2003 年第 227 號法律公告

《〈中醫藥條例〉(第 549 章) 2003 年 (生效日期) (第 2 號) 公告》

現根據《中醫藥條例》第 1(2) 條，指定 2003 年 12 月 19 日為該條例第 120 至 128、130、162、163、167 及 175 條開始實施的日期。

衞生福利及食物局局長
楊永強

2003 年 10 月 17 日

L.N. 227 of 2003

CHINESE MEDICINE ORDINANCE (CAP. 549) (COMMENCEMENT) (NO. 2) NOTICE 2003

Under section 1(2) of the Chinese Medicine Ordinance, I appoint 19 December 2003 as the day on which sections 120 to 128, 130, 162, 163, 167 and 175 of the Ordinance shall come into operation.

Dr. E. K. YEOH
Secretary for Health, Welfare and Food

17 October 2003

(4) 為施行第 (1) 款而就任何中成藥而言，除非該中成藥的詳情與註冊中成藥的註冊詳情相同，否則不得被視為已根據第 121 條註冊。

120. 中成藥的註冊申請須由製造商、進口商等提出

中成藥的註冊申請——

(*a*) 在該中成藥是在香港製造的情況下，須由有關製造商提出申請；

(*b*) 在該中成藥是在香港以外地方製造的情況下，須在其進口香港之前——

(i) 由有關進口商提出申請；或

(ii) 由有關製造商的本地代表或代理提出申請。

121. 中成藥的註冊

(1) 中成藥的註冊申請須向中藥組提出，並須——

(*a*) 採用中藥組所決定的格式並附有中藥組所決定的文件、資料、樣品及其他物料；

(*b*) 按照訂明的規定提供須註冊的中成藥的詳情；及

(*c*) 附有訂明的申請費。

(2) 在符合第 122 條的規定下，中藥組可批准該申請，並在訂明的發證費繳付後，將該中成藥註冊並向申請人就該中成藥發出一份採用由中藥組決定的格式的註冊證明書。

(3) 在有註冊證明書發出的情況下，中藥組可施加其認為適合的條件，並可在其覺得該等條件應予修訂、更改或撤銷時，修訂、更改或撤銷該等條件。

(4) 中藥組在考慮本條例的條文後，如認為為公眾利益而有此需要，則可拒絕根據第 (1) 款提出的註冊申請，並隨即將拒絕的理由以書面通知申請人。

(4) For the purpose of subsection (1), a proprietary Chinese medicine shall not be taken as registered under section 121 unless its particulars are identical with the registered particulars of the registered proprietary Chinese medicine.

120. Application for registration of proprietary Chinese medicines to be made by manufacturers, importers, etc.

An application for the registration of a proprietary Chinese medicine shall be made—

(*a*) in the case of its being manufactured in Hong Kong, by the manufacturer;

(*b*) in the case of its being manufactured outside Hong Kong—

(i) by the importer; or

(ii) by the local representative or agent of the manufacturer,

prior to its being imported into Hong Kong.

121. Registration of proprietary Chinese medicines

(1) An application for the registration of a proprietary Chinese medicine shall be made to the Medicines Board and shall—

(*a*) be in such form and accompanied by such documents, information, samples and other materials as the Medicines Board may determine;

(*b*) furnish the particulars of the proprietary Chinese medicine required to be registered in accordance with the prescribed requirements; and

(*c*) be accompanied by a prescribed application fee.

(2) Subject to section 122, the Medicines Board may approve the application and upon payment of a prescribed issue fee, register the proprietary Chinese medicine and issue a certificate of registration to the applicant in respect of the proprietary Chinese medicine in such form as it may determine.

(3) Subject to the certificate of registration being issued, the Medicines Board may impose such conditions as it thinks fit and may amend, vary or revoke the conditions if it appears to the Medicines Board that the conditions should be amended, varied or revoked.

(4) If, having regard to the provisions of the Ordinance, the Medicines Board considers it necessary in the public interest to do so, it may refuse an application for registration made under subsection (1) and thereupon notify the applicant in writing of the reasons for refusal.

122. 與註冊申請的決定有關的因素

(1) 中藥組在決定中成藥的註冊申請時，尤須——

(*a*) 考慮該申請所關乎的中成藥的安全；

(*b*) 按照該中成藥的規格說明及其製造方法或建議的製造方法，考慮該藥的品質，以及為確保所銷售或供應的藥具有該品質而建議的條文；及

(*c*) 考慮在施用該中成藥所擬達致的目的方面該藥的成效。

(2) 中藥組在考慮任何申請所關乎的中成藥就任何個別目的之成效時，對於另一款中成藥就該目的是否會或可能會具有同等成效或更具成效的問題無須理會。

(3) 為施行第 (1) 款，第 (2) 款不得解釋為規定中藥組在就施用某一款的中成藥所擬達致的目的而考慮該藥的安全時，無須理會屬另一款而就該目的具有同等成效或更具成效的中成藥就該目的是否會或可能會更安全的問題。

(4) 在決定關乎將進口的中成藥的申請時，中藥組——

(*a*) 亦尤須考慮製造該藥的方法、標準及條件；及

(*b*) 如認為適合，可規定申請人提交下述任何一項或下述各項的任何組合——

(i) 由該中成藥的製造商提交承諾書，承諾准許由中藥組或其代表視察製造或將製造該藥的處所，及在製造該藥的過程中所進行或將進行的作業；

(ii) 由該中成藥的製造商提交承諾書，承諾遵從中藥組所施加的任何條件；

122. Factors relevant to determination of application for registration

(1) In determining an application for registration of a proprietary Chinese medicine, the Medicines Board shall in particular take into consideration—

(*a*) the safety of the proprietary Chinese medicine to which the application relates;

(*b*) the quality of the proprietary Chinese medicine according to the specification and the method or proposed method of manufacture of the medicine, and the provisions proposed for securing that medicine as sold or supplied will be of that quality; and

(*c*) the efficacy of the proprietary Chinese medicine for the purposes for which the medicine is proposed to be administered.

(2) In taking into consideration the efficacy for a particular purpose of a proprietary Chinese medicine to which an application relates, the Medicines Board shall disregard any question whether a proprietary Chinese medicine of another description would or might be equally or more efficacious for that purpose.

(3) For the purpose of subsection (1), nothing in subsection (2) shall be construed as requiring the Medicines Board, in considering the safety of a proprietary Chinese medicine of a particular description, in relation to a purpose for which it is proposed to be administered, to disregard any question whether a proprietary Chinese medicine of another description, being equally or more efficacious for that purpose, would or might be safer in relation to that purpose.

(4) In determining an application relating to a proprietary Chinese medicine which is to be imported, the Medicines Board—

(*a*) shall also take into consideration in particular the methods, standards and conditions of manufacture of the medicine; and

(*b*) may, if it thinks fit, require the production by the applicant of any one or a combination of the following—

(i) an undertaking, given by the manufacturer of the proprietary Chinese medicine, to permit the premises where it is or is to be manufactured, and the operations carried on or to be carried on in the course of manufacturing it, to be inspected by or on behalf of the Medicines Board;

(ii) an undertaking, given by the manufacturer of the proprietary Chinese medicine, to comply with any conditions as imposed by the Medicines Board;

(iii) 由該中成藥的製造商或其代表提交聲明書，聲明就該中成藥的製造而言，由或根據製造或將製造該藥的所在地方的法律施加的任何規定，已獲遵從或將獲遵從。

123. 註冊的有效期及續期

(1) 根據第 121 條作出的中成藥註冊，有效期為所訂明的期間。

(2) 註冊證明書的持有人可向中藥組申請註冊續期。

(3) 中藥組可因應根據本條提出的續期申請——

(*a*) 在訂明費用繳付後，在修改或不修改以前曾施加的條件(如有的話)的情況下，按訂明期間或其認為適當的較短期間將註冊續期和發出一份註冊證明書；或

(*b*) 在考慮本條例的條文後，如認為為公眾利益而有此需要，則可拒絕該申請。

(4) 中藥組如根據本條拒絕任何續期申請，則須將拒絕的理由以書面通知申請人。

124. 更改註冊中成藥的註冊詳情

(1) 註冊證明書的持有人在繳付訂明費用後，可以書面向中藥組申請批准更改該證明書所關乎的中成藥的註冊詳情，但下述詳情則屬例外——

(*a*) 產品名稱；

(*b*) 劑型形式；及

(*c*) 任何有效成分的名稱及份量。

(2) 中藥組如信納建議的更改對有關的中成藥的安全、品質及成效不會有不利影響，則可批准該申請內所建議的更改。

(iii) a declaration, given by or on behalf of the manufacturer of the proprietary Chinese medicine that, in relation to the manufacture of the proprietary Chinese medicine any requirements imposed by or under the law of the place in which it is or is to be manufactured have been or will be complied with.

123. Duration and renewal of registration

(1) The registration of a proprietary Chinese medicine under section 121 shall have effect for such period as may be prescribed.

(2) The holder of a certificate of registration may apply to the Medicines Board for the renewal of registration.

(3) On an application for renewal under this section, the Medicines Board may—

(*a*) upon payment of a prescribed fee, renew the registration and issue a certificate of registration, with or without modifications to the conditions, if any, previously imposed for such period as may be prescribed or for such shorter period as it considers appropriate; or

(*b*) refuse the application, if, having regard to the provisions of the Ordinance, it considers it necessary in the public interest to do so.

(4) Where the Medicines Board refuses an application for renewal under this section, it shall notify the applicant in writing of the reasons for refusal.

124. Variation of registered particulars of registered proprietary Chinese medicines

(1) The holder of a certificate of registration may, on payment of a prescribed fee, apply in writing to the Medicines Board for approval to vary the registered particulars of the proprietary Chinese medicine to which the certificate relates except the following particulars—

(*a*) the product name;

(*b*) the dose form; and

(*c*) the name and quantity of any active ingredient.

(2) If the Medicines Board is satisfied that the proposed variation will not adversely affect the safety, quality and efficacy of the relevant proprietary Chinese medicine, it may approve the variation as proposed in the application.

(3) 中藥組須以書面通知申請人——
(a) 就更改而提出的申請是否獲得批准；及
(b) (如申請獲批准) 該更改開始生效的日期；或
(c) (如申請不獲批准) 不獲批准的理由。

(4) 在根據第 121 條註冊的任何中成藥的註冊詳情的更改開始生效時，在該更改前的該等註冊詳情所關乎的中成藥即告停止為根據該條註冊的中成藥。

(5) 如任何中成藥將憑藉第 (4) 款停止為根據第 121 條註冊的中成藥，則有關申請人須在有關的更改開始生效前，於合理可能的範圍內，收回或安排收回已供應的該中成藥。

125. 中成藥的取消註冊

(1) 中藥組如認為為公眾利益而有需要取消任何中成藥的註冊，則可取消該中成藥的註冊。

(2) 中藥組如擬取消任何中成藥的註冊，則須將其意向以書面通知註冊證明書的持有人，並邀請他以書面提交申述、資料或解釋。

(3) 儘管有第 (2) 款的規定，中藥組如認為有緊急情況存在，則可立即取消任何中成藥的註冊。

(4) 如中藥組決定取消任何中成藥的註冊，則須向註冊證明書的持有人送交取消註冊通知，並在該通知中述明取消註冊的理由。

(5) 中藥組在認為適當時，可在憲報刊登根據第 (1) 及 (3) 款被取消註冊的中成藥的列表。

126. 註冊中成藥的刊登

中藥組可在其認為適當的情況下，不時在憲報刊登註冊中成藥的列表。

(3) The Medicines Board shall advise the applicant in writing—
(a) whether the application for variation is approved; and
(b) if it is approved, the date on which the variation takes effect; or
(c) if it is disapproved, the reason for disapproval.

(4) Where the variation of the registered particulars of a proprietary Chinese medicine registered under section 121 takes effect, the proprietary Chinese medicine to which the registered particulars were related before the variation shall cease to be a proprietary Chinese medicine registered under that section.

(5) Where by virtue of subsection (4) a proprietary Chinese medicine ceases to be a proprietary Chinese medicine registered under section 121, the relevant applicant shall before the relevant variation takes effect, recall or cause to recall, to the extent reasonably possible, the proprietary Chinese medicine already supplied.

125. De-registration of proprietary Chinese medicines

(1) The Medicines Board may de-register a proprietary Chinese medicine if it considers it necessary in the public interest to do so.

(2) Where the Medicines Board intends to de-register a proprietary Chinese medicine, it shall notify the holder of the certificate of registration in writing of its intention and invite him to submit any representations, information or explanation in writing.

(3) Notwithstanding subsection (2), the Medicines Board may de-register a proprietary Chinese medicine forthwith if it considers that an emergency exists.

(4) Where the Medicines Board determines to de-register a proprietary Chinese medicine, it shall forward to the holder of the certificate of registration a notice of de-registration and shall state in such notice its reasons for de-registration.

(5) The Medicines Board may publish in the Gazette a list of all proprietary Chinese medicines de-registered under subsections (1) and (3) when it considers appropriate.

126. Publication of registered proprietary Chinese medicines

The Medicines Board may publish in the Gazette from time to time as it considers appropriate a list of registered proprietary Chinese medicines.

127. 註冊證明書的核證副本

中藥組可因應根據本部獲發出註冊證明書的持有人的申請以及在訂明費用繳付後，向該持有人發出該註冊證明書的核證副本。

128. 有關中成藥過渡性註冊的條文

(1) 如任何中成藥在 1999 年 3 月 1 日時——

(*a*) 在香港製造、銷售或為銷售而供應；或

(*b*) 在香港以外地方製造並在香港銷售或為銷售而供應，

而任何人在該日是——

(i) (如屬 (*a*) 段的情況) 該中成藥的製造商；或

(ii) (如屬 (*b*) 段的情況) 進口商或該中成藥製造商的本地代表或代理，

則該人在中藥組所決定的該中成藥註冊期限內，按照第 121 條就該中成藥的註冊向中藥組提出申請。

(2) 如有申請根據第 (1) 款提出，則該中成藥在所訂定的類別分類以及中藥組發給該人的書面通知中所施加的條件及限制的規限下，須當作已根據本款註冊，並須當作已根據第 121 條發出證明書。

(3) 在第 (7) 款規限下，該註冊繼續有效，直至——

(*a*) 根據第 121(2) 條獲發註冊證明書；或

(*b*) 該中成藥的註冊申請根據第 121(4) 條遭拒絕；或

(*c*) 局長藉在憲報刊登的公告所指明和公布的日期，

而上述各項中，以最早出現者為準。

(4) 中藥組就接獲申請而以書面作出的確認，即為根據第 (2) 款當作獲發出的證明書的充分證據。

(5) 中藥組可修訂、更改或撤銷根據第 (2) 款訂定的任何類別分類或根據第 (2) 款施加的條件或限制。

127. Certified copy of certificate of registration

The Medicines Board may, upon application and payment of a prescribed fee by the holder of a certificate of registration issued under this Part, issue a certified copy of that certificate of registration to the certificate holder.

128. Provision for transitional registration of proprietary Chinese medicines

(1) Where a proprietary Chinese medicine is, on 1 March 1999—

(*a*) manufactured, sold or supplied for sale in Hong Kong; or

(*b*) manufactured outside Hong Kong and is sold or supplied for sale in Hong Kong,

a person who is, on the same date—

(i) in the case of paragraph (*a*), the manufacturer; or

(ii) in the case of paragraph (*b*), an importer, or a local representative or agent of the manufacturer,

may apply to the Medicines Board within such period of time as may be determined by the Medicines Board for the registration of the proprietary Chinese medicine in accordance with section 121.

(2) Where an application is made under subsection (1), the proprietary Chinese medicine shall be deemed, under this subsection, to have been registered and a certificate is deemed to have been issued under section 121 subject to such classification of category, conditions and restrictions as may be imposed by the Medicines Board by notice in writing to the applicant.

(3) Subject to subsection (7), such registration shall continue in effect until—

(*a*) the issue of a certificate of registration under section 121(2); or

(*b*) the refusal of the application for registration of that proprietary Chinese medicine under section 121(4); or

(*c*) such date as may be specified and promulgated by the Secretary by notice published in the Gazette,

whichever is the earliest.

(4) Confirmation in writing by the Medicines Board of the receipt of an application shall be sufficient evidence of a certificate deemed to be issued under subsection (2).

(5) The Medicines Board may amend, vary or revoke any of the classification of category, conditions or restrictions imposed under subsection (2).

(6) 如任何人若非由於本款便會因買賣、進口或管有任何中成藥而可被檢控違反第 119 條，而該中成藥若非由於本款便會在其他情況下須予註冊，則該人不得被如此檢控，直至第 (1) 款所提述的期限屆滿，即使在該期限屆滿時並無向中藥組提出任何申請。

(7) 第 125 條及任何根據第 161 條訂立的規例就中成藥而訂明的規定，適用於根據本條當作獲註冊的中成藥。

129. 臨床證驗及藥物測試

(1) 為方便就任何中成藥進行臨床證驗或進行藥物測試，中藥組可因應申請而發出臨床證驗及藥物測試證明書。

(2) 該項申請須採用中藥組所決定的格式，並附有中藥組所決定的文件、資料、樣品及其他物料，以及訂明的申請費用。

(3) 在訂明的發出證明書費用繳付後，中藥組可發出臨床證驗及藥物測試證明書，而該證明書在中藥組認為適合的期間內以及在中藥組認為適合的條件的規限下有效。

(4) 中藥組在考慮本條例的條文後，如認為為公眾利益而有此需要，則可拒絕根據第 (1) 款提出的申請。

130. 中成藥銷售證明書

(1) 為出口根據第 121 條註冊而由根據第 132 條領有牌照的製造商製造的中成藥，中藥組可發出採用訂明格式的證明書，證明該中成藥獲准在香港銷售，並載有中藥組認為適當的與該中成藥有關的說明。

(2) 第 (1) 款提述的證明書須在繳付訂明費用後方予發出。

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(6) Where a person would, but for this subsection, be liable to be prosecuted for a contravention of section 119 for trading in, importing or possessing a proprietary Chinese medicine which, but for this subsection, would otherwise be required to be registered, then the person shall not be so liable until after the expiry of the period of time referred to in subsection (1) notwithstanding that on the expiry of such period of time, no application has been made to the Medicines Board.

(7) Section 125 and any requirements in respect of proprietary Chinese medicines imposed by regulations made under section 161 shall apply to proprietary Chinese medicines deemed to be registered under this section.

129. Clinical trials and medicinal tests

(1) For the purpose of facilitating the conduct of a clinical trial or medicinal test of any proprietary Chinese medicine, the Medicines Board may, upon application, issue a certificate for clinical trial and medicinal test.

(2) An application shall be in such form and accompanied by such documents, information, samples and other materials as the Medicines Board may determine and a prescribed application fee.

(3) The Medicines Board may, on payment of a prescribed issue fee, issue a certificate for clinical trial and medicinal test, and such certificate shall be valid for such period and subject to such conditions as the Medicines Board thinks fit.

(4) If, having regard to the provisions of this Ordinance, the Medicines Board considers it necessary in the public interest to do so, it may refuse an application made under subsection (1).

130. Certificate of sale of proprietary Chinese medicines

(1) For the purpose of exporting a proprietary Chinese medicine which is registered under section 121 and manufactured by a manufacturer licensed under section 132, the Medicines Board may, upon application, issue in the prescribed form a certificate certifying that the proprietary Chinese medicine is allowed to be sold in Hong Kong and containing such statements relating to the proprietary Chinese medicine as it considers appropriate.

(2) The certificate referred to in subsection (1) is issued subject to the payment of a prescribed fee.

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(*p*) 任何中成藥所須註冊的詳情；

(*q*) 豁免任何中藥材、中成藥或任何中藥業者使其免受本條例的條文規限。

(6) 在不損害第 (4) 及 (5) 款的一般性的原則下，根據上述各款訂立的規例可——

(*a*) 規定為本條例的目的而須提交的資料、詳情及文件，以及該等資料、詳情及文件須採用訂明的格式，並規定為該等目的的事項或文件須藉法定聲明或管委會所指明或批准的該等其他聲明作為支持；

(*b*) 為實施本條例的條文作一般規定。

(7) 根據本條訂立的任何規例均可訂定違反該規例任何條文即屬犯罪，並可就該罪行訂明罰則，但以不超過第 6 級罰款及監禁 2 年為限。

相應修訂

《公眾衞生及市政條例》

162. 釋義

《公眾衞生及市政條例》(第 132 章) 第 2(1) 條現予修訂，廢除"藥物"的定義而代以——

""藥物" (drug) 包括供人內服或外用的任何藥物、中藥材或中成藥；"。

《藥劑業及毒藥條例》

163. 取代條文

《藥劑業及毒藥條例》(第 138 章) 第 37 條現予廢除，代以——

(*p*) particulars to be registered for any proprietary Chinese medicines;

(*q*) exempting any Chinese herbal medicines, proprietary Chinese medicines or Chinese medicines traders from the provisions of this Ordinance.

(6) Without prejudice to the generality of subsections (4) and (5), regulations made under those subsections may—

(*a*) require information, particulars and documents for the purposes of this Ordinance to be submitted and to be in such form as may be prescribed and require matters or documents for those purposes to be supported by statutory declarations or such other declarations as specified or approved by the Council;

(*b*) generally provide for the carrying into effect the provisions of this Ordinance.

(7) Any regulation made under this section may provide that a contravention of any provisions therein shall be an offence and may prescribe penalties for such offence not exceeding a fine at level 6 and imprisonment for 2 years.

Consequential Amendments

Public Health and Municipal Services Ordinance

162. Interpretation

Section 2(1) of the Public Health and Municipal Services Ordinance (Cap. 132) is amended by repealing the definition of "drug" and substituting—

""drug" (藥物) includes any medicine, Chinese herbal medicine or proprietary Chinese medicine for internal or external use by man;".

Pharmacy and Poisons Ordinance

163. Section substituted

Section 37 of the Pharmacy and Poisons Ordinance (Cap. 138) is repealed and the following substituted—

"37. 本條例不適用於中藥材及中成藥等

(1) 除第 (2) 款另有規定外，本條例的任何條文均不適用於《中醫藥條例》(第 549 章) 第 2 條所界定的中藥材或中成藥或慣常獲華人作為藥用的其他源於植物、動物或礦物的物料的銷售、製造、配發或合成。

(2) 儘管第 (1) 款另有規定，本條例仍適用於含有任何該等中藥材或中成藥或慣常獲華人作為藥用的其他源於植物、動物或礦物的物料作為有效成分的藥劑製品。"。

《醫生註冊條例》

164. 非法使用名銜等與未經註冊執業

《醫生註冊條例》(第 161 章) 第 28 條現予修訂——

(*a*) 在第 (3) 款中——

(i) 在 (*f*) 段中，廢除"及"；

(ii) 在 (*g*) 段中，廢除句號而代以"；及"；

(iii) 加入——

"(*h*) 由根據《中醫藥條例》(第 549 章) 註冊或表列的中醫 **[*或憑藉該條例第 90(7) 條暫時繼續作中醫執業的人，]* 以中醫方式行醫作出者。"；

(*b*) 加入——

"(6) 在不影響關乎刑事罪行檢控的條例或律政司司長在刑事罪行檢控方面的權力的原則下，就與中醫執業方面有關的任何罪行而提出的檢控，只可根據《中醫藥條例》(第 549 章) 提出。"。

* 斜體部分尚未實施。

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"37. **Ordinance not to apply to Chinese herbal medicines and proprietary Chinese medicines, etc.**

(1) Subject to subsection (2), nothing in this Ordinance shall apply to the sale, manufacturing, dispensing or compounding of Chinese herbal medicines or proprietary Chinese medicines as defined in section 2 of the Chinese Medicine Ordinance (Cap. 549) or other materials of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose.

(2) Notwithstanding subsection (1), this Ordinance shall apply to pharmaceutical products containing any such Chinese herbal medicines or proprietary Chinese medicines or other materials of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose as active ingredients.".

Medical Registration Ordinance

164. **Unlawful use of title etc. and practice without registration**

Section 28 of the Medical Registration Ordinance (Cap. 161) is amended—

(*a*) in subsection (3)—

(i) in paragraph (*f*), by repealing "and";

(ii) in paragraph (*g*), by repealing the full stop and substituting "; and";

(iii) by adding—

"(*h*) by way of practising Chinese medicine by a Chinese medicine practitioner registered or listed under the Chinese Medicine Ordinance (Cap. 549) **[*or a person who continues to practise Chinese medicine provisionally by virtue of section 90(7) of that Ordinance]*.";

(*b*) by adding—

"(6) Without prejudice to any Ordinance relating to the prosecution of criminal offences or to the powers of the Secretary for Justice in relation to the prosecution of criminal offences, prosecutions for an offence in connection with the practice of Chinese medicine shall only be brought under the Chinese Medicine Ordinance (Cap. 549).".

* Italicized part is not yet in operation.

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166. *(已失時效而略去)*

《不良醫藥廣告條例》

167. 釋義

《不良醫藥廣告條例》(第 231 章)第 2(1)條現予修訂，在"藥物"的定義中，在"專利藥物"之後加入"中藥材、中成藥"。

168. 某些免責辯護；有關中醫的條文

第 5 條現予修訂——

(*a*) 廢除第 (1)(*d*) 款而代以——

"(*d*) 根據《中醫藥條例》(第 549 章)註冊或表列的中醫 **[或憑藉該條例第 90(7) 條暫時繼續作中醫執業的人]*。"；

(*b*) 在第 (2) 款中，廢除"native herbalist"而代以"Chinese medicine practitioner"。

《香港海關條例》

169. 第 17 及 17A 條內提述的條例

《香港海關條例》(第 342 章)附表 2 現予修訂，在末處加入"《中醫藥條例》(第 549 章)"。

《診療所條例》

170. 釋義

《診療所條例》(第 343 章)第 2 條現予修訂——

(*a*) 在"診療所"的定義中，廢除 (*f*) 段而代以——

* 斜體部分尚未實施。

166. *(Omitted as spent)*

Undesirable Medical Advertisements Ordinance

167. Interpretation

Section 2(1) of the Undesirable Medical Advertisements Ordinance (Cap. 231) is amended, in the definition of "medicine", by adding "a Chinese herbal medicine, a proprietary Chinese medicine," after "patent medicine,".

168. Certain defences; provision as to Chinese medicine practitioners

Section 5 is amended—

(*a*) by repealing subsection (1)(*d*) and substituting—

"(*d*) Chinese medicine practitioners registered or listed under the Chinese Medicine Ordinance (Cap. 549) **[or persons who continue to practise Chinese medicine provisionally by virtue of section 90(7) of that Ordinance]*.";

(*b*) in subsection (2), by repealing "native herbalist" and substituting "Chinese medicine practitioner".

Customs and Excise Service Ordinance

169. Ordinances referred to in sections 17 and 17A

Schedule 2 to the Customs and Excise Service Ordinance (Cap. 342) is amended by adding "Chinese Medicine Ordinance (Cap. 549)" at the end.

Medical Clinics Ordinance

170. Interpretation

Section 2 of the Medical Clinics Ordinance (Cap. 343) is amended—

(*a*) in the definition of "clinic", by repealing paragraph (*f*) and substituting—

* Italicized part is not yet in operation.

174. 修訂附表 3

附表 3 現予修訂，加入——

"1A.《中醫藥條例》(第 549 章) 附表 1 所指明的中藥材。

1B.《中醫藥條例》(第 549 章) 附表 2 所指明的 5 種中藥材，即：威靈仙 (Radix Clematidis)、凌霄花 (Flos Campsis)、製川烏 (Processed Radix Aconiti)、製草烏 (Processed Radix Aconiti Kusnezoffii) 及龍膽 (Radix Gentianae)。

1C.《中醫藥條例》(第 549 章) 第 2 條所界定的中成藥。"。

《藥劑業及毒藥規例》

175. 藥劑製品及物質的註冊

《藥劑業及毒藥規例》(第 138 章，附屬法例) 第 36 條現予修訂，加入——

"(2A) 在考慮就藥劑製品而提出的註冊申請時，如該等藥劑製品含有以下物料作為有效成分，即《中醫藥條例》(第 549 章) 第 2 條所界定的任何中藥材或中成藥或慣常獲華人作藥用的其他源於植物、動物或礦物的物料，則管理局須徵詢根據《中醫藥條例》(第 549 章) 設立的中藥組的意見。"。

附表 1　[第 2、109、110、112、113 及 146 條及附表 3 及 4]

中藥材

名稱	說明
(三劃)	
山豆根 (Radix Sophorae Tonkinensis)	豆科植物越南槐的根或根莖
(四劃)	
水銀 (Mercury)	藥用

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174. Third Schedule amended

The Third Schedule is amended by adding—

"1A. Chinese herbal medicines specified in Schedule 1 of the Chinese Medicine Ordinance (Cap. 549).

1B. 5 Chinese herbal medicines specified in Schedule 2 of the Chinese Medicine Ordinance (Cap. 549), namely, Flos Campsis (凌霄花), Processed Radix Aconiti (製川烏), Processed Radix Aconiti Kusnezoffii (製草烏), Radix Clematidis (威靈仙) and Radix Gentianae (龍膽).

1C. Proprietary Chinese medicines as defined in section 2 of the Chinese Medicine Ordinance (Cap. 549).".

Pharmacy and Poisons Regulations

175. Registration of pharmaceutical products and substances

Regulation 36 of the Pharmacy and Poisons Regulations (Cap. 138 sub. leg.) is amended by adding—

"(2A) In considering an application for registration of a pharmaceutical product which contains as active ingredients any Chinese herbal medicines or proprietary Chinese medicines as defined in section 2 of the Chinese Medicine Ordinance (Cap. 549) or other materials of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose, the Board shall seek advice from the Chinese Medicines Board established under the Chinese Medicine Ordinance (Cap. 549).".

SCHEDULE 1　[ss. 2, 109, 110, 112, 113 & 146 & Schs. 3 & 4]

CHINESE HERBAL MEDICINES

Name	Description
Arsenic trioxide (砒霜)	medicinal
Arsenolite (砒石)	Mineral of oxides of Arsenolite or the processed product of Arsenopyrite or Realgar, medicinal
Calomelas (輕粉)	Crystal of mercurous chloride, medicinal

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