# 香港對保健聲稱的規管

諮詢文件

二零零三年九月

香港特別行政區政府

衞生署

# 目錄

# 第 1 章：引言

1.1 近年來，市面上聲稱具有保健功效的食品愈來愈多。消費者以往曾投訴一些所謂保健食品的聲稱具誤導性或誇大失實。有公眾人士及立法會議員亦要求當局加緊對不負責任的保健聲稱管制，以保障公眾健康。

1.2 《不良醫藥廣告條例》(第 231 章)禁止廣告聲稱某產品對該條例附表所列的疾病有治療或預防功效。然而，現時許多「保健食品」的廣告聲稱並不是該條例明言禁止的。

1.3 為了向市民提供更佳的保障，以免他們受誤導性或誇大聲稱的影響，我們建議在《不良醫藥廣告條例》中加入新附表，列明口服產品應予禁止的保健聲稱。

1.4 本諮詢文件邀請公眾、業者、醫護專業人員及有關機構，就文中建議禁止的聲稱提出意見。

# 第 2 章：本地情況

## 本港現行的規管制度

2.1 目前，《藥劑業及毒藥條例》(第 138 章)規管任何聲稱可治療或預防某種疾病或病徵的「藥劑製品」。規管方式包括個別產品在推出市面前的註冊規定(產品的安全程度、效能及素質是審批註冊的標準)、標籤規定、製造商及銷售商的發牌制度，以及零售的管制措施(即只可由藥劑師出售，或購買時須出示醫生處方等限制)。然而，該條例並不適用於藥劑製品以外的所謂保健食品。

2.2 《中醫藥條例》(第 549 章)將對含中藥有效成分的產品施加規管。當局已於 2003 年 5 月開始為製造商、入口商及批發商發牌，而中成藥的註冊工作將在 2003 年年底展開。然而，不含中藥成分的產品並不受該條例所規管。

2.3 《公眾衞生及市政條例》(第 132 章)禁止出售及持有以供出售任何不適合人類進食的食品。因此，供人類食用的俗稱保健食品，其安全問題已受規管。

2.4 《不良醫藥廣告條例》(第 231 章)禁止廣告聲稱某產品或療法可預防或治療該條例所指的疾病或病理情況，規管範圍涵蓋產品標籤上的保健聲稱。然而，許多食品的標籤或廣告聲稱是該條例沒有明言禁止的，因此不受其規管。

## 保健聲稱：目前的情況

2.5 最近一項有關市面上口服產品的保健聲稱的調查發現，一些聲稱具誤導性或誇張失實。這些聲稱大致可分為下列兩類：

(i) **與身體功能有關的聲稱，這類聲稱可能令市民延誤尋求適當的醫療意見及治理** —— 例如調節血壓、調節血脂或膽固醇等聲稱。由於這類聲稱通常不會提及預防或治療特定疾病，因而不受《藥劑業及毒藥條例》和《不良醫藥廣告條例》等現行法例管制。

(ii) **與保健有關的誇大或誤導性聲稱** —— 例子包括有關纖體、減肥、豐胸、排毒等誤導性聲稱。規管這類聲稱需要社會的共識。規管這類聲稱必須在公眾健康及消費者的選擇自由之間取得平衡。

# 第 3 章：國際情況

## 廣告宣傳法例

3.1 歐盟、英國、澳洲、加拿大和新加坡等許多國家和地區，都有類似香港《不良醫藥廣告條例》(第 231 章)的廣告宣傳法例，禁止藉廣告向公眾宣傳任何食物、藥物、化妝品或儀器能夠治療、預防或醫治附表所指的疾病及病理情況。

3.2 歐盟、英國及中國有規例規定，凡只可憑醫生處方獲得的藥用產品，不得向公眾作廣告宣傳。

3.3 美國准許為處方藥物作廣告宣傳，但《聯邦食品、藥物及化妝品法》(以下簡稱「法案」)規定，為處方藥物作廣告宣傳的製造商、包裝商及分銷商，須在廣告披露有關宣傳產品的用途及風險的資料。法案又規定這些廣告須包含「有關副作用、禁忌及成效的扼要資料」。

## 規管保健食品及保健聲稱

3.4 目前，國際間對於如何規管所謂的保健食品或保健聲稱未有共識，對於何謂「保健食品」，也未有一致定論。類似的產品在不同情況下有很多不同的名稱，如食物補充品、營養補充劑、食療產品、天然健康食品等。

3.5 在澳洲、中國及加拿大等國家，「保健食品」須經審批才可銷售。註冊批核的準則在於產品是否安全、有效及品質良好。製造商如宣稱產品具有保健功效，須提供適當的科學證據支持。

3.6 在美國和英國等其他國家，「保健食品」無須經審批便可銷售，但該等產品宣稱的保健功效則受到規管。這些產品可作出若干

聲稱，內容通常與營養成分有關，或顯示某種成分與某種健康狀況有關。這些核准的聲稱都經界定，並有指明的使用規則。各國對「保健食品」及保健聲稱的規管詳情，請參閱附錄 1。

## 第 4 章：建議的規管

4.1 我們建議修訂《不良醫藥廣告條例》，以規管產品宣稱的保健功效。現行的《不良醫藥廣告條例》禁止藉廣告宣傳藥物、外科用具或療法作為預防或治療人類某些疾病或病理情況的用途。禁止這類聲稱的目的是預防公眾不當地自行用藥，引致由於誤用藥物，或延誤適當治療而造成傷害。《不良醫藥廣告條例》載有兩個附表，即附表 1 及 2。任何人如發布或安排發布的廣告，相當可能導致他人使用任何藥物、外科用具或療法，以治療或預防染上附表 1 第 1 欄內所指明的疾病或病理情況(但如作第 2 欄內所指明的用途(如有的話)則屬例外)，即屬違法。為附表 2 所指明的目的作出的廣告，亦在禁止之列。《不良醫藥廣告條例》的文本載於附錄 2。

4.2 我們建議在《不良醫藥廣告條例》中加入新附表，列明禁止作出的聲稱，以處理口服產品具誤導性資料和作出不良聲稱的問題。屆時，衞生署署長可視乎情況的最新發展，有需要時修訂新增的附表，並將其涵蓋範圍擴展至其他產品及服務，以保障公眾健康。此外，衞生署署長將有權授權公職人員擔任督察，執行《不良醫藥廣告條例》的相關條文。

4.3 為此，當局於 2002 年年底成立了專家委員會，成員包括消費者委員會的代表、中醫、醫生、藥劑師和營養師，負責研究及建議禁止口服產品宣稱具有的保健功效清單。

4.4 專家委員會考慮禁用個別保健聲稱時，採用了風險評估的方法。委員會普遍贊同應禁止作出可能會影響公眾健康的聲稱。風險較低的聲稱則可不納入清單內。

4.5 專家委員會檢討 13 類聲稱後，建議禁止其中 9 類保健聲稱，以附表形式納入《不良醫藥廣告條例》內。該等聲稱包括：

(i) 調節體內糖份或葡萄糖，包括改變胰臟機能。

(ii) 調節血壓。

(iii) 調節血脂或膽固醇。

(iv) 預防、消除或治療乳房腫塊。

(v) 調節泌尿生殖系統的機能，包括改善泌尿生殖問題的徵狀。

(vi) 調節內分泌系統，包括保持或改變激素分泌。

(vii) 有關纖體或減肥的聲稱，包括燒脂、去脂、控制食慾、吸脂及去水腫。

(viii) 調節身體的免疫系統，以預防包括癌症、慢性疾病及感染等疾病；或改變化療、放射治療等治療的作用。

(ix) 促進排毒、清毒或降毒。

有關聲稱的例子和禁用該等聲稱的原因載於附錄 3。

4.6 此外，專家委員會同意以下 4 類聲稱毋須納入《不良醫藥廣告條例》內：

(i) 矯正或減輕更年期出現的有關徵狀。

(ii) 刺激頭髮生長或防止脫髮。

(iii) 促進乳房豐滿或結實。

(iv) 調節或改變泌尿生殖系統的結構。

建議毋須禁止的聲稱的原因列載於附錄 4。

## 第 5 章：未來路向

5.1 對於「保健食品」或保健聲稱的規管，至今仍沒有公認的做法，各地所實施的規例亦各有不同。現正在其他地方實施的規管方法包括推出市面前的審批規定和擬定聲稱的清單等等。

5.2 中成藥註冊制度將在 2003 年稍後階段實施；屆時，很多以中藥作為有效成分的「保健食品」便須註冊。這些食品必須能夠提供不同程度的證據以證明其載述的聲稱，例如使用記錄或傳統的參考及臨床測試資料。不受《藥劑業及毒藥條例》或《中醫藥條例》管制的所謂保健食品，將會大幅減少。

5.3 在《不良醫藥廣告條例》內加上建議禁止作出的聲稱後，將可進一步加強對公眾健康的保障。

5.4 禁制聲稱附表可予修訂，以便因應最新發展並在有需要時納入新的聲稱。衞生署署長日後亦可修訂附表，以加入其他產品及服務。

5.5 當局制定新的禁制聲稱附表後，將會給予「保健食品」業者一個合適的寬限期，讓他們作出修改和準備，以符合新的規定。製造商及銷售商或須更換產品上的現有標籤，以及收回載有違法聲稱的小冊子。當局考慮到預先包裝食品有一般食用期限，而製造商和銷售商製備新標籤亦需時，因此會給予最少 18 個月的寬限期。然而，對於在報章雜誌刊載及電視電台播放違反新規定的廣告的執法行動，則會較快展開。

**徵詢意見**

5.6 請就上述對保健聲稱作出規管的建議提供意見及建議。如對本諮詢文件有意見，請在 2003 年 11 月 15 日或之前以下述方式提

出。

(a) 郵寄至：九龍南昌街 382 號公共衞生檢測中心 3 樓
保健聲稱規管諮詢秘書處

(b) 傳真至：2834 5117

(c) 電郵至：healthclaims@dh.gov.hk

5.7 本諮詢文件亦可在以下網址瀏覽及下載：

***http://www.hwfb.gov.hk***
***http://www.dh.gov.hk***

附錄 1

## 其他國家及中國內地對「保健食品」及保健聲稱的規管

### 美國

在美國，「保健食品」稱為食物補充品，而規管這類補充品的主要法例則為《食物補充品及健康教育法令》。該法令規定，製造商有責任確保食物補充品的食用安全，並訂明有關標籤及優良製造規範的規定。在食物補充品推出市面前，食物及藥物管理局(管理局)不會作出分析或審批。如有關補充品不含新成分，製造商只需在補充品推出市面前 30 天內通知管理局便可；但如產品含有新成分，製造商便須在推出市面前 75 天通知管理局。

2. 根據該法令，食物補充品可載述三類聲稱：營養成分的聲稱、保健效用的聲稱及結構／功能的聲稱。營養成分的聲稱及使用該等聲稱的規則均由管理局界定和公布 (例如每個份量含有 200 毫克以上鈣成分的產品，便可使用「高鈣」的聲稱)。保健聲稱則顯示某成分與健康狀況之間的關係，故在食物補充品標籤上刊印保健聲稱之前，製造商須獲管理局授權。至於結構／功能聲稱，則無須得到管理局授權便可使用，但製造商須對該等聲稱負上責任，確保有關聲稱內容真實，不會誤導他人，另須附有以下免責聲明：「本產品的聲明未獲食物及藥物管理局審核。本產品不擬作診斷、治療、根治或預防任何疾病之用。」

### 歐盟

3. 在歐盟，「保健食品」不受特別形式的管制，除非有關產品載述「醫療聲稱」。如屬這種情況，該產品便須如藥劑製品般受到有關管制，遵守一切有關推出市面前須經審批的規定(即註冊所需符合的安全程度、效能及素質評估，以及優良製造規範)。

## 澳洲

4. 在澳洲，「保健食品」稱為補充藥物，在推出市面前須經審批。補充藥物可分為「高風險」及「低風險」兩種，視乎所含成分及聲稱性質而定；前者須經註冊，而後者則須表列。註冊藥物的安全程度、效能及素質均會經過評核。大部分補充藥物均屬於表列藥物。表列藥物則只評核安全程度及素質。在效能方面，製造商須備存適當的科學證據，以支持其對產品所作的效能聲稱。該等聲稱必須真實、有效、不具誤導性，而且不會導致使用者把產品作危險或不當用途。一般來說，獲准載述的效能聲稱均屬「低風險」一類，即只與輕微狀況有關的聲稱。

## 加拿大

5. 加拿大憲報第 II 部分在 2003 年 6 月 18 日刊登新訂的《天然保健產品規例》。該規例將由 2004 年 1 月 1 日起生效，過渡期由 2 年(廠址領牌)至 6 年(產品領牌)不等。屬於新訂規例規管範圍的產品，包括草藥、順勢治療藥物、維生素、礦物質、傳統藥物、原抗菌素、氨基酸及基本脂肪酸等。加拿大所有天然保健產品，均須在推出市面前申領產品牌照。如要作出健康聲稱，須向當局提供使用記錄或傳統參考資料、觀察研究結果、臨床測試數據等證據。

## 中國內地

6. 在中國內地，「保健食品」受《保健食品管理辦法》所管制。保健食品的定義是，所附標籤聲稱具有特定保健成效，而並非作為治療或修復人類疾病之用的食品。「保健食品」適合特定類別的人士食用，以調節人體機能。「保健食品」在推出市面前須經衞生部審批。標籤及產品說明附頁所載述的健康聲稱，須有科學證據佐證。

7. 總的來說，對於「保健食品」或保健聲稱的規管，暫時未有獲得國際認同的方案。

附錄 2

# 不良醫藥廣告條例 231 章

條：**1** 條文標題：**簡稱** 版本日期：30/06/1997
本條例可引稱為《不良醫藥廣告條例》。

條：**2** 條文標題：**釋義** 版本日期：30/06/1997
(1) 在本條例中，除文意另有所指外—(由 1988 年第 65 號第 9 條修訂)
"廣告"(advertisement) 包括任何公告、海報、通告、標籤、封套或文件，及任何以口頭方式或藉產生或傳送光或聲音的方式所作出的宣布；
"藥物"(medicine) 包括任何種類的藥劑或其他治療性或預防性物質，不論是專有藥物、專利藥物或看來是天然藥品的物質。
(2) 就本條例而言—
(a) 出售或供應、或要約出售或要約供應、或為出售或供應而展示任何—
(i) 藥物；
(ii) 外科用具；或
(iii) 療法，
而該等藥物、外科用具或療法是載於附有標籤的容器或包裹內的，即構成廣告的發布；
(b) 在載有任何藥物、外科用具或療法的容器或包裹內提供有關該藥物、外科用具或療法的資料，或提供有關任何其他藥物、外科用具或療法的資料，並不構成廣告的發布。 (由 1988 年第 65 號第 9 條增補)

條：**3** 條文標題：**禁止有關某些疾病的廣告；例外情況** 版本日期：30/06/1997
(1) 任何人不得發布或安排發布任何相當可能導致他人為以下目的而使用任何藥物、外科用具或療法的廣告—
(a) 治療患上附表 1 第 1 欄內所指明的疾病或病理情況的人，或預防人類染上附表 1 第 1 欄內所指明的疾病或病理情況，但如作該附表第 2 欄內所指明的用途(如有的話)，則屬例外；或
(b) 為附表 2 內所指明的任何目的治療人類。 (由 1988 年第 65 號第 2 條代替)
(2) 第(1)款不適用於衞生署署長所發布或經衞生署署長授權而發布的廣告，亦不適用於由英軍軍官妥為授權只在英軍成員當中傳播的廣告。 (由 1989 年第 76 號法律公告修訂)

(3) 就在違反第(1)款的情況下發布的廣告而言，如在該廣告內顯示該廣告所指名的人—

(a) 為藥物或外科用具的製造商或供應商；或

(b) 能夠提供任何療法，

則在相反證明成立前，該人即推定為安排發布該廣告者。 (由 1988 年第 65 號第 2 條增補)

(4) 如在違反第(1)款的情況下發布的廣告載有任何人的姓名或名稱、地址或電話號碼，或註明聯絡任何人的其他方式，而該人—

(a) 製造或供應藥物或外科用具；或

(b) 提供任何療法，

則在相反證明成立前，該人即推定為安排發布該廣告者。 (由 1988 年第 65 號第 2 條增補)

(5)-(6) (已失時效而略去)

條：**3A** 條文標題：**(已失時效而略去)** 版本日期：30/06/1997

條：**4** 條文標題：**禁止有關墮胎的廣告** 版本日期：30/06/1997

(1) 除第(2)款另有規定外，任何人不得以任何方式書寫、印刷、發布或安排書寫、印刷或發布具以下內容的廣告—

(a) 要約促致婦女進行流產；

(b) 勸誘促致婦女進行流產；

(c) 吸引或誘使促致婦女進行流產；或

(d) 提述任何物品而措詞刻意導致他人使用該物品作促致婦女進行流產之用。

(2) 第(1)款不適用於衞生署署長所發布或經衞生署署長書面授權而發布的廣告。 (由 1989 年第 76 號法律公告修訂)

(3) 就在違反第(1)款的情況下發布的廣告而言，如在該廣告內顯示所指名的人—

(a) 為藥物或外科用具的製造商或供應商；或

(b) 能夠提供任何療法，

則在相反證明成立前，該人即推定為安排發布該廣告者。 (由 1988 年第 65 號第 4 條增補)

(4) 如在違反第(1)款的情況下發布的廣告載有任何人的姓名或名稱、地址或電話號碼，或註明聯絡任何人的其他方式，而該人—

(a) 製造或供應藥物或外科用具；或

(b) 提供任何療法，

則在相反證明成立前，該人即推定為安排發布該廣告者。 (由 1988 年第 65 號第 4 條增補)

(由 1980 年第 70 號第 2 條代替)

條：**5** 條文標題：**某些免責辯護；有關中醫的條文** 版本日期：01/03/2002

(1) 在任何因違反第 3 或 4 條而進行的法律程序中，如證明該法律程序所關乎的廣告只載於屬技術性質的刊物，而該刊物為主要擬在以下其中一個或幾個類別的人士當中流通者，即為免責辯護—

(a) 根據《醫生註冊條例》(第 161 章)註冊的醫生，或根據該條例第 29 條被當作為醫生的人士；

(b) 根據《藥劑業及毒藥條例》(第 138 章)註冊的藥劑師；(由 1997 年第 62 號法律公告修訂)

(c) 醫院、護養院、痲瘋病院或精神病院的專業人員；

(d) 根據《中醫藥條例》(第 549 章)註冊或表列的中醫。 (由 1999 年第 47 號第 168 條代替)

(2) 《醫生註冊條例》(第 161 章)第 31 條條文，不得視為准許任何中醫或其他人參與違反本條例條文的廣告，但如只限於第(1)款所訂定的免責辯護範圍內，則屬例外。

條：**6** 條文標題：**罰則** 版本日期：30/06/1997

任何人違反第 3 或 4 條的條文，即屬犯罪，一經首次定罪，可處罰款$10000，而在第二次或其後再被定罪，則可處罰款$25000 及監禁 1 年。

(由 1988 年第 65 號第 5 及 10 條修訂)

條：**7** 條文標題：**修訂附表的權力** 版本日期：30/06/1997

衞生署署長可藉憲報刊登的命令修訂附表。

(由 1988 年第 65 號第 6 條增補。由 1997 年第 80 號第 16 條修訂)

附表：**1** 條文標題：**禁止或限制發布的廣告所涉及的疾病或病理情況** 版本日期：30/06/1997

[第 3 條]

| | **第 1 欄**<br>**疾病或病理情況** | **第 2 欄**<br>**准予作廣告宣傳的目的** |
|---|---|---|
| 1. | 任何良性或惡性瘤。 | 沒有。 |
| 2. | 任何病毒、細菌、真菌或其他傳染性疾病，包括結核病、痢疾、肝炎及痲瘋。 | 以外用藥物施於身體外部，以治療或預防輕微的皮膚感染，包括使用製劑治療以減輕兒童感染引致的痕癢及紅疹。<br>減輕口瘡性潰瘍症狀。<br>減輕感冒、咳嗽等一般稱為流行性感冒及類似的上呼吸道感染情況。<br>治療口腔前庭及咽部的輕微急性發炎情況。 |
| 3. | 任何寄生疾病。 | 治療疥瘡或蟯蟲、虱或蠅蟲等感染，但有關廣告只可刊登於盛載所供應藥物、外科用具或療法的附有標籤的容器或包裹上。 |
| 4. | 任何性病，包括梅毒、淋病、軟下疳、性病性淋巴肉芽腫、生殖器皰疹、生殖器肉贅、尿道炎、陰道炎、尿道或陰道溢液、愛滋病及任何其他經由性接觸傳染的疾病。 | 沒有。 |
| 5. | 任何呼吸系統疾病，包括哮喘、支氣管炎及肺炎。 | 暫時減輕花粉病、鼻炎或黏膜炎症狀。<br>減輕塞竇症狀。 |

| | | |
|---|---|---|
| 6. | 任何心臟或心血管系統疾病，包括風濕性心臟病、動脈硬化、冠狀動脈病、心律失常、高血壓、腦血管病、先天性心臟病、血栓形成、末梢動脈病、水腫、視網膜血管變化及末梢靜脈病。 | 沒有。 |
| 7. | 任何胃腸病，包括膽石、肝硬化、胃腸出血、腹瀉、疝、肛門瘻及痔。 | 減輕一般稱為不消化、胃灼熱、胃酸過多、消化不良、口臭或腸胃氣脹的症狀。<br>減輕腸絞痛、胃痛或惡心症狀。<br>減輕偶發性或非持續的腹瀉或便秘症狀。<br>預防旅行病或有關症狀。<br>以局部有效製劑或軟化糞便劑及潤滑劑治療痔及減輕症狀。 |
| 8. | 任何神經系統疾病，包括羊癇、精神紊亂、精神發育遲緩及癱瘓。 | 減輕頭痛。 |
| 9. | 任何泌尿生殖系統疾病，包括腎石、腎炎、膀胱炎、任何前列腺病及包莖炎。 | 沒有。 |
| 10. | 任何血液或淋巴系統疾病，包括貧血、頸腺、出血病症、白血病及其他淋巴增生疾病。 | 給予礦物質及維他命作為預防，以避免飲食不適當或需多加調節飲食的人士陷入缺乏狀態。 |
| 11. | 任何肌與骨骼系統疾病，包括風濕病、關節炎及坐骨神經痛。 | 使用外用製劑以減輕肌肉疼痛、僵硬及痙攣症狀。 |
| 12. | 任何內分泌疾病，包括糖尿病、甲狀腺毒症、甲狀腺腫以及與該系統活動過少或過多有關的任何器官或機能性病理情況。 | 食物補充品。 |
| 13. | 任何影響視力、聽覺或平衡的器官病理情況。 | 局部使用眼製劑以減輕症狀。<br>局部使用耳垢溶劑以減輕症狀。 |

| | | |
|---|---|---|
| 14. | 任何皮膚、頭髮或頭皮疾病。 | 以外用劑預防或治療頭皮屑。<br>以外用劑施於身體外部，以治療丘疹、濕疹、皮膚敏感及腳癬。<br>以保護性外用劑預防和治療接觸皮炎及曬傷。<br>使用雞眼膏或溶劑以治療硬皮及雞眼。<br>減輕或預防一般輕微皮膚症狀，包括乾燥及皺裂皮膚、唇皰疹、痕癢、昆蟲咬傷、汗疹及尿布疹。 |

(附表 1 由 1988 年第 65 號第 8 條增補)

附表：**2** 條文標題：**禁止為以下目的而為任何藥物、外科用具或療法作廣告宣傳** 版本日期：30/06/1997

[第 3 條]

1. 通經、醫治經閉、遲經或任何其他婦產科疾病。
2. 增強性能力、性慾或生殖能力，或恢復失去的青春。
3. 矯正畸形或外科整容手術。

(附表 2 由 1988 年第 65 號第 8 條增補)

附表：**3** 條文標題：**(廢除)** 版本日期：30/06/1997
(由 1988 年第 65 號第 11 條廢除)

# 建議的口服產品禁制聲稱一覽表

| 禁制聲稱 | 例句 | 理由 | 例外情況 |
|---|---|---|---|
| 1. 調節體內糖份或葡萄糖，包括改變胰臟機能。 | 調節血糖 | 該等聲稱意味可預防或治療糖尿病，或會延誤市民尋求妥善的醫療指引及護理。 | 如產品含有《食物攙雜(人造糖)規例》所列的人造糖作為唯一主要有效成分，便可獲准載述「適合糖尿病人」的聲稱。<br><br>*備註*<br>修訂現行《不良醫藥廣告條例》附表 1 第 12 項第 2 欄，以令該欄格不包括任何項目。 |
| | 穩定血糖 | | |
| | 抑制／減低糖份吸收 | | |
| | 降血糖 | | |
| | 抗血糖 | | |
| | 增加糖份的新陳代謝 | | |
| | 適合糖尿病人 | | |
| | 適合關注高血糖人士 | | |
| | 改善胰臟功能 | | |
| | 刺激胰島素分泌 | | |
| 2. 調節血壓 | 穩定血壓 | 該等聲稱意味可預防或治療高血壓，或會延誤市民尋求妥善的醫療指引及護理。 | |
| | 調節血壓 | | |
| | 控制血壓 | | |
| | 降低高血壓 | | |
| | 適合高血壓人士 | | |
| | 適合關注血壓人士 | | |

| 禁制聲稱 | 例句 | 理由 | 例外情況 |
| --- | --- | --- | --- |
| 3. 調節血脂或膽固醇 | 預防高血脂 | 該等聲稱意味可預防或改善高血脂／膽固醇的情況，但這情況正是冠心病等重要疾病的風險因素之一，因此有關聲稱或會延誤市民尋求妥善的醫療指引及護理。 | |
| | 有助維持正常血脂 | | |
| | 降血脂 | | |
| | 降低／調節膽固醇 | | |
| | 平衡膽固醇 | | |
| | 使血管中的膽固醇排出體外 | | |
| | 適合高血脂／高膽固醇人士 | | |
| | 適合關注血脂／膽固醇人士 | | |
| 4. 預防、消除或治療乳房腫塊 | 消除乳腺障礙 | 該等聲稱意味可預防或治療乳房腫塊，但與此症狀有關的隱藏病情或須盡快尋求診治，因此有關聲稱或會延誤市民尋求妥善的醫療指引及護理。 | |
| | 幫助消除致病因素、結塊及舒緩有關不適症狀 | | |
| | 促進胸部組織之新陳代謝，有效地分解及消除不正常細胞組織結塊 | | |

| 禁制聲稱 | 例句 | 理由 | 例外情況 |
| --- | --- | --- | --- |
| 5. 調節泌尿生殖系統的機能，包括改善泌尿生殖問題的徵狀。 | 尿頻，尿急，滴尿，小便無力 | 該等聲稱意味可預防或治療泌尿生殖系統疾病，或會延誤市民尋求妥善的醫療指引及護理。 | |
| | 小便困難 | | |
| | 預防夜尿 | | |
| | 夜尿過多 | | |
| | 前列腺功能之阻滯 | | |
| | 小便失禁 | | |
| 6. 調節內分泌系統，包括保持或改變激素分泌。 | 有助維持體內荷爾蒙於最佳水平 | 該等聲稱意味可預防及／或治療內分泌疾病或與內分泌腺活躍度過低／過高有關的情況，因此往往誇大其詞或具誤導性，以吹噓產品可增強內分泌腺機能或預防生理機能異常的功效。 | *備註*<br>修訂現行《不良醫藥廣告條例》附表 1 第 12 項第 2 欄，以令該欄格不包括任何項目。 |
| | 刺激腦下垂體，加速雌激素的分泌 | | |
| | 促進女性荷爾蒙正常分泌 | | |
| | 調節婦女內分泌 | | |
| | 改善男性荷爾蒙分泌不平衡 | | |
| | 幫助男女維持荷爾蒙分泌平衡 | | |
| | 刺激荷爾蒙分泌 | | |
| | 調節內分泌 | | |
| | 平衡內分泌 | | |
| | 加速生長荷爾蒙的分泌 | | |
| | 刺激甲狀腺 | | |

| 禁制聲稱 | 例句 | 理由 | 例外情況 |
| --- | --- | --- | --- |
| 7. 與纖體／瘦身或減肥有關，包括燒脂、去脂、控制食慾、吸脂及去水腫。 | 促進脂肪代謝及幫助燃燒脂肪 | 該等聲稱誇大其詞或具誤導性，故會慫恿或誤導市民以不當方法來控制體重，繼而引起嚴重的副作用，例如代謝失調。 | 獲藥劑業及毒藥管理局或中醫藥管理局註冊的纖體產品，可在標籤或包裝附頁上載述已獲該兩個管理局批准的聲稱。 |
| | 消除囤積於體內的脂肪 | | |
| | 幫助排出多餘脂肪 | | |
| | 幫助睡覺時消除脂肪細胞 | | |
| | 分解脂肪 | | |
| | 有效吸走食物中的油脂 | | |
| | 調節脂肪代謝 | | |
| | 預防脂肪積聚 | | |
| | 平衡體內脂肪 | | |
| | 加速燃燒脂肪 | | |
| | 抑制脂肪吸收 | | |
| | 吸走脂肪／吸脂 | | |
| | 減去橙皮脂肪 | | |
| | 抑制食慾 | | |
| | 無需節食或運動而達到纖體效果 | | |
| | 能令肌肉纖瘦收緊，增加曲線美 | | |
| | 加速燃燒體內多餘卡路里 | | |
| | 加快瘦身 | | |
| | 纖體 | | |
| | 減輕體重 | | |
| | 預防／控制肥胖 | | |
| | 減低肥胖機會 | | |
| | 去水腫 | | |
| | 把體內多餘水份消除 | | |
| | 阻止多餘糖份轉化為脂肪 | | |

| 禁制聲稱 | 例句 | 理由 | 例外情況 |
| --- | --- | --- | --- |
| 8. 調節身體的免疫系統，以預防癌症、慢性疾病及感染等疾病；改變化療、放射治療等治療的作用。 | 調節免疫功能 | 意味有關產品可刺激免疫系統，以預防、穩定、改善或治療疾病，特別是癌症、慢性疾病及感染。這些產品即使有效，也應先向醫護／健康護理專業人員尋求妥善指引後才使用。不當使用這些產品，會延誤市民尋求妥善的醫療指引及治療。 | |
| | 改善免疫機能 | | |
| | 強化免疫系統 | | |
| | 刺激免疫系統 | | |
| | 製造免疫細胞 | | |
| | 提升白血球數量 | | |
| | 促進白血球能力以對抗微小侵入物 | | |
| | 抑制有害細胞生長 | | |
| | 增強癌症病人的免疫能力 | | |
| | 提高愛滋病患者的免疫功能 | | |
| | 減輕化療／電療的副作用 | | |
| | 作為癌症輔助治療劑 | | |
| 9. 促進排毒、清毒或降毒 | 有效排毒，清除血液及腸道毒物 | 排毒、清毒或降毒等字眼具誤導性。大多數作此聲稱的廣告均指其產品具有輕瀉作用，並誇大這種作用的好處。不當使用這些產品可導致嚴重副作用，例如電解質失衡、腸道機能失調、脫水等。 | 獲藥劑業及毒藥管理局或中醫藥管理局註冊的排毒、清毒或降毒產品，可在標籤或包裝附頁上載述已獲該兩個管理局批准的聲稱。 |
| | 清洗體內毒素 | | |
| | 清除血液中毒素 | | |
| | 排除重金屬，化學污染物 | | |

附錄 4

# 建議毋須禁止的保健聲稱

我們曾就以下 4 組聲稱進行討論，但認為毋須納入新的禁制表內，理由如下：

| 聲稱 | 不納入禁制一覽表的理由 |
|---|---|
| 矯正或減輕更年期出現的有關徵狀 | 關於預防及治療更年期綜合症的聲稱，已由現行《不良醫藥廣告條例》作為其中一項疾病而予以規管。<br><br>因延誤治理與更年期有關的不明確徵狀所涉及的公眾健康風險相對較低。 |
| 刺激頭髮生長或防止脫髮 | 關於頭髮或頭皮疾病的聲稱，已受現行《不良醫藥廣告條例》規管。刺激生髮所涉及的公眾健康風險不高。 |
| 促進乳房豐滿或結實 | 根據目前資料顯示，所涉及的公眾健康風險不高。 |
| 調節或改變泌尿生殖系統的結構 | 根據目前資料顯示，所涉及的公眾健康風險不高。 |

# Regulation of Health Claims in Hong Kong

## Consultation Document

## September 2003

**Department of Health**
**Government of the Hong Kong Special Administrative Region**

# CONTENTS

## CHAPTER 1 : INTRODUCTION

1.1 An increasing number of food products claiming specific beneficial health effects have been found in the local market in recent years. There have been complaints from consumers against misleading or exaggerated claims of the so-called health food products. There are also calls from the public and Legislative Council that control of irresponsible health claims should be tightened for the sake of public health.

1.2 The Undesirable Medical Advertisements Ordinance (UMAO) (Cap. 231) prohibits advertisements claiming that a product has curative or preventive effects on any of the diseases listed in the schedules to the Ordinance. However, many of the "health foods" are advertised with claims not specified in the Ordinance.

1.3 In order to better protect the public from exaggerated or misleading claims, we propose to include a list of health claims for orally consumed products which will be prohibited under a new Schedule to the UMAO.

1.4 This consultation document invites views and comments from the public, traders, health care professionals and interested bodies on the prohibited claims proposed in this paper.

## CHAPTER 2: LOCAL SITUATION

### Existing Regulatory Controls in Hong Kong

2.1 At present, the Pharmacy and Poisons Ordinance (PPO)(Cap. 138) controls as "pharmaceutical products" any product carrying a claim for the treatment, or prevention, of a specific disease or disease symptom. The controls are in the form of pre-marketing registration of individual products (the criteria of registration being safety, efficacy and quality), labelling requirements, licensing of manufacturers and sellers, and restrictions on retail sale (i.e. sale by pharmacists only, or sale on a doctor's prescription only). However, this Ordinance does not apply to so-called health foods that are not pharmaceutical products.

2.2 The Chinese Medicine Ordinance (CMO)(Cap. 549) will control products which are composed of Chinese medicines as active ingredients. The licensing of manufacturers, importers and wholesalers commenced in May 2003 and the registration of proprietary Chinese medicines will begin at the end of 2003. However, products which are not composed of Chinese medicines fall outside the ambit of this Ordinance.

2.3 The Public Health and Municipal Services Ordinance (PHMSO)(Cap. 132) prohibits the sale, and possession for the purpose of sale, of any food which is unfit for human consumption. Therefore, the safety of so-called health foods for human consumption purposes is already subject to some control.

2.4 The Undesirable Medical Advertisements Ordinance(UMAO) (Cap. 231) prohibits the advertising of products or treatments for the prevention or treatment of diseases or conditions specified in the Ordinance. Health claims appearing in the labels of products are also covered. However, many food products are labelled, or are advertised, with claims which are not specified in this Ordinance, and such claims fall outside the ambit of this Ordinance.

### Health Claims: Present Situation

2.5 In a recent survey of health claims of orally consumed products

currently available in the market, some of the claims were considered misleading or exaggerated. These claims can be broadly grouped into the following two categories:

(i) **Claims relating to body functions which may delay the public from seeking proper medical advice and management** - Examples include regulation of blood pressure, regulation of blood lipid or cholesterol, etc. As these claims usually do not mention prevention or treatment of specific diseases, they are outside the control of the existing legislation e.g. PPO and UMAO.

(ii) **Exaggerated or misleading health-related claims** - Examples include misleading claims relating to slimming, weight reduction, breast enhancement, detoxification etc. Regulation of these claims requires consensus in the community. In regulating these claims, a balance has to be struck between protection of public health and freedom of choice by consumers.

## CHAPTER 3 : THE INTERNATIONAL SCENE

### Advertising Laws

3.1 Many countries and regions like the European Union, the United Kingdom, Australia, Canada and Singapore have advertising laws similar to the Undesirable Medical Advertisements Ordinance (Cap. 231) of Hong Kong which prohibit the advertising of any food, drug, cosmetics or device to the general public as a treatment, prevention or cure of any diseases and conditions referred to in a schedule.

3.2 The European Union, the United Kingdom and China have regulations which prohibit the advertising to the general public of medicinal products which are available on medical prescription only.

3.3 The USA allows the advertising of prescription drugs but the Federal Food, Drug, and Cosmetic Act (the Act) requires that manufacturers, packers and distributors who advertise prescription drugs to disclose in advertisements certain information about the uses and risks of the advertised product. The Act also requires these advertisements to contain "information in brief summary relating to side effects, contraindications and effectiveness".

### Regulation of Health Food and Health Claims

3.4 At present, there is neither international consensus on the regulation of so-called health food or health claims, nor a universally accepted definition of "health food" products. Different terms such as dietary supplements, nutraceuticals, functional foods and natural health products are used on different occasions to refer to similar products.

3.5 In some countries such as Australia, China and Canada, "health food" products are subject to pre-marketing approval. The criteria for approval of registration will be the safety, efficacy and quality of the product. Manufacturers are required to provide appropriate scientific evidence in support of any health claims made.

3.6 In other countries such as the USA and the United Kingdom,

“health food” products are not subject to pre-marketing approval, but health claims for these products are regulated. These products can carry certain types of claims, which are usually related to the content of the nutrient or showing the link between an ingredient to a health condition. These authorized claims are defined with specified rules on their use. For details of the regulation of “health food” and health claims in different countries, please refer to Appendix 1.

## CHAPTER 4 : THE PROPOSED REGULATION

4.1 We propose to amend the UMAO for the purpose of regulating health claims. The UMAO currently prohibits the advertising of medicines, surgical appliances or treatments for prevention or treatment of certain diseases or conditions in human beings. The purpose of the prohibition is to prevent improper self-medication by members of the public, thereby causing harm as a result of either the improper self-medication itself, or the delayed proper treatment they should receive. The UMAO has two schedules, Schedules 1 and 2. It is an offence for any person to publish, or cause to be published, any advertisement likely to lead to the use of any medicine, surgical appliance or treatment for treating or preventing any disease or condition specified in column 1 of Schedule 1, except for a purpose (if any) specified in column 2. Advertisements for the purposes specified in Schedule 2 are also prohibited. A copy of the UMAO is at Appendix 2.

4.2 We propose to include in the UMAO a list of prohibited claims as a new schedule to address the misleading information and undesirable claims of orally consumed products. The Director of Health would have the power to amend the new schedule and to extend its coverage to other products and services as and when necessary having regard to latest developments and for the protection of public health. The Director of Health would have the power to authorize public officers to be inspectors to enforce the relevant provisions of the UMAO.

4.3 An Expert Committee consisting of representatives from the Consumer Council, Chinese medicine practitioners, medical practitioners, pharmacists and a nutritionist was set up at the end of 2002 to study and recommend a list of health claims to be prohibited in orally consumed products.

4.4 In considering the health claims to be prohibited, a risk assessment approach was adopted. The Expert Committee generally agreed that claims which might affect the health of the public should be prohibited. Claims with less risk may be excluded from the list.

4.5 The Expert Committee has reviewed 13 groups of claims and

recommended that nine groups of health claims should be prohibited and be included as a schedule to the UMAO. These claims are:

(i) Regulation of body sugar or glucose including alteration of functions of the pancreas.
(ii) Regulation of blood pressure.
(iii) Regulation of blood lipid or cholesterol.
(iv) Prevention, elimination or treatment of breast lumps.
(v) Regulation of function of the genitourinary system, including improvement of symptoms of genitourinary problems.
(vi) Regulation of the endocrine system including maintenance or alteration of hormonal secretions.
(vii) Claims relating to slimming or fat reduction of the body including fat burning, eliminating fat, controlling appetite, absorbing fat and eliminating fluid retention.
(viii) Regulation of body immune system against diseases including cancers, chronic diseases and infection; or alteration of the effects of treatment e.g. chemotherapy and radiotherapy, etc.
(ix) Promotion of detoxification.

Examples of claims and reasons for prohibiting these claims are appended at Appendix 3.

4.6 The Expert Committee also agreed not to include the following 4 groups of claims in the UMAO:

(i) Correction or alleviation of symptoms relating to menopause.
(ii) Stimulation of hair growth or prevention of hair loss.
(iii) Promotion of enlargement or firmness of the breast.
(iv) Regulation or alteration of structure of the genitourinary system.

The reasons for not including these claims are listed at Appendix 4.

## CHAPTER 5 : THE WAY FORWARD

5.1 There is no universal approach to the regulation of "health food" or health claims. Different places have adopted different regulations. For those with a regulatory framework in place, the types of regulation range from pre-marketing approval to prescribing a list of claims.

5.2 Following the introduction of the registration system for proprietary Chinese medicines later in 2003, a significant number of "health food" products consisting of Chinese medicines as active ingredients will be required to be registered. The claims for these products must be substantiated with different levels of evidence, such as history of use or traditional references and clinical trial data. In this connection, the so-called health food products which are not controlled by the Pharmacy and Poisons Ordinance or the Chinese Medicine Ordinance will be reduced to a small number.

5.3 The proposed inclusion of a list of prohibited claims in the UMAO could further enhance the protection of public health.

5.4 The list of prohibited claims can be amended to include new claims as and when necessary according to the latest development. The Schedule can also be amended in future by the Director of Health to include other products and services.

5.5 Upon the enactment of the new schedule of prohibited claims, the "health food" industry would be given a grace period of appropriate duration during which they can make changes and preparations in order to comply with the new requirements. The manufacturers and traders may have to change the existing labels on the products and to withdraw those pamphlets containing offending claims. In this connection, taking into consideration the shelf life of pre-packaged food in general and the lead-time needed by the manufacturers and traders to prepare for new labels, a grace period of at least 18 months is considered necessary. On the other hand, enforcement against advertisements in newspapers, magazines, television and radio contravening the new requirements can take effect at an earlier date.

**Views Sought**

5.6 We look forward to your views and comments on the regulation of health claims proposed above. Please send your comments on the consultation document on or before 15 November 2003 by

(a) Post : Secretariat
Consultation on Regulation of Health Claims
3/F Public Health Laboratory Centre
382 Nam Cheong Street, Kowloon

(b) Fax : 2834 5117

(c) E-mail : healthclaims@dh.gov.hk

5.7 This consultation document is also available at the following websites :

***http://www.hwfb.gov.hk***
***http://www.dh.gov.hk***

**Appendix 1**

## Regulation of "Health Food" and Health Claims in Other Countries and the Mainland China

### USA

In the United States, "health foods" are called dietary supplements. The principal legislation regulating dietary supplements is the Dietary Supplement and Health Education Act (DSHEA). DSHEA places the responsibility for ensuring the safety of dietary supplements on manufacturers. It also specifies labelling and Good Manufacturing Practices (GMP) requirements. The Food and Drug Administration (FDA) does not analyze or approve dietary supplements before marketing. If a dietary supplement does not contain any new ingredients, the manufacturer is simply required to notify FDA within 30 days of launch of the product. On the other hand, if it contains a new ingredient, the manufacturer will have to notify FDA 75days before product launch.

2. Under DSHEA, dietary supplements can carry three types of claims: nutrient-content claims, health claims and structure/function claims. Nutrient-content claims are defined, and rules on their use promulgated, by FDA (e.g. the claim "high calcium" can be used for products containing more than 200mg calcium per serving). Health claims show a link between an ingredient and a health condition. Manufacturers of dietary supplements are required to obtain an authorization from the FDA before they can make a health claim on the labels of dietary supplements. Structure / function claims can be made without FDA authorization. When a structure/function claim is made for a product, the manufacturer is responsible for ensuring its truthfulness and that it is not misleading, and the product label must bear the disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

### European Union

3. In the European Union, "health foods" are not subject to any

specific form of control, unless "medicinal claims" are made in relation to the product. In the latter case, the product will be controlled as a pharmaceutical product and the full requirements of marketing authorization approval (i.e. evaluation of safety, efficacy and quality for registration purpose, and GMP) will apply.

**Australia**

4. In Australia, "health foods" are called complementary medicines and are subject to pre-marketing approval. Depending on the ingredients and on the nature of the claims made, complementary medicines are classified as "high risk" and "low risk" ones. The former must be registered, while the latter must be listed. Registered medicines are evaluated for their safety, efficacy and quality. Most complementary medicines are listed. Listed medicines are evaluated for safety and quality only. As regards efficacy, manufacturers are required to keep in hand appropriate scientific evidence to support any efficacy claims they make about their products. Such claims must be true, valid, not misleading, and should not lead to the unsafe or inappropriate use of the product. In general, the efficacy claims allowed are "low risk" ones, i.e. relating to minor conditions only.

**Canada**

5. The new Natural Health Products Regulations (NHP Regulations) were published in the Canada Gazette, Part II on 18 June 2003. The NHP Regulations will come into force on 1 January 2004, with a transition period ranging from 2 years (for site licensing) to six years (for product licensing). The products that fall within the new Regulations include herbal remedies, homeopathic medicines, vitamins, minerals, traditional medicines, probiotics, amino acids and essential fatty acids. All natural health products in Canada will require a product licence before being marketed. In making health claims, evidence such as history of use or traditional references, observational studies, clinical trial data must be furnished.

**The Mainland China**

6. In the Mainland China, “health food” is controlled by the Health Food Control Act and is defined as food which is labeled with specific health effects and which does not aim at treating or remedying human diseases. The “health food” is suitable for a specific group of people and used for the regulation of the functional states of the human body. “Health food” is subject to pre-marketing approval by the Ministry of Health. Health claims made on the labels and in product inserts must be substantiated by scientific evidence.

7. In conclusion, there is yet no internationally agreed approach on the regulation of “health food” or health claims.

**Appendix 2**

## Undesirable Medical Advertisements Ordinance (Cap.231)

Section: **1** Heading: **Short title** Version Date: 30/06/1997
This Ordinance may be cited as the Undesirable Medical Advertisements Ordinance.

Section: **2** Heading: **Interpretation** Version Date: 30/06/1997
(1) In this Ordinance, unless the context otherwise requires- (Amended 65 of 1988 s. 9; L.N. 95 of 1993)
"advertisement" (廣告) includes any notice, poster, circular, label, wrapper or document, and any announcement made orally or by any means of producing or transmitting light or sound;
"medicine" (藥物) includes any kind of medicament or other curative or preventive substance, and whether a proprietary medicine, a patent medicine, or purported natural remedy.
(2) For the purposes of this Ordinance-

(a) the sale or supply, or offer or exposure for sale or supply, of any-
(i) medicine;
(ii) surgical appliance; or
(iii) treatment,
in a labelled container or package shall constitute the publication of an advertisement;

(b) the supply, inside any container or package containing any medicine, surgical appliance or treatment, of information relating to that or any other medicine, surgical appliance or treatment shall not constitute the publication of an advertisement. (Added 65 of 1988 s. 9)

Section: **3** Heading: **Prohibition of advertisements relating to certain diseases; exceptions therefrom** Version Date: 30/06/1997
(1) No person shall publish, or cause to be published, any advertisement likely to lead to the use of any medicine, surgical appliance or treatment for-

(a) the purpose of treating human beings for, or preventing human beings from contracting, any disease or condition specified in column 1 of Schedule 1, except for a purpose (if any) specified in column 2 of that Schedule; or

(b) treating human beings for any purpose specified in Schedule 2. (Replaced 65 of 1988 s. 2)

(2) Subsection (1) shall not apply to an advertisement published by or with the authority of the Director of Health or to an advertisement duly authorized by an officer of Her Majesty's forces for dissemination only amongst members of Her Majesty's forces. (Amended L.N. 76 of 1989)

(3) Where, in an advertisement published in contravention of subsection (1), a person named in that advertisement is held out-

(a) as being a manufacturer or supplier of medicine or surgical appliances; or

(b) as being able to provide any treatment,

that person is presumed, until the contrary is proved, to have caused the advertisement to be published. (Added 65 of 1988 s. 2)

(4) Where an advertisement published in contravention of subsection (1) gives the name, address or telephone number of, or indicates some other means of contacting, a person, and that person-

(a) manufactures or supplies medicine or surgical appliances; or

(b) provides any treatment,

that person is presumed, until the contrary is proved, to have caused the advertisement to be published. (Added 65 of 1988 s. 2)

(5)-(6) (Omitted as spent)

Section: **3A** Heading: **(Omitted as spent)** Version Date: 30/06/1997

(Omitted as spent)

Section: **4** Heading: **Prohibition of advertisements relating to abortion** Version Date: 30/06/1997

(1) Subject to subsection (2), no person shall in any manner write, print, or publish or cause to be written, printed or published any advertisement-

(a) offering to procure the miscarriage of women;

(b) canvassing the procuration of miscarriage of women;

(c) inviting or inducing the procuration of miscarriage of women; or

(d) referring to any thing whatsoever, in terms which are calculated to lead to the use of that thing for the procuration of miscarriage of women.

(2) Subsection (1) shall not apply to an advertisement published by or with the written authority of the Director of Health. (Amended L.N. 76 of 1989)

(3) Where, in an advertisement published in contravention of subsection (1), a person named in that advertisement is held out-

(a) as being a manufacturer or supplier of medicine or surgical appliances; or

(b) as being able to provide any treatment,

that person is presumed, until the contrary is proved, to have caused the advertisement to be published. (Added 65 of 1988 s. 4)

(4) Where any advertisement published in contravention of subsection (1) gives the name, address or telephone number of, or indicates some other means of contacting, a person, and that person-

(a) manufactures or supplies medicine or surgical appliances; or

(b) provides any treatment,

that person is presumed, until the contrary is proved, to have caused the advertisement to be published. (Added 65 of 1988 s. 4)

(Replaced 70 of 1980 s. 2)

Section: **5** Heading: **Certain defences; provision as to Chinese medicine practitioners** Version Date: 01/03/2002

(1) In any proceedings for a contravention of section 3 or 4, it shall be a defence to prove that the advertisement to which the proceedings relate was made only in a publication of a technical character intended for circulation mainly amongst persons of the following classes, or of one or some of them-

(a) medical practitioners registered under the Medical Registration Ordinance (Cap 161), or persons deemed to be medical practitioners under section 29 thereof;

(b) pharmacists registered under the Pharmacy and Poisons Ordinance (Cap 138);

(c) the professional staff of hospitals, nursing homes, leprosaria or mental hospitals;

(d) Chinese medicine practitioners registered or listed under the Chinese Medicine Ordinance (Cap 549). (Replaced 47 of 1999 s. 168)

(2) Nothing in the provisions of section 31 of the Medical Registration Ordinance (Cap 161) shall be taken to permit any Chinese medicine practitioner or other person to take any part in an advertisement infringing the provisions of this Ordinance, except to the extent of the defence provided for in subsection (1). (Amended 47 of 1999 s. 168)

Section: **6** Heading: **Penalty** Version Date: 30/06/1997

Any person who contravenes the provisions of section 3 or 4 shall be guilty of an offence and shall be liable upon a first conviction to a fine of

$10000 and upon a second or subsequent conviction to a fine of $25000 and imprisonment for 1 year.
(Amended 65 of 1988 ss. 5 & 10)

Section: **7** Heading: **Power to amend Schedules** Version Date: 30/06/1997
The Director of Health may, by order published in the Gazette, amend the Schedules.
(Added 65 of 1988 s. 6. Amended 80 of 1997 s. 16)

Schedule: **1** Heading: **DISEASES AND CONDITIONS IN RESPECT OF WHICH ADVERTISEMENTS ARE PROHIBITED OR RESTRICTED** Version Date: 30/06/1997
[section 3]

| | **Column 1**<br>**Disease**<br>**or condition** | **Column 2**<br>**Purposes for which**<br>**advertising is permitted** |
|---|---|---|
| 1. | Any benign or malignant tumour. | None. |
| 2. | Any viral, bacterial, fungal or other infectious disease, including tuberculosis, dysentery, hepatitis and leprosy. | Treatment or prevention of minor cutaneous infections where a medicinal product is to be administered to an external surface of the body, including treatment by means of preparations for the relief of pruritus or exanthematous rashes of childhood infection.<br><br>Relief of symptoms of aphthous ulcer.<br><br>Relief of symptoms of common colds, coughs, conditions commonly referred to as influenza and similar upper respiratory tract infections.<br><br>Treatment of minor acute inflammatory conditions of the buccal cavity and pharynx. |

| | | |
|---|---|---|
| 3. | Any parasitic disease. | Treatment of scabies or an infestation by threadworms, lice or roundworm, provided that the advertisement consists solely of a labelled container or package in which a medicine, surgical appliance or treatment is supplied. |
| 4. | Any venereal disease, including syphilis, gonorrhoea, soft chancre, lymphogranuloma venerum, genital herpes, genital warts, urethritis, vaginitis, urethral or vaginal discharge, acquired immunodeficiency syndrome (AIDS), and any other sexually transmitted disease. | None. |
| 5. | Any respiratory disease, including asthma, bronchitis, and pneumonia. | Temporary relief of symptoms of hay fever, rhinitis or catarrh.<br><br>Relief of blocked-up sinuses. |
| 6. | Any disease of the heart or cardiovascular system, including rheumatic heart disease, arteriosclerosis, coronary artery disease, arrythmias, hypertension, cerebrovascular disease, congenital heart disease, thrombosis, peripheral artery disease, oedema, retinal vascular change and peripheral venous disease. | None. |
| 7. | Any gastro-intestinal disease, including gallstone, cirrhosis, gastro-intestinal bleeding, diarrhoea, hernia, fistula-in-ano and haemorrhoids. | Relief of such symptoms as are commonly referred to as indigestion, heartburn, hyperacidity, dyspepsia, halitosis (bad breath) or flatulence.<br><br>Symptomatic relief of colicky pain, |

| | | |
|---|---|---|
| | | stomach ache or nausea.<br><br>Relief of occasional or non-persistent diarrhoea or constipation.<br><br>Prevention of travel sickness or related symptoms.<br><br>Treatment of haemorrhoids for relief of symptoms by means of locally effective preparations or stool-softening agents and lubricants. |
| 8. | Any disease of the nervous system, including epilepsy, mental disorder, mental retardation and paralysis. | Symptomatic relief of headaches. |
| 9. | Any disease of the genito-urinary system, including kidney stone, nephritis, cystitis, any prostatic disease and phimosis. | None. |
| 10. | Any disease of the blood or lymphatic system, including anemia, neck glands, bleeding disorders, leukemia and other lympho-proliferative diseases. | Prophylactic administration of minerals and vitamins to avoid deficiency states in persons with inadequate diet or with increased dietary requirements. |
| 11. | Any disease of the musculo-skeletal system, including rheumatism, arthritis and sciatica. | External preparations for the relief of symptoms of muscular pain and stiffness and cramp. |
| 12. | Any endocrine disease, including diabetes, thyrotoxicosis, goitre and any other organic or functional condition related to under or over activity of any part of the system. | Provision of dietary supplements. |

| | | |
|---|---|---|
| 13. | Any organic condition affecting sight, hearing or balance. | Relief of symptoms by means of the local administration of eye preparations.<br><br>Relief of symptoms by means of local administration of preparations as a solvent for ear wax. |
| 14. | Any disease of the skin, hair or scalp. | Prevention or treatment of dandruff by means of external applications.<br><br>Treatment, where applied to an external surface of the body, of pimples, eczema, skin allergies and athlete's foot.<br><br>Prevention or treatment of contact dermititis and sunburn by means of protective applications.<br><br>Treatment of hard skin and corns by means of the application of corn plasters or solvents.<br><br>Relief or prevention of common minor skin conditions including dry and chapped skin, cold sores, pruritus, insect bites, heat rash and napkin rash. |

(Schedule 1 added 65 of 1988 s. 8)

Schedule: **2** Heading: **PURPOSES FOR WHICH IT IS PROHIBITED TO ADVERTISE ANY MEDICINE, SURGICAL APPLIANCE OR TREATMENT** Version Date: 30/06/1997

[section 3]

1. The induction of menstruation or relief of amenorrhea or delayed menstruation or any other gynaecological or obstetrical disease.

2. The promotion of sexual virility, desire or fertility, or the restoration of lost youth.

3. The correction of deformity or the surgical alteration of a person's appearance.

(Schedule 2 added 65 of 1988 s. 8)

Schedule: **3** Heading: **Repealed** Version Date: 30/06/1997
(Repealed 65 of 1988 s. 11)

**Appendix 3**

## List of Proposed Prohibited Claims in Orally Consumed Products

| | Prohibited Claims | Examples | Reasons | Exemption |
|---|---|---|---|---|
| 1. | Regulation of body sugar or glucose including alteration of functions of pancreas | Regulate blood glucose<br>Stabilize blood glucose<br>Suppress / Reduce absorption of glucose<br>Reduce blood sugar level<br>Against blood sugar<br>Increase metabolism of body sugar<br>Suitable for diabetic patients<br>Suitable for people concerned about high blood sugar<br>Improve the function of pancreas<br>Stimulate the secretion of insulin | The claims imply prevention or treatment of diabetes. The claims may delay the public from seeking proper medical advice and management. | If a product contains an artificial sweetener, which is listed in Food Adulteration (Artificial Sweetener) Regulations, as the only major active ingredient, it is allowed to make the claim "Suitable for diabetic patients."<br><br>**Remarks**<br>Column 2, item 12 of Schedule 1 of the existing UMAO be amended so that nothing would be included in Column 2. |
| 2. | Regulation of blood pressure | Stabilize blood pressure<br>Regulate blood pressure<br>Control blood pressure<br>Reduce hypertension<br>Suitable for people with high blood pressure<br>Suitable for people concerned about blood pressure | The claims imply prevention or treatment of hypertension. The claims may delay the public from seeking proper medical advice and management. | |

| | | | |
|---|---|---|---|
| 3. Regulation of blood lipid or cholesterol | Prevent high blood lipid | The claims imply prevention or improvement of high blood lipid / cholesterol which are risks factor of important diseases like coronary heart disease. The claims may delay the public from seeking proper medical advice and management. | |
| | Help maintain normal blood lipid | | |
| | Lower blood lipid | | |
| | Reduce/Regulate cholesterol | | |
| | Balance blood cholesterol | | |
| | Excrete cholesterol in the blood vessel outside the body | | |
| | Suitable for people with high blood lipid / high cholesterol | | |
| | Suitable for people concerned about blood lipid / cholesterol | | |
| 4. Prevention, elimination or treatment of breast lumps | Eliminate blocking of milk duct of the breast | These claims imply prevention or treatment of breast lump which could be due to serious underlying conditions that should require prompt medical assessment and treatment. The claims may delay the public from seeking proper medical advice and management. | |
| | Help eliminate disease-causing factors, lumps and relieve the associated discomfort symptoms | | |
| | Improve the metabolism of breast tissue, effectively disintegrates and eliminates abnormal cell tissues and lumps | | |
| 5. Regulation of function of the genitourinary system, including improvement of symptoms of genitourinary problems | Frequent urination, urgent urination, dripping urination, poor stream | These claims imply the prevention or treatment of genitourinary disease. The claims may delay the public from seeking proper medical advice and management. | |
| | Difficulty in urination | | |
| | Prevent urination at night | | |
| | Frequent urination at night | | |
| | Impeded prostatic function | | |
| | For uncontrollable urinary discharge / incontinence | | |

| | | | |
|---|---|---|---|
| 6. Regulation of the endocrine system including maintenance or alteration of hormonal secretions | Help maintain hormones at optimal level | These claims imply prevention and / or treatment of endocrine diseases or conditions relating to under- or over-activity of endocrine glands. These claims are often exaggerated and misleading which promote the ability of the products to enhance the function of endocrine glands or prevent abnormal physiological functions. | **Remarks**<br>Column 2 , item 12 of Schedule 1 of the existing UMAO be amended so that nothing would be included in Column 2. |
| | Stimulate hypothalamus, increase secretion of estrogen | | |
| | Promote normal secretion of female hormone | | |
| | Regulate female endocrine function | | |
| | Improve imbalance of male hormone secretion | | |
| | Help maintain balance of hormonal secretions in men and women | | |
| | Stimulate hormonal secretions | | |
| | Regulate endocrine secretion | | |
| | Balance endocrine secretion | | |
| | Increase secretion of growth hormone | | |
| | Stimulate thyroid gland | | |

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| 7. Claims relating to slimming or fat reduction of the body including fat burning, eliminating fat, controlling appetite, absorbing fat and eliminating fluid retention | Enhance fat metabolism and help body fat burning | The claims are exaggerated or misleading. These claims will promote or lead to improper way of weight control which can result in very serious side effects e.g. metabolic disorder. | Slimming products registered under the Pharmacy and Poisons Board (PPB) or Chinese Medicines Board (CMB) are allowed to make claims in the label or package insert approved by the PPB or the CMB. |
| | Eliminate fat in the body | | |
| | Help excrete excess fat | | |
| | Help eliminate fat during sleeping | | |
| | Decompose fat | | |
| | Effectively absorb and eliminate fat / oil from the food | | |
| | Regulate fat metabolism | | |
| | Prevent fat accumulation | | |
| | Balance fat level in the body | | |
| | Increase speed of fat burning | | |
| | Control fat absorption | | |
| | Absorb fat | | |
| | Eliminate cellulite | | |
| | Suppress appetite | | |
| | Slimming can be achieved without going on a diet or exercise | | |
| | Can promote firm muscle and beautiful body curve | | |
| | Speed up the burning of excessive calorie in the body | | |
| | Speed up slimming | | |
| | Slim body | | |
| | Reduce weight | | |
| | Prevent / Control obesity | | |
| | Decrease the chance of being obese | | |
| | Eliminate oedema | | |
| | Eliminate excess water in the body | | |
| | Prevent excess sugar to convert into fat | | |

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| 8. Regulation of body immune system against diseases including cancers, chronic diseases and infection; alteration of the effects of treatment including chemotherapy and radiotherapy, etc. | Regulate the immune function<br>Improve immunity<br>Strengthen immune system<br>Stimulate immune system<br>Produce immune cells<br>Increase white blood cells count<br>Enhance ability of white blood cells to engulf microscopic invaders<br>Suppress the growth of harmful cells<br>Strengthen the immunity of cancer patients<br>Enhance the immune function of AIDS patients<br>Reduce the side effect of chemotherapy / radiotherapy<br>As supplementary treatment for cancer | Imply the products can stimulate the immune system to prevent, stabilize, improve, or treat diseases in particular cancers, chronic diseases and infection. These products, even if effective, should be used after proper advice from medical / health care professionals. Improper use of these products would lead to delay in seeking proper medical advice and delay in medical treatment. | |
| 9. Promotion of detoxification | Effective in eliminating toxin, clearing out toxin in blood and intestine<br>Cleanse toxic elements in the body<br>Remove toxic substances in the blood<br>Remove heavy metals and chemical pollutants | The term detoxification is misleading. Most of the advertisements with this claim imply laxative function of the products and exaggerate the benefits of such function. Misuse of these products can lead to serious side effect e.g. electrolytes imbalance, bowel function disturbance, dehydration. | Detoxification products registered under the Pharmacy and Poisons Board (PPB) or Chinese Medicines Board (CMB) are allowed to make claims in the label or package insert approved by the PPB or the CMB. |

**Appendix 4**

## Claims not to be Included in the Prohibited List

Four groups of claims had been discussed but considered not necessary to be included in the new prohibited list for the following reasons:

| Claims | Reason for not including in the prohibited list |
|---|---|
| Correction or alleviation of symptoms relating to menopause | Claims about prevention and treatment of menopausal syndrome are already subject to regulation under existing UMAO as a disease entity.<br><br>Public health risk relating to delayed management of non-specific symptoms relating to menopause is relatively small. |
| Stimulation of hair growth or prevention of hair loss | Claims relating to diseases of hair or scalp are already subject to regulation under existing UMAO. The public health risk relating to the stimulation of hair growth is small. |
| Promotion of enlargement or firmness of the breast | Based on current knowledge, the public health risk is considered small. |
| Regulation or alteration of structure of the genitourinary system | Based on current knowledge, the public health risk is considered small. |