DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION
AND IMPORT/EXPORT CONTROL DIVISION

Guidelines on the Labelling of Pharmaceutical Products

Introduction

These guidelines set out the labelling requirements in respect of pharmaceutical products for the purpose of registration. The requirements should not be treated as exhaustive. Other supplementary labelling may be required for particular products taking into consideration the nature and the intended uses of such products. In case of any doubt, the Pharmacy and Poisons Ordinance and Regulations, Cap.138 should be consulted.

A. General Labelling Requirements

1. Name of the product.
2. Name and quantity of each active ingredient.
3. Name and address of the manufacturer.
4. Hong Kong registration number of the product.
5. Batch Number.
6. Expiry date.
7. Specific storage conditions, if any.

B. Additional Labelling Requirements for Sterile Products

1. Name of preservatives, if any.
2. Batch number and expiry date (on sales pack and on each ampoule/vial).

C. Additional Labelling Requirements for Certain Classes of Products

1. For embrocations, liniments, lotions, liquid antiseptics or other liquid medicines for external application -

   "For external use only. 只供外用。"

2. For veterinary products -
   "For animal treatment only. 只限醫治禽畜用。"

3. For mouthwashes -
   "Not to be swallowed. 不可吞服。"

4. For eye-drops -
   "Not to be used one month after opening. 開蓋一個月後不可使用。"

D. Additional Labelling Requirements for Non-poisons and Part 2 Poisons

1. Dosage, route and frequency of administration in both English and Chinese.
(For injectable products, words such as "To be used only as directed by a medical practitioner 請遵照醫生指示使用。" may be used instead).

E. Additional Labelling Requirements for Poisons

1. Poisons except Part 1, First Schedule (P1 S1) and Part 1, First and Third Schedules (P1 S1 S3) Poisons made up ready for the internal treatment of human ailments (see **Note**)

Caution. It is dangerous to exceed the stated dose. 注意：服食過量有危險。

2. Medicines made up ready for the internal treatment of human ailments (see **Note**) and containing an antihistamine (except Astemizole, Bilastine, Cetirizine, Desloratadine, Fexofenadine, Loratadine and Terfenadine) -

Caution. This may cause drowsiness. If affected, do not drive or operate machinery. 注意：此藥可使人昏昏欲睡，服後如有此情形，不得駕駛或動用機械。

3. Medicines containing insulin -

Caution. It is dangerous to take this preparation except under medical supervision. 注意：非經醫生指示，服食此藥有危險。

4. Medicines made up ready for the treatment of animals -

Poison. For animal treatment only. 毒藥：只限醫治禽畜用。

5. Medicines containing Part 1 Poisons (except Third Schedule Poison e.g. P1 S1 S3 Poisons) -

Drug under Supervised Sales 監督售賣藥物

6. Medicines containing Third Schedule Poison e.g. P1 S1 S3 Poisons -

Prescription Drug 處方藥物

Note - As a general rule, medicines "made up ready for the internal treatment of human ailments" refer to such medicines of a package size of 500 tablets/capsules or below (for solid dosage forms), 500 millilitres or below (for liquid medicines) and medicines which are injectable products regardless of package size.

F. Additional Labelling Requirements for Certain Drugs

1. For **Angiotensin - Converting Enzyme Inhibitors (ACEI)** -

   "Caution. Contraindicated in pregnancy. 注意：孕婦忌食。"

2. For **oral contraceptives** -

   "Caution. While you are receiving this medication, you should see a doctor at least once a year for advice on suitability of continued use. 注意：你在服用此藥物期間，應至少每年一次向醫生請教是否適宜繼續服用。"
   A package insert in both English and Chinese must also be made available in which information in dosage instructions and side effects should be included.

3. For medicines containing **Phenylpropanolamine** -
   The maximum daily dose should not exceed 100mg and on the label or in the package insert :-
   (i) "If you are under the care of your doctor or receiving continual prescribed medication or are pregnant then consult your doctor.
   假如你是在醫生的照料下或長期服用藥物或懷孕，請徵詢醫生意見。"

   (ii) "Patients with high blood pressure, hyperthyroidism, heart disease or who are receiving monoamine oxidase inhibitors should not take the product. 患有高血壓、甲狀腺素高、心臟病或正接受單氨基酸抑制劑治療的病人不可服用此葯。"

   (iii) "The product may aggravate conditions such as diabetes, glaucoma, or prostatic enlargement.此葯可使糖尿病、青光眼和前列腺肥大等病症的病情轉壞。"

   (iv) "The product should not be used as appetite suppressant.此葯不可作食慾抑制劑使用。"

4. For medicines containing **Salicylamide** -

   The following is required on the label and/or package insert -

   "Keep out of reach of children. This medicine should not be given to children under 16 except on medical advice. 避免兒童誤取。非經醫生指示，十六歲以下兒童不可服用。"

5. For medicines containing **Aspirin** -

   The following is required on the label and/or package insert -

   "Keep out of reach of children. This medicine should not be given to children under 16 except on medical advice. 避免兒童誤取。非經醫生指示，十六歲以下兒童不可服用。"

The following are required on the label or in a package insert -

"Consult your physician before taking aspirin during pregnancy or when nursing. 在懷孕或哺乳期的婦女，在服用阿司匹靈前需要徵詢醫生意見。" and
"Aspirin irritates the stomach and can cause bleeding. It should not be taken by patients with stomach ulcers, persistent indigestion or liver disease. 阿司匹靈刺激胃部而可能引致出血，患有胃潰瘍、持續性消化不良或肝病的病人不可服用。"

6. For oral medicines containing **Tetracycline** -

"To avoid dental disfigurement and discolouration, tetracycline should not be given to children under 12 years. 四環素會令牙齒損形變色，十二歲以下兒童不可服用。"

7. For medicines containing Vitamin A at a daily dose of 10,000 iu or above -

"For the treatment of severe Vitamin A deficiency only. For pregnant women and children, medical advice should be sought before use. 只限醫治嚴重缺乏維他命A症狀。孕婦和兒童在服用前需先徵詢醫生意見。"

8. For medicines containing **Phenylbutazone** -

In the package insert -

Indications: — Active ankylosing spondylitis.
— Attacks of gout and pseudo-gout.
— Acute severe inflammation due to major surgery.

The following conditions, when no adequate response to other non-steroidal anti-inflammatory drugs:

— Acute exacerbations of rheumatoid arthritis and osteoarthritis.
— Acute states of non-articular rheumatic disease

Duration of treatment: 7 days; when a longer period of treatment is unavoidable, special precautions should be taken.

Age Limit: — Not for patients below 14 years of age.

9. For medicines containing **Chlormezanone** -

An appropriate statement highlighting the product's potential to cause serious cutaneous reactions must be included in the package insert or label, e.g. "Severe cutaneous reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis have occurred infrequently. If skin reaction occurs, the drug should be stopped immediately".

10. For medicines containing **Fluoroquinolones** for systemic use -

A warning concerning the product's potential to cause tendinitis or tendon rupture must be included in the package insert or label.

11. For medicines containing **Allopurinol** -

An appropriate statement concerning the product's potential to cause serious cutaneous reactions must be included in the package insert or label, e.g. "Allopurinol should be discontinued at the first appearance of skin rash or other signs which may indicate an allergic reaction. In some instances, a skin rash may be followed by more severe reactions such as exfoliative, urticarial and purpuric lesions as well as Stevens-Johnson syndrome".

12. For medicines containing **Sulfonamides** -

An appropriate statement concerning the product's potential to cause serious cutaneous reactions must be included in the package insert or label, e.g. "Fatalities associated with the administration of sulfonamides, although rare, have occurred due to severe reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis".

13. For medicines containing **Astemizole** -

An appropriate statement related to cardiovascular adverse events, drug interactions and rare reports of anaphylaxis must be included in the package insert or label.

14. For medicines containing **Terfenadine** -

An appropriate statement related to the serious cardiovascular adverse events and drug interaction must be included in the package insert or label.

15. For medicines containing **Ticlopidine** -

An appropriate statement, is required on the label or package insert to the effect that this drug can cause life-threatening hematological adverse reactions, including neutropenia/agranulocytosis and thrombotic thrombocytopenic purpura.

16. For medicines containing topical **Minoxidil** for alopecia -

An appropriate statement is required on the label and / or in the package insert to the effect that this product is not effective for all types of alopecia.

17. For medicines containing **Miconazole** :-

The following statement must be included in the package insert and/or label for preparations intended for oral or vaginal use.
"Caution : Ask a doctor or pharmacist before use if you are taking the prescription blood thinning medicine warfarin, because bleeding or bruising may occur. 注意: 在服食抗凝血藥華法林期間使用本品可引致出血或瘀傷，請於使用前先向醫生或藥劑師諮詢意見。"

18. For medicines containing **Benzbromarone** –
An appropriate statement concerning the product's potential to cause severe hepatic lesions must be included in the package insert or label.
"Caution : Severe hepatic lesions have been associated with the use of Benzbromarone. Patients who have hepatic disorders should avoid taking this product. 注意：服用苯溴馬隆(Benzbromarone)引致肝臟嚴重損傷。肝臟病患者應避免服用。

19. For medicines containing **Loratadine** or **Desloratadine** –
An appropriate warning statement must be included in the package insert and/or label e.g. "Caution : Safe use of this product during pregnancy has not been established."

20. For medicines containing **Codeine** –

Appropriate statements related to the following safety information must be included in the package insert or label:

(i) Codeine is contraindicated for all children younger than 12 years of age.
(ii) Codeine should only be used to treat acute moderate pain in children above 12 years of age, and only if it cannot be relieved by other painkillers such as paracetamol or ibuprofen.
(iii) Codeine is contraindicated for post-operative management in children younger than 18 years of age following tonsillectomy and/or adenoidectomy.
(iv) Avoid the use of codeine in adolescents 12 to 18 years of age who have other risk factors that may increase their sensitivity to the respiratory depressant effects of codeine unless the benefits outweigh the risks. Risk factors include conditions associated with hypoventilation, such as postoperative status, obstructive sleep apnea, obesity, severe pulmonary disease, neuromuscular disease, and concomitant use of other medications that cause respiratory depression.
(v) Codeine should not be used in people of any age who are known to be ultra-rapid metabolisers. Because of the potential for serious adverse reactions, including excess sedation, respiratory depression, and death in a breastfed infant, breastfeeding is not recommended during treatment with codeine.

For cough medicines containing **Codeine** –

The dosage instructions should be compatible with the following recommendations (given in respect of codeine phosphate) :

Adults and children above 12 years : 15 - 30mg three or four times daily

21. For medicines containing **Lindane :-**

"The product should only be used in patients who cannot tolerate, or have failed first-line treatment with safer medications. It must not be used on broken skin. It should not be used in infants, children under 6 years of age, pregnant women or nursing mothers, or the elderly with a history of seizure activity except on the advice of a physician. 此產品只應用於不能耐受較安全藥物或曾以較安全藥物作第一線治療但無效用的病人。切勿將此產品用於破損皮膚。除非醫生建議使用，否則此產品不應用於新生嬰兒、六歲以下兒童、懷孕或哺乳婦女，以及曾有痙攣發作的長者。"

22. For medicines containing **Chlorhexidine :-**

The following is required on the label and/or package insert -

"Warnings: Allergy Alert
This product may cause a severe allergic reaction. Symptoms may include: wheezing/difficulty breathing, shock, facial swelling, hives, rash. If an allergic reaction occurs, stop use and seek medical help right away.

警告：過敏警示
此製品可導致嚴重過敏反應。症狀包括：喘鳴/呼吸困難、休克、面部腫脹、蕁麻疹、皮疹。如果出現過敏反應，請立即停用並盡快求醫。"

G. Points to Note

1. For **Cold and Cough (over the counter) products:-**

The product should not have the dosage instructions on the sale pack label and/or the package insert for children under 6 years of age.

2. **Undesirable Medical Advertisements Ordinance:-**

Any labelling should not contravene the provisions of the Undesirable Medical Advertisements Ordinance, Cap.231.