Guidelines on labels of proprietary Chinese medicines

(Reference for the Trade)

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The contents of the labels of proprietary Chinese medicines (pCms) are the very basic information and points to note for the use of the medicines obtained by the public. Hence, to ensure safe use of medicine by the public, the Chinese Medicines Board has formulated these guidelines for convenience of the trade to prepare the contents on the labels. As for the details of the legal provisions, the relevant legislation shall prevail.

According to the Chinese Medicine Ordinance (Chapter 549, Laws of Hong Kong), no pCms shall be sold unless they are properly labelled. Contents of the labels are also specified in sections 26 to 27 of the Chinese Medicines Regulation. Whether being the outermost package to be sold or distributed to an ultimate user of the pCm shall include the following particulars which are clearly and distinctly set out, at least in Chinese:-

(a) the name of the medicine;

(b) if-

  (i) the medicine is composed of less than 3 kinds of active ingredients, the name of each kind of active ingredient; or

  (ii) the medicine is composed of 3 or more kinds of active ingredients, the names of more than half of the total number of kinds of active ingredients;

(c) the name of the country or territory in which the medicine is produced;

(d) the registration number of the medicine as specified in its certificate of registration;

(e) if the package-

(i) is the outermost package, the name of the holder of the certificate of registration of the medicine as specified in the certificate; or

(ii) is not the outermost package, either the particulars set out in paragraph (e)(i) or the name of the manufacturer who produces the medicine;

(f) its packing specification;

(g) its dosage and method of usage;

(h) its expiry date; and

(i) its batch number.

According to the above requirements, the contents should be indicated on the labels of the pCms under the requirements of the following guidelines:-

(a) 【name of the medicine】

- It should be consistent with the name of the registered pCm, including the【product name】 and 【trademark text (if any)】;
- The【product name】should be displayed in order prominently and remarkably. The font, size and colour of the words should be consistent. It should not be named using both Chinese medicine and Western medicine theory, and should not be misleading or exaggerated in any way;
- If the name of pCm is also indicated in English, the【product name】and 【trademark text (if any)】 shall be indicated under the same requirements of indication of the name in Chinese as above.

(b) 【name of the active ingredient】

- It should be consistent with the name of the Chinese herbal medicine in the "master formula" and displayed in its official name under the sequence of the Chinese Medicine Ordinance, Pharmacopoeia of the People's Republic of China and ancient literature such as Zhonghua Bencao. If the active ingredients are extracts or synthetic products, they should be clearly specified (e.g. Scutellaria Extract, Bovis Calculus Artifactus). If compound liquid extracts are the major active ingredients, the ingredients of the Chinese herbal medicine in the formula of the liquid extracts should be indicated;
- The names of the Chinese herbal medicines under Schedule 1 of the Chinese Medicine Ordinance and/or other Chinese medicines specified by the Chinese Medicines Board, including Radix Tripterygii Wilfordii, Herba Gelsemii Elegantis, Radix et Rhizoma Asari, Radix Polygoni Multiflori, Semen cum Monasci Fermentatum, Chinese herbal medicine belongs to the Cordyceps genus, Cordyceps mycelium and other mycelium belongs to the Cordyceps genus which are contained in the "master formula" should be indicated;
- The names of all the Chinese herbal medicines in a master formula should be indicated if the medicine only contains 2 kinds of active ingredients; while the names of more than half of the total number of the Chinese herbal medicines in the master formula should be indicated if the medicine contains 3 or more kinds of active ingredients;
- If the active ingredients indicated are not the whole of the master formula, the word "etc." should be added after the active ingredients.

(c) 【name of the country or territory in which the medicine is produced】

- It should include at least the name of the country or territory in which the medicine is produced (e.g. “Produced in China”, “Produced in Hong Kong”);
- If the name of the manufacturer is to be listed, the name of the country/territory should be included, e.g. “XXX Pharmaceutical Company, Guangzhou, China”.

(d) 【registration number of the medicine as specified in its certificate of registration】

- The registration number will only be printed on the Certificate of Registration of pCm after the application for registration is approved. Therefore, the label should contain the words of “registration number of pCm”. The registration number of pCm is in a format of “HKC-XXXXX”; while “HKP-XXXXX” should be displayed if the pCm is issued with the “Notice of Confirmation of Transitional Registration of pCm”.

(e) 【name or title of the holder of the certificate/the manufacturer who <u>produces</u> the medicine】

- The holder of the certificate should be the same person as the holder specified in the certificate of registration of the medicine;
- The name or title of the manufacturer who is responsible for the process of “production” during the whole manufacturing process of the pCm

should be indicated.

(f) 【its packing specification】

- The pack size should be specified. The specification of the pCm should be shown in terms of weight, quantity or assay, etc. of each unit of preparation (in metric system), e.g. “0.6 gram per tablet, 100 tablets per bottle” or “100 mL per bottle, 12 bottles per box”, etc..

(g) 【its dosage and method of usage】

- The dose of application, frequency of use and method of usage should be listed clearly and accurately;
- The dosage should be indicated in terms of daily dose or each dose (subject to the dose form) while route of administration of medicine and precautions should be clearly indicated under the method of usage;
- Method of usage and dosage should be clearly listed if the product is suitable for different groups of people such as children;
- Clauses or reminders should be indicated for the condition listed in the **Schedule**.

(h) 【its expiry date】

- The expiry date of the whole batch of pCms should be indicated for consumers according to the data obtained from the stability test of the pCms conducted by the manufacturer;
- Words in Chinese such as “expiry date” or in similar meaning should be displayed on the label to show clearly that the medicine should not be administered after that date. The wording of “year, month and day”

must be included.

(i) 【its batch number】

- The batch number is stipulated for the products of the same quality which are produced by the manufacturer at one go. Therefore, words such as "batch number XXXXX" or "batch no. XXXXX" or similar wording should be printed on the label.

"Points to note"

The label shall not contain any wording or words that are without the approval of the Chinese Medicines Board. Besides, the relevant information required should be displayed clearly on ***each label*** *of the packing which contains more than one product when the names and quantities of the major ingredients of the products as well as the dose forms of the products are different from one to another.*

In addition to the requirements as stipulated in the Chinese Medicine Ordinance, applicants should also comply with the provisions of other relevant ordinances when labelling their products. Applicants should make sure that their products are in line with the legal requirements when preparing the labels for pCms. The relevant legal requirements are:

(a) Undesirable Medical Advertisements Ordinance (Cap. 231): relevant sections on regulating the names, claims and labels of medicinal products;

(b) Trade Marks Ordinance (Cap. 559): relevant sections on regulating the use of registered trade marks;

(c) Trade Descriptions Ordinance (Cap. 362): relevant sections on prohibition of false description, false signs and fraudulent statements of products.

Schedule

Condition		Clauses or reminders should be indicated **on the outermost package** under the item of【dosage and method of usage of the medicine】
1.	pCms containing methyl salicylate	1. Consult a Chinese medicine practitioner or seek advice from a doctor before the use of this product by children. 2. Avoid contacts with eyes and mucous membranes when in use.
2.	pCms containing Herba Ephedrae (For internal and external application)	This product is not suitable for long term use or this product should be used in accordance with a doctor's or a Chinese medicine practitioner's instruction.
3.	Orally consumed pCms containing Semen cum Monasci Fermentatum	Should avoid using this product concurrently with statin drugs or other products containing red yeast rice, or seek medical advice before use.