Approved Suppliers Scheme. Details of suppliers can be obtained from the RCHM. A parallel scheme is also being developed by the British Herbal Manufacturing Association (BHMA) for western herbal suppliers. You are strongly advised to use suppliers on these lists or ensure that you are satisfied with your own auditing system if the need should arise.

**For more information on UK herbal medicines law please refer to the document "The Human Medicines Regulations 2012 No.1916 (14 August 2012) - Summary of the Regulations relevant to herbal practitioners" which has been issued to all RCHM members and is available to view on the members area of the RCHM's website at [www.rchm.co.uk/members](http://www.rchm.co.uk/members)**

### **Version control**

**This document was created on April 12<sup>th</sup> 2019. All previous versions should be destroyed or marked obsolete. Additions or edits to previous document dated January 23<sup>rd</sup> 2017:**

- a) Chuan shan jia moved to appendix 1**
- b) Clarification that PA generating herbs listed in section (C) that are permitted for external use should not be used externally for more than 3 weeks.**
- c) New section (F) clarifying use of animal and mineral products**