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THE GOVERNMENT OF THE HONG KONG
SPECIAL ADMINISTRATIVE REGION
DEPARTMENT OF HEALTH
CHINESE MEDICINE DIVISION
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本署檔號 OUR REF. (146/04) in DH/TCMD/1-60/17 Pt. 2
來函檔號 YOUR REF.
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11 June 2004

Dear Chinese medicines traders,

Management of Aristolochic Acid (AA) Containing Herbs and Products

On 24 April 2004, Department of Health informed all Chinese medicines traders in writing that, following discussion with the Chinese Medicines Board (CMB) of Chinese Medicine Council of Hong Kong, it was decided that Chinese herbs of the *Aristolochia* Linn. (馬兜鈴屬) shall be prohibited from importation and sale, and that Chinese herbs of the *Asarum* Linn. (細辛屬) shall be temporarily suspended from use with effect from 1 June 2004. The lists of the relevant Chinese herbs were announced and issued to all Chinese medicines traders together with the notification on 24 April 2004. On the other hand, the CMB decided that AA-containing proprietary Chinese medicines (pCms) should be prohibited from sale, and AA-containing pCms will not be registered.

In collaboration with Government Laboratory and Hong Kong Baptist University, Department of Health had conducted tests on certain Chinese herbs and pCms, using AA as the target. With regard to the research and test results, the CMB has reviewed the relevant regulatory measures, and decided that the ban on the importation and sale of the designated Chinese herbs of the *Aristolochiaceae* shall be imposed on 1 June 2004, according to the original timetable. For the names of the relevant Chinese herbs, please refer to the "List of Herbal Medicines Prohibited from Importation and Sale" (Appendix 1). As for Chinese herbs of the *Asarum* Linn., the CMB decided that they might be used under suitable circumstances. To assist the Chinese medicine trade in

handling the relevant herbs, the CMB has drawn up detailed guidelines for their management. Please refer to the “Guidelines on AA-containing Herbs and Products” (Appendix 2). Department of Health shall conduct briefing sessions for the Chinese medicine trade in due course.

Department of Health informed all Chinese medicines traders on 13 March 2004 that the Chinese herb Herba Solani Lyrati (白英) was suspended from use. Due to the fact that the confusion in the market has now been rectified, it has been decided that Herba Solani Lyrati should be allowed to be sold again with effect from 14 June 2004. To assist the Chinese medicine trade in understanding and distinguishing Herba Solani Lyrati better, a fact sheet on how to distinguish Herba Solani Lyrati and Herba Aristolochiae Mollissimae (尋骨風) is attached (Appendix 3) for your reference.

If you have any enquiry, please telephone the Chinese Medicines Section of Department of Health at 23195119.

Yours Sincerely,



(Dr. Constance Chan)
for Director of Health

禁止進口及銷售的藥材名單(由 2004 年 6 月 1 日起生效)
List of Herbal Medicines Prohibited from Importation and Sale
(Effective from 1st June 2004)

Item 項目	Name of Herbal Medicines 藥材名	Name of Species 品種名稱	Medicinal Part 藥用部位	Scientific Name 學名
1.	大葉青木香	川南馬兜鈴	塊根 Tuber	<i>Aristolochia austroszechuanica</i> Chien et C. Y. Cheng
2.	滇南馬兜鈴	滇南馬兜鈴	根 Root	<i>Aristolochia austroyunnanensis</i> S. M. Hwang
3.	南木香	青香藤	根、根莖、藤 Root, Rhizome, Stem	<i>Aristolochia calcicola</i> C. Y. Wu
4.	管南香	管蘭香	塊根 Tuber	<i>Aristolochia cathcartii</i> Hook. f.
5.	三筒管	長葉馬兜鈴	塊根 Tuber	<i>Aristolochia championii</i> Merr. et Chun [<i>A. longifolia</i> Champ. ex Benth.]
6.	苞葉馬兜鈴	苞葉包兜鈴	根 Root	<i>Aristolochia chlamydophylla</i> C. Y. Wu ex S. M. Hwang
7.	朱砂蓮	四川朱砂蓮	塊根 Tuber	<i>Aristolochia cinnabarina</i> C. Y. Cheng et J. L. Wu
8.	馬兜鈴	北馬兜鈴	果實 Fruit	<i>Aristolochia contorta</i> Bunge
9.		馬兜鈴	果實 Fruit	<i>Aristolochia debilis</i> Sieb. et Zucc.
10.	天仙藤	北馬兜鈴	莖葉 Stem and Leave	<i>Aristolochia contorta</i> Bunge
11.		馬兜鈴	莖葉 Stem and Leave	<i>Aristolochia debilis</i> Sieb. et Zucc.
12.	青木香	北馬兜鈴	根 Root	<i>Aristolochia contorta</i> Bunge
13.		馬兜鈴	根 Root	<i>Aristolochia debilis</i> Sieb. et Zucc.
14.	葫蘆葉馬兜鈴	葫蘆葉馬兜鈴	根 Root	<i>Aristolochia cucurbitoides</i> C. F. Liang
15.	廣防己	廣防己	根 Root	<i>Aristolochia fangchi</i> Y. C. Wu ex L. D. Chow et S. M. Hwang [<i>Aristolochia westlandii</i> auct. non Hemsl.]
16.	通城虎	通城虎	根、全草 Root, Whole Plant	<i>Aristolochia fordiana</i> Hemsl.
17.	海南馬兜鈴	海南馬兜鈴	葉、根 Leaf, Root	<i>Aristolochia hainanensis</i> Merr.
18.	漢中防己	異葉馬兜鈴	根 Root	<i>Aristolochia heterophylla</i> Hemsl. [<i>A. kaempferi</i> Willd. f. <i>heterophylla</i> (Hemsl.) S. M. Hwang]
19.	藤香	窄葉馬兜鈴	根莖及根	<i>Aristolochia heterophylla</i> Hemsl. var. <i>linearifolia</i>

			Rhizoma and Root	S. M. Hwang
20.	南粵馬兜鈴	南粵馬兜鈴	塊根 Tuber	<i>Aristolochia howii</i> Merr. et Chun
21.	凹脉馬兜鈴	凹脉馬兜鈴	全株 Whole Plant	<i>Aristolochia impresinervis</i> C. F. Liang
22.	淮通	大葉馬兜鈴	根、莖、果實 Root, Stem, Fruit	<i>Aristolochia kaempferi</i> Willd. [<i>A. mollis</i> Dunn; <i>A. shimadai</i> Hayata]
23.	背蛇生	川西馬兜鈴	根、藤 Root, Stem	<i>Aristolochia kaempferi</i> Willd. f. <i>thibetica</i> (Franch.) S. M. Hwang [<i>A. feddei</i> Levl.]
24.	管南香	廣西馬兜鈴	塊根 Tuber	<i>Aristolochia kwangsiensis</i> Chun et How ex C. F. Liang
25.	關木通	木通馬兜鈴	藤莖 Stem	<i>Aristolochia manshuriensis</i> Kom. [<i>Hocquartia manshuriensis</i> (Kom.) Nakai]
26.	尋骨風	尋骨風	根、全草 Root, Whole Plant	<i>Aristolochia mollissima</i> Hance
27.	淮通	寶興馬兜鈴	根、藤 Root, Stem	<i>Aristolochia moupinensis</i> Franch.
28.	革葉馬兜鈴	革葉馬兜鈴	塊根 Tuber	<i>Aristolochia scytophylla</i> S. M. Hwang et D. Y. Chen
29.	假大薯	耳葉馬兜鈴	根 Root	<i>Aristolochia tagala</i> Champ.
30.	蝴蝶暗消	粉質花馬兜鈴	根 Root	<i>Aristolochia transsecta</i> (Chatt.) C. Y. Wu [<i>Isotrema transsecta</i> Chatt.]
31.	白朱砂蓮	廣西朱砂蓮	塊根 Tuber	<i>Aristolochia tuberosa</i> C. F. Liang et S. M. Hwang [<i>Aristolochia kaempferi</i> auct. non Willd.]
32.	逼血雷	管花馬兜鈴	根、果實 Root, Fruit	<i>Aristolochia tubiflora</i> Dunn [<i>Aristolochia gentilis</i> auct. non Franch.]
33.	白金果欖	變色馬兜鈴	塊根 Tuber	<i>Aristolochia versicolor</i> S. M. Hwang [<i>A. westlandii</i> auct. non Hemsl.]
34.	小南木香	雲南馬兜鈴	根、藤 Root, Stem	<i>Aristolochia yunnanensis</i> Franch. [<i>Aristolochia westlandii</i> auct. non Hemsl. ; <i>Aristolochia kaempferi</i> auct. non Willd.]
35.	細辛	北細辛	全草(根部除外) Whole Plant (Except the root)	<i>Asarum heterotropoides</i> Fr. Schmidt var. <i>mandshuricum</i> (Maxim.) Kitag.
36.		細辛 (華細辛)	全草(根部除外) Whole Plant (Except the root)	<i>Asarum sieboldii</i> Miq.
37.		漢城細辛	全草(根部除外) Whole Plant (Except the root)	<i>Asarum sieboldii</i> Miq. f. <i>seoulense</i> (Nakai) C.Y. Cheng et C.S. Yang [<i>Asiasarum heterotropoides</i> Fr. Schmidt var. <i>seoulense</i> (Nakai) Maekawa]

備註： (1) 細辛屬中藥材除細辛根外將繼續暫時停用，中藥組在適當時候會因應科學檢驗結果，檢討有關措施。(2) 上列名單可從香港中醫藥管理委員會網頁下載 (網址: www.cmchk.org.hk)

Remark: (1) Other than the root of *Herba Asari*, Chinese herbs of *Asarum* Linn shall continue to be suspended from use. The Chinese Medicines Board shall review the measure at appropriate time, having regard to the result of scientific tests. (2) The above list can be downloaded from the homepage of the Chinese Medicine Council of Hong Kong (Website: www.cmchk.org.hk)

**“Guidelines on Aristolochic Acid (AA)
containing Herbs and Products”**

I Guidelines on Aristolochic Acid containing herbs

- 1 The AA-containing Chinese herbs at Appendix 1 shall be prohibited from importation and sale, and they include *Aristolochia manshuriensis* Kom. [*Hocquartia manshuriensis* (Kom.) Nakai] (關木通), *Aristolochia contorta* Bunge and *Aristolochia debilis* Sieb. et Zucc. (青木香), *Aristolochia contorta* Bunge and *Aristolochia debilis* Sieb. et Zucc. (馬兜鈴), *Aristolochia mollissima* Hance (尋骨風), *Aristolochia fangchi* Y. C. Wu ex L. D. Chow et S. M. Hwang [*Aristolochia westlandii* auct. non Hemsl.] (廣防己) of the *Aristolochia* Linn (馬兜鈴屬), and whole part (except the root) of *Asarum heterotropoides* Fr. var. *mandshuricum* (maxim.) Kitag., (北細辛), *Asarum sieboldii* Miq. *seoulense* Nakai (漢城細辛), and *Asarum sieboldii* Miq. (華細辛) of the *Asarum* Linn. (細辛屬). For details of the names of the Chinese herbs, please refer to the “List of Herbal Medicines Prohibited from Importation and Sale” at Appendix 1.
- 2 Only the roots of *Asarum heterotropoides* Fr. var. *mandshuricum* (maxim.) Kitag., *Asarum sieboldii* Miq. *seoulense* Nakai, *Asarum sieboldii* Miq. may be used for medicinal purpose. The daily dosage of an adult should not exceed 1 qian (錢) or 3 grams. They should be decocted with water for not less than 60 minutes for feeding, and never be ground into powder for oral administration. The species for medicinal use must be the botanical species of *Asarum heterotropoides* Fr. var. *mandshuricum* (maxim.) Kitag., *Asarum sieboldii* Miq. *seoulense* Nakai, *Asarum sieboldii* Miq. of the *Aristolochiaceae* (馬兜鈴科) as stipulated in Chinese Medicine Ordinance (Laws of Hong Kong Cap. 549) (the Ordinance). Wholesalers of Chinese herbal medicines should purchase such herbs from licensed manufacturers of processed herbal medicines.
- 3 The Chinese herbs of *Asarum heterotropoides* Fr. var. *mandshuricum* (maxim.) Kitag., *Asarum sieboldii* Miq. *seoulense* Nakai, *Asarum sieboldii* Miq. should be used in accordance with the guidance of Chinese medicine practitioners. Retailers of Chinese herbal medicine should purchase such Chinese herbs from licensed wholesalers of Chinese herbal medicines, and dispense the herbs in accordance with the prescriptions of Chinese medicine practitioners.

II. Guidelines on proprietary Chinese medicines composing Chinese herbs containing Aristolochic Acid

1. Importation and sale of all AA-containing pCms must be discontinued. The Chinese Medicines Board (CMB) will not approve application for pCm registration for such medicines. As a result, applicants for pCm registration should ensure that their pCms which are going to apply for registration shall not contain AA.
2. The AA-containing herbs at Appendix 1 shall be prohibited from use as raw materials of pCms. Please refer to the “List of Herbal Medicines Prohibited from Importation and Sale” at Appendix 1 for the details of the names of the relevant Chinese herbs. All pCms indicating the use of Chinese herbs of the *Aristolochia* Linn as ingredients shall be prohibited from importation and sale, and the CMB will not accept application for pCm registration related to such medicines.
3. As for pCms containing Chinese herbs of the *Asarum* Linn, they may continue to be imported or sold provided that the relevant test results do not indicate the presence of AA. The CMB has decided that, when applying for registration, such medicines shall have to formulate detection method, and to include a parameter of “Aristolochic Acid I not detected” in the finished products’ specification. Moreover, the applicants are required to submit test report showing the absence of AA in the test results. As regards the test laboratories, they should fulfill the current standards imposed by the CMB for laboratories conducting quality tests, i.e. ISO/IEC 17025 or GLP, or equivalent, and 15 laboratories in the Mainland recognized by the CMB. For the methodology in testing AA, the laboratories may make reference to the methods adopted by the US Food and Drug Administration, Health Canada, and the Pharmacopoeia of Japan (14th edition). The detection limit for the test should be 0.5µg/g (using the sample as basis).
4. For the manufacturing techniques, the manufacturers should use botanical species of *Asarum heterotropoides* Fr. var. *mandshuricum* (maxim.) Kitag., *Asarum sieboldii* Miq. *seoulense* Nakai, *Asarum sieboldii* Miq. of the *Aristolochiaceae* as stipulated in the Ordinance, and use the root for producing the medicine. Besides, in using *Asari* as raw materials, the manufacturers should use water as extraction solvent, and avoid using organic solvent such as ethanol as extraction solvent. It is also not appropriate to grind the relevant herbs into powder in making medicines.

III. Guidelines on the Chinese herb Herba Solani Lyrati (白英)

1. In using Herba Solani Lyrati (plant of the Solanaceae (茄科)), confusion with Herba Aristolochiae Mollissimae (尋骨風) (plant of the Aristolochiaceae) must be avoided, and there must be a label showing Herba Solani Lyrati (plant of the Solanaceae). To assist Chinese medicines traders in understanding and distinguishing Herba Solani Lyrati better, a fact sheet on how to distinguish Herba Solani Lyrati and Herba Aristolochiae Mollissimae is attached (Annex 3) for reference.

Department of Health

11 June 2004

The Important Points for the Authentication of *Herba Solani Lyrati* and *Herba Aristolochiae Mollissimae*

Herba Solani Lyrati



Any or whole part of *Solanum lyratum* Thunb. [*S. dulcamara* L. var. *lyratum* (Thunb.) Sieb. et Zucc.] (Fam. Solanaceae)

To remove damp-heat;
To remove toxic materials and promote the subsidence of swelling.

Source

Any or whole part of *Aristolochia mollissima* Hance (Fam. Aristolochiaceae)

Action

To relieve rheumatic condition;
to promote blood circulation and remove obstruction of collaterals;
and
to alleviate pain.

Herba Aristolochiae Mollissimae



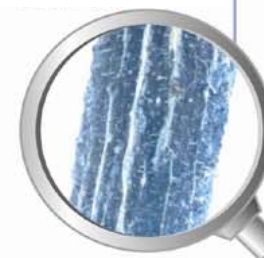
The Important Points for the Authentication of *Herba Solani Lyrati* and *Herba Aristolochiae Mollissimae*

Characteristic features

Herba Solani Lyrati



Examined under the magnifier



Yellowish green to brownish green stem covered with grayish white pubescent. No or rare pubescent on coarse part of stem.

Leaves dark green, usually broken, pinnate.

Herba Aristolochiae Mollissimae



Examined under the magnifier



Pale green stem covered with densely pubescent.



Leaves grayish green, oval-cordate, usually unbroken, palmate.

