

Guidelines on package inserts of proprietary Chinese medicines

(Reference for the Trade)

(Jan 2020 version)

The contents of the package inserts of proprietary Chinese medicines (pCms) are the detailed 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 package inserts. 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 attached with package inserts which are prepared under the requirements. Contents of the package inserts are also specified in section 28 of the Chinese Medicines Regulation. The package inserts 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 and its quantity; 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 and their respective quantities;
- (c) either the name of the holder of the certificate of registration of the medicine as specified in the certificate or the name of the manufacturer who produces the medicine;
- (d) its dosage and method of usage;
- (e) its functions or pharmacological action;
- (f) its indications (if any);
- (g) its contra-indications (if any);
- (h) its side-effects (if any);
- (i) its toxic effects (if any);
- (j) the precautions to be taken regarding its use (if any);
- (k) its storage instructions; and
- (l) its packing specification.

According to the above requirements, the contents indicated on the package inserts of the pCms should be consistent with the contents contained in the labels and

shall not contain any contents that are without the approval of the Chinese Medicines Board. The applicants may indicate the contents 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 and its quantity】

- It should be consistent with the name of the Chinese medicines 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 Artificatus). If compound liquid extracts are the major active ingredients, the ingredients of the Chinese herbal medicines in the formula of the liquid extracts should be indicated;
- The names and quantities 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 and Semen cum Monasci Fermentatum which are contained in the “master formula” should be indicated;
- The names and quantities 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 and quantities 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 than 3 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;
- If the Chinese herbal medicine in a master formula is shown in terms of

weight or volume, the net weight/net volume of each unit of preparation should be displayed.

- Unit of weight should be in milligram/mg, gram/g;
- Unit of volume should be in metric system such as millilitre/mL, microlitre/ μ L;
- If the amount is shown in percentage, it should include all the active ingredients together with the excipients and indicate the net weight of a single unit of preparation for conversion of measurement.

(c) **【 name or title of the holder of the certificate/the manufacturer who produces the medicine 】**

- The holder of the certificate should be the same person as the holder specified in the certificate of registration of the medicine; or
- 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.

(d) **【 its dosage and method of usage 】**

- The dosage 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.

(e) **【 its functions or pharmacological action 】**

- The functions or pharmacological action should be clear, distinct and consistent with the contents submitted and approved;
- If the product is under a pharmacopoeia prescription or a prescription from the National Drug Standards, its functions or pharmacological action should not be extended and should be consistent with those under the relevant standards.

(f) **【 its indications (if any) 】**

- The indications of the pCm shall follow the contents of the “indications” from the interpretation and principle of formulating the prescription of the pCm as submitted;
- The curative effect of the product under a pharmacopoeia prescription or a prescription from National Drug Standards shall not be extended. The

indications of the product should be consistent with those under the Chinese Pharmacopoeia or National Drug Standards;

- As for the health-preserving medicines under non-established medicines, only the functions of these medicines shall be described. The indications of these medicines shall not be displayed.

(g) 【its contra-indications (if any)】

- To illustrate the conditions where the medicine shall not be used. To indicate properly the contra-indications of the product for specific groups of persons according to the properties of the medicine;
- Clauses or reminders should be indicated for the conditions listed in the Schedule I.

(h) 【its side-effects (if any)】

- To indicate the effects that are not associated with the medicine which are likely or probably to be arising from the normal method of usage and dosage of the medicine.

(i) 【its toxic effects (if any)】

- To indicate the toxic effects that are not associated with the medicine arising from the normal method of usage and dosage of the medicine.

(j) 【the precautions to be taken regarding its use (if any)】

- To outline the points to note when using the medicine, including the conditions requiring cautions of the medicine (e.g. problems of liver and kidney functions), factors affecting the curative effects of the medicine (e.g. food, cigarette, alcohol etc.), conditions requiring observations during the process of the use of the medicine (e.g. allergic reaction), the use of the medicine for special groups of people such as pregnant women, breastfeeding women, children and the elderly, the effects on the indicators of clinical examination due to the use of the medicine, drug abuse and drug dependence, as well as the contents that safeguard the user of the medicine when using the medicine on his own;
- Clauses or reminders should be indicated for the conditions listed in the Schedule II.

(k) 【its storage instructions】

- Should be indicated according to the summary of the results of the stability test. Instructions should be given accurately on the package inserts if the product is required to be kept under specific conditions (temperature such

as “Store at 2°C to 5°C”, humidity such as “Keep in a cool and dry place”, lighting such as “Protect from light”).

(l) 【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..

“Points to note”

The package inserts 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 the package inserts 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 preparing the package inserts of the pCms.

Condition	Clauses or reminders should be indicated under the item of 【its contra-indications】
1. pCms containing Radix Tripterygii Wilfordii (for internal application)	<ol style="list-style-type: none"> 1. Contraindicated in children, women in their child-bearing period who want to become pregnant, pregnant women and breastfeeding women. 2. Contraindicated in those suffering from heart, liver or kidney malfunction; also contraindicated in those suffering from severe anaemia, decreased leukocyte and platelet count. 3. Contraindicated in patients with active gastric or duodenal ulcer. 4. Contraindicated in those suffering from severe arrhythmia.
2. pCms containing Radix Polygoni Multiflori	<ol style="list-style-type: none"> 1. Contra-indicated in those suffering from liver or kidney malfunction. 2. Contra-indicated in pregnant women. 3. Not recommended for patients with known personal history of liver injury from this product or ingredients in this formula.

Condition	Clauses or reminders should be indicated under the item of 【precautions to be taken regarding its use】
1. pCms containing Chinese herbal medicines under Schedule 1 or other toxic Chinese medicines (For internal and external application)	Overdose may cause danger
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. pCms of preparation for external application	For external application only
4. pCms of preparation for ophthalmic application	Use within ' <i>time specified</i> ' after opening
5. pCms in suspension and emulsion	Shake well before use
6. pCms containing methyl salicylate	<ol style="list-style-type: none"> 1. Avoid to use products containing methyl salicylate in children who have a flu, chickenpox or fever 2. People who are allergic to salicylic acid should consult a Chinese medicine practitioner or a doctor before using this product
7. pCms containing Radix Tripterygii Wilfordii (for internal application)	<ol style="list-style-type: none"> 1. Adverse reactions of using preparations of Radix Tripterygii Wilfordii may involve damage to various systems. It should be used strictly in accordance with a Chinese medicine practitioner's instruction. The adverse reactions include - <ol style="list-style-type: none"> (a) Digestive system: dry mouth, nausea, vomiting, fatigue, loss of appetite, abdominal distention, diarrhea, jaundice, elevations in transaminase; acute toxic liver injury and gastric bleeding may occur in severe cases.

Condition	Clauses or reminders should be indicated under the item of 【precautions to be taken regarding its use】
	<p>(b) Blood system : decreased leukocyte and platelet count; agranulocytosis and decreased complete blood count may occur in severe cases.</p> <p>(c) Renal system: kidney impairment such as decreased or excessive urination, oedema and kidney disorders; acute renal failure may occur in severe cases.</p> <p>(d) Cardiovascular system: palpitation, oppression in chest, arrhythmia, high or low blood pressure, electrocardiographic abnormalities.</p> <p>(e) Reproductive and endocrine system: menstrual disorder, hypomenorrhea or amenorrhea in women; decreased sperm count and sperm motility in men.</p> <p>(f) Nervous system: vertigo, dizziness, somnolence, insomnia, neuritis, diplopia.</p> <p>(g) Others: skin rashes, pruritus, hair loss, facial pigmentation.</p> <p>2. This product should be used strictly in accordance with the dosage indicated on the package insert and under a doctor's guidance. Overdose is not allowed.</p> <p>3. While taking the drug, the patient should note that regular follow-up consultations should be made for blood tests, urinalysis, electrocardiograms and examinations for liver and kidney functions. Stop taking the drug if necessary and seek treatment accordingly.</p> <p>4. This drug should not be taken continuously for over three months in general. The decision of taking it for over three months should be made by a doctor having regard to the patient's conditions and treatment needs.</p>

Condition	Clauses or reminders should be indicated under the item of 【precautions to be taken regarding its use】
<p>8. pCms containing Radix Polygoni Multiflori (For internal and external application)</p>	<ol style="list-style-type: none"> 1. Biochemical parameters of liver function should be monitored while on use. Stop using the medicine and seek medical consultation promptly if abnormalities are found in the biochemical parameters of liver function, or clinical symptoms possibly related to liver injury such as fatigue, loss of appetite, sick of eating greasy food, nausea, dark urine, yellow eyes and yellow discoloration of the skin are observed, or aggravation of previous abnormalities in biochemical examination of liver and clinical symptoms of liver injury. 2. Use strictly in accordance with the method of usage and dosage. Avoid overdose or prolonged use. 3. Used with caution in the elderly, people with abnormalities in the biochemical parameters of liver function and patients with history of liver disease. 4. Breast-feeding women should either choose to discontinue breast-feeding while this product is on use or stop using this product. 5. Used with caution in children as systematic research data on the safe use of this medicine in children is not available. 6. Used with caution in patients with known family history of liver injury from this product or ingredients in this formula. 7. Should avoid using this product concurrently with other medicines that may cause hepatotoxicity.

Condition	Clauses or reminders should be indicated under the item of 【precautions to be taken regarding its use】
9. pCms in oral dosage form containing Tremolitus	<p>(Capsule): This product contains Tremolitus. Take the capsule by swallowing it whole. Don't open the capsule.</p> <p>(Pill): This product contains Tremolitus. Take the pill by swallowing it whole. Don't crush the pill.</p>
10. 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.