Guidelines on the Labelling of Pharmaceutical Products

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Pharmacy and Poisons Board of Hong Kong

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1. Introduction

1.1 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.

2. General Labelling Requirements

2.1 Name of the product.
2.2 Name and quantity of each active ingredient[a].
2.3 Name and address of the manufacturer.
2.4 Hong Kong registration number of the product.
2.5 Batch Number.
2.6 Expiry date.
2.7 Product pack size and unit of quantity.
2.8 Storage condition (including specific storage condition, if any)[b].

3. Additional Labelling Requirements for Sterile Products

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

4. Additional Labelling Requirements for Certain Classes of Products

4.1 For embrocations, liniments, lotions, liquid antiseptics or other liquid medicines for external application –
"For external use only. 祇供外用。"

[a] Labelling of name of poison shall be in accordance with the Pharmacy and Poisons Regulations, Cap138A. For the accepted scientific name, please take reference to the International Nonproprietary Name (INN) recommended by the World Health Organization.

[b] Storage condition should be supported by stability study. If applicable, the label should include specific storage condition e.g. do not freeze, special storage after reconstitutions/dilution/opening, etc. Terms such as "ambient conditions" or "room temperature" should be avoided.

4.2 For eye-drops, (unless otherwise specified) –
"Not to be used one month after opening. 開蓋一個月後不可使用。" [c]

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

4.4 For veterinary products (for veterinary products which contain Poisons, please refer to section 6.6) –
"For animal treatment only. 祇限醫治禽畜用。"

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

5.1 Dosage, route and frequency of administration in both English and Chinese.

6. Additional Labelling Requirements for Poisons

6.1 Medicines containing Part 1 Poisons (except for Schedule 3 Poisons) -
"Drug under Supervised Sales 監督售賣藥物"

6.2 Medicines containing Schedule 3 Poisons (e.g. P1 S1 S3 Poisons) -
"Prescription Drug 處方藥物"

6.3 Medicines containing Poisons except Schedule 1 Poisons made up ready for the internal treatment of human ailments [d] [*other than medicines containing insulin and antihistamine as specified below*] –
"Caution. It is dangerous to exceed the stated dose."
「注意：服食過量有危險。」

6.4 Medicines containing insulin and made up ready for the internal treatment of human ailments[d] -
"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。」

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[c] Other in-use shelf life may be allowed on a case by case basis with justifications.

[d] 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.

6.5 Medicines containing an antihistamine [*except Astemizole, Bilastine, Cetirizine, Desloratadine, Fexofenadine, Loratadine and Terfenadine*] and made up ready for the internal treatment of human ailments[d] -

"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。」

6.6 Medicines containing poisons made up ready for the treatment of animals -

"Poison. For animal treatment only."

「毒藥：祇限醫治禽畜用。」

7. Additional Labelling Requirements for Biosimilar Products and Advanced Therapy Products

7.1 For biosimilar products -

Please refer to paragraph 6.1 to 6.3 of the <Guidance Notes on Registration of Biosimilar Products> for the additional labelling requirements.

7.2 For advanced therapy products -

(i) Product code

(ii) Unique donation identifier

(iii) If the product is for autologous use only

- Unique recipient identifier
- "For autologous use only" or the Chinese characters "只供自體使用"

The product code, unique donation identifier and unique recipient identifier must be assigned in accordance with the <Guidance on Labelling Requirements of Product Code, Unique Donation Identifier and Unique Recipient Identifier for Advanced Therapy Products>.

8. Additional Safety Information Required for Certain Drugs

8.1 As a good practice for ensuring safe and proper use of the pharmaceutical product, registration holders should have the responsibility to include and update the latest safety information in their products. Regarding additional safety information requirement for specific product, please refer to relevant part(s) provided in PRS 2.0 for inclusion.

9. Points to Note

9.1 For Cold and cough (over the counter) products -

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

9.2 Undesirable Medical Advertisements Ordinance, Cap. 231 -

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